AMENDMENT TO FORM 10

27 April 2026 – Melbourne, Australia (**26 April 2026** – Minneapolis, MN United States) – **Imricor Medical Systems, Inc.** (**Company** or **Imricor**) (**ASX: IMR**) announces that it has filed an amendment to its Form 10 Registration Statement (originally filed 18 March in the U.S.) with the U.S. Securities and Exchange Commission (**SEC**). As previously communicated by the Company, the Form 10 is not being used to conduct a U.S. initial public offering or a U.S. stock exchange listing.

The amendment to the Form 10 has been lodged today with the ASX, following the filing with the SEC. The amendment addresses certain minor edits and clarifications raised in the SEC review process, which follows the standard process for the SEC review of such filings.

The Company expects the Form 10 to become effective on 17 May 2026.

ENDS

Authorised for release by Steve Wedan, Executive Chair, President, and CEO.

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About Imricor

Imricor Medical Systems, Inc. (ASX:IMR) is striving to make interventional medical procedures better, safer, and more cost effective by making it possible for these procedures to be performed under real-time magnetic resonance imaging (MRI) guidance, rather than under x-ray fluoroscopy guidance, thus taking advantage of MRI's superior imaging capabilities.

Imricor's Products

Imricor is a pioneer and world leader in developing MRI-compatible products for cardiac catheter ablation procedures. The Company's products include capital equipment, such as the NorthStar® Mapping System and the Advantage-MR® EP Recorder/Stimulator. Single-use devices include a variety of ablation catheters, diagnostic catheters, steerable sheaths, and other tools used for cardiac ablations.

Imricor's products are approved in the European Union, the Kingdom of Saudi Arabia, and New Zealand. US FDA approval is in process, and further approvals in other geographies such as Australia are being planned.

Foreign Ownership Restrictions

Imricor's CHESS Depositary Interests (**CDIs**) are issued in reliance on the exemption from registration contained in Regulation S of the US Securities Act of 1933 (**Securities Act**) for offers which are made outside the US. Accordingly, the CDIs have not been, and will not be, registered under the Securities Act or the laws of any state or other jurisdiction in the US. As a result of relying on the Regulation S exemption, the CDIs are 'restricted securities' under Rule 144 of the Securities Act. This means that you are unable to sell the CDIs into the US or to a US person for the foreseeable future except in very limited circumstances after the expiration of a restricted period, unless the re-sale of the CDIs is registered under the Securities Act or an exemption is available. To enforce the above transfer restrictions, all CDIs issued bear a 'FOR US' designation on the Australian Securities Exchange (**ASX**). This designation restricts any CDIs from being sold on ASX to US persons excluding qualified institutional buyers (QIBs, as defined in Rule 144A under

the Securities Act). However, you are still able to freely transfer your CDIs on ASX to any person other than a US person. In addition, hedging transactions with regard to the CDIs may only be conducted in accordance with the Securities Act.

Forward-Looking Statements

This announcement contains or may contain forward-looking statements that are based on the Company's management's beliefs, assumptions and expectations and on information currently available to management. All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements. These include, without limitation, EU commercial market acceptance and EU. sales of our product as well as our expectations with respect to our ability to develop and commercialise new products. Management believes that these forward-looking statements are reasonable when made. You should not place undue reliance on forward-looking statements because they speak only as of the date when made. Imricor does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. Imricor may not actually achieve the plans, projections or expectations disclosed in forward-looking statements. Actual results, developments or events could differ materially from those disclosed in the forward-looking statements.

As filed with the Securities and Exchange Commission on April 24, 2026

File No. 000-56826

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

AMENDMENT NO. 1 TO
FORM 10
GENERAL FORM FOR REGISTRATION OF SECURITIES

Pursuant to Section 12(b) or (g) of The Securities Exchange Act of 1934

IMRICOR MEDICAL SYSTEMS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**20-4914480**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
400 Gateway Blvd. **Burnsville, Minnesota** (Address of principal executive office)	**55337** (Zip Code)

(952) 818-8400
(Registrant's telephone number, including area code)

Securities to be registered pursuant to Section 12(b) of the Act: None

Securities to be registered pursuant to Section 12(g) of the Act:
Class A Common Stock, par value $0.0001 per share
(Title of class)

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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Introductory Note

Imricor Medical Systems, Inc., a Delaware corporation (the "Company"), is filing this Registration Statement on Form 10 (as may be amended from time to time, the "Registration Statement") with the Securities and Exchange Commission ("SEC") under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), on a voluntary basis to register our common stock, par value $0.0001 per share. The common stock is publicly traded on the Australian Securities Exchange ("ASX") under the ticker "IMR", in the form of Clearing House Electronic Subregister System ("CHESS") Depositary Interests ("CDIs"), each representing one share of our Class A common stock. CDIs are units of beneficial ownership in our shares of Class A common stock held by CHESS Depositary Nominees Pty Limited ("CDN"), a wholly owned subsidiary of ASX Limited, the company that operates the ASX. Unless the context requires otherwise, all references to our common stock in this Registration Statement refer to our Class A common stock. For purposes of this Registration Statement, unless otherwise noted, each of the "Company," "we," "us," "our," and "Imricor" refers to Imricor Medical Systems, Inc. and its consolidated subsidiary, Imricor B.V.

This Registration Statement will become effective automatically by lapse of time 60 days from the date of its filing pursuant to Section 12(g)(1) of the Exchange Act. As of the effective date of the Registration Statement, we will be subject to the requirements of Regulation 13(a) under the Exchange Act and will be required to file annual reports on Form 10-K, quarterly reports on Form 10-Q, and current reports on Form 8-K, and we will be required to comply with all other obligations of the Exchange Act applicable to issuers filing registration statements pursuant to Section 12(g) of the Exchange Act.

We own or have rights to various trademarks, service marks, and trade names that we use in connection with the operation of our business. All other trademarks, trade names, and service marks mentioned in this Registration Statement are the property of their respective owners. Solely for convenience, our trademarks, service marks, and trade names referred to in this Registration Statement may appear without the ®, TM or SM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks, service marks, and trade names.

The market data and other statistical information contained in this Registration Statement are based on independent industry publications, government publications, reports by market research firms, other publicly available information, and management estimates. Management estimates are derived from publicly available information released by independent industry analysts and third-party sources, as well as data from our internal research, and are based on assumptions made by us upon reviewing such data and our knowledge of such industry and markets, which we believe to be reasonable. Any industry forecasts are based on data (including third-party data), models, and experience of various professionals and are based on various assumptions, all of which are subject to change without notice. Projections, assumptions, and estimates of the future performance of the industry in which we operate, and our future performance are necessarily subject to uncertainty and risk due to a variety of factors, including those described in "Risk Factors" and "Disclosure Regarding Forward-Looking Statements." These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

Unless indicated otherwise in this Registration Statement, all references to "$", "US$", or "dollars" refer to United States dollars, the lawful currency of the United States of America.

Implications of Being an Emerging Growth Company

As a company with less than $1.235 billion of revenue during our last fiscal year, we qualify as an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). As such, we are eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to:

- exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act");
- exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board (the "PCAOB") regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, unless the SEC determines that the application of such requirements to emerging growth companies is necessary;
- exemption from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved by stockholders;
- option to adopt new or revised accounting standards on the same timeline as private companies through the extended transition period permitted under Section 13(a) of the Exchange Act and Section 107 of the JOBS Act;
- reduced financial statement disclosure obligations, permitting the presentation of only two years of audited financial statements in a registration statement, rather than three; and
- reduced disclosure obligations regarding executive compensation arrangements in our periodic reports, registration statements, and proxy statements.

We will remain an emerging growth company until the earlier of (i) the last day of our fiscal year following the fifth anniversary of the date of our first sale of our common stock pursuant to an effective registration statement under the Securities Act of 1933, as amended (the "Securities Act"); (ii) the last day of the fiscal year in which our total annual gross revenues equal or exceed $1.235 billion; (iii) the last day of the fiscal year in which we become a large accelerated filer, which generally requires (a) our market value of our ordinary shares held by non-affiliates (public float) exceeds $700 million as of the end of our second fiscal quarter, (b) we have been subject to the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 for at least twelve months, and (c) we have filed at least one annual report pursuant to those sections; and (iv) the date on which we have issued more than $1 billion in non-convertible debt securities over the prior three-year period.

Additionally, we are a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. Smaller reporting companies may take advantage of certain scaled disclosure obligations, including, among other things, providing only two years of audited financial statements and reduced disclosure obligations regarding executive compensation in our periodic reports, registration statements, and proxy statements. We will remain a smaller reporting company for each fiscal year in which, as of the end of that year's second fiscal quarter, either (i) the market value of our ordinary shares held by non-affiliates (public float) is less than $250 million, or (ii) our annual revenues are less than $100 million in such completed fiscal year and either (a) we have no public float, or (b) our public float is less than $700 million.

We have elected to take advantage of certain reduced disclosure obligations in this Registration Statement and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different from what you might receive from other public reporting companies in which you hold equity interests.

Disclosure Regarding Forward-Looking Statements

The statements contained in this Registration Statement that are not purely historical are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Our forward-looking statements include, but are not limited to, statements regarding our expectations, hopes, beliefs, intentions, or strategies regarding the future. In addition, any statements that refer to projections, forecasts, or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "will," "may," "expect," "intend," "seek," "would," "should," "could," "continue," "plan," "estimate," "anticipate," "believe," "probability," "risk," "aim," or other similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward looking. Forward-looking statements in this Registration Statement may include, for example, statements about the topics below and are subject to risks and uncertainties including without limitation those described below:

- our ability to obtain and maintain regulatory clearances and approvals for our products in the European Union, the Middle East, the United States, and other jurisdictions, and the timing of such clearances and approvals
- the clinical and commercial success of our Vision-MR Ablation Catheter, NorthStar Mapping System, and related Magnetic Resonance Imaging ("MRI")-compatible products for cardiac catheter ablation procedures
- the adoption and market acceptance of MRI-guided cardiac ablation technology by hospitals, clinics, and physicians
- our ability to compete effectively with established competitors in the cardiac ablation market, including competition from pulsed field ablation technologies
- our ability to achieve and sustain profitability and positive cash flow
- our reliance on MRI manufacturers for integration of our products with their equipment systems
- our ability to scale manufacturing operations to meet commercial demand
- our dependence on third-party suppliers, including single-source suppliers, for critical product components
- our ability to attract, retain, and train qualified personnel, including sales, clinical, and research and development staff
- our ability to obtain adequate reimbursement from third-party payers for procedures using our products
- our ability to maintain satisfactory pricing and margins for our products

- our reliance on a limited number of customers and our ability to broaden our customer base
- the success of our research and development programs and our ability to develop new products and expand applications to treat additional cardiac arrhythmias
- our ability to protect and enforce our intellectual property rights
- our future capital requirements and ability to obtain additional financing on acceptable terms
- the impact of foreign currency exchange rate fluctuations on our financial results
- our status as an emerging growth company and smaller reporting company
- the impact of healthcare policy changes and reforms on our business

The forward-looking statements contained in this Registration Statement are based upon our expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments affecting us will be those that we have anticipated or that any such developments will have the effects we expect. These forward-looking statements involve a number of risks, uncertainties, or assumptions, many of which are beyond our control, which may cause actual results or performance to differ materially from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described in the "Risk Factors" section of this Registration Statement.

These forward-looking statements speak only as of the date of this Registration Statement. Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, except as may be required under applicable securities laws.

Sources of Additional Information

We will be subject to the requirements of Section 13(a) under the Exchange Act, which requires us to file annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and proxy statements with the SEC. We will also be required to comply with all other obligations of the Exchange Act applicable to issuers filing registration statements pursuant to Section 12(g) of the Exchange Act.

Electronic copies of the materials we file with the SEC will be available to the public at the web site maintained by the SEC at http://www.sec.gov.

We also maintain a website at http://www.imricor.com, at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with or furnished to the SEC. Our website and the information contained therein or connected thereto shall not be deemed to be incorporated into this Registration Statement. We have included our website address as an inactive textual reference only.

Item 1. Business

Overview and Company History

Imricor Medical Systems, Inc. ("Imricor," "we," "us," "our," or the "Company") is a medical technology company pioneering the development and commercialization of magnetic resonance imaging ("MRI")-compatible interventional products for cardiac ablation and other procedures. Headquartered in Burnsville, Minnesota and incorporated in Delaware in 2006, Imricor is dedicated to transforming the treatment of cardiac arrhythmias and other interventions by leveraging MRI guidance, periprocedurally, with the aim of delivering superior clinical outcomes, improved procedural safety, lower treatment costs, and the elimination of radiation exposure for patients and medical personnel alike.

The broadest description of the field Imricor is pioneering is "interventional magnetic resonance" or "iMR," meaning interventional procedures which utilize periprocedural magnetic resonance imaging for guidance within the body. We are focused, initially, on cardiovascular interventional procedures, which we call "interventional cardiac magnetic resonance" or "iCMR" procedures. iCMR is a subset field of iMR. More specifically, the first cardiovascular iCMR procedures we are delivering are cardiac ablations for the treatment of arrhythmias.

Our Mission and Value Proposition

Cardiac arrhythmias affect millions of patients worldwide and represent a rapidly growing healthcare challenge. Current standard-of-care ablation procedures rely on X-ray fluoroscopy for basic procedural guidance, which provides limited visualization of cardiac tissue structures, arrhythmogenic substrate, therapy lesions, and potential complications. We believe these limitations contribute to suboptimal, first-time procedural success rates, prolonged procedure times, additional costs, and increased risk of complications (*Ranjan et al., "Identification and Acute Targeting of Gaps in Atrial Ablation Lesions Sets using a Real Time MRI System," Circulation: Arrhythmia and Electrophysiology, 2012*). In addition, X-ray fluoroscopy exposes patients and medical staff to cumulative doses of ionizing radiation, which we believe contributes to a treatment and work environment in which safety is suboptimal for patients and medical staff.

Imricor's iCMR cardiac ablation technology addresses these fundamental limitations by delivering MRI-compatible systems and tools that allow physicians to perform cardiac ablations that are guided by MRI rather than X-ray. This means the patient is imaged with MRI throughout the procedure, and the use of periprocedural MRI opens new possibilities for patients and physicians. MRI allows the physician to see the heart in detail, and also to see the tissue characteristics of the heart muscle that may be causing the arrhythmia (the arrhythmogenic substrate). After therapy delivery (ablating), MRI can determine the quality of the ablation lesions, providing the ability for physicians to check their work, prior to sending a patient home. This is not possible with X-ray, and with MRI, it offers the potential to improve first-time procedural success. Because MRI can directly visualize the heart and arrhythmogenic substrate, time need not be spent generating surrogate guidance volumes and electrophysiological mapping time may be reduced. In addition, certain tools often used in a conventional X-ray procedure may not be needed in an iCMR procedure, due to the MRI's ability to visualize soft tissue. One example is an intracardiac echo ("ICE") catheter for transseptal crossings, which is used in a conventional X-ray procedure to provide real-time imaging of cardiac structures. iCMR provides high fidelity real-time visualization of the interatrial septum, a thin wall separating the right and left atria, that is crossed in order to perform left-sided cardiac procedures. The native imaging capabilities of the MRI allow for the visualization of this structure to guide the crossing without the need for an additional device to be inserted in the heart.

Finally, there is increasing awareness of the dangers associated with working in an X-ray environment, including direct exposure to ionizing radiation and the orthopedic stresses of wearing heavy protective lead garments daily. X-ray labs expose patients and medical personnel to ionizing radiation, and this exposure is eliminated by the adoption of an iCMR or iMR lab, creating a safer treatment environment for patients and a safer work environment for medical personnel.

We use the term "iCMR lab" to refer to an electrophysiology lab ("EP lab") setting in which cardiac ablation procedures are performed under real-time MRI guidance instead of conventional X-ray fluoroscopy guidance, using MRI scanners together with Imricor's MRI-compatible electrophysiology ("EP") products. Our preferred implementation is the development of MRI suites that are part of, or closely associated with, the hospital's cardiology or EP department, so that MRI becomes the primary imaging modality within the EP lab where cardiac ablations are performed. However, our products can also be used with compatible MRI scanners located in radiology departments, provided the hospital's MRI environment and workflow support interventional electrophysiology procedures. Importantly, iCMR labs can be implemented using existing MRI scanners, allowing hospitals to adopt real-time MRI-guided electrophysiology without investing in a new or standalone lab, though hospitals may choose to do so to optimize workflow and capacity.

Corporate History and Development

Imricor was founded in 2006 in Savage, Minnesota by a team comprising engineers and doctors, who recognized the transformative potential of interventional MRI for cardiac procedures. From inception, the Company pursued collaborative relationships with leading academic medical centers, MRI equipment manufacturers, and other third-party partners to overcome the substantial technical challenges inherent in developing all the devices needed to perform complex cardiac ablations safely and effectively in an MRI environment. The Company's key corporate and technology milestones are summarized as follows:

- **2006**: Company incorporated in Delaware; headquarters and early research operations established in Savage, Minnesota
- **2007**: Established headquarters facility including research and development ("R&D") and manufacturing space in Burnsville, Minnesota
- **2009**: Achieved breakthrough innovations in MRI compatibility technology with creation of technology for electrophysiology catheters, enabling safe device operation in MRI environments
- **2011**: Conducted first-in-human MRI-guided cardiac ablation procedures at Leipzig Heart Center in Germany, demonstrating clinical feasibility and safety of the Advantage-MR® platform and Vision-MR® consumables.
- **2014:** Conducted first human pilot study using Active magnetic resonance ("MR") Tracking at King's College London
- **2015:** Entered joint research agreement with Siemens supporting MR-guided EP and cardiovascular intervention research
- **2016**: Received CE Mark approval for Advantage-MR EP Recorder/Stimulator System, enabling commercial sales in the European Union
- **August 2019**: Completed initial public offering on the Australian Securities Exchange (ASX: IMR), raising capital to accelerate commercialization and expand clinical development programs
- **January 2020**: Received CE Mark approval for Vision-MR Ablation Catheter (with an indication for treating Type I atrial flutter) and Vision-MR Dispersive Electrode, marking the commercial launch of our consumable device portfolio

- **2022-2025**: Transitioned all CE Mark certifications from the European Medical Device Directive ("MDD") to the more rigorous European Union Medical Device Regulation ("EU-MDR") framework, to ensure ongoing European market access and regulatory compliance
- **March 2024**: Received CE Mark under EU-MDR for Vision-MR Diagnostic Catheter, expanding our consumable device portfolio
- **June 2024**: Enrolled first patient in Vision-MR Ablation of Atrial Flutter ("VISABL-AFL") clinical trial at Institut Cardiovasculaire Paris Sud ("ICPS") in France, initiating U.S. Food and Drug Administration ("FDA") approval pathway
- **August 2024**: Enrolled first U.S. patient in VISABL-AFL clinical trial at Johns Hopkins Hospital
- **March 2025**: Established Imricor B.V., our Dutch subsidiary, to support clinical research activities in the European Union and facilitate direct collaboration with European medical centers
- **June 2025**: Received CE Mark under EU-MDR for our NorthStar Mapping System ("NorthStar"), the world's first commercial MRI-native cardiovascular mapping and guidance platform
- **October 2025**: Treated first ischemic ventricular tachycardia ("VT") patient in Vision-MR Ablation of VT ("VISABL-VT") clinical trial
- **January 2026**: Received FDA clearance under 510(k) pathway for the Vision-MR Diagnostic Catheter and NorthStar Mapping System

Current Stage of Development and Commercialization

As of the date of this filing, Imricor is in the early commercial stage of operations in the European Union ("EU"), the Middle East ("ME"), and the United States ("U.S."). In the EU, we have active commercial sales of capital equipment (Advantage-MR®, NorthStar®) and consumable devices (Vision-MR® Ablation Catheter, Diagnostic Catheter, Dispersive Electrode). In the ME, we are preparing for commercial sales in Qatar and the Kingdom of Saudi Arabia ("Saudi Arabia" or "KSA") through exclusive distribution partnerships. In the U.S., we are pursuing regulatory clearances and approvals for several products across multiple FDA pathways, including 510(k) and premarket approval ("PMA"). The Vision-MR Diagnostic Catheter and NorthStar Mapping System are the first two Imricor devices to gain 510(k) clearance.

We operate at a pre-profitability stage, with revenue generated primarily from European sales of capital equipment and consumable devices. Our business strategy prioritizes:

1. Growing adoption and sales across the EU (European direct sales team was established and trained in July 2025, and has been building a pipeline of new customers which are progressing through the sales process; new customers expected to begin issuing purchase orders in the second half of 2026);
2. Initiating and growing adoption and sales in the ME (sales through distributor expected to commence in the second half of 2026 following review of CE marked products by the Saudi Food and Drug Authority and registration with Saudi National Unified Procurement Company ("NUPCO"); and
3. Gaining market access and growing adoption and sales in the U.S. (FDA approval/clearance of product suite expected by the end of 2026, with direct sales of our cardiac ablation products commencing in early 2027).

Industry Background

Cardiac Arrhythmias: Clinical Overview and Burden of Disease

Cardiac arrhythmias are abnormal heart rhythms caused by disruptions in the heart's electrical conduction system. These conditions range from benign rhythm irregularities to life-threatening disorders that can lead to stroke, heart failure, or sudden cardiac death. The most common clinically significant arrhythmias include:

- **Atrial Fibrillation ("AF")**: According to a 2025 analysis published in *Europace*, AF is the most prevalent sustained cardiac arrhythmia, affecting an estimated 50 million people globally. AF occurs when the atria beat out of coordination with the ventricles (lower chambers). It is caused by erratic electrical signals, normally originating in the left atrium, which lead to a quivering or twitching of the atria. AF causes irregular, rapid atrial contractions that impair cardiac output and significantly increase stroke risk (5-fold elevation). According to a 2025 review in *Arrhythmia and Electrophysiology Review*, AF prevalence increases dramatically with age, with men and women over age 40 having a one in four chance of developing AF in their lifetime. The disease burden is substantial: AF patients suffer from fatigue, dyspnea, reduced exercise capacity, and diminished quality of life. AF also substantially increases healthcare costs through hospitalizations, emergency department visits, and stroke prevention therapies.

- **Atrial Flutter ("AFL")**: According to a population-based analysis published in the *Journal of the American College of Cardiology* in 2000, which remains a reference point in recent health-economic analyses, AFL is a macro-reentrant tachycardia affecting approximately 200,000 new patients annually in the United States alone. AFL is similar to AF, but is less chaotic, as the rhythm in the atria is more organized than the abnormal patterns commonly experienced by patients with AF. In AFL, the atria (upper chambers) of the heart beat too fast, which results in atrial muscle contractions that are faster than and out of sync with the ventricles. Type I atrial flutter involves a reentrant circuit around the tricuspid valve annulus in the right atrium, representing the most common form of organized atrial arrhythmia. Left untreated, atrial flutter shares AF's stroke risk profile and frequently coexists with or progresses to AF. According to a 2017 review in *Arrhythmia and Electrophysiology Review***,** Type I atrial flutter is highly responsive to catheter ablation, with reported success rates exceeding 90% in appropriately selected patients.

- **Ventricular Tachycardia ("VT")**: A potentially life-threatening arrhythmia that is associated with a rapid heart rhythm originating in the heart's ventricles, commonly affecting patients with structural heart disease (prior myocardial infarction, cardiomyopathy). The rapid heart rate may not allow the ventricles to fill and contract efficiently to pump enough blood to the body. VT can degenerate into ventricular fibrillation and sudden cardiac death. VT is particularly common in patients with prior myocardial infarction, where scar tissue creates reentrant circuits that sustain the arrhythmia. Catheter ablation has emerged as an important therapeutic option for patients with VT refractory to antiarrhythmic medication and has been shown to reduce implantable cardioverter defibrillator ("ICD") shocks and improve quality of life.

Standard of Care: Catheter Ablation Procedures

For many patients with arrhythmias, catheter ablation has emerged as a highly effective treatment option. During ablation procedures, electrophysiologists navigate specialized catheters through blood vessels into the heart, identify the tissue responsible for generating or sustaining the arrhythmia, and deliver energy (radiofrequency heat, cryogenic cold, or pulsed electric fields) to selectively destroy the targeted tissue, thereby restoring normal heart rhythm.

The fundamental principle underlying all ablation procedures is precise identification and elimination of arrhythmogenic substrate. Success depends on accurate anatomical localization of arrhythmogenic substrate and effective delivery of permanent therapeutic lesions at proper locations. Current X-ray fluoroscopy-guided procedures rely heavily on indirect methods to determine the location of ablation targets and assess therapeutic tissue injury, because X-ray provides no direct visualization of cardiac tissue.

Market Size and Growth

The global cardiac ablation market is substantial and growing rapidly. According to *S&S Insider Strategy and Stats*, the market was estimated at approximately $14.7 billion globally in 2025 with a compound annual growth rate of approximately 15% projected through 2035. This projected growth rate reflects *S&S Insider Strategy and Stats*' expectation that:

- the prevalence and diagnosis of atrial fibrillation and other arrhythmias will continue to rise in aging populations, driven in part by comorbidities such as hypertension, obesity, and diabetes;
- providers will adopt next-generation ablation technologies in place of older systems; and
- electrophysiology laboratory capacity and reimbursement frameworks will continue to expand across both developed and emerging markets.

Imricor estimates over 1 million ablation procedures are performed annually worldwide. In addition, we believe other market drivers include expanding clinical indications, improved procedural outcomes, improved safety profiles, and expanded physician training and diffusion of ablation expertise. According to *Precedence Research*, the United States represents approximately 40-45% of global market value, Europe represents approximately 30% of global market value, and Asia-Pacific and the rest of the world represent approximately 25-30% of global market value.

We have received initial approvals to market our devices for the treatment of AFL in Europe and the Middle East and are pursuing similar approvals in the U.S. as further discussed below. According to *S&S Insider Strategy and Stats,* the global market for devices used in the treatment of AFL was estimated at approximately $2.3 billion in 2025. For the markets where we are currently approved and are pursuing approvals, the market for devices used in the treatment of AFL was estimated at approximately $1.2 billion in 2025. Following the initial approvals for AFL, we are pursuing, or plan to pursue, additional approvals to market our Vision-MR® Ablation Catheter 2.0 for the treatment of VT and have completed technical development on our NavTrac-MR family of consumable devices that are utilized in those procedures. The global market for devices used in the treatment of VT was estimated at approximately $1.8 billion in 2025.

The MRI-Guided Ablation Opportunity

The addressable market for MRI guided cardiac ablation is the overall $14.7 billion cardiac ablation market, if Imricor's products are approved for all arrhythmia indications in all geographies. In the near term, our addressable market consists of the portions of this overall market that correspond to the indications and geographies described under "Market Size and Growth" above. Initially, the market subsets we are focused on include:

1. **Centers of Excellence**: High volume academic medical centers and specialized arrhythmia centers with existing cardiac magnetic resonance ("CMR") capabilities, which are easier and faster to convert to iCMR labs, or sites with strong interest in adopting advanced imaging technologies
2. **Radiation-Sensitive Patients**: Procedures involving patients for which radiation exposure is of particular concern, for example in pediatric settings

Imricor's ablation catheter (Vision-MR Ablation Catheter 2.0) is currently approved in the EU for treatment of Type I atrial flutter, and it is being evaluated in the VISABL-AFL clinical trial to support U.S. FDA approval for Type I atrial flutter. In addition, the Vision-MR Ablation Catheter 2.0 is being evaluated in the VISABL-VT trial in Europe to support an expansion of its indications to include the treatment of ventricular tachycardia. As clinical evidence accumulates through our ongoing VISABL-AFL and VISABL-VT trials, and our indications of use are expanded in various geographies, we anticipate expanding adoption across broader segments of the cardiac ablation market.

Products and Technology

Imricor has developed a comprehensive portfolio of MRI-compatible cardiac electrophysiology products consisting of capital equipment systems and single-use consumable devices. Our products are specifically engineered to operate safely and effectively within the powerful electromagnetic fields of clinical MRI scanners while delivering the imaging guidance and therapeutic capabilities required for cardiac ablation procedures.

Note that MRI-compatible medical devices are technically labeled as “MR Conditional,” which is the language used in the descriptions below.

Our business model emphasizes recurring revenue through consumable devices used in MRI-guided cardiac ablation procedures, supported by capital equipment sales that enable hospital adoption of iCMR technology. This model aligns with industry best practices in medical device commercialization, where capital equipment generates initial revenue and establishes customer relationships, while consumables provide predictable, high-margin revenue streams as procedure volumes grow.

Imricor products are designed to integrate with MRI systems and supporting equipment from leading MRI manufacturers and third-party partners, enabling hospitals to establish complete, turnkey iCMR labs.

Capital Equipment Systems

Advantage-MR EP Recorder/Stimulator System

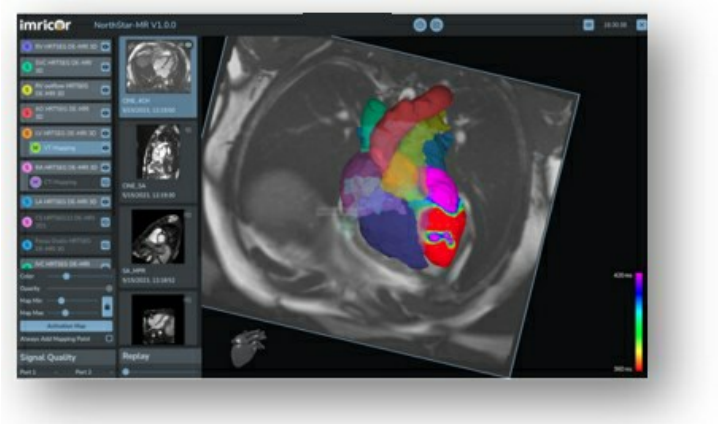
The Advantage-MR EP Recorder/Stimulator is a MR Conditional cardiac electrophysiology recording system (“EP Recorder”) used to measure physiological data in the EP laboratory. It provides high-fidelity signal acquisition and display of intracardiac electrogram (“EGM”) and electrocardiogram (“ECG”) signals. The system incorporates a cardiac stimulator which facilitates manual and programmed pacing stimulation of the heart. In addition, the Advantage-MR system provides an interface to MRI scanners, through which catheter active tracking coil signals may be passed. Advantage-MR also interfaces and communicates with the ablation generator and NorthStar mapping system, tying all these various systems together in a way that provides a comprehensive iCMR ablation environment.

Advantage-MR is approved for commercialization in the EU and ME. The system has been submitted for premarket notification clearance in the U.S., under the FDA’s 510(k) process.

NorthStar Mapping System

The NorthStar™ Mapping System is an MR Conditional 3D mapping and navigation system for use in iCMR procedures. NorthStar provides a 3D environment in which real-time MR images of the anatomy, 3D representations of the anatomy, and device(s) are displayed. In addition, during EP procedures, NorthStar can display electroanatomical maps (voltage or activation) and/or therapy delivery information. These capabilities allow for procedure planning and guidance, and procedural therapy assessment.

NorthStar communicates with MRI scanners to enable scanner control and real-time image streaming. During ablation procedures, NorthStar also communicates with the Advantage-MR system to facilitate electroanatomical mapping and other capabilities.



Key features of NorthStar include:

- **MRI-Native Platform**: Built from the ground up to operate in the MRI suite using MRI image data rather than fluoroscopy-based localization.
- **Real-Time Catheter Visualization**: Displays catheter position dynamically using Imricor's proprietary and patented active tracking technologies.
- **High-Resolution Anatomical Geometry**: Displays detailed 3D anatomy models directly from MRI datasets for outstanding anatomical accuracy.
- **Activation, Voltage & Substrate Mapping**: Supports, in conjunction with the Advantage-MR system, the full range of EP mapping modalities needed for diagnostic and therapeutic electrophysiology (ablation) procedures.
- **Compatibility with Multiple MRI Vendors**: Designed to operate across major MRI platforms, including Siemens and Philips, and shortly GE, providing customers with a wide range of choices for imaging systems when establishing an iCMR lab.
- **Future-Ready Architecture**: Software platform engineered to support ongoing enhancements, including PFA integration, advanced substrate imaging, and automated lesion assessment.

NorthStar is approved/cleared for commercialization in the U.S. (currently operating with the Siemens platform only) and EU (currently operating with the Siemens and Philips platforms), and has been submitted to the Saudi Food and Drug Authority for Medical Device Marketing Authorization.

RF-5000 Ablation Generator System

The RF-5000 ablation generator system is a set of components: a radiofrequency ("RF") ablation generator, an associated remote control unit, and an irrigation pump. The system is used in iCMR ablation procedures to provide therapeutic RF energy while simultaneously cooling the catheter tip. The system communicates with the Advantage-MR system which then communicates with NorthStar to provide a comprehensive ablation solution.

A predecessor device, the HAT500 RF ablation generator system, was designed in a collaboration between Osypka GmbH ("Osypka") and livetec Ingenieurbüro GmbH ("livetec"), both in Germany, and is approved for commercialization in the EU. The HAT500 is manufactured by livetec, and it is sold under the Osypka brand.

Imricor has entered into an Intellectual Property License Agreement with livetec ("livetec Agreement"), dated November 13, 2023. Under the livetec Agreement, Imricor has purchased a royalty-free, perpetual, worldwide, non-transferable, non-exclusive license to livetec intellectual property related to the HAT500 system. The HAT500 design is being transferred into the Imricor Quality Management System and, once transfer is complete, will be manufactured and, upon approvals for the manufacturer change, sold by Imricor under the new name: RF-5000. Until that time, the device will be manufactured by livetec and sold in the EU under the name HAT500; once PMA approval is obtained, it will be sold under the name RF-5000 in the U.S.

There are no regulatory implications for the Advantage-MR system nor the NorthStar system, associated with the RF-5000 system's manufacturer change.

Consumable Devices – Vision-MR and NavTrac-MR Families

Our Vision-MR and NavTrac-MR family of consumable devices represents the core of our commercial strategy and recurring revenue model. These single-use devices are essential components of MRI-guided cardiac ablation procedures. We have deliberately designed these products to look, feel, and function like standard consumable devices used in conventional fluoroscopic guided ablation procedures.

Vision-MR Ablation Catheter 2.0

Our flagship product is a steerable cardiac ablation catheter specifically designed for use in MRI environments and capable of delivering RF ablation energy under real-time MRI guidance. The Vision-MR Ablation Catheter 2.0 is a steerable catheter available with either a 32mm or 48mm curve diameter, with integrated gold electrodes enabling thermal ablation of cardiac tissue and electrical sensing and pacing.

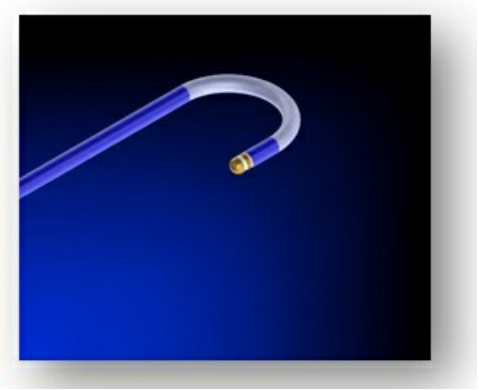
The catheter is constructed from MRI-compatible materials and incorporates proprietary and patented design features enabling active device tracking and safe operation in MRI environments.

The Vision-MR Ablation Catheter 2.0 is currently approved in the EU and ME for treatment of Type I atrial flutter and it is being evaluated in the VISABL-AFL clinical trial to support U.S. FDA approval for Type I atrial flutter. In addition, the Vision-MR Ablation Catheter 2.0 is being evaluated in the VISABL-VT clinical trial in Europe to support an expansion of its indications to include the treatment of ventricular tachycardia.

Vision-MR Diagnostic Catheter

The Vision-MR Diagnostic Catheter is an MR Conditional deflectable multi-electrode diagnostic catheter designed for electrophysiological mapping of the heart (i.e. sensing and pacing).

The Vision-MR Diagnostic Catheter is approved/cleared for commercialization in the EU, ME, and U.S.



Vision-MR Dispersive Electrode

The Vision-MR Dispersive Electrode is an MR Conditional sterile, single-use dispersive return electrode required to complete the radiofrequency ablation circuit during an ablation procedure.

The Vision-MR Dispersive Electrode is approved for commercialization in the EU and ME, and has been submitted for premarket notification clearance in the U.S., under the FDA's 510(k) process.

NavTrac-MR Steerable Introducer

The NavTrac-MR Steerable Introducer is an MR Conditional steerable sheath and dilator used to better position the Vision-MR Ablation Catheter 2.0, Vision-MR Diagnostic Catheter, or the NavTrac-MR Transseptal Needle during ablation procedures.

The NavTrac-MR Steerable Introducer is currently being evaluated in the VISABL-AFL and VISABL-VT trials in the U.S. and Europe to support EU, ME, and U.S. approvals/clearances.

NavTrac-MR Transseptal Needle

The NavTrac-MR Transseptal Needle is an MR Conditional polymer needle used in conjunction with the NavTrac-MR Steerable Introducer and NavTrac-MR Dilator for gaining left-sided access during ablation procedures.

The NavTrac-MR Transseptal Needle is currently being evaluated in the VISABL-VT trial in Europe to support EU, ME, and U.S. approvals/clearances. The VISABL-VT trial collects ancillary endpoints on the performance of supportive devices like the NavTrac-MR Transseptal Needle. This data is required for EU MDR submission and subsequent approval in the EU. The same data submitted for EU MDR is used for ME applications, if required per respective ME countries. Although clinical data is not explicitly required for clearance of the transeptal needle in the US, it may be helpful during the review process.

Product Pipeline and Development Programs

Pulsed Field Ablation Research

While our current commercial focus is on RF ablation in the MRI environment, we recognize that pulsed field ablation represents an emerging, high-growth ablation modality. We are in early-stage research activities to evaluate the MRI compatibility and clinical applicability of PFA energy delivery in the MRI environment.

Pulsed field ablation offers potential clinical advantages over RF ablation, and we believe MRI guidance can provide benefits to PFA in the same way it does for RF ablation, including superior periprocedural tissue visualization, arrhythmogenic substrate imaging, and lesion assessment. We believe MRI is an imaging modality that can enhance the utilization of any ablation energy source, including RF, cryo, and PFA, and we aim to deliver iCMR solutions for whatever ablative energy source physicians prefer.

MRI Guided Endomyocardial Biopsy Device

MRI-guided endomyocardial biopsy is a potentially groundbreaking procedure used to obtain targeted myocardial tissue samples for diagnostic, therapeutic, and research purposes, particularly in cases of myocarditis, cardiac sarcoidosis, infiltrative cardiomyopathies, and emerging molecular and genetic profiling applications. Today, biopsy procedures are performed under X-ray fluoroscopic guidance, which provides limited soft-tissue visualization and forces operators to rely on indirect anatomical landmarks rather than direct real-time targeting of the myocardium. This lack of targeting has limited the usefulness and adoption of cardiac biopsies, relegating it to being primarily used for transplant rejection monitoring which does not require precise tissue targeting. Periprocedural MRI for cardiac biopsies is uniquely suited to address the limitations of X-ray, by offering the ability to visualize and identify target locations on the heart and guiding an MR Conditional biopsy system to those locations for precise sampling.

We believe MRI-guided endomyocardial biopsy represents a meaningful opportunity for innovation. Imricor is developing an MR Conditional endomyocardial biopsy system designed to enable real-time device tracking, precise navigation, and targeted myocardial sampling within the MRI environment, all aimed at enhancing the accuracy, safety, and diagnostic yield of cardiac biopsy procedures.

Clinical Development Programs

Imricor is running two clinical trials, as mentioned above: the VISABL-AFL Trial and the VISABL-VT Trial. The following is a more detailed description of each.

VISABL-AFL Trial – FDA Approval Pathway for Type I Atrial Flutter

The VISABL-AFL (**Vis**ion-MR **Abl**ation of **A**trial **Fl**utter) pivotal clinical trial is a prospective, single-arm, multi-center global investigational study of the safety and efficacy of Type I atrial flutter ablation procedures performed with the Vision-MR Ablation Catheter 2.0 and Osypka HAT500 RF ablation generator system (the HAT500 will be released in the U.S. under the name RF-5000). The study includes three sites in Europe, and up to five sites in the U.S., with a sample size of 91 patients. Imricor is the sole sponsor of this VISABL-AFL clinical trial.

VISABL-AFL is designed to support U.S. market entry of the studied devices following successful trial completion and FDA approval via the FDA's PMA process.

The primary endpoints of the trial are (1) confirmation of bidirectional conduction block of the cavotricuspid isthmus ("CTI"), assessed immediately following final ablation energy delivery; and (2) composite of serious cardiovascular adverse events through 7 days post-procedure, adjudicated by an independent clinical events committee. The secondary endpoints of the trial are (1) freedom from documented Type I atrial flutter recurrence at 90 days; and (2) all serious adverse event rate through 3-month study duration.

Patient inclusion criteria are:

- Indicated for type I atrial flutter ablation with at least 1 documented episode of type 1 atrial flutter within 6 months (180 days) of enrollment by 12-lead ECG
- 18 years or older

Patient exclusion criteria are:

- Contraindications for MRI procedures
- Cannot have anti-arrhythmic drugs (class I or class III) prescribed for the treatment of type I atrial flutter stopped prior to the procedure
- Previous CTI ablation procedures
- Myocardial infarction within 60 days of enrollment
- Current unstable angina
- Cardiac surgery within 90 days of enrollment
- Any cerebral ischemic event (including transient ischemic attacks) within 6 months (180 days) of enrollment
- Thrombocytosis or thrombocytopenia
- Contraindication to anticoagulation therapy
- Currently documented intracardiac thrombus or myxoma
- Implantation of permanent leads of an implantable device in or through the right atrium within 90 days of enrollment
- Prosthetic valve through which the catheter must pass
- Interatrial baffle or patch through which the catheter must pass
- Moderate or severe tricuspid valve regurgitation or stenosis
- Uncompensated congestive heart failure
- Active systemic infection
- Pregnancy or if subject plans to become pregnant during the trial
- Uncontrolled hyperthyroidism
- Any other significant uncontrolled or unstable medical condition
- Enrollment in any concurrent study without Imricor written approval
- Life expectancy of less than or equal to 2 years (730 days) per physician opinion

Enrollment of patients for VISABL-AFL commenced in June 2024. We anticipate completing enrollment in the VISABL-AFL trial in the second quarter of 2026, with data analysis and FDA submission targeted for the middle of 2026. Regulatory approval timeline is contingent on trial outcomes and FDA feedback.

VISABL-VT Trial – European Indication Expansion for Ventricular Tachycardia

The VISABL-VT (**Vis**ion-MR **Abl**ation of **V**entricular **T**achycardia) is a prospective single-arm, multi-center interventional investigation of the safety and efficacy of RF ablation of ventricular tachycardia associated with ischemic cardiomyopathy performed with the Vision-MR Ablation Catheter 2.0 in the iCMR environment. The study calls for treating 64 patients and includes a 6-month follow-up for each patient, as is typical. Up to 6 European sites are expected to participate in the study. Imricor is the sole sponsor of this VISABL-VT clinical trial.

VISABL-VT is designed to support expanded indications for the Vision-MR Ablation Catheter 2.0 in the EU, to include VT ablation. Successful VT indication approval would substantially expand Imricor's addressable market and clinical impact.

The primary endpoints of the trial are (1) absence of inducible clinical ventricular tachycardia following the last radiofrequency ablation application with the Vision-MR Ablation Catheter 2.0 and (2) composite of any procedure- or device-related serious adverse events through 7 days post-index ablation procedure. The secondary endpoints of the trial are (1) six-month freedom from recurrence of sustained VT or VT requiring intervention, freedom from new or increased dose of Class I or III antiarrhythmic drugs ("AAD") at six months following index ablation and (2) rate of all serious adverse events occurring during follow up. Ancillary endpoints include (1) procedure time, (2) RF time per patient, (3) number of RF applications per patient, (4) fluoroscopy time (expected to be zero with MRI guidance), and (5) performance of supportive investigational devices.

Patient inclusion criteria are:

- Roll-in subjects only: Documentation of premature ventricular contractions indicated for ablation therapy (subjects may or may not be diagnosed with Ischemic Cardiomyopathy)
- Documented (ECG/EGM) spontaneous episode of sustained ventricular tachycardia within 6 months of the procedure
- Diagnosis of Ischemic Cardiomyopathy
- AAD therapy refractory, contraindicated, not tolerated, or not desired
- 18 years or older

Patient exclusion criteria are:

- Implanted with non-MR compatible medical devices or contraindicated for an MRI
- Presence of intracardiac thrombus (verified via CT/MRI/TEE/TTE within 48 hours of procedure or at start of procedure)
- Thrombocytopenia or coagulopathy
- Mechanical mitral and/or aortic valve precluding access to the left ventricle
- Severe aortic stenosis
- Myocardial infarction requiring stent implantation within 90 days of procedure
- Previous cardiac surgery within 60 days of procedure
- Known/uncontrolled stroke risks
- Class IV Heart Failure
- Ejection fraction ("EF") < 25%
- Patients with glomerular filtration rate ("GFR") < 30
- Women who are pregnant
- Allergy to contrast agents (e.g., Gadolinium)
- Active infection
- Known or suspected myxoma
- Unstable angina
- Patients who do not tolerate anticoagulation therapy
- Previous interatrial septal patch or prosthetic atrial septal defect closure device
- Life expectancy < 12 months
- Enrollment in another study without Imricor approval

The VISABL-VT trial has achieved several world-first milestones demonstrating the clinical feasibility and safety of MRI-guided ablation for complex ventricular arrhythmias. These milestones, all performed at Amsterdam University Medical Center, include:

- First-in-human MRI-guided left ventricular mapping and ablation (April 2025), with the successful mapping and treatment of premature ventricular complexes ("PVCs") originating from the left ventricle;
- First-in-human MRI-guided transseptal crossing (October 2025), with the successful crossing of the atrial septum under real-time MRI guidance to access the left atrium and left ventricle;
- First-in-human substrate-guided ablation using periprocedural MRI (October 2025), with the successful identification and ablation of scar-based ventricular tachycardia substrate visualized on MRI during the procedure;
- First-in-human MRI-guided ablation in patient with an ICD (October 2025), demonstrating the safe and effective utilization of MRI-guidance for ablation procedures in high-risk patients with an active implantable cardiac device; and
- First-in-human acute procedural ischemic VT ablation success (October 2025), with the patient being non-inducible for VT at completion of ablation.

The first-in-human PVC case report from VISABL-VT was published in *JAMA Cardiology* in September 2025 (*Götte et al.;* "*MR-Guided Ventricular Ablation for Idiopathic Outflow Tract Premature Ventricular Complexes*"*)*, documenting successful MR-guided ablation for right and left ventricular outflow tract premature ventricular complexes, resulting in complete PVC suppression (100% reduction in PVC burden), and no procedural complications through 2-month clinical follow-up.

The first-in-human ischemic VT case report from VISABL-VT was published in *Circulation* in April 2026 (*Hopman et al.;* "*Interventional MRI for VT Ablation*"*)*, documenting successful MR-guided ablation for ischemic VT, with no recurrent VT or ICD therapies at 3-month follow-up and no procedural complications.

Enrollment of patients for VISABL-VT has been limited to roll-in patients to date. Non-roll-in patient enrollment is expected to commence in Q3 2026. We anticipate completing enrollment in the VISABL-VT trial by the end of 2026, followed by 6-month follow-up. Regulatory approval timeline for expanded VT indications in the EU is contingent on trial outcomes and Notified Body feedback.

Intellectual Property

Imricor's intellectual property strategy is designed to protect our core innovations in MRI-compatible devices while enabling efficient commercialization through partnerships and licensing arrangements. Our IP portfolio consists of internally developed patents, proprietary trade secrets, and licensed technologies.

Patent Portfolio

Imricor has developed and maintains a portfolio of patents covering core technologies for our MRI-compatible devices. We actively file patent applications to protect new developments as our product pipeline advances. Imricor files patent applications in the United States, either directly or as national-stage applications that claim priority to international applications filed under the Patent Cooperation Treaty. We also pursue protection of our intellectual property outside of the United States through the prosecution of national stage applications that claim priority to international applications under the PCT. These PCT applications typically share subject matter with related U.S. applications. National stage applications that claim priority to these PCT applications have been filed in specific jurisdictions, typically Europe, Japan, Australia, Canada, and the United States. Imricor's earliest patents expire in 2030, while new patent applications have been submitted as recently as 2025.

Material patents covering our products are found in the following table:

Patent Number	Issue Date	Expiration Date	Application Title	Type	Jurisdiction / Country
8,588,934	November 19, 2013	November 15, 2030	MRI Compatible Electrode Circuit	Utility	U.S.
8,855,788	October 7, 2014	March 4, 2030	MRI Compatible Electrode Circuit	Utility	U.S.
8,761,900	June 24, 2014	March 4, 2030	MRI Compatible Electrode Circuit	Utility	U.S.
8,831,743	September 9, 2014	March 4, 2030	MRI Compatible Electrode Circuit	Utility	U.S.
2010221228	August 15, 2013	March 4, 2030	MRI Compatible Electrode Circuit	Utility	Australia
2013206743	February 12, 2015	March 4, 2030	MRI Compatible Electrode Circuit	Utility	Australia
2014253481	June 9, 2016	March 4, 2030	MRI Compatible Electrode Circuit	Utility	Australia
2014248852	July 6, 2017	March 12, 2034	MRI Compatible Electrode Circuit	Utility	Australia
2,754,045	April 6, 2021	March 4, 2030	MRI Compatible Electrode Circuit	Utility	Canada
2902564	September 4, 2018	March 12, 2034	MRI Compatible Electrode Circuit	Utility	Canada
ZL201410643489.4	November 21, 2017	March 4, 2030	MRI Compatible Electrode Circuit	Utility	China
ZL2010080010330.9	November 26, 2014	March 4, 2030	MRI Compatible Electrode Circuit	Utility	China
ZL201310392581.3	August 17, 2016	March 4, 2030	MRI Compatible Electrode Circuit	Utility	China
ZL201480016102.0	December 15, 2017	March 12, 2034	MRI Compatible Electrode Circuit	Utility	China
2403404	May 6, 2020	March 4, 2030	MRI Compatible Electrode Circuit	Utility	Czech Republic
2983778	January 16, 2019	March 12, 2034	MRI Compatible Electrode Circuit	Utility	Germany
2403404	May 6, 2020	March 4, 2030	MRI Compatible Electrode Circuit	Utility	Germany
2403404	May 6, 2020	March 4, 2030	MRI Compatible Electrode Circuit	Utility	European Patent Office
2983778	January 16, 2019	March 12, 2034	MRI Compatible Electrode Circuit	Utility	European Patent Office
2983778	January 16, 2019	March 12, 2034	MRI Compatible Electrode Circuit	Utility	Spain
2983778	January 16, 2019	March 12, 2034	MRI Compatible Electrode Circuit	Utility	Finland
2983778	January 16, 2019	March 12, 2034	MRI Compatible Electrode Circuit	Utility	France
2403404	May 6, 2020	March 4, 2030	MRI Compatible Electrode Circuit	Utility	France
2983778	January 16, 2019	March 12, 2034	MRI Compatible Electrode Circuit	Utility	United Kingdom
2403404	May 6, 2020	March 4, 2030	MRI Compatible Electrode Circuit	Utility	United Kingdom
2983778	January 16, 2019	March 4, 2030	MRI Compatible Electrode Circuit	Utility	Greece
1217096	November 8, 2019	March 4, 2030	MRI Compatible Electrode Circuit	Utility	Hong Kong
1165974	January 15, 2021	March 4, 2030	MRI Compatible Electrode Wire	Utility	Hong Kong
2983778	January 16, 2019	March 12, 2034	MRI Compatible Electrode Circuit	Utility	Hungary
2983778	January 16, 2019	March 12, 2034	MRI Compatible Electrode Circuit	Utility	Ireland
2403404	May 6, 2020	March 4, 2030	MRI Compatible Electrode Circuit	Utility	Ireland
2983778	January 16, 2019	March 12, 2034	MRI Compatible Electrode Circuit	Utility	Italy
2403404	May 6, 2020	March 4, 2030	MRI Compatible Electrode Circuit	Utility	Italy
10-1387841	April 15, 2014	March 4, 2030	MRI Compatible Electrode Circuit	Utility	South Korea
10-1825279	January 29, 2018	March 12, 2034	MRI Compatible Electrode Circuit	Utility	South Korea
2983778	January 16, 2019	March 12, 2034	MRI Compatible Electrode Circuit	Utility	Netherlands
2403404	May 6, 2020	March 4, 2030	MRI Compatible Electrode Circuit	Utility	Netherlands
2983778	January 16, 2019	March 12, 2034	MRI Compatible Electrode Circuit	Utility	Norway
2983778	January 16, 2019	March 12, 2034	MRI Compatible Electrode Circuit	Utility	Poland
2983778	January 16, 2019	March 12, 2034	MRI Compatible Electrode Circuit	Utility	Sweden
2983778	January 16, 2019	March 12, 2034	MRI Compatible Electrode Circuit	Utility	Turkey
8,731,687	May 20, 2014	March 4, 2030	Method of Constructing MRI Compatible Electrode Circuit	Method	U.S.
8,761,899	June 24, 2014	March 4, 2030	MRI Compatible Conductive Wires	Utility	U.S.
8,588,938	November 19, 2013	March 4, 2030	MRI Compatible Co-Radially Wound Electrode Circuit	Utility	U.S.
8,843,212	September 23, 2014	March 4, 2030	MRI Compatible Co-Radially Wound Lead Assembly	Utility	U.S.
8,843,213	September 23, 2014	March 4, 2030	MRI Compatible Co-Radially Wound Lead Assembly	Utility	U.S.
8,805,540	August 12, 2014	March 4, 2030	MRI Compatible Cable	Utility	U.S.
9,138,561	September 22, 2015	December 13, 2032	MRI Compatible Handle and Steerable Sheath	Utility	U.S.
9,192,743	November 24, 2015	December 13, 2032	MRI Compatible Handle and Steerable Sheath	Utility	U.S.
2013359395	November 3, 2016	December 11, 2033	MRI Compatible Handle and Steerable Sheath	Utility	Australia
2,894,763	September 19, 2017	December 11, 2033	MRI Compatible Handle and Steerable Sheath	Utility	Canada
ZL201380065624.5	June 22, 2018	December 11, 2033	MRI Compatible Handle and Steerable Sheath	Utility	China
2931111	May 1, 2019	December 11, 2033	MRI Compatible Handle and Steerable Sheath	Utility	Germany
2931111	May 1, 2019	December 11, 2033	MRI Compatible Handle and Steerable Sheath	Utility	European Patent Office
2931111	May 1, 2019	December 11, 2033	MRI Compatible Handle and Steerable Sheath	Utility	France
2931111	May 1, 2019	December 11, 2033	MRI Compatible Handle and Steerable Sheath	Utility	United Kingdom
1211824	July 10, 2020	December 11, 2033	MRI Compatible Handle and Steerable Sheath	Utility	Hong Kong
10-1737720	May 12, 2017	December 11, 2033	MRI Compatible Handle and Steerable Sheath	Utility	South Korea
2931111	May 1, 2019	December 11, 2033	MRI Compatible Handle and Steerable Sheath	Utility	Netherlands

Trademark and Trade Name Protection

In addition to protection of intellectual property rights through patents, Imricor pursues protection of its marks through trademark registration. Imricor asserts U.S. trademark rights to the mark VISION-MR, ADVANTAGE-MR, NORTHSTAR, and IMRICOR and other registered marks both foreign and U.S.

Licensed Intellectual Property

Imricor holds a Patent License Agreement, which grants us a non-exclusive non-transferable fully-paid worldwide license to certain patents owned by Koninklijke Philips N.V. ("Philips N.V.") for technology embodied in the Vision-MR Ablation Catheter 2.0. The Patent License Agreement was entered into on December 1, 2023 and is effective until January 1, 2031. In consideration of this license, Imricor paid a fixed royalty to Philips N.V. and no future royalties are owed under the agreement. Philips N.V. may terminate the agreement due to non-performance by Imricor, if Imricor enters into bankruptcy proceedings, if Imricor brings a claim of infringement against Philips N.V. or their affiliates, or upon a change of control in relation to Imricor.

We also hold a non-exclusive fully-paid worldwide Intellectual Property License to market and manufacture the HAT500 and RF-5000 ablation generator systems from livetec Ingenieurbüro GmbH. The Intellectual Property License Agreement was entered into on November 13, 2023 and remains in effect until terminated by either party. In consideration of this license, Imricor paid a fixed royalty to livetec Ingenieurbüro GmbH and no future royalties are owed under the agreement. The agreement allows termination only in limited circumstances, specifically if a material breach or a default occurs and is not cured.

Proprietary Technologies and Trade Secrets

Imricor has developed substantial proprietary knowledge and trade secrets that provide competitive advantage, including know-how developed through nearly 20 years of R&D on how to engineer devices that operate safely and effectively in MRI environments; proprietary approaches to integrating imaging, electrophysiology, and ablation technologies; experiential knowledge regarding procedural techniques, workflow design, and best practices for MRI-guided ablation; and specialized manufacturing knowledge for producing MRI-compatible medical devices with consistent quality. This proprietary knowledge is protected through a combination of patents, trade secret agreements with employees and contractors, and operational security measures.

Regulatory Environment and Strategy

European Union Regulatory Framework

The EU Medical Device Regulation ("EU MDR") governs medical devices in the European Union and focuses on safety, performance, and clinical evidence across the full product lifecycle. Devices are classified by risk (Class I, IIa, IIb, III) and generally require conformity assessment by a Notified Body for higher-risk products. Manufacturers must implement a compliant Quality Management System (ISO 13485), maintain comprehensive Technical Documentation, assign a Person Responsible for Regulatory Compliance ("PRRC"), and meet strict requirements for clinical evaluation, post-market surveillance, and vigilance. The EU MDR framework places strong emphasis on traceability, transparency, and lifecycle oversight, including registration in the European Database on Medical Devices, EUDAMED, and compliance with economic operator responsibilities.

All Imricor's currently commercialized cardiac electrophysiology products, including the Advantage-MR EP Recorder/Stimulator System, Vision-MR Ablation Catheter 2.0, Vision-MR Dispersive Electrode, Vision-MR Diagnostic Catheter, and NorthStar Mapping System, have received CE Mark certification under the EU MDR.

Product	Date of Approval	Classification	Intended Use/Indications for Use
Advantage-MR EP Recorder/Stimulator	April 15, 2025	IIb	Acquire, amplify, filter, digitize, display, and record electrical signals obtained during electrophysiological studies and related procedures.
NorthStar	June 4, 2025	IIa	Aid interventional MRI procedures, including electrophysiology procedures, by providing a 3D environment in which MR images, devices, and procedure-related data are displayed.
Vision-MR Ablation Catheter 2.0	June 11, 2024	III	Cardiac electrophysiological mapping (stimulating and recording) for the diagnosis of arrhythmias and radiofrequency ablation and treatment of Type I atrial flutter in patients age 18 years or older.
Vision-MR Diagnostic Catheter	October 10, 2023	III	Cardiac electrophysiological mapping (stimulating and recording) during electrophysiology procedures to diagnose arrhythmias and/or guide therapeutic decisions in patients 18 years or older.
Vision-MR Dispersive Electrode	March 6, 2025	I	The Vision-MR Dispersive Electrode is a self-adhesive, ready-to-use product and is an accessory for RF surgery in monopolar applications. The Vision-MR Dispersive Electrode is intended for use with patients > 15kg.

U.S. FDA Regulatory Framework

The FDA regulates medical devices in the United States under the Federal Food, Drug, and Cosmetic Act using a risk-based classification system (Class I, II, and III). Devices are regulated through different pathways depending on risk and intended use, including 510(k) premarket notification, De Novo classification, and premarket approval. Manufacturers must comply with Quality System Regulation ("QSR") (21 CFR Part 820), labeling requirements, registration and listing, and post-market surveillance obligations such as Medical Device Reporting ("MDR"). The FDA framework emphasizes demonstrating substantial equivalence or safety and effectiveness, maintaining manufacturing controls, and ongoing compliance throughout the device lifecycle.

510(k) Clearance Pathway Devices

We are pursuing or will pursue clearance through the 510(k) pathway for most of our products (other than as stated below). The Vision-MR Diagnostic Catheter and NorthStar Mapping System received market clearance via the 510(k) process in January 2026.

Product	Date of Approval	Classification	Intended Use/Indications for Use
NorthStar	January 28, 2026	II	Aid interventional Cardiovascular Magnetic Resonance Imaging procedures, including electrophysiology procedures, by providing a 3D environment in which MR images, devices, and procedure-related data are displayed.
Vision-MR Diagnostic Catheter	January 8, 2026	II	Cardiac electrophysiological mapping (stimulating and recording) during electrophysiology procedures to diagnose arrhythmias and/or guide therapeutic decisions in patients 18 years or older.

Submissions have been and will continue to be made sequentially, with the goal of receiving clearance for these devices in 2026.

Product Candidate	Date Submitted	Classification	Intended Use/Indications for Use
Advantage-MR EP Recorder/Stimulator	February 5, 2026	II	Acquire, amplify, filter, digitize, display, and record electrical signals obtained during electrophysiological studies and related procedures.
Vision-MR Dispersive Electrode	October 3, 2025	II	The Vision-MR Dispersive Electrode is a self-adhesive, ready-to-use product and is an accessory for RF surgery in monopolar applications. The Vision-MR Dispersive Electrode is intended for use with patients > 15kg.

Premarket Approval Pathway Devices

We are pursuing approval of our Vision-MR Ablation Catheter 2.0 (for treating Type I atrial flutter) and RF-5000 ablation generator system through the PMA pathway. We are utilizing a modular PMA submission strategy for these products, with the first module submitted in June 2024 and the second module submitted in March 2025. We expect to submit the third module in Q2 2026 and plan to submit the fourth module following completion of enrollment in the VISABL-AFL clinical trial and when the resulting clinical data have been cleaned and analyzed. Following submission of the fourth module, we expect the FDA to review the complete PMA application under its standard PMA review procedures, and we are targeting receipt of FDA approval for these devices in 2026.

Quality System and Compliance Requirements

All Imricor manufacturing operations are required to comply with the FDA's QSR and current Good Manufacturing Practices ("cGMP"). Our quality system includes systematic design and development processes ensuring devices meet user needs and intended uses; management of design documentation, manufacturing procedures, and quality procedures; validated manufacturing processes ensuring consistent product quality; real-time monitoring and testing during manufacturing; comprehensive testing of finished devices before release; lot serialization and traceability systems enabling product tracking and recall capability; systems for receiving, investigating, and responding to customer complaints; and systematic processes for addressing quality issues and preventing recurrence.

Imricor maintains ISO 13485:2016 certification, an international standard for medical device quality management systems, which also serves as evidence of compliance with FDA QSR requirements and EU MDR requirements. This certification is maintained through annual surveillance audits by certification bodies, quality management system maintenance and continuous improvement, regular training and employee competency assessment, and a management review process.

Middle East Regulatory Framework

Regulatory frameworks across the Middle East vary by country. Approvals for Qatar and Saudi Arabia have been obtained through respective national regulatory pathways, and commercial sales efforts are underway in both markets through East Agency WLL, our exclusive distribution partner in Qatar, and Al Faisaliah Medical Systems, our exclusive distribution partner in Saudi Arabia.

Sales, Marketing, Distribution, and Reimbursement

Imricor has implemented a hybrid sales and distribution model designed to optimize market penetration and capital efficiency across different geographic regions. Our strategy reflects the infrastructure maturity, regulatory environment, and competitive dynamics in each market. We have sales employees in the United States and in Europe. In certain European countries and Middle East countries, we maintain partnerships with local distributors.

European Union

As of April 21, 2026, Imricor's European direct sales team comprises five full-time employees: a sales director based in Europe and four sales managers. This team focuses on identifying and engaging academic medical centers, specialized arrhythmia centers, and high-volume EP programs interested in MRI-guided ablation technology; providing physicians with technical training, clinical evidence, and procedural support; supporting hospitals in establishing iCMR labs, including facility design consultation, equipment selection, and workflow optimization; and on-site support during early procedure cases to ensure optimal outcomes and build physician confidence.

United States

Imricor is implementing commercialization activities to position for rapid U.S. market entry as portfolio devices gain regulatory clearances and approvals. We are building relationships with leading U.S. electrophysiologists and academic centers to ensure awareness of MRI-guided ablation technology, and we are giving presentations and education programs at major electrophysiology and cardiovascular magnetic resonance conferences. We maintain an ongoing dialogue with the FDA to ensure alignment on our regulatory pathway and post-approval commercialization strategy.

Similar to Europe, the U.S. strategy focuses on centers of excellence, including academic medical centers, specialized arrhythmia centers, and high-volume EP programs. We are establishing a dedicated U.S. direct sales team, and sales force size will be scaled based on market dynamics, product demand, and capital availability.

Exclusive Distribution Partnerships

Our sales in the Middle East are made through exclusive distributor partnerships. In Saudi Arabia, Al Faisaliah Medical Systems is our exclusive distributor and has established medical device distribution network and hospital relationships in Saudi Arabia. In Qatar, East Agency WLL is our exclusive distributor and has market expertise and customer relationships in Qatar. Imricor provides distributor partners with product training and clinical education programs, technical support and customer service resources, marketing materials and clinical evidence documentation, and pricing and reorder logistics support. The agreements do not contain minimum purchase commitments. We expect to enter into additional distribution agreements in other international markets from time to time in the ordinary course of business.

Marketing Strategy

Our primary marketing strategy emphasizes clinical evidence and physician education. Additionally, we cultivate relationships with leading electrophysiologists and cardiac imaging specialists who serve as advisors and consultants on clinical and regulatory strategy; generate clinical evidence through trials and real-world outcomes studies; educate peers through presentations, publications, and teaching activities; and advocate for MRI-guided ablation technology adoption.

Imricor offers medical education and physician training. We offer hands-on training, which involves phantom and simulator-based training to provide procedural practice for physicians new to MRI-guided ablation. Additionally, we offer case conferences (physician-led case discussions and technical training), regular presentations at industry conferences and other scientific meetings, and educational materials, such as clinical evidence summaries, technique guides, and safety information for physician reference.

Customer Base and Market Segments

Primary Customer Segments

Our primary customer segments include academic medical centers, specialized arrhythmia centers, and high-volume community hospitals.

Academic medical centers include university-affiliated hospitals with clinical research programs, cardiac imaging centers, and high-volume EP services. We look for academic medical centers with strong clinical leadership, infrastructure for new technologies, research interest, and a volume of more than 500 procedures annually. We have initially focused on EU centers and intend to expand to U.S. centers post-FDA approval.

Specialized arrhythmia centers include non-academic hospitals focused on electrophysiology and arrhythmia treatment. We look for specialized arrhythmia centers with high EP procedure volumes, specialized equipment and infrastructure, and experienced EP teams. In the EU, we have initially focused on centers in major metropolitan areas with a concentration of cardiac services.

High-volume community hospitals include large community hospitals with established cardiac programs and high EP procedure volumes. We look for high-volume community hospitals that are volume-driven, workflow-efficient, price-conscious, and quality-focused. We intend to focus on hospitals in the U.S. post-FDA approval.

We generate revenue to these hospitals and medical centers through initial sales of capital equipment that enable customers to establish iCMR labs, including our Advantage-MR EP Recorder/Stimulator System and NorthStar Mapping System, and related third-party equipment, along with recurring revenue for service agreements related to capital equipment and certain third-party equipment. We also generate recurring revenue through sales of single-use consumable products, which are used in iCMR-guided cardiac ablation procedures. We expect that, as procedure volumes increase at existing customer sites and as we add new sites, a growing proportion of our revenue will be derived from recurring sales of single-use consumable products. In certain markets, such as the Middle East, we generate revenue through sales of capital equipment and consumable products to hospitals and other providers via distributor partners pursuant to distribution agreements.

Customer Concentration

Customer concentration risk exists in our early commercialization stage, with sales currently concentrated in a limited number of European hospital systems and country markets. As our European customer base expands and U.S. commercialization begins, we anticipate customer concentration declining to typical levels for medical device companies. For additional detail on customer concentration risk, see the footnotes to our audited consolidated financial statements for the years ended December 31, 2025, and 2024, included elsewhere in this Registration Statement.

Reimbursement Strategy

European Reimbursement

In Europe, Imricor's products fit within existing procedural coding and reimbursement frameworks:

- **Procedural Codes**: Existing Diagnosis Related Group ("DRG") codes and procedural codes accommodate cardiac ablation procedures regardless of imaging guidance modality and have been utilized for commercial procedures in the EU
- **Reimbursement Coverage**: Hospitals are reimbursed for cardiac ablation procedures using existing codes; no need for new codes or special reimbursement approval
- **Payer Discussions**: We have held discussions with national payers and healthcare systems in the EU regarding specific reimbursement rates and coverage policies for our products; however, there is no assurance that such rates or policies will be granted

United States Reimbursement

In the United States, Imricor expects its products to fit into existing procedural coding and reimbursement:

- **Current Procedural Terminology ("CPT") Codes**: Existing CPT codes for Type I atrial flutter ablation and other EP procedures do not specify the imaging modality used to guide the procedure. Existing CPT codes accurately describe the procedures that will be performed with our products and are anticipated to be applicable
- **Centers for Medicare & Medicaid Services ("CMS") Reimbursement**: Medicare reimbursement through existing procedural codes (not requiring establishment of new codes)
- **Private Payer Coverage**: Private insurers typically follow Medicare/CMS coding and reimbursement determinations; accordingly, we have not initiated discussions with private payers in the U.S.

Middle East Reimbursement

In the Middle East, reimbursement and funding mechanisms vary by country but we expect to fit into existing reimbursement structures in our current target markets of Saudi Arabia and Qatar.

In Qatar, public hospitals typically operate under annual budgets, and costs for procedures using our products are paid directly from these budgets as part of overall hospital operating expenses. In Saudi Arabia, we expect that products will be purchased centrally through the National Unified Procurement Company ("NUPCO"), which manages government procurement of pharmaceuticals, medical supplies, and medical devices for public healthcare providers. Following receipt of required regulatory clearances in Saudi Arabia, we intend to apply for NUPCO listing and pricing to enable hospital purchasing of our products in that market.

Reimbursement Advantages

Our products fit within existing codes, which provides several advantages. There is no need to establish new procedural codes, which can delay reimbursement and market adoption. Our products have pricing parity with alternative ablation technologies, avoiding price disadvantage.

Potential Reimbursement Challenges

Reimbursement is complicated, and our products may face certain reimbursement challenges. For example, hospitals may face increased costs if MRI scanner time or facility utilization increases compared to fluoroscopy-based procedures. Some payers may require health economic justification for adoption despite code fit. Additionally, international reimbursement environments vary significantly by country.

Manufacturing and Supply Chain

Manufacturing Operations

Imricor's manufacturing operations are located in Burnsville, Minnesota, where we maintain a facility dedicated to the production of our MRI-compatible devices. The site is equipped for scalable manufacturing of both capital equipment and single-use consumables, including the Vision-MR and NavTrac-MR product families and the Advantage-MR and NorthStar platforms.

Our production strategy is founded on:

- **Quality control:** Utilizing ISO 13485:2016-certified systems to ensure product reliability, patient safety, and regulatory compliance across domestic and international markets.
- **Process validation:** Rigorous process validation and ongoing monitoring to maintain high manufacturing standards and efficient ramp-up during periods of demand growth.
- **Workforce expertise:** Cross-trained operators, ongoing employee training, and process documentation to underpin consistent quality.

Imricor currently has sufficient installed manufacturing capacity to meet near-term demand projections and to support initial U.S. commercial launch upon FDA approval. We continue to evaluate scaling options in anticipation of future FDA approval and revenue growth in other markets, but no facility expansion or off-site contract manufacturing of consumable devices is currently planned.

Supply Chain and Sourcing

Our key manufacturing inputs include specialized medical-grade polymers, electronics, and MRI-compatible components not broadly available from standard medical supply catalogs, which leads us to be reliant upon multiple third-party suppliers for these components, sub-assemblies, and materials. The majority of these items are sourced domestically, with a limited number of specific parts obtained overseas.

We require our suppliers to complete a qualification process embedded within our Quality Management System to ensure compliance with our quality specifications. While continued supplier diligence and dual sourcing (where practical) are ongoing priorities, we currently source some components, subassemblies, and materials from single source suppliers. Many of the components or sub-assemblies in our products are custom built to our specifications but use standard materials that can be provided by multiple suppliers. However, due to the manufacturing requirements of the FDA and other regulatory authorities, we may not be able to quickly establish replacement or additional sources for certain components, sub-assemblies, or materials if we experience an unexpected interruption in supply. We are not dependent on any single supplier for a substantial portion of our raw materials.

Competition and Market Position

Imricor competes in the global cardiac ablation market, which is dominated by well-capitalized companies offering X-ray fluoroscopy-guided ablation solutions and, increasingly, by innovators commercializing emerging PFA technology.

Major Competitors

Our major competitors include Abbott Laboratories, Boston Scientific Corp., Johnson & Johnson, and Medtronic, Inc. All of these competitors' systems rely on X-ray fluoroscopy (and/or ultrasound) for navigation. PFA is a rapidly growing, but still emerging, ablation modality shown in recent studies to be as effective as existing thermal ablation offerings, particularly for atrial fibrillation.

Imricor's Market Position and Differentiation

Imricor is the only company with commercial, regulatory-cleared MRI-compatible ablation systems enabling periprocedural soft-tissue imaging, lesion visualization, and entirely radiation-free procedures. Clinical workflow and procedural outcomes associated with Imricor's ablation system were evaluated in a Company-sponsored clinical study (ClinicalTrials.gov Identifier: NCT03078985), with results published in *European Heart Journal – Cardiovascular Imaging (2019)*. That study reported mean procedure times of approximately 48 minutes for the treatment of Type I atrial flutter. By comparison, published literature describing conventional catheter ablation techniques, incorporating electroanatomical mapping systems, for treating Type I atrial flutter, reports procedure times of up to approximately 88 minutes, including the prospective randomized multicenter study by Hindricks et al. (2009) published in the *Journal of Cardiovascular Electrophysiology*.

Pulsed Field Ablation and MRI Guidance

Imricor sees MRI and PFA as complementary, rather than competitive. As PFA adoption increases for atrial fibrillation and other arrhythmias, we believe MRI's benefits for tissue visualization and acute lesion assessment will remain relevant regardless of energy modality. Accordingly, Imricor is investing in early-stage R&D aimed at "MRI-guided PFA," with the goal that MRI imaging improves safety, precision, and outcomes for all ablation technologies.

Strategic Partnerships and Ecosystem Development

Recognizing that successful MRI-guided cardiac electrophysiology procedures require a complete ecosystem of MRI-compatible equipment beyond our core ablation products, Imricor has cultivated strategic partnerships with leading medical technology companies specializing in MRI systems and equipment, including MiRTLE Medical, NordicNeuroLab, Optoacoustics, livetec Ingenieurbuero GmbH, and MIPM GmbH. These partnerships allow us to deliver integrated iCMR lab solutions and enable hospitals to establish turnkey iCMR labs capable of performing complete cardiac electrophysiology procedures under MRI guidance, accelerating adoption, and reducing implementation barriers.

MRI Vendor Relationships

Imricor's iCMR platform is designed to operate within MRI environments manufactured by three of the world's largest MRI vendors: Siemens Healthineers, Philips, and GE Healthcare. Our strategy focuses on ensuring technical compatibility, workflow integration, and coordinated site enablement to support hospitals adopting MRI-guided cardiac ablation programs. These vendor relationships provide critical access to the installed base of approximately 50,000 clinical MRI systems worldwide, eliminating the need for hospitals to purchase proprietary imaging equipment and enabling adoption at any site with a suitable MRI scanner and EP lab proximity.

Barriers to Entry

Barriers to enter our line of business include technical R&D complexity, intellectual property protection, and clinical trial site activation hurdles. Imricor's position as the pioneer of MRI-guided ablation, validated through completed CE Mark, pivotal multicenter trials, and real-world evidence, creates a deep moat and first-mover status for recruiting and retaining leading electrophysiologists and sites.

Research and Development

Imricor's R&D philosophy is centered on continuous product improvement, the extension of MRI-guided ablation beyond Type I atrial flutter to more complex arrhythmias, and technological leadership in image-guided therapy. Our current R&D pipeline includes next-generation RF ablation catheters, mapping software, advanced diagnostic catheters, and initial PFA research for the iCMR environment. We additionally offer clinical trial support, field clinical engineers, field clinical specialists, and data scientists embedded at trial sites for rapid protocol feedback, and support investigator-led research and non-pivotal studies to broaden the evidence base for MRI-guided cardiac interventions. Our R&D team consists of 53 employees as of April 21, 2026, representing the majority of our total staff. All R&D and manufacturing activities are conducted at our Burnsville, Minnesota, headquarters. Our Dutch subsidiary, Imricor B.V., supports European research coordination.

Human Capital

As of April 21, 2026, we employed 88 full-time staff: 53 in R&D, 16 in sales and marketing, 11 in manufacturing, and 8 in administrative roles. As of April 21, 2026, we had 78 employees in the U.S., 9 in Europe, and 1 in Australia. We are not party to any labor union contracts, and none of our employees are covered by collective bargaining agreements.

Corporate Structure and Available Information

Imricor Medical Systems, Inc. is a Delaware corporation, with principal operations in Burnsville, Minnesota and a subsidiary, Imricor B.V., in the Netherlands. The Company is listed on the Australian Securities Exchange (ASX: IMR). Following effectiveness of this Registration Statement, Imricor will file reports with the SEC, including annual reports on Form 10-K, quarterly reports on Form 10-Q, and current reports on Form 8-K.

Item 1A. Risk Factors.

Summary of Risk Factors

Our business and operations are subject to a number of risks, which you should be aware of prior to deciding to invest in our common stock. Listed below is a summary of these risks, which are discussed more fully immediately following this summary.

Risks related to Our Business and the Development, Manufacturing, and Commercialization of our Products

- We may not be able to pass the regulatory hurdles and gain the necessary approvals and clearances to sell our key products.
- Hospitals and clinics may not adopt MRI-guided technology for cardiac catheter ablation procedures.
- New or competing technologies or products could emerge.
- If early commercialization efforts are not effectively executed, our ability to achieve profitability, and our overall financial condition, may be materially and adversely affected.
- We have limited sales and marketing resources.
- We rely on MRI manufacturers for integration of our products with their equipment.
- We may not be able to effectively manage our growth.
- We rely on key suppliers for product components.
- We currently use a single location to perform our manufacturing activities and are highly dependent on the continued availability of our facilities.
- We have limited management resources and must attract and retain skilled staff.
- Our customers may not be able to achieve adequate reimbursement from third-party payers for using our products.
- We may not be able to achieve or maintain satisfactory pricing and margins for our products.
- Adoption of our products depends upon appropriate physician training, and inadequate training may lead to negative patient outcomes, affect adoption of our products, and adversely affect our business.
- We may not realize benefits from continued research and development costs.

Risks Related to Our Industry

- Clinical trials may be delayed, suspended, or terminated for many reasons, which will increase our expenses and delay the time it takes to develop our current or new products or seek new indications.
- Hospitals and other healthcare organizations can face budget constraints which at times may impact their ability to fund new capital projects.
- We face risks related to product liability claims, which could exceed the limits of available insurance coverage.
- Security breaches, loss of data, and other disruptions could compromise sensitive information related to our business or our customers' patients or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.
- We may become involved in securities litigation, which is expensive and could divert management's attention and harm our business.

Risks Related to our Financial Position and Need for Additional Capital

- In order to fund our continued operations and strategic objectives, we may seek to raise additional capital, which may not be available on acceptable terms, or at all.
- Our business, financial condition, and results of operations could be materially and adversely affected by fluctuations in foreign currency exchange rates.
- Our quarterly and annual results may fluctuate significantly due to various factors, many of which are outside our control, and period-to-period comparisons may not be indicative of future performance.
- We are an emerging growth company and a smaller reporting company and the reduced reporting requirements applicable to smaller reporting companies may make our common stock less attractive to investors and may make it more difficult to compare our performance with other companies.
- Our ability to utilize our net operating loss carryforwards may be limited.
- Uncertainties in the interpretation and application of existing, new, and proposed tax laws and regulations could materially affect our tax obligations and effective tax rate.

Risks Related to Government Regulation

- Regulatory registrations or market clearances may be withdrawn or regulatory requirements may change.
- The manufacturing facilities for our products must comply with stringent regulatory requirements.
- Defects or failures associated with our products could lead to recalls, safety alerts or litigation, as well as significant costs and negative publicity.
- The use, misuse or off-label use of our products may harm our image in the marketplace or result in injuries that lead to product liability suits, which could be costly to our business or result in FDA sanctions if we are deemed to have engaged in improper promotion of our products.
- If any of our products cause or contribute to a death or a serious injury or malfunction in certain ways, we will be required to report under applicable medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.
- Healthcare reform initiatives, policy changes, and other administrative and legislative proposals may adversely affect our business, financial condition, results of operations, and cash flows in our key markets.

Risks Related to our Intellectual Property

- We are dependent on the protection and enforcement of our intellectual property rights.
- We may be subject to future third-party intellectual property rights disputes.
- If we are unable to protect the confidentiality of our other proprietary information, our business and competitive position may be harmed.
- If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets, and our business may be adversely affected.
- We may become a party to intellectual property litigation or administrative proceedings that could be costly and could interfere with our ability to sell and market our products.

Risks Related to our CDIs and Common Stock

- Our common stock may never be listed on a major U.S. stock exchange which could materially limit liquidity and increase volatility for investors.
- Investors may have difficulty in reselling their CDIs or shares of common stock due to the lack of an established trading market in the U.S. or potentially restrictive state securities laws.
- The issuance of additional securities in connection with financings, investments, our equity incentive plans, or otherwise will dilute all other stockholders and may adversely affect the value and rights associated with our common stock.
- The market price of our CDIs and common stock may be volatile, which could cause the value of our common stock to decline and limit an investor's ability to realize any return on investment.
- If securities and industry analysts do not publish, regularly update, or publish inaccurate or unfavorable research about our business, the trading price and trading volume of the common stock could decline.

Risks related to Our Business and the Development, Manufacturing, and Commercialization of our Products

We may not be able to pass the regulatory hurdles and gain the necessary approvals and clearances to sell our key products.

We will, subject to regulatory clearances, seek to sell our key products in the European Union, the Middle East, the U.S., and other jurisdictions. We are not assured of receiving future regulatory clearances and approvals for other indications or in other jurisdictions and cannot predict with certainty the timelines for such clearances and approvals, or other requirements that may be imposed by regulatory authorities (e.g. further clinical trials or other requirements to prove the safety and effectiveness of our products). In addition, future changes or updates to our products which affect their safety or efficacy may require new regulatory clearance or approval in some jurisdictions before we may sell the revised product. Any barriers or delays to obtaining future regulatory clearances would limit the size of the market opportunity for our ablation system.

Hospitals and clinics may not adopt MRI-guided technology for cardiac catheter ablation procedures.

Our business model depends on hospitals and clinics with ablation centers in markets where we obtain the required regulatory approvals establishing an iCMR lab and adopting our MRI-compatible technology for cardiac catheter ablation procedures. The time to establish an iCMR lab can also vary significantly from months to years depending on the individual hospital and clinic and its internal processes. If MRI-guided technology for cardiac catheter ablation procedures is not increasingly adopted or favored by hospitals and clinics, along with physicians, our ability to achieve our growth strategy and generate revenue will be significantly impaired.

New or competing technologies or products could emerge.

We expect to generate the vast majority of future revenue from the sale of products used for MRI-guided cardiac catheter ablation procedures. The medical device industry is competitive, subject to rapid change and significantly affected by new product introductions. Although we believe that there are currently no products or technologies that are commercially comparable to our MRI-compatible cardiac catheter ablation products, there are a number of other products and devices on the market which are not traditionally MRI-compatible, but which are commonly used to perform conventional cardiac catheter ablation procedures. To this end, we compete with larger companies who manufacture and sell ablation and diagnostic electrophysiology products, including Abbott Laboratories, Boston Scientific Corp., Johnson & Johnson, and Medtronic, Inc. If competitors develop new products (which could include devices or drugs) or technologies that offer better combinations of price and performance than we can offer for the treatment of arrhythmia, our products or future products may become obsolete or not competitive, which would have a significant negative effect on our business and financial position.

If early commercialization efforts are not effectively executed, our ability to achieve profitability, and our overall financial condition, may be materially and adversely affected.

Historically, the Company generated revenue from licensing some of its intellectual property for use in implantable devices and performing contract research but expects to generate most of its future revenue from the sale of the MRI-compatible products it has developed for use in cardiac catheter ablation procedures (comprising single-use consumables and capital goods). We are currently in the early stages of commercializing our key MRI-compatible products in the European Union, the Kingdom of Saudi Arabia, and Qatar. We have incurred net losses since inception, have never been profitable, and there is no assurance that we will achieve or sustain profitability or positive cash flow in the future. We face the risks typically encountered by companies early in their commercialization, particularly those developing and selling medical devices.

These risks include our ability to:

- transition into a commercialization-stage company, and implement and execute our business strategy;
- increase awareness of our brand and market acceptance of our products;
- obtain future regulatory registrations and market clearances;
- manage expanding operations; and
- respond effectively to competitive pressures and developments

As we expand our commercialization activities, we expect to continue incurring substantial sales and marketing, research and development, regulatory, and general and administrative expenses. We also expect to incur costs associated with expanding our customer relationships, obtaining regulatory clearances or approvals for our planned and future products, conducting clinical trials on our existing and planned or future products, and developing new products or adding new features to our existing products. In addition, as a company subject to SEC reporting requirements, we will incur incremental legal, accounting, compliance, and other expenses that we have not previously incurred. Accordingly, we cannot assure you that we will achieve or sustain profitability. If we are unable to achieve and sustain profitability, our ability to finance our business and accomplish our strategic objectives would be impaired, which could have a material adverse effect on our business, financial condition, and results of operations.

We have limited sales and marketing resources.

We currently have limited sales and marketing resources and will need to, among other things, expand our sales team. We will sell all of our products to hospitals and clinics either directly or through distributors and will therefore need to commit increased resources to product sales and marketing to execute our current growth strategy. There is a risk that we will be unable to develop sufficient sales and marketing capabilities to effectively commercialize our products and maintain a competitive position in our market.

We rely on MRI manufacturers for integration of our products with their equipment.

Our products must first be integrated with MRI manufacturer systems before hospitals can proceed with iCMR lab installation. We collaborate with GE Healthcare, Philips, and Siemens, three global MRI vendors who provide MRI systems for iCMR labs, to integrate our products with their systems. The pace and prioritization of integration projects are largely dictated by MRI manufacturers, which may lead to delays or suboptimal compatibility if project timelines are extended or shifted. If MRI manufacturers focus on their own proprietary technologies over the integration of our products, we may be required to invest more heavily to maintain compatibility, increasing development costs and project risks.

We may not be able to effectively manage our growth.

Because we have only limited experience in manufacturing our products in commercial quantities, we may encounter production delays or shortfalls. Such production delays or shortfalls may be caused by many factors, including the following:

- key components of our products are provided by a single supplier or limited number of suppliers, and we do not maintain large inventory levels of these components;
- if we experience a shortage or quality issues in any of these components, we will need to identify and qualify new supply sources, which could increase our expenses and result in manufacturing delays; and
- our ability to attract and retain qualified employees for our operations in order to significantly increase our manufacturing output.

If we are unable to keep up with demand for our products, our growth could be impaired, and market acceptance for our products could be harmed and physicians may instead elect to use our competitors' products. Our inability to successfully manufacture our products in sufficient quantities would materially harm our business. We expect that our current manufacturing capabilities will be sufficient to support our projected growth profile through the end of 2027. If we gain significant market share over and above our current short-term expectations and, in any case, from 2028 onwards, we will need to expand our manufacturing capacity, including additional facilities, and invest in systems and processes to support the development of the business. The failure to address projected growth in a timely, robust, and efficient manner may negatively impact our financial performance.

We rely on key suppliers for product components.

Our products include components that are manufactured and supplied by third parties. The products are then assembled, validated, and tested at our headquarters in Burnsville, Minnesota. There are inherent risks in relying on third party suppliers for our product components, especially since any change to the manufacturing process of an approved medical device requires significant documentation and, in many cases, supplemental testing. Certain components and products that meet our requirements are available only from a single supplier or a limited number of suppliers. This concentration creates potential for disruptions, which may include issues with availability of product components and pricing. Our suppliers may decide, or be required, for reasons beyond our control, to cease supplying such product components to us or to raise their prices. Shortages of product components, quality control problems, production capacity constraints, or delays by suppliers could negatively affect our ability to meet our production goals. A disruption at a key supplier could cause a substantial delay in the availability of our products, leading to a potential loss of sales.

We currently use a single location to perform our manufacturing activities and are highly dependent on the continued availability of our facilities.

We perform all of our manufacturing activities at our headquarters in Burnsville, Minnesota. Should operations at the facility be disrupted or production halted for any reason (e.g. due to labor strikes, extreme weather, issues arising from FDA or other regulatory inspections, or other events outside our control), we may incur significant costs and disruptions that could reduce our revenues and harm our business, reputation, and financial results. While alternative arrangements could be made to transfer the manufacturing process to a different facility, this would take some time and may involve other risks. The regulatory process for approval of facilities is time-consuming, and our ability to rebuild facilities would take a considerable amount of time and expense and cause a significant disruption in service to our customers. If such disruption were to occur, it would adversely affect our ability to sell our products and customers might instead purchase ablation products from our competitors. There may also be an ongoing sales impact in the form of a reduction of goodwill as a result of us being unable to supply hospitals, clinics, and physicians with the product in a timely manner.

We have limited management resources and must attract and retain skilled staff.

Our long-term growth and performance are dependent on attracting and retaining highly skilled staff. Despite having structured incentive programs, there is a risk that we will be unable to attract and retain the necessary staff to pursue our business model. In particular, if Mr. Steve Wedan, our CEO and a founder, were to leave Imricor, we would lose significant technical and business expertise, and we may not be able to find a suitable replacement. This would affect how efficiently we operate our business and our future financial performance could be impacted.

In addition, our research and development programs, clinical operations, and sales and marketing efforts depend on our ability to attract and retain highly skilled engineers, sales staff, and other professionals. Competition for skilled personnel in our market is intense, and we have from time to time experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications on acceptable terms, or at all. Many of the companies with which we compete for experienced personnel have greater resources than we do, and any of our employees may terminate their employment with us at any time. In addition, job candidates and existing employees often consider the value of the stock awards they receive in connection with their employment. If the perceived benefits of our stock awards decline, it may harm our ability to recruit and retain highly skilled employees. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business and future growth prospects will be harmed.

Our customers may not be able to achieve adequate reimbursement from third-party payers for using our products.

We expect our products will generally be purchased by hospitals and clinics who will then seek reimbursement from various public and private third-party payers once those products are used to provide health care services to patients. Existing reimbursement codes apply to the sale of the Vision-MR Ablation Catheter and Vision-MR Diagnostic Catheter in the European Union, and we expect our products will qualify for reimbursement codes in the U.S. There is no assurance, however, that third-party payers will provide adequate reimbursement for hospitals and physicians to consider our products cost-effective for patients requiring ablation procedures. In addition, the overall amount of reimbursement available for ablation procedures could decrease in the future. If third-party payer reimbursement to providers for procedures involving our products is eliminated or reduced, some of our target customers may be unwilling to purchase our products and may choose to instead purchase less expensive alternatives from our competitors. In addition, third-party payers for hospital services and hospital outpatient services, including Medicare, Medicaid, and private healthcare insurers, typically revise their coverage and payment policies, methodologies, and amounts on an annual basis, which can result in noncoverage, stricter standards for reimbursement of hospital charges for certain medical procedures, or the elimination of or reduction in reimbursement. Further, Medicare, Medicaid, and private healthcare insurer cutbacks could create downward price pressure on our products. Healthcare reform legislation at federal and state levels in the U.S. could result in changes in coverage of and reimbursement for our products. Finally, our revenues also depend upon timely reimbursement data input from our independent agents. Failure by hospitals and other users of our products to obtain sufficient reimbursement could cause our business to suffer.

We may not be able to achieve or maintain satisfactory pricing and margins for our products.

Manufacturers of medical devices have a history of price competition, and we can give no assurance that we will be able to achieve satisfactory prices for our products or maintain prices at the levels we have historically achieved. Any decline in the amount that payers reimburse our customers for procedures involving the use of our products could make it difficult for customers to continue using, or to adopt, our products and could create additional pricing pressure for us. If we are forced to lower the price we charge for our products, our revenue and gross margins will decrease, which will adversely affect our ability to invest in and grow our business. If we are unable to maintain our prices, or if our costs increase and we are unable to offset such an increase with an increase in our prices, our margins could erode. We will continue to be subject to significant pricing pressure, which could harm our business, financial condition, and results of operations.

Adoption of our products depends upon appropriate physician training, and inadequate training may lead to negative patient outcomes, affect adoption of our products, and adversely affect our business.

The success of our MRI-compatible cardiac ablation products depends in part on hospitals and physicians adhering to appropriate patient selection criteria and following the proper techniques provided in our training and support programs. Physicians may rely on previous medical training or experience, and we cannot guarantee that all such practitioners will have the necessary skills or complete the required training to effectively utilize our Vision-MR Ablation Catheter, NorthStar Mapping System, and related devices. If physicians use our products in a manner inconsistent with their labeled indications, in combination with components not compatible with our devices, or without adequate training, patient outcomes may diverge from those observed in clinical trials or published studies. This could negatively impact perceptions of patient safety and therapeutic benefit, limit hospital adoption of our technologies, and materially affect our business, financial condition, and results of operations.

We may not realize benefits from continued research and development costs.

Developing medical devices and related technologies is expensive and the investment in the development of these product offerings often involves an extended period of time to achieve a return on investment. An important element of our business strategy is to continue to make investments in innovation and related product opportunities. We believe that we must continue to dedicate resources to our innovation efforts to develop product offerings in order to maintain our competitive position and expand the total addressable market opportunity. We may not, however, receive significant revenues from these investments for several years, or may not realize such benefits at all.

We may not be able to successfully expand applications of our products to treat additional cardiac arrhythmias, enhance the capabilities of our existing products to keep pace with rapidly changing technology and customer requirements, develop new related products, or successfully commercialize such expanded applications or new related products, any of which could have a material adverse effect on our business, financial condition, and results of operations.

Our success depends on our ability to develop and commercialize expanded applications of our products for the treatment of additional cardiac arrhythmias and to develop new related products, while improving the performance and cost-effectiveness of our existing products, in each case in ways that address current and anticipated customer requirements. We intend to develop and commercialize such expanded applications and related products through our research and development program and, if necessary, by licensing or acquiring complementary components and technologies from third parties. Such success is dependent upon several factors, including functionality, competitive pricing, ease of use, the safety and efficacy of our products, and our ability to identify, select, and acquire the rights to products and technologies on terms that are acceptable to us.

Our industry is characterized by rapid technological change and innovation. New technologies, techniques or products may emerge that might offer better combinations of price and performance or better address customer requirements as compared to our current or future products. Competitors who have greater financial, marketing and sales resources than we do may be able to respond more quickly and effectively than we can to new or changing opportunities, technologies, standards, or customer requirements. Any expanded application or new related product we identify for internal development may require additional development efforts prior to commercial sale. Due to the significant lead time and complexity involved in bringing an expanded application or new related product to the market, we are required to make a number of assumptions and estimates regarding the commercial feasibility of such expansion or new product. These assumptions and estimates may prove incorrect, resulting in our introduction of an expanded application or new product that is not competitive at the time of launch. We anticipate that we will face increased competition in the future as existing companies and competitors develop new or improved products and as new companies enter the market with new technologies and sales mechanisms which we may be unable to adopt or offer for sale. Our ability to mitigate downward pressure on the prices of the products that we offer for sale will be dependent on our ability to maintain and/or increase the value we offer to suppliers, vendors, strategic partners, and consumers. We cannot assure you that any expanded applications or new related products that we develop or offer for sale will be manufactured or produced economically, successfully commercialized, or widely accepted in the marketplace. The expenses or losses associated with unsuccessful development or launch activities, or a lack of market acceptance of expanded applications or new related products, could adversely affect our business, financial condition, and results of operation.

Our ability to attract new customers and increase revenue from existing customers depends in large part on our ability to enhance and improve our own products, maintain relationships with other vendors and suppliers, and to develop expanded applications or new related products. Any expanded application or new related product that we develop or offer for sale may not be introduced in a timely or cost-effective manner, may contain defects, or may not achieve the marketplace acceptance necessary to generate significant revenue. If we are unable to successfully expand applications of our products to treat additional cardiac arrhythmias, enhance our existing product capabilities to meet customer requirements, develop new related products, or otherwise gain market acceptance, our business, financial condition, and results of operation would be harmed.

A material amount of our revenues and accounts receivable are concentrated in a small number of customers. If we do not broaden our customer base, our revenues may fluctuate substantially, and our results of operations and financial condition may be harmed.

We recognized an aggregate of approximately 79% of our revenue from 2 customers for the year ended December 31, 2025 and approximately 67% of our revenue from 4 customers for the year ended December 31, 2024. Accordingly, until we grow our customer base, there are a limited number of customers from whom we generate a significant proportion of our revenue. Any negative changes in demand from these customers or in our broader strategic relationship with these customers would adversely affect our business, operating results, financial condition, and future prospects. We anticipate that we will continue to derive a significant portion of our revenue from a small number of customers for the foreseeable future.

We rely on distributors to generate revenues in certain parts of the world, subjecting us to risks associated with those relationships.

We hold agreements with distributors to facilitate sales in certain parts of the world, and as a result, do not have as much control over distributor performance as we do with our own sales team. Distributors may struggle with operational inefficiencies, logistic challenges, and inventory management, affecting timely delivery and sales volume. External events such as geopolitical tensions, regulatory changes, or raw material shortages can disrupt distributor networks and threaten market access. Additionally, if we fail to maintain positive relationships with our distributors or fail to ensure that our distributors adhere to our sales processes, compliance, and other priorities, this could have an adverse effect on our operations. Changes in the key personnel or management within our distributors could adversely affect our business if such changes are not managed effectively. Further, distributors may decide to terminate their relationship with us. A loss of a significant number of our distributors could have a material adverse effect on our business and results of operations.

In addition, we rely on our distributors to comply with applicable laws and regulations in connection with the distribution of our products, including local anti-corruption and anti-bribery laws. Any failure by our distributors to comply with such laws and regulations could result in liability, penalties, or other sanctions, which could negatively affect our business, financial condition, and results of operation.

Service, maintenance, and support obligations under service agreements for iCMR sites include ongoing responsibilities that may pose operational and financial risks to the company.

To the extent we enter into service, maintenance, or support agreements for installed iCMR sites, we may be required to provide ongoing software updates to maintain compatibility with new MRI equipment versions, ensure safety, and address any technical issues that arise post-installation. Ongoing support includes training clinical staff on new indications and future product iterations, requiring sustained educational efforts and resource allocation over the lifespan of the product at the site.

Maintenance and support entail technical and clinical coordination to respond to emerging operational challenges unique to MRI environments, including equipment safety, compatibility, and procedural workflow optimization.

The obligation to provide long-term maintenance and continuous training may increase operational expenses and resource commitments over time, which could impact margins if not managed efficiently. Failure to provide adequate service and support could result in equipment downtime, reduced customer satisfaction, and potential reputational harm, affecting client retention and future sales of equipment and consumable products.

Risks Related to Our Industry

Clinical trials may be delayed, suspended, or terminated for many reasons, which will increase our expenses and delay the time it takes to develop our current or new products or seek new indications.

We may experience delays in our ongoing or future preclinical studies and clinical trials, or such studies may not commence on time, may need to be redesigned, may fail to enroll sufficient numbers of patients, or may not be completed on schedule, if at all. The commencement and completion of our clinical trials for both current and future products or indications may be delayed, suspended, or terminated as a result of many factors, including but not limited to:

- regulatory authorities such as the FDA, Therapeutic Goods Administration ("TGA"), or relevant bodies in the European Union or Middle East may disagree with the design, protocol, or implementation of our clinical trials, or may change requirements, policies, or guidelines mid-study, necessitating protocol amendments or additional data;
- regulators or institutional review boards ("IRBs") or Ethics Committees may delay or refuse to authorize us to commence a clinical trial at prospective sites, or may suspend or terminate an ongoing trial due to noncompliance, perceived conflicts of interest, safety concerns, or other reasons;
- delays or inability to reach agreement with contract research organizations ("CROs") or clinical trial sites, whose terms may vary widely and require lengthy contract negotiations;
- delays in patient enrollment, or inability to enroll a sufficient and representative number of patients in our studies, or patient withdrawal and loss to follow-up, reducing the statistical power and integrity of trial results;
- negative or inconclusive preclinical or clinical trial results may require us to conduct additional studies or abandon lines of development that we otherwise expect to be promising, adversely impacting our product pipeline and prospects;
- the occurrence of serious patient adverse events or deaths during clinical trials—even if unrelated to our devices—may result in clinical holds, additional oversight, and reputational harm;
- device malfunctions, manufacturing failures, or product quality deficiencies, particularly for novel or first-of-kind technologies used in MRI environments, could prevent initiation or continuation of clinical studies and may prompt regulatory investigations.
- data integrity concerns, including protocol deviations, data entry errors, lost data, or inadequate monitoring, that require data exclusion, study repetition, or additional trials;
- delays relating to adding new clinical trial sites or competition from other active trials for similar patient populations;
- exceeding budgeted costs for clinical trials or difficulty in accurately predicting and controlling trial costs, potentially resulting in the need for additional capital; and
- supply chain constraints or the inability to manufacture and distribute sufficient quantities of our products for use in clinical trials.

Clinical trials for our products may also be suspended or terminated by us, IRBs, Ethics Committees, data safety monitoring boards, or regulatory authorities due to noncompliance with regulatory requirements, safety concerns, results not demonstrating safety or effectiveness, or other unforeseen issues. Additionally, delays or adverse findings relating to financial relationships with investigators, such as perceived or actual conflicts of interest, could impact the interpretation and acceptance of trial data by regulatory agencies.

The impact of these risks could include material increases in our expenses, lengthened product development timelines, reduced competitive opportunity, delays in securing regulatory clearance or expanded indications, or even the inability to commercialize one or more products. Any such developments could harm our business, financial condition, and operating results in a manner that is significant and not readily predictable.

Hospitals and other healthcare organizations can face budget constraints which at times may impact their ability to fund new capital projects.

Our ability to generate revenue will largely depend on how effectively we can market and sell our MRI-compatible cardiac catheter ablation products to the healthcare industry. Hospitals and healthcare organizations are constantly facing significant budget constraints, the competition for limited capital budgets is intense and the budget allocation process and approvals for spending on medical devices is complex and time consuming. As a result, marketing and sales to hospitals and other healthcare organizations requires significant time and expense, is intensely competitive, and the revenue cycle for medical devices can be lengthy, unpredictable, and results highly variable. These factors may cause our operating results to fluctuate or adversely affect our ability to achieve our forecasted growth strategy.

We face risks related to product liability claims, which could exceed the limits of available insurance coverage.

The medical device industry is subject to substantial litigation, and we face an inherent risk of exposure to product liability claims in the event that the use of our products results or is alleged to have resulted in adverse effects to a patient. We may incur material liabilities relating to product liability claims, and although we maintain product liability insurance, we cannot assure you that the coverage limits of our insurance policies will be adequate, or that insurance will be available to us on acceptable terms, if at all. A product liability or other claim with respect to uninsured liabilities or in excess of our insurance coverage would materially impact our business, financial condition, and operating results.

We also could experience a material design or manufacturing failure in our products, a quality system failure, other safety issues, or heightened regulatory scrutiny that would warrant a recall of some of our products. Product liability lawsuits and claims, safety alerts, and product recalls, regardless of their ultimate outcome, could result in decreased demand for our products, injury to our reputation, significant litigation and other costs, substantial monetary awards to or costly settlements with patients, product recalls, loss of revenue, increased regulatory scrutiny, and the inability to commercialize new products or product candidates, and otherwise have a material adverse effect on our business, our reputation, and our ability to attract and retain customers.

Security breaches, loss of data, and other disruptions could compromise sensitive information related to our business or our customers' patients or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we may collect, store, or otherwise process sensitive data, including procedure-based information and protected health information, and other potentially personally identifiable information. We also store sensitive intellectual property and other proprietary business information. Although we take measures to protect sensitive data from unauthorized access or disclosure, our information technology ("IT") and infrastructure, and that of other technology partners, are vulnerable to cyber-attacks by hackers or viruses or breached due to employee error, malfeasance, or other disruptions. We rely on IT systems, networks, services, including internet sites, data hosting and processing facilities, tools, physical security systems, and other hardware, software, and technical applications and platforms, some of which are managed, hosted, provided, and/or used by third parties or their vendors, to assist in conducting our business. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If the third parties with whom we work experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if the third parties with whom we work fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such an award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or that of the third parties with whom we work have not been compromised.

A significant breakdown, invasion, corruption, destruction, or interruption of critical information technology systems or infrastructure could negatively impact operations. We could also experience a business interruption, theft of confidential information or reputational damage from industrial espionage attacks, malware, ransomware, failures during the process of upgrading or replacing software, databases, or components thereof, power outages, damage or interruption from fires or other natural disasters, hardware failures, telecommunication failures and user errors, or other cyber-attacks or other interruptions, which may compromise our system infrastructure or lead to data leakage, either internally or at our third-party providers. We have been the target of such events in the past and expect them to continue as cybersecurity threats have been rapidly evolving in sophistication and becoming more prevalent in the industry. Although we are investing in protection and monitoring practices of our data and IT to try to reduce these risks and we monitor our systems on an ongoing basis for any current or potential threats, there can be no assurance that our efforts will prevent breakdowns or breaches of our or our third-party providers' databases or systems that could materially and adversely affect our business, financial condition, and results of operations.

Additionally, remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit, and in public locations.

Currently, we carry business interruption coverage to mitigate certain potential losses, but this insurance is limited in amount and may not be sufficient in type or amount to cover us against claims related to security breaches, cyber-attacks, and other related data and system disruptions. We cannot be certain that such potential losses will not exceed our policy limits, insurance will continue to be available to us on economically reasonable terms, or at all, or any insurer will not deny coverage as to any future claim. In addition, we may be subject to changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements.

We may become involved in securities litigation, which is expensive and could divert management's attention and harm our business.

We may be the target of securities litigation, especially following periods of market volatility. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

Risks Related to our Financial Position and Need for Additional Capital

In order to fund our continued operations and strategic objectives, we may seek to raise additional capital, which may not be available on acceptable terms, or at all.

Our current capital reserves may not be adequate to fund our operations and execution of our strategic objectives. We intend to use our existing cash primarily to support the commercial launch of our products in the European Union, the Middle East, and the United States, as well as to advance our ongoing and planned clinical development programs in the United States, European Union, and other jurisdictions. We may decide to use the proceeds differently from our current plans or may need to obtain additional funding to continue operations (or both). Our future liquidity and capital funding requirements will depend on numerous factors including, but not limited to:

- our revenue growth;
- the expansion of our sales and distribution networks;
- our ability to raise additional funds to finance our operations;
- our research and development efforts;
- the outcome, costs, and timing of any clinical trial results for our current or future products;
- the outcome, costs, and timing of regulatory approvals for our future products;
- the emergence and effect of competing or complementary products;
- the availability and amount of reimbursement for procedures using our products;
- our ability to maintain, expand, and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense, and enforcement of any patents or other intellectual property rights;
- our ability to retain our current employees and the need and ability to hire additional management and sales, scientific, and medical personnel;
- the terms and timing of any licensing or other arrangements that we have or may establish with third parties; and
- the impact of adverse worldwide economic conditions.

If we determine that additional capital is required, we, and indirectly, our stockholders and CDI holders, will bear the cost of issuing and servicing such securities. We may seek to raise funds through the issuance of equity securities, debt financing, or other strategic transactions. If we raise additional funds by issuing equity securities, the interests held by stockholders and CDI holders may be diluted. Debt financing, if available, would result in increased fixed payment obligations and may involve covenants restricting our ability to incur additional debt, limitations on our ability to acquire, sell, or license intellectual property rights, and other operating restrictions that could adversely impact our ability to conduct our business. We cannot guarantee the future availability of funds or that the funds will be available on terms that are favorable to us.

If we require additional funding and are unable to raise the funds, it could adversely impact our business. If we are unable to maintain sufficient financial resources, our business, financial condition, and results of operations will be materially and adversely affected, including potentially requiring us to delay, limit, reduce, or terminate certain research and development activities or commercialization efforts.

Our business, financial condition, and results of operations could be materially and adversely affected by fluctuations in foreign currency exchange rates.

Although we intend to seek regulatory approval to place our key MRI-compatible products on the market in the U.S., unless and until we obtain such regulatory approvals, we expect to derive a significant portion of our revenue in the foreseeable future from the sale of our key MRI-compatible products in the European Union and the Middle East. Revenue from products sold in the European Union will largely be denominated in Euros, while our functional and reporting currency is the U.S. dollar. Our results of operations and cash flows will be subject to fluctuations due to changes in foreign currency exchange rates, which could harm our business in the future. For example, if the value of the U.S. dollar increases relative to foreign currencies, in the absence of a corresponding change in local currency prices, our revenue could be adversely affected as we convert revenue from local currencies to U.S. dollars.

In addition, because we conduct business in currencies other than U.S. dollars, but report our results of operations in U.S. dollars, we also face remeasurement exposure to fluctuations in currency exchange rates, which could hinder our ability to predict our future results and earnings and could impact our results of operations.

We do not currently maintain a program to hedge exposures to non-U.S. dollar currencies, and consequently, we are exposed to the risk of adverse movements in foreign currency exchange rates. In connection with any capital raising activities or offerings on the ASX where proceeds are received in Australian dollars, adverse movements in the U.S. dollar-Australian dollar exchange rate between pricing and closing may reduce the U.S. dollar amount of our net proceeds. In addition, fluctuations in foreign exchange rates may result in a discrepancy between our actual results of operations and investors' expectations of returns on securities expressed in Australian dollars. If we are unable to address these risks effectively, it could have a material adverse effect on our business, financial condition, and results of operations.

Our quarterly and annual results may fluctuate significantly due to various factors, many of which are outside our control, and period-to-period comparisons may not be indicative of future performance.

Our quarterly and annual results of operations, including potential future revenue, profitability or losses, and cash flow, may vary significantly in the future, and period-to-period comparisons of our operating results may not be meaningful. Accordingly, the results of any one quarter or other period should not be relied upon as an indication of future performance. Our quarterly and annual financial results may fluctuate because of a variety of factors, many of which are outside our control and, as a result, may not fully reflect the underlying performance of our business. Factors that may cause fluctuations in our quarterly and annual results include, but are not limited to:

- the level of demand for our products, which may vary significantly from period to period;
- expenditures that we may incur to acquire, develop, or commercialize additional products and technologies;
- the timing and cost of clinical trials, including obtaining regulatory approvals or clearances for planned or future products;
- the rate at which we grow our sales force and the speed at which newly hired salespeople become effective, and the cost and level of investment therein;
- the degree of competition in our industry and any change in the competitive landscape of our industry, including consolidation among our competitors or future partners;
- coverage and reimbursement policies with respect to the procedures using our products and potential future products that compete with our products;
- the timing and success or failure of clinical trials for our current or planned products or any future products we develop or competing products;
- the timing of customer orders or medical procedures, the number of available selling days in a particular period, which can be impacted by a number of factors, such as holidays or days of severe inclement weather in a particular geography, the mix of products sold, and the geographic mix of where products are sold;
- the timing and cost of, and level of investment in, research, development, regulatory approval, and commercialization activities relating to our products, which may change from time to time;
- the cost of manufacturing our products, which may vary depending on the quantity of production and the terms of our agreements with third-party suppliers and manufacturers;
- natural disasters, or outbreaks of disease or public health crises;
- the timing and nature of any future acquisitions or strategic partnerships; and
- future accounting pronouncements or changes in our accounting policies.

Given the potential for fluctuations in our quarterly and annual results, period-to-period comparisons may not be the best indication of the underlying results of our business and should only be relied upon as one factor in determining how our business is performing.

Forecasts that we may provide to the market are based on assumptions that we believe to be reasonable, but which are inherently uncertain, unpredictable, and based on certain contingencies that are outside our control. Due to this uncertainty and unpredictability, our results may fail to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, it may result in a decrease in the price of our common stock.

We are an emerging growth company and a smaller reporting company and the reduced reporting requirements applicable to smaller reporting companies may make our common stock less attractive to investors and may make it more difficult to compare our performance with other companies.

We are an "emerging growth company," as defined in the JOBS Act. As such, we are eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to:

- exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act;
- exemption from any requirement that may be adopted by the PCAOB regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, unless the SEC determines that the application of such requirements to emerging growth companies is necessary;
- exemption from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved by stockholders;
- option to adopt new or revised accounting standards on the same timeline as private companies through the extended transition period permitted under Section 13(a) of the Exchange Act and Section 107 of the JOBS Act;
- reduced financial statement disclosure obligations, permitting the presentation of only two years of audited financial statements in a registration statement, rather than three; and
- reduced disclosure obligations regarding executive compensation arrangements in our periodic reports, registration statements, and proxy statements.

We will remain an emerging growth company until the earlier of (i) the last day of our fiscal year following the fifth anniversary of the date of our first sale of our common stock pursuant to an effective registration statement under the Securities Act; (ii) the last day of the fiscal year in which our total annual gross revenues equal or exceed $1.235 billion; (iii) on the last day of the fiscal year in which we become a large accelerated filer, which generally requires (a) our market value of our ordinary shares held by non-affiliates (public float) exceeds $700 million as of the end of our second fiscal quarter, (b) we have been subject to the requirements of Section 13(a) or 15(d) of the Exchange Act for at least twelve months, and (c) we have filed at least one annual report pursuant to those sections; and (iv) the date on which we have issued more than $1 billion in non-convertible debt securities over the prior three-year period.

We cannot predict if investors will find our common stock less attractive if we choose to rely on any of the exemptions afforded to emerging growth companies. If some investors find our securities less attractive as a result of our reliance on these exemptions, the trading price of our common stock could suffer, the trading market for our common stock may be less liquid, and our common stock price may be subject to increased volatility.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. We have elected to use this extended transition period until we are no longer an emerging growth company or until we affirmatively and irrevocably opt out of the extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard.

This may make comparison of our financial statements with another public company which is neither an emerging growth company nor an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

Additionally, we are a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. Smaller reporting companies may take advantage of certain scaled disclosure obligations, including, among other things, providing only two years of audited financial statements and reduced disclosure obligations regarding executive compensation in our periodic reports, registration statements and proxy statements. We will remain a smaller reporting company for each fiscal year in which, as of the end of that year's second fiscal quarter, either (i) the market value of our ordinary shares held by non-affiliates (public float) is less than $250 million, or (ii) our annual revenues are less than $100 million in such completed fiscal year and either (a) we have no public float, or (b) our public float is less than $700 million.

We have elected to take advantage of certain reduced disclosure obligations in this Registration Statement and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different from what you might receive from other public reporting companies in which you hold equity interests.

Our ability to utilize our net operating loss carryforwards may be limited.

As of December 31, 2025, we had U.S. federal and state net operating loss ("NOL") carryforwards of approximately $116.3 million and $36.9 million, respectively. Subject to certain limitations, we may use these NOL carryforwards to offset our taxable income for U.S. federal and state income tax purposes. If not utilized, our U.S. federal NOL carryforwards (and our state NOL carryforwards in conforming states) arising in taxable years beginning before 2018 will begin to expire in 2027. Under current law, U.S. federal NOL carryforwards arising in taxable years beginning after 2017 may be carried forward indefinitely, but their deductibility in any tax year is limited to 80% of our taxable income in such year before the deduction for such NOL carryforwards. Additionally, Section 382 of the Internal Revenue Code of 1986, as amended, may limit the NOL carryforwards we may use in any year for U.S. federal income tax purposes in the event we undergo an "ownership change." A Section 382 "ownership change" generally occurs if one or more stockholders or groups of stockholders who own at least 5% of a company's stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Similar rules may apply under state tax laws.

We have conducted analyses of past equity offerings, and other transactions that had an impact on our ownership structure, with respect to the impact of Section 382 on our NOL carryforwards for all tax years from inception through December 31, 2025. Those analyses concluded that we experienced ownership changes in 2009, 2011, and 2020 and further determined that there were limitations on the amount of pre-ownership change NOL carryforwards that can be utilized annually to offset future taxable incomes. In addition, any future issuances or sales of our stock, including certain transactions involving our stock that are outside of our control, could result in future "ownership changes." "Ownership changes" that may occur in the future could result in the imposition of an annual limit on the amount of pre-ownership change NOL carryforwards and other tax attributes we can use to reduce our taxable income, potentially increasing and accelerating our liability for income taxes, and also potentially causing certain of those tax attributes to expire unused. Any limitation on our ability to use NOL carryforwards could, depending on the extent of such limitation and the NOL carryforwards previously used, result in our retaining less cash after payment of U.S. federal and state income taxes during any year in which we have taxable income, than we would retain if such NOL carryforwards were available as an offset against such income for U.S. federal and state income tax reporting purposes, which could adversely impact operating results.

Uncertainties in the interpretation and application of existing, new, and proposed tax laws and regulations could materially affect our tax obligations and effective tax rate.

The tax regimes to which we are subject or under which we operate are unsettled and may be subject to significant change. The issuance of additional guidance related to existing or future tax laws, or changes to tax laws, tax treaties or regulations proposed or implemented by the current or a future U.S. presidential administration, Congress, or taxing authorities in other jurisdictions, including jurisdictions outside of the United States, could materially affect our tax obligations and effective tax rate. To the extent that such changes have a negative impact on us, including as a result of related uncertainty, these changes may adversely impact our business, financial condition, results of operations, and cash flows.

The amount of taxes we pay in different jurisdictions depends on the application of the tax laws of various jurisdictions, including the United States, to our international business activities, the relative amounts of income before taxes in the various jurisdictions in which we operate, new or revised tax laws, or interpretations of tax laws and policies, the outcome of current and future tax audits, examinations or administrative appeals, our ability to realize our deferred tax assets, and our ability to operate our business in a manner consistent with our corporate structure and intercompany arrangements. The taxing authorities of the jurisdictions in which we operate may challenge our methodologies for pricing intercompany transactions pursuant to our intercompany arrangements or disagree with our determinations as to the income and expenses attributable to specific jurisdictions. If such a challenge or disagreement were to occur, and our position was not sustained, we could be required to pay additional taxes, interest, and penalties, which could result in one-time tax charges, higher effective tax rates, reduced cash flows, and lower overall profitability of our operations. Our financial statements could fail to reflect adequate reserves to cover such a contingency. Similarly, a taxing authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a “permanent establishment” under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions.

Risks Related to Government Regulation

Regulatory registrations or market clearances may be withdrawn or regulatory requirements may change.

The manufacturing, testing, labelling, sale, and marketing of medical devices are subject to extensive regulation in the European Union, the Middle East, the U.S., and other jurisdictions. We have received CE mark approval to place many of our key products on the market in the European Union as well as Medical Device Marketing Authorization from the Saudi Food & Drug Authority to place certain of our products on the market in Saudi Arabia and Qatar, and are pursuing the required regulatory approvals to place our key products on the market in the U.S. However, regulatory registrations or market clearance of products can subsequently be withdrawn for a variety of reasons including failure by us or any third-party contractors we engage to manufacture our products from time to time to comply with manufacturing regulatory requirements. Regulators have the power to ban products we sell as well as to require the recall, repair, replacement, or refund of such products. Further, regulators may change their clearance policies or impose additional regulatory requirements on us that could increase our compliance costs, restrict our ability to maintain our current regulatory registrations or market clearances, prevent or delay clearance of future products under development, or impact our ability to modify our currently cleared products. We cannot guarantee that we will successfully maintain the registrations and clearances we currently have or obtain the additional registrations and clearances that we are seeking or may receive in the future, or that we will successfully obtain the registrations and clearances required for future products.

The manufacturing facilities for our products must comply with stringent regulatory requirements.

The manufacturing facilities for our products must meet stringent quality standards, including compliance with the FDA's Quality System Regulations in the United States and equivalent quality management standards internationally. Compliance with these complex quality system requirements is costly and resource intensive. We must maintain documentation, implement controls, and undergo regular audits to demonstrate ongoing compliance. To maintain CE mark approval, our Notified Body will regularly audit us and our suppliers. Although we have passed all audits to date, any failure to comply with the applicable regulatory requirements in the future can result in, among other things, temporary manufacturing shutdowns, product recalls, product shortages, bans on imports and exports and a damaged brand name.

Defects or failures associated with our products could lead to recalls, safety alerts or litigation, as well as significant costs and negative publicity.

Manufacturing flaws, component failures, design defects, off-label uses, or inadequate disclosure of product-related information could result in an unsafe condition or the injury or death of a patient. These problems could lead to a recall of, or issuance of a safety alert relating to, our products and result in significant costs, negative publicity, and adverse competitive pressure. The circumstances giving rise to recalls are, however, unpredictable, and any recalls of existing or future products could materially adversely affect our business, results of operations, financial condition, or cash flows.

The medical device industry has historically been subject to extensive litigation over product liability claims. There are high rates of mortality and other complications associated with some of the medical conditions suffered by the patients whom specialist physicians use our devices to treat, and we may be subject to product liability claims if our products cause, or merely appear to have caused, an injury or death. In addition, an injury or death that is caused by the activities of our suppliers, such as those that provide us with components and raw materials, or by an aspect of a treatment used in combination with our products, such as a complementary drug or anesthesia, may be the basis for a claim against us by patients, hospitals, healthcare providers, or others purchasing or using our products, even if our products were not the actual cause of such injury or death. An adverse outcome involving one of our products could result in reduced market acceptance and demand for all of our products and could harm our reputation and our ability to market our products in the future. In some circumstances, adverse events arising from or associated with the design, manufacture, or marketing of our products could result in the suspension or delay of regulatory reviews of our premarket notifications or applications for marketing. Any of the foregoing problems could disrupt our business and have a material adverse effect on our business, results of operation, financial condition, or cash flows.

The use, misuse or off-label use of our products may harm our image in the marketplace or result in injuries that lead to product liability suits, which could be costly to our business or result in FDA sanctions if we are deemed to have engaged in improper promotion of our products.

We are only permitted to market, promote, label, or train physicians in our ablation products for the uses cleared by the relevant regulatory bodies in each market. Use of a device outside of its cleared or approved indication is known as "off-label" use. We cannot prevent a physician from using our products for off-label use, as the FDA does not restrict or regulate a physician's choice of treatment within the practice of medicine. However, if the FDA determines that our promotional activities, reimbursement advice, or training of sales representatives or physicians constitute promotion of an off-label use, the FDA could request that we modify our training or promotional or reimbursement materials or subject us to regulatory or enforcement actions, including, among other things, the issuance of an untitled letter, a warning letter, injunction, seizure, disgorgement of profits, civil fines, and criminal penalties. Other federal, state or foreign governmental authorities also might take action if they consider our promotion or training materials to constitute promotion of an uncleared or unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. For example, the government may take the position that off-label promotion resulted in inappropriate reimbursement for an off-label use in violation of the Federal False Claims Act for which it might impose a civil fine and even pursue criminal action. In those possible events, our reputation could be damaged, and adoption of the products would be impaired. Although we train our sales force not to promote our products for off-label uses, and our instructions for use in all markets specify the intended use of our products, the FDA or another regulatory agency could conclude that we have engaged in off-label promotion.

There may be increased risk of injury and product liability if surgeons attempt to use our products off-label, misuse our products or do not follow recommended user techniques and guidelines. Product liability claims are expensive to defend and could divert our management's attention and result in substantial damage awards against us. Furthermore, the use of our products for indications other than those indications for which our products have been cleared by the FDA may not effectively treat such conditions, which could harm our reputation in the marketplace among surgeons and patients. Any of these events could harm our business and operating results.

If any of our products cause or contribute to a death or a serious injury or malfunction in certain ways, we will be required to report under applicable medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA medical device reporting regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. If we fail to report these events to the FDA within the required timeframes, or at all, the FDA could take enforcement action against us. Any such adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

Healthcare reform initiatives, policy changes, and other administrative and legislative proposals may adversely affect our business, financial condition, results of operations, and cash flows in our key markets.

Many countries have instituted healthcare policy changes in an attempt to bring increasing spending on healthcare under control, which changes could limit the prices we are able to charge for our products or the coverage and reimbursement available for our products. For example, in the U.S., the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the "ACA"), enacted in March 2010, made changes that significantly impact the healthcare industry. In addition to the ACA, various healthcare reform proposals have also been proposed by U.S. federal and state governments and other national governments that may subject us to additional U.S. or foreign regulatory requirements. We cannot predict whether future healthcare initiatives will be implemented in or outside of the U.S., or the effect any future legislation or regulation will have on us. The expansion in any government's regulation of the healthcare industry may result in decreased profits, limited coverage or reimbursement available for our products, decreased acceptance and availability of our products, and reduced medical procedure volumes, all of which may adversely affect our business, financial condition, and results of operations.

There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future or their full impact. The continuing efforts of the government, insurance companies, managed care organizations and other payers of healthcare services to contain or reduce costs of healthcare may harm:

- our ability to set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability; and
- the availability of capital.

Recently there has been heightened governmental scrutiny over the manner in which companies set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal legislation designed to bring transparency to product pricing and reduce the cost of products and services under government healthcare programs. Additionally, individual states in the United States have also increasingly passed legislation and implemented regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures. Moreover, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what products to purchase and which suppliers will be included in their healthcare programs. Adoption of price controls and other cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures may prevent or limit our ability to generate revenue and attain profitability.

Various new healthcare reform proposals are emerging at the federal and state level. Any new federal and state healthcare initiatives that may be adopted could limit the amounts that federal and state governments will pay for healthcare products and services, and could harm our business, financial condition, and results of operations.

If we fail to comply with U.S. federal and state fraud and abuse and other healthcare laws and regulations, including those relating to kickbacks and false claims for reimbursement, we could face substantial penalties, and our business operations and financial condition could be adversely affected.

Healthcare providers and third-party payers play a primary role in the distribution, recommendation, ordering, and purchasing of any product for which we have or obtain marketing clearance or approval. Through our arrangements with principal investigators, healthcare professionals, and customers, we are exposed to broadly applicable anti-fraud and abuse, anti-kickback, false claims, and other healthcare laws and regulations that may constrain our business, our arrangements, and relationships with customers, and how we market, sell, and distribute our marketed medical devices. We have certain policies and procedures in place (a Code of Conduct and Anti-Bribery and Anti-Corruption Policy), but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent noncompliance may not be effective in protecting us from governmental investigations for failure to comply with applicable fraud and abuse or other healthcare laws and regulations.

In the United States, we are subject to various state and federal anti-fraud and abuse laws, including, without limitation, the federal healthcare Anti-Kickback Statute and federal civil False Claims Act, federal data privacy and security laws, and federal transparency laws related to payments and/or other transfers of value made to physicians, other healthcare professionals, and teaching hospitals. There are similar laws in other countries. Our relationships and our distributors' relationships with physicians, other health care professionals, and hospitals are subject to scrutiny under these laws.

Healthcare fraud and abuse laws and related regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. The laws that may affect our ability to operate include:

- The Anti-Kickback Statute, which prohibits, among other things, knowingly and willingly soliciting, offering, receiving or paying remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual, or the purchase, order, or recommendation of, items or services for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value, and the government can establish a violation of the Anti- Kickback Statute without proving that a person or entity had actual knowledge of the law or a specific intent to violate. In addition, the government may assert that a claim, including items or services resulting from a violation of the Anti-Kickback Statute, constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. The Anti-Kickback Statute is subject to evolving interpretations and has been applied by government enforcement officials to a number of common business arrangements in the medical device industry. There are a number of statutory exceptions and regulatory safe harbors protecting certain business arrangements from prosecution under the Anti- Kickback Statute; however, those exceptions and safe harbors are drawn narrowly, and there may be limited or no exception or safe harbor for many common business activities, such as reimbursement support programs, educational and research grants, or charitable donations. Practices that involve remuneration to those who prescribe, purchase, or recommend medical devices, including discounts, providing items or services for free or engaging such individuals as consultants, advisors, or speakers, may be subject to scrutiny if they do not fit squarely within an exception or safe harbor and would be subject to a facts and circumstances analysis to determine compliance with the Anti-Kickback Statute.
- Federal civil and criminal false claims laws, including the federal civil False Claims Act, and civil monetary penalties laws, which prohibit, among other things, persons or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds and knowingly making, using or causing to be made or used, a false record or statement to get a false claim paid or to avoid, decrease, or conceal an obligation to pay money to the federal government. A claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Actions under the federal civil False Claims Act may be brought by the government or as a qui tam action by a private individual in the name of the government. These individuals, sometimes known as "relators" or, more commonly, as "whistleblowers," may share in any amounts paid by the entity to the government in fines or settlement. Many pharmaceutical and medical device manufacturers have been investigated and have reached substantial financial settlements with the federal government under the federal civil False Claims Act for a variety of alleged improper activities, including causing false claims to be submitted as a result of the marketing of their products for unapproved and thus non-reimbursable uses and interactions with prescribers and other customers, including those that may have affected their billing or coding practices and submission of claims to the federal government. Federal civil False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory monetary penalties for each false or fraudulent claim or statement. Because of the potential for large monetary exposure, healthcare and medical device companies often resolve allegations without admissions of liability for significant and material amounts to avoid the uncertainty of treble damages and per claim penalties that may be awarded in litigation proceedings.

- HIPAA, which imposes criminal and civil liability for, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payers, or knowingly and willfully falsifying, concealing or covering up a material fact or making a materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items, or services;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH Act, and their implementing regulations, also impose obligations, including mandatory contractual terms, on covered entities subject to the rule, such as health plans, healthcare clearinghouses, and certain healthcare providers, as well as their business associates and their subcontractors that perform certain services for them or on their behalf involving the use or disclosure of individually identifiable health information with respect to safeguarding the privacy, security, and transmission of individually identifiable health information;
- The federal Physician Payments Sunshine Act, also known as Open Payments, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program to report annually, with certain exceptions, to the Centers for Medicare and Medicaid Services ("CMS") information related to payments or other "transfers of value" made to physicians, (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members; and
- Analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers; state and foreign laws that require medical device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and foreign beneficiary inducement laws, which are laws that require medical device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

State and federal regulatory and enforcement agencies continue to actively investigate violations of healthcare laws and regulations, and the U.S. Congress continues to strengthen the arsenal of enforcement tools. Most recently, the Bipartisan Budget Act of 2018 ("BBA") increased the criminal and civil penalties that can be imposed for violating certain federal health care laws, including the Anti-Kickback Statute. Enforcement agencies also continue to pursue novel theories of liability under these laws. Government agencies have continued regulatory scrutiny and enforcement activity with respect to manufacturer reimbursement support activities and patient support programs, including bringing criminal charges or civil enforcement actions under the Anti-Kickback Statute, federal civil False Claims Act, and HIPAA's healthcare fraud and privacy provisions.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our business activities, including certain sales and marketing practices, and financial arrangements with physicians, other healthcare providers and other customers, could be subject to challenge under one or more such laws. If an arrangement were deemed to violate the Anti- Kickback Statute, it may also subject us to violations under other fraud and abuse laws such as the federal civil False Claims Act and civil monetary penalties laws. Moreover, such arrangements could be found to violate comparable state fraud and abuse laws.

Achieving and sustaining compliance with applicable federal and state anti-fraud and abuse laws may prove costly. If we or our employees are found to have violated any of the above laws, we may be subjected to substantial criminal, civil, and administrative penalties, including imprisonment, exclusion from participation in federal healthcare programs, such as Medicare and Medicaid, and significant fines, monetary penalties, forfeiture, disgorgement and damages, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. Any action or investigation against us for the violation of these healthcare fraud and abuse laws, even if successfully defended, could result in significant legal expenses, and could divert our management's attention from the operation of our business. Companies settling federal civil False Claims Act, Anti-Kickback Statute, or civil monetary penalties law cases also may be required to enter into a Corporate Integrity Agreement with the Office of Inspector General in order to avoid exclusion from participation (i.e., loss of coverage for their products) in federal healthcare programs such as Medicare and Medicaid. Corporate Integrity Agreements typically impose substantial costs on companies to ensure compliance. Defending against any such actions can be costly, time-consuming, and may require significant personnel resources, and may have a material adverse effect on our business, financial condition, and results of operations.

Our employees, independent contractors, consultants, strategic partners, distributors, and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, consultants, or vendors may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless, and/or negligent conduct or disclosure of unauthorized activities to us that violates: FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA; manufacturing standards; federal and state health care fraud and abuse laws and regulations; or laws that require the true, complete, and accurate reporting of financial information or data. In addition, sales, marketing, and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials or creating fraudulent data in our nonclinical studies or clinical trials, which could result in regulatory sanctions and serious harm to our reputation.

It is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal, and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid, and other federal health care programs, contractual damages, reputational harm, diminished potential profits and future earnings, and curtailment of our operations, any of which could adversely affect our business, financial condition, results of operations, or prospects.

We could be adversely affected by violations of the Foreign Corrupt Practices Act ("FCPA") and similar worldwide anti-bribery laws and any investigation.

Because of our international operations we could be adversely affected by violations of the FCPA and similar anti-bribery laws of other countries in which we provide services or have employees. The FCPA and similar anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to government officials or other third parties for the purpose of obtaining or retaining business or gaining any business advantage. While our policies mandate compliance with these anti-bribery laws, we cannot provide assurance that our internal control policies and procedures always protect us from reckless or criminal acts committed by our employees, contractors, or agents. Failure to comply with the FCPA could result in the imposition of civil or criminal fines and penalties and could disrupt our business and adversely affect our results of operations, cash flows, and financial condition.

Failure to comply with anti-bribery, anti-corruption, and anti-money laundering laws, including the FCPA, as well as export control laws, customs laws, sanctions laws, and other laws governing our operations could result in civil or criminal penalties, other remedial measures, and legal expenses.

As we grow our international presence, we are increasingly exposed to anti-corruption, trade and economic sanctions, and other restrictions imposed by the United States, the European Union, and other governments and organizations. The FCPA generally prohibits companies and their employees and third-party intermediaries from offering, promising, giving, or authorizing the provision of anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action or otherwise obtain or retain business. We may have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. Violations of the FCPA and anti-corruption laws could result in fines, criminal sanctions against us, our officers, or our employees, and prohibitions on the conduct of our business. Violations would also negatively affect our business, reputation, financial condition, and results of operations.

In addition, our solutions may be subject to U.S. and foreign export controls, trade sanctions, and import laws and regulations. Governmental regulation of the import or export of our solutions, or our failure to obtain any required import or export authorization for our solutions, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our solutions may create delays in the introduction of our solutions in international markets or, in some cases, prevent the export of our solutions to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or products targeted by such regulations, could result in decreased use of our solutions by, or in our decreased ability to export our solutions to, existing or potential customers with international operations. Any decreased use of our solutions or limitation on our ability to export or sell access to our solutions would likely adversely affect our business.

We have implemented policies and procedures designed to ensure compliance by us and our directors, officers, employees, representatives, consultants, and agents with the FCPA, export control and economic sanctions laws, and other anti-corruption, anti-money-laundering and anti-terrorism laws, and regulations. We cannot assure you, however, that our policies and procedures are or will be sufficient or that directors, officers, employees, representatives, consultants, and agents have not engaged and will not engage in prohibited conduct for which we may be held responsible. Violations of the FCPA, export control and economic sanctions laws, or other anti-corruption, anti-money laundering and anti-terrorism laws, or regulations may result in severe criminal or civil sanctions, and we may be subject to other liabilities, which could have a material adverse effect on our business, financial condition, and results of operations.

We have identified a material weakness in our internal control over financial reporting and, if we are unable to remediate this material weakness, if we identify additional material weaknesses in the future, or if we are unable to implement and maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock may be negatively affected.

As a company subject to SEC reporting requirements, we will be required to maintain internal controls over financial reporting and to report any material weaknesses in such internal controls. In addition, beginning with our second annual report on Form 10-K, we expect we will be required to furnish annual management assessments of the effectiveness of our internal control over financial reporting. However, while we remain an emerging growth company, we will not be required to include a report by our independent registered public accounting firm addressing these assessments pursuant to Section 404 of the Sarbanes-Oxley Act. We are continuing to develop and enhance our internal control over financial reporting to align with the standards contemplated by Section 404 of the Sarbanes-Oxley Act. Accordingly, our internal controls over financial reporting do not currently meet all of the standards contemplated by Section 404 of the Sarbanes-Oxley Act that we will eventually be required to meet. These reporting and other obligations may place significant demands on management, and administrative and operational resources, including accounting systems and resources.

The process of designing, implementing, and testing the internal control over financial reporting required to comply with this obligation is time consuming, costly, and complicated. If we identify material weaknesses in our internal control over financial reporting, if we are unable to comply with the applicable requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner or to assert that our internal control over financial reporting is effective, or, when applicable, if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be negatively affected, and we could become subject to investigations by the stock exchange on which our securities are then listed, the SEC, or other regulatory authorities, which could require additional financial and management resources.

In connection with the audit of our financial statements for the year ended December 31, 2025, we identified a material weakness in our internal control over financial reporting related to the Control Activities component of the COSO framework. This material weakness reflects that we did not maintain sufficient documented evidence that internal reviews were completed and we did not have a formal process to conduct a secondary review of manual journal entries.

We are in the process of designing and implementing a remediation plan intended to address the identified material weakness, including enhancing documentation of internal reviews, formalizing secondary review procedures over manual journal entries, and implementing additional controls to validate the completeness and accuracy of information used in our financial close process.

There can be no assurance that our remediation efforts will remediate the identified material weakness in a timely manner or at all, or that we will not identify additional material weaknesses or significant deficiencies in the future, any of which could further adversely affect our ability to accurately and timely report our financial condition and results of operations.

Changes in U.S. trade policies, including tariffs and import restrictions, may increase our costs, disrupt our supply chain, and harm our competitive position.

The U.S. government has imposed, and may continue to impose, tariffs and other trade restrictions on imports from various countries, including tariffs on medical devices, components, raw materials, and related goods. While the majority of our products are manufactured in our Burnsville, Minnesota facility using domestically-sourced components and materials, we face material exposure to the effects of U.S. trade policy and retaliatory tariffs imposed by foreign governments, particularly in our key international markets.

In response to U.S. tariffs, the European Union has imposed retaliatory tariffs on selected U.S. exports, and additional measures remain under consideration. Although U.S.-manufactured medical devices currently benefit from relatively lower tariff exposure compared to other product categories, the European Union has considered broader retaliatory measures that could include medical device-related products and components. If the European Union or other trading partners increase tariffs on U.S. medical devices or medical technology imports, European hospitals and healthcare providers may face higher procurement costs, which could result in reduced demand for our products, delayed purchasing decisions, or price reductions we may be forced to accept to remain competitive.

The tariff environment remains highly fluid, with frequent policy changes, legal challenges to tariff authority, and ongoing trade negotiations. If trade tensions escalate further or retaliatory tariffs are imposed on U.S. medical device exports, our ability to penetrate and expand in international markets could be materially adversely affected, our international revenue growth could be substantially delayed or reduced, and our ability to achieve profitability and positive cash flow could be materially impaired.

We are or may become subject to stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security, and changes in such laws, regulations, policies, contractual obligations and failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations.

There are multiple privacy and data security laws that may impact our business activities in the U.S. and in other countries where we conduct trials or where we may do business in the future. These laws are evolving and may increase both our obligations and our regulatory risks in the future. Currently, we receive sensitive personally identifiable information, including health and genetic information, through the clinical trial process and may receive such information the course of research collaborations. As such, we also may be subject to various state laws regulating the use or disclosure of this information or requiring notification of affected individuals and state regulators in the event of a breach of personal information.

Furthermore, certain health privacy laws, data breach notification laws, consumer protection laws and genetic information laws may apply directly to our operations and/or those of our collaborators and may impose restrictions on our collection, use and dissemination of individuals' health information. Individuals from whom we or our collaborators may obtain health information, as well as the healthcare providers who may share this information with us, may have statutory or contractual rights that limit the ability to use and disclose the information. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

Risks Related to our Intellectual Property

We are dependent on the protection and enforcement of our intellectual property rights.

Among other intellectual property rights, we rely on patents to establish our intellectual property rights and protect our products. The protection of the intellectual property we rely upon is critical to our business and commercial success. If we are unable to protect or enforce the intellectual property rights embodied in our products, there is a risk that other companies will incorporate the intellectual property into their technology, which could adversely affect our ability to compete in the cardiac catheter ablation market. Our patent portfolio comprises of 21 issued U.S. patents, 71 corresponding granted foreign patents, and 10 pending applications in national phase or published. No assurance can be given that the pending applications will result in granted patents. Furthermore, there is a risk that our granted patents could be found by a court to be invalid or unenforceable or revoked before their planned expiry. There is also the risk that the granted patents may not provide us with sufficient protection against competitive products and therefore we may not be able to prevent competitors from copying our products and technology. If our patents and other intellectual property rights do not adequately protect our products, we may lose market share to our competitors and be unable to operate our business profitably.

We may be subject to future third-party intellectual property rights disputes.

We do not believe that our activities infringe any third-party's intellectual property rights. However, in the future we may be subjected to infringement claims or litigation arising out of patents and pending applications of our competitors, or third parties or intellectual property authorities may re-examine the patentability of licensed or owned patents. The defense and prosecution of intellectual property claims are costly and time consuming to pursue, and their outcome is uncertain. If we infringe the rights of third parties, we could be prevented from selling products, which would have a significant negative effect on our business and financial position. We have not budgeted for potential legal costs of intellectual property claims and significant legal costs would have a negative effect on our financial position.

If we are unable to protect the confidentiality of our other proprietary information, our business and competitive position may be harmed.

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, and other proprietary information that is not patentable or that we elect not to patent. However, trade secrets can be difficult to protect, and some courts are less willing or unwilling to protect trade secrets. To maintain the confidentiality of our trade secrets and proprietary information, we rely heavily on confidentiality provisions that we have in contracts with our employees, consultants, contractors, collaborators, and others upon the commencement of their relationship with us. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by such third parties, despite the existence generally of these confidentiality restrictions. These contracts may not provide meaningful protection for our trade secrets, know-how, or other proprietary information in the event of any unauthorized use, misappropriation or disclosure of such trade secrets, know-how, or other proprietary information. Despite the protections we place on our intellectual property or other proprietary rights, monitoring unauthorized use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property or other proprietary rights will be adequate. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. The laws of many foreign countries will not protect our intellectual property or other proprietary rights to the same extent as the laws of the United States. Consequently, we may be unable to prevent our proprietary technology from being exploited in the United States and abroad, which could affect our ability to expand in domestic and international markets or require costly efforts to protect our technology.

To the extent our intellectual property or other proprietary information protection is incomplete, we are exposed to a greater risk of direct competition. A third party could, without authorization, copy or otherwise obtain and use our products or technology, or develop similar technology. Our competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts or design around our protected technology. Our failure to secure, protect, and enforce our intellectual property rights could substantially harm the value of our products, brand, and business. The theft or unauthorized use or publication of our trade secrets and other confidential business information could reduce the differentiation of our products and harm our business, the value of our investment in development or business acquisitions could be reduced, and third parties might make claims against us related to losses of their confidential or proprietary information.

Further, it is possible that others will independently develop the same or similar technology or otherwise obtain access to our unpatented technology, and in such cases, we could not assert any trade secret rights against such parties. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our trade secret rights and related confidentiality and nondisclosure provisions. If we fail to obtain or maintain trade secret protection, or if our competitors obtain our trade secrets or independently develop technology similar to ours or competing technologies, our competitive market position could be materially and adversely affected. In addition, some courts are less willing or unwilling to protect trade secrets, and agreement terms that address non-competition are difficult to enforce in many jurisdictions and might not be enforceable in certain cases.

We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations, and systems, agreements or security measures may be breached and detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive, and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach. Any of the foregoing could materially and adversely affect our business, financial condition, and results of operations.

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

The registered and unregistered trademarks and trade names that we own may be challenged, infringed, circumvented, declared generic, lapsed, or determined to be infringing on or dilutive of other marks. We may not be able to protect our rights in these trademarks and trade names, which we need in order to build name recognition with potential customers and collaborators. In addition, third parties may file for registration of trademarks similar or identical to our trademarks, thereby impeding our ability to build brand identity and possibly leading to market confusion. If they succeed in registering or developing common-law rights in such trademarks, and if we are not successful in challenging such third-party rights, we may not be able to use these trademarks to develop brand recognition of our technologies, products, or services. In addition, there could be potential trademark infringement claims brought by owners of other registered or unregistered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may become a party to intellectual property litigation or administrative proceedings that could be costly and could interfere with our ability to sell and market our products.

The medical device industry has been characterized by extensive litigation regarding patents, trademarks, trade secrets, and other intellectual property rights, and companies in the industry have used intellectual property litigation to gain a competitive advantage. It is possible that U.S. and foreign patents and pending patent applications or trademarks controlled by third parties may be alleged to cover our products, or that we may be accused of misappropriating third parties' trade secrets. Our competitors, many of which have substantially greater resources and have made substantial investments in patent portfolios, trade secrets, trademarks, and competing technologies, may have applied for or obtained, or may in the future apply for or obtain, patents or trademarks that will prevent, limit, or otherwise interfere with our ability to make, use, sell, and/or export our products or to use product names. Because patent applications can take years to issue and are often afforded confidentiality for some period of time, there may currently be pending applications, unknown to us, that later result in issued patents that could cover one or more of our products. Moreover, in recent years, individuals and groups that are non-practicing entities, commonly referred to as "patent trolls," have purchased patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or "invitations to license," or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others. The defense of these matters can be time consuming, costly to defend in litigation, divert management's attention and resources, damage our reputation and brand, and cause us to incur significant expenses or make substantial payments. Vendors from whom we purchase hardware or software may not indemnify us in the event that such hardware or software is accused of infringing a third party's patent or trademark or of misappropriating a third party's trade secret, or any indemnification granted by such vendors may not be sufficient to address any liability and costs we incur as a result of such claims. Additionally, we may be obligated to indemnify our customers or business partners in connection with litigation and to obtain licenses or refund subscription fees, which could further exhaust our resources.

Even if we believe a third party's intellectual property claims are without merit, there is no assurance that a court would find in our favor, including on questions of infringement, validity, enforceability, or priority of patents. The strength of our defenses will depend on the patents asserted, the interpretation of these patents, and our ability to invalidate the asserted patents. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable, and infringed, which could materially and adversely affect our ability to commercialize any products or technology we may develop, and any other products or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. Conversely, the patent owner need only prove infringement by a preponderance of the evidence, which is a lower burden of proof.

Further, if patents, trademarks, or trade secrets are successfully asserted against us, this may harm our business and result in injunctions preventing us from developing, manufacturing, or selling our products, or result in obligations to pay license fees, damages, attorney fees, and court costs, which could be significant. In addition, if we are found to willfully infringe on third-party patents or trademarks or to have misappropriated trade secrets, we could be required to pay treble damages in addition to other penalties.

Although patent, trademark, trade secret, and other intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. We may be unable to obtain necessary licenses on satisfactory terms, if at all. In addition, if any license we obtain is non-exclusive, we may not be able to prevent our competitors and other third parties from using the intellectual property or technology covered by such license to compete with us. If we do not obtain the necessary licenses, we may not be able to redesign our products to avoid infringement. Any of these events could materially and adversely affect our business, financial condition, and results of operations.

Similarly, interference or derivation proceedings provoked by third parties or brought by the U.S. Patent and Trademark Office ("USPTO") may be necessary to determine priority with respect to our patents, patent applications, trademarks, or trademark applications. We may also become involved in other proceedings, such as reexamination, inter partes review, derivation, or opposition proceedings before the USPTO or other jurisdictional body relating to our intellectual property rights or the intellectual property rights of others. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing our products or using product names, which would have a significant adverse impact on our business, financial condition, and results of operations.

Additionally, we may file lawsuits or initiate other proceedings to protect or enforce our patents or other intellectual property rights, which could be expensive, time consuming, and unsuccessful. Competitors may infringe our issued patents or other intellectual property, which we may not always be able to detect. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property or alleging that our intellectual property is invalid or unenforceable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may raise challenges to the validity of certain of our owned or in-licensed patent claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). In any such lawsuit or other proceedings, a court or other administrative body may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly, or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question.

The outcome following legal assertions of invalidity and unenforceability is unpredictable. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products or products that we may develop. If our patents are found to be valid and infringed, a court may refuse to grant injunctive relief against the infringer and instead grant us monetary damages and/or ongoing royalties. Such monetary compensation may be insufficient to adequately offset the damage to our business caused by the infringer's competition in the market. An adverse result in any litigation or other proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Any of these events could materially and adversely affect our business, financial condition, and results of operations.

Even if resolved in our favor, litigation or other proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential or sensitive information could be compromised by disclosure in the event of litigation. Uncertainties resulting from the initiation and continuation of patent and other intellectual property litigation or other proceedings could have a material adverse effect on our business, financial condition, and results of operations.

Risks Related to our CDIs and Common Stock

Our common stock may never be listed on a major U.S. stock exchange which could materially limit liquidity and increase volatility for investors.

While we may seek the listing of our common stock on a U.S. securities exchange at some time in the future, there can be no assurance as to if, when, or under what circumstances we will be able to satisfy such listing standards or that our common stock will be accepted for listing on any such exchange. Should we fail to satisfy the initial listing standards of such exchange, or our common stock is otherwise rejected for listing, the trading price of our CDIs could suffer, the trading market for our CDIs may be less liquid, and our CDI price may be subject to increased volatility.

Investors may have difficulty in reselling their CDIs or shares of common stock due to the lack of an established trading market in the U.S. or potentially restrictive state securities laws.

In compliance with the SEC's no-action position taken in *Regulation S - Initial Public Offerings of U.S. Companies on the Australian Stock Exchange Limited (January 7, 2000)* providing relief from certain requirements of Regulation S under the Securities Act for U.S. companies listed on the ASX, our ASX trading ticker was tagged with a "FOR US" designation following the August 30, 2019, Australian initial public offering (the "IPO"), indicating that the CDIs are restricted under Regulation S and, as a result, may not be sold to U.S. persons (except for "qualified institutional buyers" as such term is defined in Rule 144A under the Securities Act). We expect that the securities will trade under the "FOR US" designation for the foreseeable future. Neither our CDIs nor the shares of our common stock trade on any U.S. over-the-counter market or securities exchange, and we have no current plans to seek quotation on an over-the-counter market or list our shares on a national securities exchange in the U.S. (although we may do so in the future).

To our knowledge, there is no current trading activity among our U.S.-domiciled stockholders. As such, there can be no guarantee that an active market in our securities will develop or continue, whether in the U.S., Australia, or elsewhere, or that the market price of our securities will increase. If a market does not develop or is not sustained, it may be difficult for investors to sell their securities. The holders of our shares of common stock, as well as potential purchasers, should be aware that there might be significant state securities laws, or "blue sky" regulations, limiting the ability of investors to resell our shares. Furthermore, the market price for our CDIs may fall or be made more volatile because of the relatively low volume of trading in our securities. When trading volume is low, significant price movement can be caused by trading in a relatively small number of CDIs. If illiquidity arises, there is a risk that stockholders will be unable to realize their investment in us.

The issuance of additional securities in connection with financings, investments, our equity incentive plans, or otherwise will dilute all other stockholders and may adversely affect the value of and rights associated with our common stock.

Our current stockholders do not have preemptive rights to any shares that we issue in the future. Under our Amended and Restated Certificate of Incorporation, we have the authority to issue a total of 560,000,000 shares of capital stock, consisting of 535,000,000 shares of common stock and 25,000,000 shares of undesignated preferred stock. Of the total shares of common stock authorized, 500,000,000 are classified as Class A common stock and 35,000,000 are classified as Class B common stock.

Subject to compliance with applicable laws, rules, and regulations and the provisions of our Amended and Restated Certificate of Incorporation, the Board of Directors ("Board") is authorized to issue preferred stock from time to time in one or more series, to fix the number of shares, and to determine or alter for each such series the voting powers, designation, preferences, and rights and such qualifications, limitations, or restrictions thereof. The voting powers, designation, preferences, and rights of these series of preferred stock may (i) be senior to or on parity with our common stock, which may reduce its value, and (ii) adversely affect the rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, delay, defer, discourage, or prevent a change in control of Imricor and may adversely affect the market price of our common stock and the rights of the holders of common stock.

Subject to compliance with applicable laws, rules, and regulations (including the listing rules of the ASX "the ASX Listing Rules") and the provisions of our Amended and Restated Certificate of Incorporation, the Board may also issue common stock or securities convertible into common stock from time to time in connection with financing, investment, our equity incentive plans, or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and may also reduce their proportionate voting power and ownership interest. Our common stock consists of two classes, Class A common stock and Class B common stock, which have distinct rights and limitations. Subject to the rights of the preferred stock that may come into existence from time to time, each share of Class A common stock entitles the holder to one vote on each matter properly submitted to stockholders and participates equally in dividends and other distributions as may be declared by the Board. Class B common stock does not carry voting rights and is not entitled to receive dividends or other distributions. The issuance of additional Class A common stock or securities convertible into Class A common stock may dilute the proportionate voting power and ownership interest of existing Class A stockholders. Such issuance could cause the market price of our common stock to decline, which will negatively impact the value of a stockholder's investment, especially if we sell these securities at prices less than the price paid for shares.

The market price of our CDIs and common stock may be volatile, which could cause the value of our common stock to decline and limit an investor's ability to realize any return on investment.

The ability for investors to achieve a return on their investment will largely depend on an appreciation in the market price of our CDIs. The CDIs and the underlying common stock carry no guarantee with respect to the payment of dividends, return of capital, or market value, and, as we do not currently intend to pay dividends in the foreseeable future, investor returns will depend entirely on the market performance of these securities. There is no assurance that the CDIs or common stock will appreciate in value or even maintain their current price, and therefore investors may not achieve any return on investment.

The trading price of our CDIs on the ASX has been volatile and may continue to be subject to fluctuations. In addition, the trading volume of our CDIs may fluctuate and cause significant price variations to occur. Securities markets worldwide experience significant price and volume fluctuations as a result of a variety of factors, many of which are beyond our control but may nonetheless decrease the market price of our CDIs, regardless of our actual operating performance including, but not limited to:

- public reaction to our press releases, announcements, and filings with the SEC and ASX;
- our operating and financial performance;
- changes in market valuations of similar companies;
- departures of key personnel;
- commencement of or involvement in litigation;
- changes in economic and political conditions, financial markets, and/or the technology industry;
- interest rate fluctuations;
- changes in accounting standards, policies, guidance, interpretations, or principles;
- actions by our stockholders;
- the failure of securities analysts to cover our CDIs and/or changes in their recommendations and estimates of our financial performance;
- future sales of our common stock or CDIs;
- trading prices and trading volumes of our CDIs on the ASX; and
- the other factors described in these "Risk Factors".

The fluctuations could become even larger if our securities trade on more than one stock exchange or in different markets. Our CDIs are currently listed on the ASX, and we may list our common stock on a U.S. securities exchange in the future. Trading in our common stock and CDIs therefore may take place in different currencies (U.S. dollars on a U.S. securities exchange and Australian dollars on the ASX), and at different times (resulting from different time zones, different trading days, and different public holidays in the United States and Australia). The trading prices of our CDIs and our common stock on two markets may differ because of these, or other, factors. Any decrease in the price of our CDIs or common stock on either market could cause a decrease in the trading prices of our CDIs or our common stock on the other market.

In addition, investors may seek to profit by exploiting the difference, if any, between the price of our CDIs on the ASX and the price of shares of our common stock on a U.S. securities exchange. Such arbitrage activities could cause our stock price in the market with the higher value to decrease to the price set by the market with the lower value and could also lead to significant volatility in the price of our common stock or CDIs.

The requirements of being an SEC registrant may strain our resources, divert management's attention, and affect our ability to attract and retain qualified directors and officers.

As an SEC registrant, we will be subject to the reporting and corporate governance requirements of the Exchange Act. Compliance with these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time-consuming, or costly and increase demand on our systems and resources, particularly after we are no longer an "emerging growth company" as defined in the JOBS Act. Among other things, the Exchange Act requires that we file annual, quarterly, and current reports with respect to our business and results of operations and maintain effective disclosure controls and procedures and internal control over financial reporting.

In order to improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. Our current controls and any new controls that we develop may become inadequate and material weaknesses in our internal control over financial reporting may be discovered in the future. If we cannot demonstrate effective internal control over financial reporting, or if our internal control over financial reporting is perceived as inadequate, or if we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results, and the price of our common stock could decline. Furthermore, management's attention may be diverted from other business concerns, which could harm our business, financial condition, results of operations, and prospects. Although we have already hired additional personnel to help comply with these requirements, we may need to further expand our legal and finance departments in the future, which will increase our costs and expenses.

In addition, changing laws, regulations, and standards relating to corporate governance and public disclosure may create uncertainty for SEC registrants, increasing legal and financial compliance costs and making some activities more time-consuming. These laws, regulations, and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations, and standards, and this investment may result in increased general and administrative expense and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations, and standards differ from the activities intended by regulatory or governing bodies, regulatory authorities may initiate legal proceedings against us, and our business and prospects may be harmed. As a result of disclosure of information in the filings required of an SEC registrant and in this Registration Statement, our business and financial condition will become more visible, which may result in threatened or actual litigation. If such claims are successful, our business, financial condition, results of operations, and prospects could be materially harmed, and even if the claims do not result in litigation or are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and materially harm our business, financial condition, results of operations, and prospects.

Being an SEC registrant and these new rules and regulations may make it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified executive officers and members of our Board, particularly to serve on our Audit and Risk Committee and Nomination and Remuneration Committee.

Our senior management team has limited experience managing an SEC registrant, and regulatory compliance may divert our attention from the day-to-day management of our business.

The individuals who constitute our senior management team have limited experience managing an SEC registrant and limited experience complying with the increasingly complex laws pertaining to SEC registrants. Our senior management team may not successfully or efficiently manage an SEC registrant subject to significant regulatory oversight and reporting obligations under United States securities laws. In particular, these obligations require substantial attention from our senior management team and could divert their attention from the day-to-day management of our business.

If securities and industry analysts do not publish, regularly update, or publish inaccurate or unfavorable research about our business, the trading price and trading volume of the common stock could decline.

The trading market for our CDIs on the ASX may be influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of the analysts currently covering our securities ceases coverage, the trading price for our CDIs on the ASX could be negatively impacted. If one or more of these analysts fail to publish reports on us regularly, we could lose visibility in the financial markets and the trading price for our CDIs on the ASX could be negatively impacted. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property, or our CDI performance, or if our results of operations fail to meet the expectations of analysts, the trading price or trading volume of our CDIs would likely decline.

The costs and management time involved in complying with Delaware laws, Australian laws, and U.S. reporting requirements are likely to be significant.

As a U.S. reporting company, we will incur significant legal, accounting, and other expenses in connection with our public disclosure and other obligations. For example, we will incur costs associated with compliance with the rules and regulations of the SEC, the Sarbanes-Oxley Act, and the Dodd-Frank Wall Street Reform and Consumer Protection Act. Registration under the Exchange Act will involve our filing of an initial registration statement with the SEC and the filing of ongoing annual, quarterly, and current reports on Forms 10-K, 10-Q and 8-K, respectively. These SEC periodic reports will be in addition to the periodic filings required by the ASX Listing Rules, although we intend to seek a waiver from ASX to allow us to file our SEC reports with ASX.

As a Delaware company with an ASX listing and a registration as a foreign company in Australia, we will also need to ensure ongoing compliance with Delaware law and relevant Australian laws and regulations, including the ASX Listing Rules and certain provisions of the Australian *Corporations Act 2001* (Cth) ("Corporations Act"). To the extent of any inconsistency between Delaware law and Australian law and regulations, we may need to make changes to our business operations, structure, or policies to resolve such inconsistency. If we are required to make such changes, this is likely to result in interruptions to our operations, additional demands on key managers and extra costs.

We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly, although we are currently unable to estimate these costs to any degree of certainty. Our management will need to devote a substantial amount of time to new compliance requirements, and we may need to implement additional procedures and controls in order to satisfy new reporting requirements. These laws and regulations also could make it more difficult and costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. These laws and regulations could also make it more difficult to attract and retain qualified people to serve on our Board and Board committees and serve as executive officers due to perceived risk. Furthermore, if we are unable to satisfy our obligations as a reporting company, we could be subject to fines, sanctions, and other regulatory action and potentially civil litigation.

Provisions of our constituent documents and Delaware law could make an acquisition of us more difficult.

Certain provisions of our Certificate of Incorporation and Bylaws could discourage, delay, or prevent a merger, acquisition, tender offer, or other means of effecting a change of control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their CDIs. Furthermore, these provisions could frustrate attempts by stockholders to replace or remove members of the Board or make other changes in management. These provisions could also limit the price that investors might be willing to pay in the future for the CDIs, thereby depressing the market price of the CDIs. There is also a risk that stockholders who wish to participate in these transactions or other actions may not have the opportunity to do so. In addition, we are governed by the provisions of section 203 of the Delaware General Corporation Law, which may, unless certain criteria are met, prohibit certain interested stockholders, in particular those owning 15% or more of the voting rights on shares, from merging or engaging in various other business combinations with us for a prescribed period.

Our Amended and Restated Bylaws designate the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain litigation.

Our Amended and Restated Bylaws provide that unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for certain actions involving the Company. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock (including holders of CDIs) will be deemed to have notice of, and consented to, this forum selection provision. This provision in our Amended and Restated Bylaws may have the effect of discouraging lawsuits against us or our directors and officers and may limit the ability of stockholders to obtain a favorable judicial forum for disputes with us. Notwithstanding the foregoing, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder, and Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. As a result, the exclusive forum provision will not apply to suits brought to enforce any duty or liability created by the Exchange Act, the Securities Act, or any other claim for which the federal courts have exclusive jurisdiction. The exclusive forum provision will result in increased costs for investors to file lawsuits against us.

The different characteristics of the capital markets in Australia and the United States may negatively affect the trading price of our CDIs and common stock and may limit our ability to take certain actions typically performed by a U.S. company.

We are subject to the ASX Listing Rules, applicable provisions of the Corporations Act, and certain other Australian regulatory requirements, and may in the future determine to concurrently list our shares on a U.S. securities exchange as well, which will have its own listing and regulatory requirements. Such exchanges will have different trading hours, trading characteristics (including trading volume and liquidity), trading and listing rules, and investor bases (including different levels of retail and institutional participation). As a result of these differences, the trading prices of our CDIs and our common stock may not be the same, even allowing for currency differences. Fluctuations in the price of our common stock due to circumstances unusual to the U.S. capital markets could materially and adversely affect the price of the CDIs, or vice versa. Certain events having significant negative impact specifically on the Australian capital markets may result in a decline in the trading price of our CDIs notwithstanding that such event may not impact the trading prices of securities listed in the United States generally or to the same extent, or vice versa.

In addition, the listing and regulatory requirements of the ASX may limit our ability to take certain actions typically performed by a U.S. company. For example, the ASX Listing Rules limit the amount of equity securities that a listed company can issue without the approval of its stockholders over any 12-month period to 15% of the outstanding share capital on issue at the start of the period, unless an exception applies. Failure to obtain this approval may make it more difficult for us to issue equity securities in the future at a time and at a price that we deem appropriate. The ASX Listing Rules also require stockholder approval for the granting of options and restricted stock units to our directors, even when the underlying equity incentive plan has already been approved. This creates a risk that, if stockholders do not approve the grants, our directors will not receive their expected amount of equity compensation. This may make it more difficult for us to attract and retain directors, which could have a material adverse effect on our business, results of operations, financial condition, and prospects.

Further, ASX Listing Rules prohibit us from buying back CDIs on-market at a price which is 5% or more above the volume weighted average market price of our CDIs, calculated over the last five days on which sales of CDIs were recorded before the day on which the purchase under the buy-back was made, which, as a result, may make it more difficult to repurchase our CDIs on-market. In addition, should we wish to undertake an on-market buy-back, the ASX may impose further requirements on us as if we were subject to the Corporations Act, which may include the need to obtain stockholder approval to do so.

Lastly, the ASX Listing Rules prohibit the issuance of equity securities by a company without stockholder approval during the three-month period after it learns that a person is making, or proposes to make, a takeover for its securities, unless an exception applies. As a result, if a hostile takeover bid is made in respect of our CDIs or common stock, the ASX Listing Rules may limit our ability to issue equity securities, either as a countermeasure to the takeover bid or to fund operations.

Item 2. Financial Information.

Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read together with our audited consolidated financial statements and the related notes for the years ended December 31, 2025, and 2024, which are included elsewhere in this Registration Statement. Our discussion contains forward-looking statements based upon expectations and beliefs concerning future developments and their potential effect upon our business that involve risks, uncertainties, and assumptions, such as statements regarding our plans, objectives, expectations, and intentions for our business. Our actual results and the timing of selected events could differ materially from those described in or implied by these forward-looking statements as a result of several factors, including those set forth in the section entitled "Risk Factors". See also the section entitled "Disclosure Regarding Forward-Looking Statements."

Overview

Imricor is a U.S.-based medical device company that is leading the new field of real-time iCMR cardiac ablations – that is, cardiac ablations guided by real-time MRI, rather than by conventional x-ray fluoroscopy. Our principal focus is the design, manufacturing, sale, and distribution of MRI-compatible products for cardiac catheter ablation procedures.

The Vision-MR Ablation Catheter is our prime product offering, specifically designed to work under real-time MRI guidance, with the intent of enabling higher success rates along with a faster and safer treatment compared to conventional procedures using x-ray guided catheters. The Vision-MR Ablation Catheter has been approved in the EU, Qatar, and KSA with an indication for treating Type I atrial flutter. We also have approval for the sale of our capital product, the Advantage-MR EP Recorder/Stimulator System, in the EU, Qatar, KSA, and Australia. In June 2025, we received approval for our NorthStar Mapping System in the EU.

We are continuing enrollment in our VISABL-AFL clinical trial to support U.S. market entry of the Vision-MR Ablation Catheter and RF-5000 ablation generator system. In parallel with the clinical trial, we have secured market clearance from the FDA for the Vision-MR Diagnostic Catheter and NorthStar Mapping System. We are pursuing approvals for our other products, including the Advantage-MR EP Recorder/Stimulator System and the Vision-MR Dispersive Electrode, while the VISABL-AFL clinical trial is ongoing.

We sell our capital and consumable products to hospitals and clinics for use in iCMR labs, in which ablation procedures using the Vision-MR Ablation Catheter can be performed. We collaborate with GE Healthcare, Philips, and Siemens, the three leading global MRI vendors who provide MRI systems for iCMR labs, to target certain sites and support the design and construction of iCMR labs for those sites.

Financial overview

Imricor is in the early commercialization phase and is not yet profitable. For the fiscal year ended December 31, 2025, the Company incurred a net loss of $25,319 thousand on revenues of $292 thousand, as we continue to invest in clinical validation, regulatory approvals, and commercial infrastructure to support adoption of iCMR procedures. Operating expenses, primarily in research and development, sales and marketing, and general and administrative functions, reflect planned investments in pursuing U.S. regulatory approval, expanding our clinical support and sales teams, and building iCMR lab infrastructure in our target markets.

As of December 31, 2025, the Company had cash and cash equivalents of $19,502 thousand and marketable securities of $21,278 thousand. We have funded our operations to date primarily through the sale of our common stock and CDIs and through indebtedness. We expect to continue to incur operating losses for the foreseeable future as we execute our commercialization and clinical strategies. We anticipate that achieving profitability will require significant growth in iCMR procedure volume and geographic expansion, and the Company may require additional financing to support these objectives.

Key Factors Affecting Our Business

There are a number of factors that have impacted, and we believe will continue to impact, our results of operations and growth. These factors include:

- ***Regulatory approvals/clearances.*** The sale of our products requires regulatory approval in each relevant jurisdiction. We are not assured of receiving future regulatory clearances for our existing products outside of the European Union or approvals for expanding indications or additional products currently in our product pipeline.

- ***Market adoption.*** Our ability to generate revenue is dependent on hospitals and clinics with ablation centers in markets where we obtain the required regulatory approval establishing an iCMR lab and adopting our MRI-compatible technology for cardiac catheter ablation procedures. While we work collaboratively with leading MRI vendors to drive lab adoption, there can be no guarantee on the outcome.

- ***Competition.*** We expect to generate the vast majority of our future revenue from the sale of our products used for MRI-guided cardiac catheter ablation procedures. The medical device industry is competitive, subject to rapid change, and significantly affected by new product introductions. There are a number of other products and devices on the market which are not traditionally MRI-compatible, but which are commonly used to perform conventional cardiac catheter ablation procedures. To this end, we will compete with larger companies who manufacture and sell ablation and diagnostic electrophysiology products. We must strive to be successful in light of our competitors' existing and future products and related pricing and their resources to successfully market to the physicians who use our products.

- ***Sales and marketing resources.*** We currently have limited sales and marketing resources and will need to, among other things, expand our sales team. We will sell all our products to hospitals and clinics either directly or through distributors and will therefore need to commit increased resources to sales and marketing to execute our current growth strategy. The rate at which we grow our sales force and the speed at which newly hired salespeople or distributors become effective can impact our revenue growth or our costs incurred in anticipation of such growth.

While these factors may present significant opportunities for us, they also pose significant risks and challenges that we must address.

Recent Developments

On March 27, 2025, we completed a placement in which we issued 49,645,391 CDIs. We raised $42,828 thousand in net proceeds after deducting issuance costs. Proceeds from this placement supported our ongoing sales and marketing efforts, research and development activities, clinical trials, regulatory compliance, and associated offer costs. For details of these securities offerings, see Item 10. Recent Sales of Unregistered Securities.

Components of our Consolidated Results of Operations

Revenues

We generate revenue from three primary sources: product sales, service revenue, and consulting revenue. Revenue is recognized when control of the product or service transfers to the customer. For product sales that contain a single performance obligation, revenue is recognized at a point in time when title to the goods and risk of loss transfers to the customer, which typically occurs upon shipment. For product sales that contain multiple performance obligations, such as equipment sales that include installation services, we allocate the transaction price to each performance obligation based on the estimated or observable standalone selling price and recognize revenue for each performance obligation when (or as) control is transferred to the customer and the performance obligation is satisfied. Service and consulting revenue is recognized over time as services are provided. Sales tax and value added taxes in foreign jurisdictions that are collected from customers and remitted to governmental authorities are accounted for on a net basis and therefore are excluded from net sales. Product sales include shipping and handling fees charged to customers. Shipping and handling costs associated with outbound freight after control over a product has transferred to a customer are accounted for as a fulfillment cost and are included in cost of goods sold.

Product Revenue

Our product revenue is derived from sales of our cardiac ablation systems, associated consumables, and third-party equipment to hospitals, clinics, and other providers. Our primary products include the Vision-MR Ablation Catheter and Vision-MR Diagnostic Catheter, which are used in iCMR-guided ablation procedures. Customers select our products based on clinical efficacy, ease of use, pricing, and third-party reimbursement availability. We currently derive revenue from international markets, particularly the European Union, where we maintain a direct sales organization. In other international markets, including the Middle East, we distribute our products through exclusive distributors. We evaluate sales returns and allowances for variable consideration on a monthly basis and allowance for credit losses at each reporting period. We have historically not considered provisions for these items necessary.

Service Revenue

Our service revenue is derived from service agreements for maintenance on our Advantage-MR EP Recorder/Stimulator System and third-party equipment products provided to hospitals, clinics, and other providers. Service revenue is recognized over the contract period on a straight-line basis as customers benefit from the services throughout the service contract period.

Consulting Revenue

Our consulting revenue is derived from technology development work with research institutions and corporate partners evaluating MRI-guided cardiac ablation technologies. We recognize consulting revenue over time using the "as invoiced" practical expedient where appropriate.

Costs and Expenses

Costs of Goods Sold

Cost of goods sold represents costs directly related to production and distribution of our products, including raw materials and components, manufacturing labor, quality assurance testing, product sterilization and packaging, shipping and handling costs, and manufacturing overhead. Shipping and handling costs associated with outbound freight after control over a product has transferred to a customer are accounted for as a fulfillment cost and are included in cost of goods sold. Manufacturing overhead costs include the cost of material procurement, inventory control, and equipment and operations supervision. Cost of goods sold also includes depreciation expense for product tooling, production equipment, and equipment placed at customer sites as part of commercial sales agreements. Costs associated with any inventory write-downs resulting from quarterly physical inventory counts and product obsolescence are also included within cost of goods sold. Fluctuations in our cost of goods sold correspond with the fluctuations in these costs as well as sales volume.

Sales and Marketing

Sales and marketing expenses consist primarily of sales and marketing personnel, field sales travel, trade show expenses, physician training and education programs, and consultant fees related to market development and commercialization strategy. We anticipate that our sales and marketing expenses will increase as we expand our direct sales force in the U.S. and EU, establish and support international distribution partnerships, and increase marketing investments to drive adoption of our MRI-guided ablation systems.

Research and Development Expenses

Research and development include salaries for our research and development, regulatory, quality, and clinical personnel, clinical trial expenses, regulatory submissions, manufacturing process improvements, product development costs, enhancements to our currently commercialized products, and additional investments in our product development pipeline. We expense research and development expenses as incurred. We track external costs on a development program basis for our key programs, including VISABL-AFL and VISABL-VT. However, we do not track internal costs, including personnel-related costs, equipment costs, facility costs, and supplies, on a development program basis because these costs are deployed across multiple programs and are monitored in total rather than by individual program. We generally expect that research and development expenses will increase as we conduct our VISABL-AFL and VISABL-VT clinical trials, pursue additional regulatory approvals in the U.S. and international markets, advance next-generation product development, and optimize our manufacturing processes.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries for our executive, finance, accounting, and human resources personnel; share-based compensation; professional fees for accounting, audit, legal, and tax services; public company compliance costs; directors and officers liability insurance; and facility costs. We anticipate general and administrative expenses will increase as we hire additional personnel to support growth in our commercial and research and development teams, comply with SEC reporting requirements, and enhance our internal systems and controls infrastructure.

Other Income (Expense)

Other income (expense) consists primarily of changes in fair value of our financial instruments, including convertible notes (related party), option liabilities, and warrant liabilities that are remeasured to fair value at each reporting period, as well as interest income from our investments in cash, cash equivalents, and marketable securities. Additionally, other income and expense may include foreign currency exchange gains and losses resulting from remeasurements on our cash holdings, receivables, and liabilities denominated in foreign currencies such as Euros and Australian dollars, government grant income related to our research and development activities, and interest expense on financing agreements.

Results of Operations

The following discussion analyzes our results of operations for the year ended December 31, 2025, and compares those results to results for the year ended December 31, 2024. We suggest that you read the following information in conjunction with our audited consolidated financial statements and the related notes for the years ended December 31, 2025, and 2024, contained elsewhere in this Registration Statement.

Comparison of the Years Ended December 31, 2025, and 2024

(in thousands)	Year Ended December 31, 2025	2024	Change Amount	%
Revenues:	292	959	(667)	-70%
Costs and Expenses:				
Cost of goods sold	2,326	1,884	442	23%
Sales and marketing	4,300	2,272	2,028	89%
Research and development	11,156	8,180	2,976	36%
General and administrative	5,301	4,920	381	8%
Total Costs and Expenses	23,083	17,256	5,827	34%
Loss from Operations	(22,791)	(16,297)	(6,494)	40%
Total Other Income (Expense)	(2,528)	(13,396)	10,868	-81%
Net Loss	$ (25,319)	$ (29,693)	$ 4,374	-15%

Total Revenues

Our total revenues are derived from product revenue, service revenue, and consulting revenue. We earned total revenues of $292 thousand for the year ended December 31, 2025, as compared to $959 thousand for the year ended December 31, 2024, a decrease of $667 thousand. The decrease in total revenues was primarily due to lower sales volumes of third-party equipment and consumable devices compared to the prior year and the absence of consulting revenue in 2025, partially offset by a slight increase in service revenue.

Product revenue decreased $559 thousand, or 73%, primarily due to lower sales volumes of third-party equipment and consumable devices. Equipment sales were lower due to timing of installations at customer sites in the European Union. Sales of consumable devices in 2025 were impacted by certain customer sites in Europe exclusively enrolling patients in our VISABL-AFL clinical trial. Procedures performed as part of this trial do not generate product revenue. In contrast, during 2024, many of these sites treated patients commercially, and the use of consumable devices in those procedures resulted in recognized product revenue. We currently expect that, following completion of enrollment in our VISABL-AFL clinical trial, these customer sites in the European Union will transition back to commercial use of our consumable devices, and based on our assessment, this trend is reasonably likely to have a favorable impact on future product revenues. Service revenue increased $8 thousand, or 11%, primarily due to ongoing maintenance and support services provided to existing customers throughout the year. Consulting revenue decreased $116 thousand, or 100%, primarily due to consulting projects occurring in 2024, including ongoing product integration work with GE Healthcare and work completed with a research institution utilizing our MRI scanner, with no similar consulting engagements undertaken in 2025. Consulting projects are not part of our current core operational plan, and, based on our current expectations, we do not anticipate consulting revenue to be a significant contributor to our future revenues.

Cost of Goods Sold

Costs of goods sold during the year ended December 31, 2025, were $2,326 thousand, compared to $1,884 thousand during the year ended December 31, 2024, representing an increase of $442 thousand. The increase in cost of goods sold, despite a $667 thousand decrease in revenues, was primarily due to higher personnel-related costs and increased inventory reserve expense compared to 2024. The increase in personnel-related costs of $519 thousand, including salaries, bonuses, benefits, and other employee expenses, followed the expansion of our manufacturing and quality assurance teams. The inventory reserve increase of $339 thousand included a charge related to obsolescence of first-generation consumable devices following the mid-year product transition to second-generation consumable products. This was primarily offset by a decrease in inventory costs, due to lower volume of sales, of $485 thousand.

Sales and Marketing

Sales and marketing expenses during the year ended December 31, 2025, were $4,300 thousand, compared to $2,272 thousand during the year ended December 31, 2024, representing an increase of $2,028 thousand. This increase was primarily attributed to higher personnel-related costs and travel expenses for field sales activities, as well as expanded marketing initiatives to support both European market growth and anticipated U.S. market entry following FDA approval. Personnel-related costs, including salaries, bonuses, benefits, and other employee expenses, increased $1,534 thousand, reflecting the expansion of our European sales team and the hiring of additional U.S. commercial staff to support commercial activities following FDA approval. Travel expenses, including airfare and lodging costs associated with field demonstrations and customer engagement, increased $189 thousand.

Research and Development

Research and development expenses during the year ended December 31, 2025, were $11,156 thousand, compared to $8,180 thousand during the year ended December 31, 2024, representing an increase of $2,976 thousand. This increase was primarily attributed to higher personnel-related costs, including salaries, bonuses, benefits, and other employee expenses, which increased $2,496 thousand as the Company expanded its research and development team to support multiple concurrent development programs and regulatory initiatives. Additionally, external clinical expenses increased $289 thousand and external regulatory expenses increased $196 thousand, reflecting expanded clinical trial activities, including an increase of $113 thousand in external costs associated with the VISABL-AFL trial, which commenced enrollment in 2024 and continued through 2025, and an increase of $149 thousand in external costs associated with the VISABL-VT trial, which commenced enrollment in 2025.

General and Administrative

General and administrative expenses during the year ended December 31, 2025, were $5,301 thousand, compared to $4,920 thousand during the year ended December 31, 2024, representing an increase of $381 thousand. This increase was primarily attributed to higher professional services, including audit and legal expenses, of $222 thousand, reflecting additional audit and compliance requirements associated with preparation for SEC registration and reporting obligations. The increase also reflected higher personnel-related costs, including salaries, bonuses, benefits, and other employee expenses, which increased $124 thousand as the Company recruited additional personnel to support its expanding administrative and compliance infrastructure in preparation for anticipated U.S. commercialization following expected FDA approval. Additionally, the Company incurred increased expenses of $161 thousand related to general office operations and corporate activities as a result of our growing workforce. This was primarily offset by a decrease in director and officer insurance of $237 thousand.

Other Income (Expense)

Total other income (expense) during the year ended December 31, 2025, was an expense of $2,528 thousand, compared to an expense of $13,396 thousand during the year ended December 31, 2024, representing a decrease in expense of $10,868 thousand. This decrease was primarily attributed to a significant reduction in the non-cash expense for fair value change on financial instruments, which decreased from $14,138 thousand in 2024 to $5,838 thousand in 2025, representing a favorable change of $8,300 thousand. Additionally, we benefited from favorable foreign currency exchange gains of $1,312 thousand related to foreign currency remeasurement on our cash held in Australian dollars, higher interest income of $923 thousand due to increased cash balances and investments in U.S. Treasury bills, and increased government grant income of $333 thousand.

Net loss

As a result of the above factors, our net loss was $25,319 thousand for the year ended December 31, 2025, as compared to a net loss of $29,693 thousand for the year ended December 31, 2024. We expect to continue incurring net losses until such time as we obtain additional regulatory approvals for our MRI-compatible cardiac catheter ablation products, expand our commercialization, and generate sufficient revenue to offset our costs and expenses.

Liquidity and Capital Resources

We believe that we maintain adequate liquidity to allow us to meet our financial obligations as they become due for the next 12 months. We continuously assess our working capital needs, financing obligations, commitments, and future investment requirements. As of December 31, 2025, we had cash and cash equivalents of $19,502 thousand and marketable securities of $21,278 thousand. As of December 31, 2024, we had cash and cash equivalents of $15,708 thousand. A portion of our cash, cash equivalents, and marketable securities is denominated in foreign currencies. As of December 31, 2025 and 2024, cash and cash equivalents denominated in foreign currencies totaled $11,967 thousand and $1,302 thousand, respectively, representing 29% and 8% of our total cash, cash equivalents, and marketable securities for those periods, and are held primarily in Australian dollars as time deposits. These foreign currency denominated balances are remeasured into U.S. dollars at period-end exchange rates. Foreign currency exchange gains of $1,510 thousand and $198 thousand for the years ended December 31, 2025 and 2024, respectively, primarily reflect remeasurement effects on these foreign currency denominated cash balances, with the higher gain in 2025 largely driven by changes in the Australian dollar exchange rate on our Australian dollar-denominated cash. Consistent with this, the effect of foreign currency exchange rate changes on cash and cash equivalents reported in the consolidated statements of cash flows was $1,541 thousand for the year ended December 31, 2025, which includes $819 thousand of realized gains as of December 31, 2025.

Our future capital requirements will depend on several factors, including the pace of commercialization activities, our ability to generate revenue from product sales, and costs associated with ongoing research and development, clinical trials, and regulatory submissions. In the long term, we expect to fund these activities through a combination of existing cash resources, cash generated from future operations, and, if necessary, issuances of equity or debt financings.

We may require additional capital to fund our future business activities and execute our growth strategy. To the extent additional funds are necessary, we may seek additional funds through the issuance of equity securities, debt financing, or other strategic transactions. If we raise additional funds by issuing equity securities, the interests held in the Company by stockholders and CDI holders may be diluted. Debt financing, if available, would result in increased fixed payment obligations and may involve covenants restricting our ability to incur additional debt, limitations on our ability to acquire, sell, or license intellectual property rights, and other operating restrictions that could adversely impact our ability to conduct our business. We cannot guarantee the future availability of funds or that the funds will be available on terms that are favorable to us. If we are unable to obtain or maintain sufficient financial resources, our business, financial condition, and results of operations will be materially and adversely affected, including potentially requiring us to delay, limit, reduce, or terminate certain research and development activities or commercialization efforts.

Working Capital

As of December 31, 2025, we had working capital of $25,546 thousand, comprised of current assets of $42,917 thousand and current liabilities of $17,371 thousand. Current liabilities include the current portions of the Company's convertible notes (related party) and option liabilities, which are recorded at fair value, and their carrying amounts may differ significantly from the contractual principal and interest or other cash obligations associated with settling these instruments. See Note 7 – Convertible Notes with Warrants (related party) to our audited consolidated financial statements included elsewhere in this Registration Statement for disclosure of the contractual principal and interest outstanding on the Company's convertible notes (related party) as of December 31, 2025. As of December 31, 2024, we had working capital of $15,993 thousand, comprised of current assets of $18,349 thousand and current liabilities of $2,356 thousand.

Current assets increased by $24,568 thousand as of December 31, 2025, compared to December 31, 2024, primarily driven by the sale of CDIs under the March 2025 placement, which generated net proceeds of $42,828 thousand, which as of December 31, 2025, resulted in an increase in cash and cash equivalents of $3,794 thousand and marketable securities of $21,278 thousand. Current liabilities increased by $15,015 thousand as of December 31, 2025, compared to December 31, 2024, primarily due to the reclassification of $11,746 thousand of convertible notes (related party) and $3,158 thousand of option liabilities to current.

Cash Flows

The following table summarizes our cash flows for the years ended December 31:

	Year Ended December 31,		Change	
(in thousands)	2025	2024	Amount	%
Net cash used in operating activities	$ (19,081)	$ (15,574)	$ (3,507)	23%
Net cash used in investing activities	(21,712)	(75)	(21,637)	28849%
Net cash provided by financing activities	43,046	30,334	12,712	42%
Net change in cash	2,253	14,685	(12,432)	-85%
Beginning cash balance	15,708	832	14,876	1788%
Effect of exchange rate changes on cash	1,541	191	1,350	707%
Ending cash balance	$ 19,502	$ 15,708	$ 3,794	24%

Operating Activities

Net cash used in operating activities during the year ended December 31, 2025, was $19,081 thousand, compared to $15,574 thousand during the year ended December 31, 2024, representing an increase in cash used of $3,507 thousand. This increase was primarily attributed to higher loss from operations of $6,494 thousand in 2025 compared to 2024, partially offset by an increase in non-cash charges included in operating loss of $521 thousand in stock-based compensation expense and $339 thousand in inventory reserves. The remaining increase in cash used was further offset by increased interest income of $923 thousand and favorable changes in working capital, specifically a reduction in accounts payable outflows of $1,788 thousand compared to 2024.

Investing Activities

Net cash used in investing activities during the year ended December 31, 2025, was $21,712 thousand, compared to $75 thousand during the year ended December 31, 2024, representing an increase in cash used of $21,637 thousand. This increase was primarily attributed to purchases of marketable securities totaling $28,683 thousand, partially offset by proceeds of $7,406 thousand from the maturity of marketable securities during 2025. The Company held no marketable securities during 2024.

Financing Activities

Net cash provided by financing activities during the year ended December 31, 2025, was $43,046 thousand, compared to $30,334 thousand during the year ended December 31, 2024, representing an increase in cash provided of $12,712 thousand. This increase was primarily attributed to higher proceeds from the issuance of common stock and restricted stock, net of issuance costs, driven largely by our March 2025 equity placement. For details of these securities offerings, see Item 10. Recent Sales of Unregistered Securities.

Contractual Obligations and Commitments

As of December 31, 2025, and December 31, 2024, we had $951 thousand and $1,135 thousand in operating lease obligations, respectively, for our corporate headquarters and warehouse space, located in Burnsville, Minnesota, and for our leased vehicles, of which $634 thousand and $876 thousand were included in operating lease liabilities, net of current portion as of December 31, 2025 and 2024, respectively. Operating cash outflows from operating leases during the year ended December 31, 2025 were $329 thousand, compared to $308 thousand during the year ended December 31, 2024. Future minimum lease payments total $1,055 thousand, with present value of lease liabilities of $951 thousand after discounting at a weighted-average discount rate of 5.8%.

We also have outstanding firm purchase commitments for raw materials inventory and prototype components used in research and development activities. As of December 31, 2025 and 2024, we had $219 thousand and $367 thousand, respectively, in outstanding firm purchase commitments. As of December 31, 2025, payment of the purchase commitments is expected to be made within one year.

For more information regarding our contractual commitments, see Note 6 – Commitments and Contingencies, in the audited consolidated financial statements for the years ended December 31, 2025, and 2024, included elsewhere in this Registration Statement.

Securities Purchase Agreement

On December 16, 2022, we entered into a Securities Purchase Agreement for the issuance of unsecured, unquoted convertible promissory notes in two tranches with a maximum aggregate amount of $5,000 thousand. The first tranche, issued on December 23, 2022, has a principal amount of $2,325 thousand, and the second tranche, issued on March 28, 2023, has a principal amount of $2,675 thousand. Both tranches bear interest at 10% per annum, compounded annually, with principal convertible into CDIs at $0.2691 per share and accrued interest convertible at $0.2563 per share. The convertible notes mature on the earlier of a change-in-control event or the four-year anniversary of each tranche closing date. The maximum number of CDIs to be issued upon conversion of the principal and interest is no more than 12,849,949 CDIs for the first tranche and 14,784,350 CDIs for the second tranche. The convertible notes are measured at fair value, with a total fair value of $25,014 thousand as of December 31, 2025, compared to $19,870 thousand as of December 31, 2024. The change in fair value of $5,145 thousand was recorded as a non-cash expense in change in fair value of convertible notes (related party) in our consolidated statement of operations for the year ended December 31, 2025. As of December 31, 2025, the principal amount outstanding was $2,325 thousand and $2,675 thousand, with accrued interest of $776 thousand and $808 thousand, for the first and second tranche, respectively. As of December 31, 2025, 11,669,009 CDIs and 13,094,172 CDIs would be issued for the first and second tranche, respectively, if the principal and accrued interest were converted.

On March 28, 2023 and December 23, 2022, pursuant to the Securities Purchase Agreement, the Company issued warrants exercisable for 1,043,699 and 907,141 CDIs, respectively, with an exercise price of $0.2563 per share. The warrants expire five years after the dates of issuance.

See Note 7 – Convertible Notes with Warrants (related party) to our audited consolidated financial statements for the years ended December 31, 2025, and 2024, included elsewhere in this Registration Statement for further information.

Capital Commitments

On July 6, 2023, we entered into a Capital Commitment Agreement with GEM Global Yield LLC SCS (”GGY”) under which GGY agreed to provide us with up to $30 million Australian dollars through a Security Subscription Facility (the “Facility”) over a 3-year term. We control the timing of drawdowns under the Facility and there is no minimum drawdown obligation. The subscription price of the CDIs to be issued to GGY for each drawdown is the higher of (i) 90% of the average closing bid price of our CDIs over the 15 consecutive trading days after we give the drawdown notice, subject to certain adjustments; or (ii) a fixed floor price nominated by us in the drawdown notice. The issue of CDIs to GGY is conditional on having sufficient placement capacity under ASX Listing Rules or obtaining requisite stockholder approval.

Since issuance, we have drawn $444,992 Australian dollars on the Facility, and $29,555,078 Australian dollars is available as of December 31, 2025. Converted to U.S. dollars using the exchange rate of $1 Australian dollar to $0.67 U.S. dollar as of December 31, 2025, these amounts are $298 thousand and $19,781 thousand, respectively.

In connection with the Capital Commitment Agreement, we issued options to purchase 5,700,000 CDIs at $0.61 Australian dollars per CDI with a 3-year term from July 6, 2023. We received proceeds from the exercise of CDI options issued under our Capital Commitment Agreement (see "Recent Financings" below).

For more information regarding our capital commitments, see Note 9 – Capital Commitments, in the audited consolidated financial statements for the years ended December 31, 2025, and 2024, included elsewhere in this Registration Statement.

Recent Financings

On March 27, 2025, we completed a placement in which we issued 49,645,391 CDIs. We raised $42,827,577 in net proceeds after deducting issuance costs.

We also received net proceeds from the exercise of options as follows:

- 163,935 CDI options were exercised on February 6, 2025 for $61,419;
- 340,000 CDI options were exercised on March 25, 2025 for $130,842;
- 344,900 Class A common stock options were exercised on September 5, 2025 for $177,434;
- 11,250 Class A common stock options were exercised on September 12, 2025 for $3,488; and
- 144,526 CDI options were exercised on October 24, 2025 for $56,160.

In February and April 2024, we completed a capital raising consisting of an institutional placement, a U.S. placement, and an accelerated pro-rata non-renounceable entitlement offer (which consisted of institutional and retail components). On February 9, 2024, we issued 14,069,396 CDIs in the institutional placement (including the institutional component of the entitlement offer), and 3,766,666 shares of common stock in the U.S. placement. Under the retail component of the entitlement offer, we issued 1,419,069 CDIs on February 27, 2024, and 14,378,862 CDIs on April 5, 2024. We raised $9,210,618 in net proceeds after deducting issuance costs.

In July and September 2024, we completed a two-tranche placement. In the first tranche on July 25, 2024, we issued 49,514,682 CDIs. In the second tranche on September 5, 2024, we issued 17,550,154 CDIs and 242,857 shares of common stock. We raised $21,791,209 in net proceeds after deducting issuance costs.

Proceeds from the placements, entitlement offers, and option exercises have supported our ongoing sales and marketing efforts, research and development activities, clinical trials, regulatory compliance, and associated offer costs. For details of these securities offerings, see Item 10. Recent Sales of Unregistered Securities.

Off-Balance Sheet Arrangements

As of December 31, 2025, and 2024, we did not have any off-balance sheet arrangements, except as discussed under "*Contractual Obligations and Commitments*" above and in Note 6 – Commitments and Contingencies to our audited consolidated financial statements included elsewhere in this Registration Statement.

Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States ("GAAP"). The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported expenses incurred during the reporting periods. In accordance with GAAP, our estimates are based on our historical experience and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities and recorded amounts of expenses that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our audited consolidated financial statements appearing elsewhere in this Registration Statement, we believe the following accounting policies used in the preparation of our consolidated financial statements require the most significant judgments and estimates. Accordingly, these are the policies we believe are the most critical to aid in fully understanding and evaluating our consolidated financial statements.

Stock-Based Compensation

We measure stock-based compensation expense for equity awards granted to directors and employees based on the fair value of the award on the date of grant. The fair value of stock option awards is estimated using the Black-Scholes option-pricing model, which incorporates assumptions and estimates that require significant management judgment, including expected stock price volatility, expected term, risk-free interest rate, and expected dividend yield.

Expected volatility is estimated based on a combination of our own historical stock price volatility and the historical volatilities of traded shares from a selected publicly traded peer group, believed to be comparable after consideration of size, maturity, profitability, growth, risk, and return on investment. The selection of peer companies and the time periods used to calculate historical volatility require management judgment and can materially impact the fair value of options granted.

The expected term reflects our estimate of the period over which the stock options will remain outstanding before exercise or expiration. As we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term, the expected term of stock option awards granted has been determined using the simplified method, which is the average of the weighted-average vesting period and the contractual term. For awards with service-based vesting conditions, the weighted-average vesting period is calculated based on the service period. For awards with performance-based vesting conditions, the weighted-average vesting period is calculated based on our estimate of the period to achieve the performance milestone. The expected term is used to determine the appropriate maturity term for the risk-free interest rate input. The risk-free interest rate is based on the yield of constant maturity treasury bonds denominated in the same currency as the stock option exercise price with a remaining term equal to the expected term of the stock options at the grant date. We assume a dividend yield of zero, as we have not paid dividends and do not expect to pay dividends in the foreseeable future.

Stock-based compensation expense for awards with service-based vesting conditions is recognized on a straight-line basis over the requisite service period, which is typically the vesting period of the award. This approach results in a proportional allocation of the fair value of the award across the periods in which employees provide the required services.

For awards with performance-based vesting conditions, we recognize expense only when achievement of the performance condition is deemed probable. Management regularly assesses the probability of achieving performance conditions based on our progress toward regulatory approvals, sales milestones, or other operational metrics. Changes in management's assessment of the probability of achieving performance conditions can result in significant adjustments to previously recognized expense, including full reversal if the condition is no longer deemed probable.

The assumptions used in our option pricing models have a significant impact on the amount of stock-based compensation expense we recognize. Changes in expected stock price volatility, expected term, risk-free interest rates, or the probability of achieving performance conditions could materially impact stock-based compensation expense recognized in future periods.

Option Liabilities and Warrant Liabilities

Certain options and warrants we have issued are classified as liabilities rather than equity due to the exercise price being denominated in a currency other than our functional currency. These liability-classified instruments are initially recorded at fair value and are subsequently remeasured at fair value at each reporting date, with changes in fair value recognized as changes in fair value of option liabilities and changes in fair value of warrant liabilities, respectively, in our consolidated statements of operations. This fair value remeasurement at each reporting date can result in significant volatility in our reported results from period to period.

We estimate the fair value of liability-classified options and warrants using the Black-Scholes option-pricing model. This valuation model incorporates contractual inputs, market-derived inputs, and estimated inputs. Contractual and market-derived inputs include the stock price, contractual exercise price, and the prevailing exchange rate, all of which are determined by contract or the market and do not require management judgment. Estimated inputs include the expected volatility, expected remaining term, risk-free interest rate, and expected dividend yield, which are subject to judgment and uncertainty.

Stock price is determined using the closing market price of our CDIs as quoted on the ASX, converted to U.S. dollars using the prevailing exchange rate on the measurement date. The exercise price, which is denominated in a currency other than our functional currency, is contractually fixed and converted to U.S. dollars using the prevailing exchange rate. Changes in the prevailing exchange rate directly affect the fair value of these instruments; a strengthening foreign currency increases the U.S. dollar equivalent of the exercise price and generally reduces the fair value of the liability, while a weakening foreign currency has the opposite effect.

Expected volatility is estimated based on a combination of our own historical stock price volatility and the historical volatilities of traded shares from a selected publicly traded peer group, believed to be comparable after consideration of size, maturity, profitability, growth, risk, and return on investment. The selection of peer companies and the time periods used to calculate historical volatility require management judgment and can materially impact the fair value of option liabilities and warrant liabilities.

The expected remaining term reflects our estimate of the period over which the warrants and options will remain outstanding before exercise or expiration. This estimate considers the contractual expiration date and our evaluation of historic expected lives from option and warrants. The expected remaining term is used to determine the appropriate maturity term for the risk-free interest rate input. As time passes and the expected remaining term decreases, the fair value of the warrant and option liabilities generally declines, independent of changes in stock price or volatility. The risk-free interest rate is based on the yield of constant maturity treasury bonds denominated in the same currency as the contractual exercise price with a remaining term equal to the expected remaining term at the measurement date. We assume a dividend yield of zero, as we have not paid dividends and do not expect to pay dividends in the foreseeable future.

The fair value of these instruments is highly sensitive to changes in our stock price, expected volatility, and the prevailing exchange rate. Increases in our stock price or expected volatility will generally result in an increase in the fair value of these liabilities, resulting in a non-cash loss. A strengthening of the foreign currency relative to the U.S. dollar will generally result in a decrease in the fair value of these liabilities, resulting in a non-cash gain. Conversely, decreases in stock price or expected volatility, or weakening of the foreign currency, will generally have the opposite effect. Because we remeasure these instruments at each reporting date, our results of operations may experience significant volatility unrelated to our operational performance.

Convertible Notes

We account for our convertible promissory notes under the fair value option, recording them at fair value on the date of issuance and subsequently remeasuring them at each reporting date. Changes in the estimated fair value of the notes are recognized as a change in fair value of convertible notes (related party) in the consolidated statements of operations.

We measure the fair value of our convertible notes using the Monte Carlo simulation method. The Monte Carlo model uses a probabilistic approach to model various potential outcomes and determines estimated fair value based on the probability-weighted present value of expected future cash flows. This valuation model incorporates contractual inputs, market-derived inputs, and estimated inputs. Contractual and market-derived inputs include the stock price, conversion price, remaining contractual term, and the prevailing exchange rate. Estimated inputs include the expected volatility, risk-free interest rate selected based on remaining contractual term, expected dividend yield, credit spread, and the probability of a change in control event, which are subject to significant judgment and uncertainty.

Stock price is determined using the closing market price of our CDIs as quoted on the ASX, converted to U.S. dollars using the prevailing exchange rate on the measurement date. The conversion price is denominated in U.S. dollars and is contractually fixed. Because our stock price is quoted in Australian dollars on the ASX but converted to U.S. dollars for valuation purposes, changes in the prevailing exchange rate directly affect the fair value of the convertible notes. The remaining contractual term represents the simulation horizon for the Monte Carlo model, calculated as the time remaining until the four-year anniversary of each tranche closing date.

Expected volatility is estimated based our own historical stock price volatility calculated over a period consistent with the remaining contractual term of the convertible notes. The risk-free interest rate incorporated into the model is based on the yield of constant maturity treasury bonds denominated in the same currency as the convertible note conversion price with a remaining term equal to the remaining contractual term at the measurement date. We assume a dividend yield of zero, as we have not paid dividends and do not expect to pay dividends in the foreseeable future. The credit spread is determined based on our estimate of our credit rating, which is derived from our financial condition, and market yields for similar instruments issued by companies with comparable credit ratings.

Our convertible notes mature upon the earlier of a change in control event or the four-year anniversary of each tranche closing date. Upon a change in control event, the holder automatically receives a payment equal to the greater of 125% of the outstanding principal and accrued interest or the value the holder would have received had the notes been converted to CDIs immediately prior to the change in control. The likelihood and timing of a change in control event is inherently uncertain and requires us to make subjective assessments based on our strategic plans, market conditions, and general industry trends. We regularly evaluate these factors and update probability assessments accordingly. Changes in our assessment of the likelihood or timing of a change in control event can have a significant impact on the fair value of the convertible notes.

The fair value of the convertible notes is highly sensitive to changes in these key assumptions. Increases in our stock price, increases in expected volatility, or increases in the estimated probability of a change in control event will generally result in an increase in the fair value of the convertible note liability, resulting in a non-cash loss. Conversely, decreases in these inputs will generally result in a non-cash gain. Because we remeasure this instrument at each reporting date, our results of operations may experience significant volatility unrelated to our operational performance.

Allowance for Expiring, Excess, and Obsolete Inventory

Inventory is stated at the lower of cost or net realizable value, with cost determined on the first-in, first-out (“FIFO”) method. We utilize significant estimates in determining the net realizable value of our inventory, including evaluating the likelihood of future product sales, timing of expiration of products compared to anticipated sales, and the potential impact of product design changes to existing inventory on hand, to establish allowances for expiring, excess, and obsolete inventories. The determination of net realizable value and the establishment of inventory reserves require significant management judgment and could materially impact our consolidated balance sheet and results of operations.

We develop forecasts of future product sales based on current order patterns, discussions with customers and distributors, anticipated regulatory approvals that may expand our addressable market, and general economic conditions in our target markets. These forecasts are inherently uncertain and may be impacted by factors outside our control, including changes in physician acceptance of our products, healthcare reimbursement policies, and macroeconomic conditions. If actual product demand is lower than forecasted, we may need to increase reserves for excess inventory.

We continually monitor the shelf life and timing of expiration of products on hand and assess the likelihood that inventory will be sold before expiration based on current sales trends and sales forecasts. Inventory not expected to be sold before expiration is reserved.

We are engaged in ongoing research and development activities to improve our products and manufacturing processes. Changes in product specifications, the introduction of next-generation products, or modifications to manufacturing processes may render existing inventory obsolete or reduce its net realizable value. We continually evaluate our research and development pipeline and assess the potential impact of planned product changes on existing inventory.

The establishment of an allowance for expiring, excess, and obsolete inventory creates a new cost basis for the affected inventory. Future sales of inventory on hand will result in recognition of cost of sales based on initial inventory costs, net of reserves taken for expected realization values. Any increase in reserve for expiring, excess, and obsolete inventory will adversely impact our results of operations in the period the reserve is increased.

Income Taxes

The calculation of our provision for income taxes involves the use of estimates, assumptions, and judgments while considering current tax laws, our interpretation of current tax laws, and possible outcomes of future tax audits in multiple jurisdictions. We review our tax positions each reporting period and adjust the balances as new information becomes available.

We record income taxes under the liability method, recognizing deferred tax assets and liabilities for temporary differences between financial statement and tax bases of assets and liabilities. We recognize tax benefits from uncertain tax positions only when it is more likely than not that a tax position will be sustained on examination by taxing authorities based on the technical merits of the position. We maintain a valuation allowance to reduce deferred tax assets for uncertain tax positions and evaluate our tax positions regularly as facts and circumstances change. We have incurred operating losses since inception and currently maintain a valuation allowance against our net deferred tax assets because we lack sufficient evidence of future taxable income to support their realization. Significant management judgment is required in assessing whether it is more likely than not that deferred tax assets will be realized and in determining the appropriate level of the valuation allowance.

Our ability to use net operating loss and research and development tax credit carryforwards may be limited under Sections 382 and 383 of the Internal Revenue Code if we experience ownership changes exceeding 50% within a three-year period. Such ownership changes may restrict the amount of carryforwards available annually to offset future taxable income. We regularly analyze our equity transactions for potential ownership changes under Sections 382 and 383 and may need to adjust the realizability of our deferred tax assets based on any changes in our ownership structure. Future equity offerings or other changes in our ownership could trigger additional limitations on our tax attributes.

If we achieve sustained profitability, we may release all or a portion of our valuation allowance, which would decrease income tax expense. Conversely, changes in tax law, additional ownership changes, or unfavorable examination outcomes could require adjustments to our tax assets and effective tax rate.

Recent Accounting Pronouncements

See Note 1 – Summary of Significant Accounting Policies – Recent Accounting Pronouncements in our audited consolidated financial statements as of and for the years ended December 31, 2025, and 2024, included elsewhere in this Registration Statement.

Quantitative and Qualitative Disclosures about Market Risk

We are a smaller reporting company, as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Item 3. Properties.

We lease an office and manufacturing space, which also serves as our corporate headquarters, located at 400 Gateway Blvd in Burnsville, Minnesota, where we occupy approximately 15,115 square feet of space under a lease until April 30, 2027, at a base rent of $12,029 per month as of the filing of this Registration Statement, subject to scheduled annual increases over the term of the lease.

We also lease an office and warehouse space, located at 12259 Nicollet Ave. in Burnsville, Minnesota, where we occupy approximately 14,617 square feet of space under a lease until May 30, 2030, at a base rent of $13,336 per month as of the filing of this Registration Statement, subject to scheduled annual increases over the term of the lease.

These properties are utilized for administrative, manufacturing, and warehousing activities and are considered adequate for our current needs.

Item 4. Security Ownership of Certain Beneficial Owners and Management.

The following table sets forth information known to the Company regarding beneficial ownership of our common stock, and common stock held as CDIs, as of April 21, 2026, by:

- each person, or group of affiliated persons, whom we know to beneficially own more than 5% of any class of our voting securities;
- each of our directors;
- each of our named executive officers; and
- all directors and executive officers as a group.

In accordance with the rules of the SEC, beneficial ownership is when a person possesses sole or shared voting or investment power over that security and includes the shares issuable pursuant to stock options and warrants that are exercisable within 60 days of April 21, 2026. Shares issuable pursuant to stock options and warrants are deemed outstanding for computing the percentage of the person holding such options but are not outstanding for computing the percentage of any other person.

We have based our calculation of the percentage of beneficial ownership on 320,947,028 shares of our common stock outstanding as of April 21, 2026.

Unless otherwise indicated, the address for each listed stockholder is c/o Imricor Medical Systems, Inc., 400 Gateway Blvd, Burnsville, MN 55337. To our knowledge, except as indicated in the footnotes to this table and pursuant to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock.

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership	Percent of Class
Named Executive Officers and Directors:		
Steve Wedan[1]	7,205,693	2.23%
Mark Tibbles[2]	6,555,619	2.04%
Gregg Stenzel[3]	1,640,822	0.51%
Peter McGregor[4]	1,161,041	0.36%
Jonathon Gut[5]	572,610	0.18%
Anita Messal[6]	430,204	0.13%
Jeffrey Leighton[7]	245,746	0.08%
Aldo Denti	-	0.00%
All directors and executive officers as a group (8 persons)[8]	17,811,735	5.53%
All Other Greater than 5% Owners:		
K.A.H.R. Foundation[9]	30,859,168	8.85%
Hart Capital Partners[10]	20,442,948	6.37%
Greencape Capital[11]	18,462,138	5.75%

(1) Consists of (a) 5,083,586 shares held by Mr. Wedan, of which 1,427,373 shares are held jointly with Cherri Wedan, and (b) 2,122,107 shares issuable pursuant to a stock option exercisable within 60 days after April 21, 2026.

(2) Includes 526,608 shares issuable pursuant to a stock option exercisable within 60 days after April 21, 2026.

(3) Includes 1,068,732 shares issuable pursuant to a stock option exercisable within 60 days after April 21, 2026.

(4) Includes 246,906 shares issuable pursuant to a stock option exercisable within 60 days after April 21, 2026.

(5) Includes 532,610 shares issuable pursuant to a stock option exercisable within 60 days after April 21, 2026.

(6) Includes 38,340 shares issuable pursuant to a stock option exercisable within 60 days after April 21, 2026.

(7) Consists of 245,746 shares held jointly with Nikki Joy Leighton.

(8) Consists of 4,535,501 shares issuable pursuant to a stock option exercisable within 60 days after April 21, 2026.

(9) Consists of (a) 2,951,661 shares held by K.A.H.R. Foundation, (b) 1,950,840 shares issuable upon exercise of certain warrants, and (c) 25,956,667 shares issuable upon exercise of convertible debt within 60 days after April 21, 2026. The address for K.A.H.R. Foundation is 4305 Trillium Way, Minnetrista, MN 55346. The board members of K.A.H.R. Foundation are Warren G. Herreid II, Erik Kolz, Nikki Leighton and Jeannine M. Rivet. These individuals each disclaim beneficial ownership of the securities held by K.A.H.R. Foundation.

(10) Consists of 20,442,948 shares of common stock beneficially owned by Public Trust Class 10 Nominees Ltd. Hart Capital Partners serves as investment manager for Public Trust Class 10 Nominees Ltd. Alistair Hart is the principal of Hart Capital Partners and may be deemed to beneficially own the shares owned by Public Trust Class 10 Nominees Ltd. The principal business address of Hart Capital Partners is Unit A3, Level 1, 1 North City Road, Rototuna Village, Hamilton 3214, New Zealand.

(11) Consists of 18,462,138 shares of common stock beneficially owned by, or that may be deemed to be beneficially owned through, Greencape Capital Pty Ltd ("Greencape Capital"). Greencape Capital exercises its voting and investment power through a management committee comprised of Matt Ryland, Marc Hester, and Ryan Green, each of whom disclaims beneficial ownership of the securities held by Greencape Capital. The principal business address of Greencape Capital is Level 2, 5 Martin Place, Sydney NSW 2000, Australia.

Item 5. Directors and Executive Officers.

The following table sets forth information regarding our executive officers and directors as of April 21, 2026:

Name	Age	Positions(s) with the Company
Executive Officers		
Steve Wedan	58	President, Chief Executive Officer, and Board Chair
Jonathon Gut	40	Vice President of Finance and Chief Financial Officer
Gregg Stenzel	52	Vice President of Research and Development[1]
Non-Employee Directors		
Mark Tibbles	59	Deputy Chair and Lead Independent Director - Chairperson of the Nomination and Remuneration Committee
Peter McGregor	59	Non-executive Director - Chairperson of the Audit and Risk Committee
Anita Messal	62	Non-executive Director
Jeffrey Leighton	63	Non-independent Non-executive Director
Aldo Denti	58	Non-executive Director

(1) Effective January 1, 2026, Mr. Stenzel's title changed from Chief Operating Officer to Vice President of Research and Development. See the biographical section below.

Our Board of Directors ("Board") is divided into three classes (Class I, Class II, and Class III) with staggered three-year terms. Only one class of directors will be elected at each annual meeting of stockholders, with the other classes continuing for the remainder of their respective three-year terms. Each of our directors is serving a term which expires at the next annual meeting of stockholders at which his or her class is up for election until his or her successor is duly elected and qualified or until his or her earlier death or until such individual resigns or is removed. Our officers serve at the will of our Board.

In connection with the Securities Purchase Agreement dated December 16, 2022 between the Company and K.A.H.R. Foundation, K.A.H.R. Foundation has the right to nominate one individual (the "Lender Nominee") to our Board, subject to customary background checks, regulatory approvals, and compliance with ASX Listing Rules. If stockholders fail to elect the initial Lender Nominee, the Company shall increase the Board size by one seat and appoint the nominee selected by K.A.H.R. Foundation to fill the vacancy. For so long as the convertible notes remain outstanding, if the Lender Nominee resigns or otherwise ceases to serve as a director, K.A.H.R. Foundation has the right to designate a successor, and the Company shall promptly appoint such successor to the Board. K.A.H.R. Foundation's nomination and appointment rights automatically terminate when the convertible notes are no longer outstanding, at which time the serving Lender Nominee shall resign from the Board immediately upon the Company's written request.

Dr. Jeffrey Leighton was appointed as a Class III director effective July 2024 pursuant to these nomination rights granted to the K.A.H.R. Foundation.

See Note 7 – Convertible Notes with Warrants (related party) to our audited consolidated financial statements included elsewhere in this Registration Statement for further information.

Except as described above, there are no arrangements or understandings with major stockholders, customers, suppliers, or others pursuant to which any of our executive management or our directors were selected.

Executive Officers and Directors

Steve Wedan

Mr. Wedan co-founded the Company in 2006 and has served as CEO since that time. Mr. Wedan is responsible for the overall management and strategic direction of the Company. Mr. Wedan has over 30 years of experience in the medical device industry including design engineering of MRI and ultrasound systems for GE Healthcare, as well as Vice President and Chief Technology Officer for Applied Biometrics Inc. Immediately prior to co-founding Imricor, Mr. Wedan founded and operated a technical consulting company, Wedan Technologies Inc., from 2000-2006. Mr. Wedan is a member of various international standards committees in the fields of MRI safety and the compatibility of implanted and interventional products in MRI. Mr. Wedan currently serves on the Board of Directors of Medical Device Research Forum, Inc. and Water Rescue Innovations, Inc., as well as the Advisory Board of Poiesis Medical, LLC. Mr. Wedan holds a Bachelor of Science in Electrical Engineering from Michigan Technological University (summa cum laude), and a Master of Science in Electrical Engineering from Marquette University.

We believe Mr. Wedan is qualified to serve as a member of our Board of Directors because of his leadership experience in various roles, extensive knowledge of our business and technology as our co-founder and Chief Executive Officer, and expertise in MRI systems and device compatibility standards.

Gregg Stenzel

Mr. Stenzel commenced his role as Vice President of Research and Development in January 2026. From January 2021 through December 2025, he served as our Chief Operating Officer and was responsible for leading the execution of Imricor's strategic plan across most functional areas of the business. Prior to January 2021, Mr. Stenzel served as Imricor's Vice President of Operations with responsibility for the Company's operations and the development of manufacturing strategies, including personnel, facilities, and outsourcing. He has over 25 years of medical device experience with deep knowledge in new product development, supply chain management, quality and regulatory systems, and customer support. Prior to joining Imricor in 2007, Mr. Stenzel was the Manager of Instrument Technical Operations at Beckman Coulter, Inc. a leading manufacturer of In Vitro Diagnostic Systems. Mr. Stenzel holds a Bachelor of Science in Electrical Engineering from the University of Wisconsin - Madison and a Master of Business Administration from the University of Minnesota - Carlson School of Management.

Jonathon Gut

Mr. Gut has served as the Company's Vice President of Finance and Chief Financial Officer since July 2022 and has been employed by Imricor in finance leadership roles since August 2020, including as Controller and Director of Finance from August 2020 to July 2022. Mr. Gut has over 15 years of accounting and finance experience, the last 13 of them in the medical device industry, having previously worked for both private and publicly owned companies, including Galil Medical and Boston Scientific. Mr. Gut holds a Bachelor of Accounting from the University of Minnesota- Duluth and a Master of Accountancy from the University of Minnesota-Twin Cities. He is a licensed Certified Public Accountant.

Mark Tibbles

Mr. Tibbles joined the Board in September 2014. Mr. Tibbles is an entrepreneur, business owner, company director and active venture investor in and advisor to technology, life science, and medical device companies. Mr. Tibbles is currently a Co-Founder and Director of PERMnet, Inc., a policy, evidence, and reasoning-driven multinetwork artificial intelligence information system for healthcare administration, focused on improving utilization management of health insurance preauthorizations; PERMnet incorporated in October 2024. Mr. Tibbles has also served as a managing member of STEM Fuse, LLC, one of the largest providers of digital K-12 STEM curriculum in the U.S., since December 2016; a Director of FamGenix, Inc., a leading provider of genetic risk assessment tools that help identify patients at hereditary risk of disease, since July 2023; and the Managing Director of Strategic Stage Ventures, LLC, a strategic investment firm that partners with visionary entrepreneurs driving innovation in Life Sciences, Medical Devices and Healthcare IT and AI companies, since March 2013. Prior to his current roles, Mr. Tibbles was a Board member of CorVent Medical, Inc., a medical device company focused on improving medical ventilation systems, from July 2023 to May 2025; a Board member of Operandi, Inc., from August 2022 to October 2023; a Board member of OMEDZA.com, Inc., from October 2019 to September 2024; a Board member of the Nerdery, LLC, from January 2021 to December 2022; the Chief Strategy Office and Executive Committee Member of Poiesis Medical LLC, a medical device company specializing in urinary care solutions, from April 2021 to June 2023 then transitioned to an Advisory Board member; an owner and member of Intuitive Technology Group, an IT staffing and consulting company, from January 2013 until August 2017; and a President and founder of PRC Consulting, Inc., a company specializing in the management and implementation of IT projects for Fortune 1000 Companies, from 1998 until 2013. Mr. Tibbles holds a Bachelor of Arts from Oral Roberts University.

We believe Mr. Tibbles is qualified to serve as a member of our Board of Directors because of his experience building and leading medical device and life science companies, his venture investment expertise, and his board service with other medical device companies.

Peter McGregor

Mr. McGregor joined the Board in May 2019. Mr. McGregor has over 30 years of experience in senior finance and management roles, including having been a Partner in the investment banking firm of Goldman Sachs JBWere from January 1999 to January 2005 and a Managing Director in the Institutional Banking & Markets division of Commonwealth Bank of Australia from June 2012 to April 2016. He is also a former Chief Financial Officer of Asciano Limited (ASX: AIO), an Australian freight logistics and transport company, from January 2008 to May 2011 and Chief Operating Officer of ASX listed Australian Infrastructure Fund Limited (ASX: AIX), a transport infrastructure fund, from February 2005 to January 2008. Mr. McGregor is an experienced company director who has served as a Director of Treasury Corporation of Victoria, the central financing authority for the State of Victoria, since May 2023; and a Director of Infrastructure Specialist Asset Management Pty Ltd, an Australian-based investment and asset management company, since April 2025. He previously served as a director of Pivotal Systems Corporation (ASX: PVS), from August 2018 to April 2023; and TRUE Infrastructure Management Pty Ltd, from June 2020 to November 2023. Mr. McGregor holds a Bachelor of Commerce from the University of Melbourne, is a member of the Australian Institute of Company Directors and a Fellow of the Financial Services Institute of Australasia.

We believe Mr. McGregor is qualified to serve as a member of our Board of Directors because of his leadership experience in investment banking and corporate finance, his service as chief financial officer of a publicly traded company, and his extensive board experience.

Anita Messal

Ms. Messal joined the Board in March 2021. Ms. Messal is an executive with 40 years of demonstrated accomplishments in the healthcare sector and has served on the Board of Directors of Ideon, a healthcare and insurance data services company, since August 2023. She has served as Executive Chair since September 2023. She is an Advisor to Poiesis Medical, a medical device company specializing in urinary care solutions. Ms. Messal previously served as the Chief Integration Officer at AccentCare, a U.S. based national company in home health, hospice, and personal care services, from July 2020 to February 2023 and as President and Chief Operating Officer at PlanSource, a technology company that offers software solutions for employee benefits, from March 2013 to January 2020. Her experience also includes over 10 years in leadership roles with Optum, a UnitedHealth Group company. She holds a Bachelor of Arts from the University of Minnesota and a Master of Business Administration from the University of Minnesota - Carlson School of Management.

We believe Ms. Messal is qualified to serve as a member of our Board of Directors because of her extensive healthcare industry experience, her leadership in operations, technology, and strategic business development, and her board experience.

Jeffrey Leighton

Dr. Leighton joined the Board in July 2024. Dr. Leighton is a cognitive neuroscientist with extensive experience in both academic and corporate settings. He holds a PhD in Cognitive Psychology from Grand Canyon University and has a robust research, teaching, and leadership background. Beyond his academic achievements, Dr. Leighton has served as Chief Financial Officer at NDS Wellness, a regional provider of mobile neuroimaging and wellness centers, from September 2010 to June 2022. Dr. Leighton has held key corporate governance and advisory roles, including serving as an Institutional Review Board (IRB) member at Quiet Minds Foundation, a non-profit neuromodulatory research center, since January 2023.

We believe Dr. Leighton is qualified to serve as a member of our Board of Directors because of his neuroscience and healthcare industry expertise, his financial and operational leadership as chief financial officer, and his experience in corporate governance and regulatory oversight through his IRB service.

Aldo Denti

Aldo Denti joined the Board in November 2025. Mr. Denti has over 30 years of global experience in the medical device industry and has served as the Chief Commercial Officer for Dentsply Sirona, the world's largest and most diversified dental equipment company, since October 2025. Prior to this role, from January 2019 to October 2025, he was the Company Group Chairman of Global Orthopaedics for Johnson & Johnson MedTech, an orthopaedic devices division within one of the world's largest medical device companies. Since becoming Company Group Chairman in 2019, Mr. Denti grew the business to $9 billion in annual sales, making it the world's largest orthopaedics company. Prior to his role in orthopaedics, Mr. Denti served as Global Leader at Johnson & Johnson Vision, a contact lens and ophthalmology products division, from May 2014 to December 2018. Mr. Denti's other experiences include various sales and marketing roles with companies such as DePuy, Medtronic, and Pfizer. Mr. Denti holds a Bachelor of Arts, with Specialized Honors, from York University.

We believe Mr. Denti is qualified to serve as a member of our Board of Directors because of his extensive business and leadership experience with the medical device industry, particularly his executive leadership scaling the orthopaedics division of Johnson & Johnson MedTech.

Family Relationships

There are no family relationships among any of our current executive officers or directors.

Executive Officers

Each of our executive officers serves at the discretion of our Board of Directors and holds office until their resignation or removal.

Board of Directors

Our Board of Directors currently consists of six members. The current members of our Board of Directors were elected pursuant to our current Amended and Restated Certificate of Incorporation.

Our Amended and Restated Certificate of Incorporation provides that our Board of Directors is divided into three classes (Class I, Class II, and Class III) with staggered three-year terms. Only one class of directors will be elected at each annual meeting of stockholders, with the other classes continuing for the remainder of their respective three-year terms. Our directors are divided among the three classes as follows:

- the Class I directors are Mr. Tibbles and Mr. Denti, and their terms will expire at the annual meeting of stockholders to be held in 2026;
- the Class II director is Ms. Messal, and her term will expire at the annual meeting of stockholders to be held in 2027; and
- the Class III directors are Mr. Wedan, Mr. McGregor, and Dr. Leighton, and their terms will expire at the annual meeting of stockholders to be held in 2028. Under ASX Listing Rule 14.4, Mr. Wedan (as managing director) is not required to stand for re-election every three years.

At each annual meeting of stockholders, upon the expiration of the term of a class of directors, the successor to each such director in the class will be elected to serve from the time of election and qualification until the third annual meeting following his or her election and until his or her successor is duly elected and qualified, in accordance with our Amended and Restated Certificate of Incorporation.

This classification of our Board of Directors may have the effect of delaying or preventing changes in control of our company.

Item 6. Executive Compensation.

This section discusses the material components of the executive compensation program for our named executive officers ("NEOs"). In fiscal year 2025, our NEOs and their positions were as follows:

- Steve Wedan, President, Chief Executive Officer, and Board Chair;
- Gregg Stenzel, Chief Operating Officer; and
- Jonathon Gut, Vice President of Finance and Chief Financial Officer.

The titles set forth above reflect the positions in which each NEO served during fiscal year 2025 for purposes of the compensation reported below.

Summary Compensation Table

This discussion contains forward looking statements that are based on our current plans, considerations, expectations, and determinations regarding future compensation programs. Actual compensation programs that we adopt may differ materially from currently planned programs as summarized in this discussion. As an "emerging growth company" as defined in the JOBS Act, we are not required to include a Compensation Discussion and Analysis section and have elected to comply with the scaled disclosure requirements applicable to emerging growth companies.

The following table sets forth information concerning the compensation awarded to or earned by our NEOs during the fiscal year ended December 31, 2025:

Name and principal position	Year	Salary ($)	Option awards ($)[1]	Non-equity incentive plan compensation ($)[2]	All other compensation ($)[3]	Total ($)
Steve Wedan *President, Chief Executive Officer, and Board Chair*	2025	479,000	91,901 [4]	136,515	13,306	720,722
Gregg Stenzel *Chief Operating Officer* [7]	2025	315,000	57,743 [5]	71,820	14,201	458,764
Jonathon Gut *Vice President of Finance and Chief Financial Officer*	2025	280,000	47,900 [6]	47,880	13,469	389,249

(1) Amounts do not reflect dollar amounts actually received by our NEOs and instead, in accordance with SEC rules, represent the aggregate grant date fair values of option awards granted in 2025 as computed in accordance with Financial Accounting Standards Board ("FASB") Accounting Standard Codification ("ASC") Topic 718. See Note 10 – Stockholders' Equity to our audited consolidated financial statements included elsewhere in this Registration Statement for a discussion of the assumptions used in the calculation of these amounts.

(2) Amounts disclosed under the "Non-Equity Incentive Plan Compensation" column represent the portion of the annual performance-based bonuses earned pursuant to objective performance criteria established as part of our annual performance-based bonus plan for the indicated year for the achievement of pre-established corporate and other goals. For further discussion on performance-based bonuses paid for 2025, see the sub-section entitled "2025 Annual Performance-Based Bonuses."

(3) Amounts disclosed under the "All Other Compensation" column include company contributions under our 401(k) plan of $12,919, $13,993, and $13,379 for Mr. Wedan, Mr. Stenzel, and Mr. Gut, respectively.

(4) The option awards reported in the table represent the grant date fair value computed in accordance with FASB ASC Topic 718 based on the probable outcome of performance conditions. Assuming the highest level of performance conditions is achieved, the grant date fair value of the option awards during 2025 would be $777,524.

(5) The option awards reported in the table represent the grant date fair value computed in accordance with FASB ASC Topic 718 based on the probable outcome of performance conditions. Assuming the highest level of performance conditions is achieved, the grant date fair value of the option awards during 2025 would be $643,576.

(6) The option awards reported in the table represent the grant date fair value computed in accordance with FASB ASC Topic 718 based on the probable outcome of performance conditions. Assuming the highest level of performance conditions is achieved, the grant date fair value of the option awards during 2025 would be $604,978.

(7) Effective January 1, 2026, Mr. Stenzel's title changed from Chief Operating Officer to Vice President of Research and Development.

Narrative to Summary Compensation Table

Annual Base Salary

Our named executive officers receive a base salary to compensate them for services rendered to us. The base salary payable to each named executive officer is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role, and responsibilities. The base salary of our named executive officers is generally determined and approved by our Board of Directors in connection with the commencement of employment of the named executive officer and may be adjusted from time to time thereafter as the Board of Directors determines appropriate. The 2025 annual base salary rates for our named executive officers were as follows: (1) for Mr. Wedan, $479,000; (2) for Mr. Stenzel, $315,000; and (3) for Mr. Gut, $280,000.

2025 Annual Performance-Based Bonuses

We generally provide each of our named executive officers with an opportunity to receive an annual cash incentive payment under our short-term incentive ("STI") plan, which is a component of our annual remuneration plan. The amount of any cash incentive payable under the STI plan is linked to annual performance targets determined by the Board of Directors. These targets are established to promote and reward outstanding performance, beyond what is expected in the ordinary course of business. The target STI opportunity is set as a percentage of fixed remuneration. For 2025, the maximum target opportunity was 50% for the President and CEO, Steve Wedan, 40% for the COO, Gregg Stenzel, and 30% for the CFO, Jonathon Gut. Furthermore, the 2025 annual performance targets determined by the Board of Directors were weighted as follows: product pipeline and regulatory approvals (50%), financial metrics (25%), and commercialization and strategic initiatives (25%).

The annual cash bonuses awarded to each named executive officer for 2025 performance are set forth above in the Summary Compensation Table in the column titled "Non-Equity Incentive Plan Compensation." If, in our board's discretion, an amount is paid over and above the amounts earned by meeting the performance measures in the STI Plan, such excess amount (if any) will be set forth in the Summary Compensation Table in the column titled "Bonus."

For 2025, the target incentive amounts and actual payments for our named executive officers under our 2025 Remuneration Plan, as determined by the Board of Directors based on its assessment of individual and company achievements throughout the year, were as follows:

Name Executive Officer	Target Award ($)	Actual Award ($)
Steve Wedan	239,500	136,515
Gregg Stenzel	126,000	71,820
Jonathon Gut	84,000	47,880

Equity-Based Incentive Awards

We generally provide each of our named executive officers with an opportunity to receive an annual equity-based incentive award under our long-term incentive ("LTI") plan, which is a component of our annual remuneration plan. Our LTI plan is designed to align the interests of management with its stockholders, while maintaining a total remuneration opportunity that enables the Company to retain, attract, and motivate qualified and high-performing executives. Our Board of Directors is responsible for approving equity grants. Additional grants may occur periodically to specifically align the interests of management with the interests of our stockholders. Vesting of equity awards is generally tied to continuous service with us and serves as an additional retention measure.

We currently grant equity-based incentive awards pursuant to our 2019 Equity Incentive Plan (the "2019 Plan"). As of April 21, 2026, all outstanding stock options held by our named executive officers were granted under the 2019 Plan. The terms of our 2019 Plan are described below under "Equity Incentive Plans."

In May 2025, our Board of Directors granted to each of our named executive officers stock options with a grant date fair value equaling 50% of their fiscal year 2025 base salary plus STI paid in 2025. Mr. Wedan, Mr. Stenzel, and Mr. Gut received stock options to purchase 455,893, 286,455, and 237,617 shares of our common stock, respectively. The performance vesting conditions for these options were weighted as follows:

- 50% when the first U.S. customer site orders product following FDA approval;
- 25% upon the submission for regulatory approval of our first non-EP product anywhere in the world; and
- 25% upon FDA approval of NorthStar.

The actual grant date fair values of these awards may vary from the planned allocation as a percentage of annual base salary plus STI paid due to fluctuations in our stock price and, where applicable, currency translation adjustments occurring between the initial fair value measurement, stockholder approval at the Annual General Meeting, and the grant date. Additionally, in May 2025, our Board of Directors granted Mr. Wedan, Mr. Stenzel, and Mr. Gut additional options to purchase 500,000 shares of our common stock each. These additional options will vest on the last day of the second consecutive fiscal quarter during which the Company generates positive cash flow from operations. Vesting of all options granted in 2025 is subject to each named executive officer's continued service through each applicable vesting date.

Outstanding Equity Awards as of December 31, 2025

The following table sets forth information regarding outstanding stock options and stock awards held by our named executive officers as of December 31, 2025:

		Option Awards[1]			
Name	Vesting Start Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)[2]	Option Expiration Date
Steve Wedan	3/15/2019	1,060,800	-	0.52	3/15/2029
	8/30/2019	200,000	-	0.98	8/30/2029
	5/13/2020	289,594	115,837 [3]	0.89	5/13/2030
	5/7/2021	-	304,254 [4]	1.57	5/7/2031
	5/9/2022	-	1,098,627 [5]	0.28	5/9/2032
	7/26/2022	-	174,264 [5]	0.21	7/26/2032
	5/12/2023	-	1,426,949 [6]	0.19	5/12/2033
	5/15/2024	-	2,113,342 [7]	0.30	5/15/2034
	5/14/2025	-	955,893 [8]	1.07	5/14/2035
Gregg Stenzel	3/15/2019	628,600	-	0.52	3/15/2029
	1/6/2020	47,619	19,048 [9]	0.80	1/6/2030
	5/13/2020	52,813	21,125 [3]	0.89	5/13/2030
	5/7/2021	-	161,372 [4]	1.57	5/7/2031
	5/9/2022	-	793,671 [5]	0.28	5/9/2032
	5/12/2023	-	966,851 [6]	0.19	5/12/2033
	5/15/2024	-	1,146,413 [7]	0.30	5/15/2034
	5/14/2025	-	786,445 [8]	1.07	5/14/2035
Jonathon Gut	10/7/2020	100,000	-	1.96	10/7/2030
	5/5/2021	25,300	-	1.55	5/5/2031
	2/10/2022	135,000	45,000 [10]	0.65	2/10/2032
	5/12/2023	-	796,117 [6]	0.19	5/12/2033
	5/15/2024	-	1,032,265 [7]	0.30	5/15/2034
	5/14/2025	-	737,617 [8]	1.07	5/14/2035

(1) Each of the outstanding equity awards was granted pursuant to our 2019 Plan (as defined below).

(2) The exercise price of each option is the fair market value of our common stock on the date of grant, as determined by our Board of Directors.

(3) Of the 136,962 unexercised options unexercisable, 12,403 shall vest upon the company achieving approval of a company's medical device by the Australian Therapeutic Goods Administration on or prior to the expiration of such option; 12,403 shall vest upon the company achieving approval of any of the company's medical devices by the United States Food and Drug Administration on or prior to the expiration of such option; and 112,156 shall vest upon the number of customer sites (labs) performing cardiac ablation procedures using the Company's products equals or exceeds 50 customer sites on or prior to the expiration of such option.

(4) Each option grant shall be subject to the following vesting schedule and shall become exercisable: with respect to 50% of the number of shares granted, such percentage shall vest upon the first sale of the Company's products within the United States of America on or prior to the expiration of such option; with respect to 25% of the number of shares granted, such percentage shall vest upon the first sale of the Company's products within Australia on or prior to the expiration of such option; and with respect to 25% of the number of shares granted, such percentage shall vest upon the first sale of the Company's VT Ablation product anywhere in the world on or prior to the expiration of such option.

(5) Each option grant shall be subject to the following vesting schedule and shall become exercisable: with respect to 20% of the number of shares granted, such percentage shall vest upon the opening of operations of three (3) clinical sites in Australia after the date hereof on or prior to the expiration of such option; with respect to 30% of the number of shares granted, such percentage shall vest upon the opening of operations of five (5) clinical sites in the United States after the date hereof on or prior to the expiration of such option; and with respect to 50% of the number of shares granted, such percentage shall vest upon the Company achieving profitable half-year results.

(6) Each option grant shall be subject to the following vesting schedule and shall become exercisable: with respect to 35% of the number of shares granted, such percentage shall vest upon the opening of operations of three (3) clinical sites in Australia after the date hereof on or prior to the expiration of such option; with respect to 35% of the number of shares granted, such percentage shall vest upon the opening of operations of five (5) clinical sites in the United States after the date hereof on or prior to the expiration of such option; and with respect to 30% of the number of shares granted, such percentage shall vest upon the first sale of the Company's VT Ablation product anywhere in the world on or prior to the expiration of such option.

(7) Mr. Wedan, Mr. Stenzel, and Mr. Gut received stock options to purchase 1,113,342, 646,413, and 532,265 shares of our common stock, respectively. The performance vesting conditions for these options were weighted as follows: with respect to 30% of the number of shares granted, such percentage shall vest upon the first sale of the Company's products into a dedicated iCMR lab in the Middle East after the date hereof on or prior to the expiration of such option; with respect to 40% of the number of shares granted, such percentage shall vest upon the approval or clearance of at least one capital or consumable product of the Company by the U.S. Food and Drug Administration for sale within the United States after the date hereof on or prior to the expiration of such option; and with respect to 30% of the number of shares granted, such percentage shall vest upon the first sale of the Company's consumable products in the United States on or prior to the expiration of such option. Additionally, Mr. Wedan, Mr. Stenzel, and Mr. Gut received additional options to purchase 1,000,000, 500,000, and 500,000 shares of our common stock, respectively. These additional options shall vest on the last day of the fiscal quarter during which the Company generates positive cash flow from operations, on or prior to the expiration of such option.

(8) Mr. Wedan, Mr. Stenzel, and Mr. Gut received stock options to purchase 455,893, 286,445, and 237,617 shares of our common stock, respectively. The performance vesting conditions for these options were weighted as follows: with respect to 50% of the number of shares granted, such percentage shall vest upon the first order of the Company's products in the United States following U.S. Food and Drug Administration approval after the date hereof on or prior to the expiration of such option; with respect to 25% of the number of shares granted, such percentage shall vest upon the approval or clearance of the NorthStar product of the Company by the U.S. Food and Drug Administration for sale within the United States after the date hereof on or prior to the expiration of such option; and with respect to 25% of the number of shares granted, such percentage shall vest upon the first regulatory submission anywhere in the world of a Non-EP product of the Company after the date hereof on or prior to the expiration of such option. Additionally, Mr. Wedan, Mr. Stenzel, and Mr. Gut received additional options to purchase 500,000 shares of our common stock each. These additional options shall vest on the last day of the second consecutive fiscal quarter during which the Company generates positive cash flow from operations, on or prior to the expiration of such option.

(9) Each option grant shall be subject to the following vesting schedule and shall become exercisable: with respect to 50% of the number of shares granted, a pro-rata portion of such percentage shall vest on each yearly anniversary of the Grant Date over four years; with respect to 10% of the number of shares granted, such percentage shall vest upon the Company achieving approval of a Company's medical device by the Australian Therapeutic Goods Administration; and with respect to 10% of the number of shares granted, such percentage shall vest upon the Company achieving approval of a Company's medical device by the United States Food and Drug Administration.

(10) This option vests over four years from the vesting commencement date in 4 equal annual installments, subject to continued service through each such vesting date.

Employment Agreements with Our Named Executive Officers

Steve Wedan

We are party to an amended and restated employment agreement dated as of April 11, 2019, with Mr. Wedan, our President, Chief Executive Officer, and Board Chair. The amended and restated employment agreement does not have a specific term and provides that Mr. Wedan is an at-will employee.

As approved by our Board of Directors in October 2025, Mr. Wedan's current annual base salary is $595,000 and his current annual target under our cash-based STI plan is 60% of his annual base salary. Subject to stockholder and Board approval, his current annual stock option grant under our equity-based LTI plan will have a grant date fair value equal to 60% of his fiscal year 2026 base salary plus STI paid in 2026. To be eligible to receive any annual cash-based STI compensation, Mr. Wedan must be actively employed by us on the payment date and in compliance with his obligations under his employment agreement.

The amended and restated employment agreement can be terminated by us for cause, by us without cause or due to disability, by Mr. Wedan's 30-day written notice of resignation, or upon the death of Mr. Wedan.

If we terminate Mr. Wedan's employment for cause, he will be entitled only to (i) any earned and unpaid salary accrued through the date of termination and (ii) any vested benefits under our employee benefit plans.

If we terminate Mr. Wedan's employment without cause or due to disability, and Mr. Wedan executes a general release of claims that becomes effective within 60 days of termination, he will be entitled to (i) twelve months of his then-current base salary, payable over twelve months in accordance with our normal payroll schedule, and (ii) reimbursement for monthly COBRA premiums until the earlier of twelve months following termination of employment or the date on which he becomes eligible for substantially equivalent health insurance coverage under another employer's group plan.

If Mr. Wedan provides 30-day written notice of resignation, he will be entitled only to (i) any earned and unpaid salary accrued through the date of termination and (ii) any vested benefits under our employee benefit plans.

Upon Mr. Wedan's death his estate will receive his annual base salary and all vested employee benefits through the date of termination.

We refer you to the copy of Mr. Wedan's amended and restated employment agreement, which is attached as Exhibit 10.12 to this Registration Statement, as this summary is subject to, and is qualified in its entirety by reference to, the full amended and restated employment agreement.

Gregg Stenzel

We are party to an employment agreement dated as of October 23, 2019, with Mr. Stenzel, who served as our Chief Operating Officer during fiscal year 2025 and, effective January 1, 2026, serves as our Vice President of Research and Development. The employment agreement does not have a specific term and provides that Mr. Stenzel is an at-will employee.

As approved by our Board of Directors in October 2025, Mr. Stenzel's current annual base salary is $320,000 and his current annual target under our cash-based STI plan is 30% of his annual base salary. Subject to Board approval, his current annual stock option grant under our equity-based LTI plan will have a grant date fair value equal to 30% of his fiscal year 2026 base salary plus STI paid in 2026. To be eligible to receive any annual cash-based STI compensation, Mr. Stenzel must be actively employed by us on the payment date and in compliance with his obligations under his employment agreement.

The employment agreement can be terminated by us for cause, by us without cause, by Mr. Stenzel's 30-day written notice of resignation, or upon the death or disability of Mr. Stenzel.

If we terminate Mr. Stenzel's employment for cause, he will be entitled only to (i) any earned and unpaid salary accrued through the date of termination and (ii) any vested benefits under our employee benefit plans.

If we terminate Mr. Stenzel's employment without cause, and Mr. Stenzel executes a general release of claims that becomes effective within 60 days of termination, he will be entitled to (i) six months of his then-current base salary, payable over six months in accordance with our normal payroll schedule, and (ii) reimbursement for monthly COBRA premiums until the earlier of six months following termination of employment or the date on which he becomes eligible for substantially equivalent health insurance coverage under another employer's group plan.

If Mr. Stenzel provides 30-day written notice of resignation, he will be entitled only to (i) any earned and unpaid salary accrued through the date of termination and (ii) any vested benefits under our employee benefit plans.

Upon Mr. Stenzel's death or disability his estate will receive his annual base salary and all vested employee benefits through the date of termination.

We refer you to the copy of Mr. Stenzel's employment agreement, which is attached as Exhibit 10.13 to this Registration Statement, as this summary is subject to, and is qualified in its entirety by reference to, the full employment agreement.

Jonathon Gut

We are party to an employment agreement dated as of February 20, 2024, with Mr. Gut, our Vice President of Finance and Chief Financial Officer. The employment agreement does not have a specific term and provides that Mr. Gut is an at-will employee.

As approved by our Board of Directors in October 2025, Mr. Gut's current annual base salary is $353,000 and his current annual target under our cash-based STI plan is 40% of his annual base salary. Subject to Board approval, his current annual stock option grant under our equity-based LTI plan will have a grant date fair value equal to 60% of his fiscal year 2026 base salary plus STI paid in 2026. To be eligible to receive any annual cash-based STI compensation, Mr. Gut must be actively employed by us on the payment date and in compliance with his obligations under his employment agreement.

The employment agreement can be terminated by us for cause, by us without cause, by Mr. Gut's 30-day written notice of resignation, or upon the death or disability of Mr. Gut.

If we terminate Mr. Gut's employment for cause, he will be entitled only to (i) any earned and unpaid salary accrued through the date of termination and (ii) any vested benefits under our employee benefit plans.

If we terminate Mr. Gut's employment without cause, and Mr. Gut executes a general release of claims that becomes effective within 60 days of termination, he will be entitled to (i) six months of his then-current base salary, payable over six months in accordance with our normal payroll schedule, and (ii) reimbursement for monthly COBRA premiums until the earlier of six months following termination of employment or the date on which he becomes eligible for substantially equivalent health insurance coverage under another employer's group plan.

If Mr. Gut provides 30-day written notice of resignation, he will be entitled only to (i) any earned and unpaid salary accrued through the date of termination and (ii) any vested benefits under our employee benefit plans.

Upon Mr. Gut's death or disability his estate will receive his annual base salary and all vested employee benefits through the date of termination.

We refer you to the copy of Mr. Gut's employment agreement, which is attached as Exhibit 10.14 to this Registration Statement, as this summary is subject to, and is qualified in its entirety by reference to, the full employment agreement.

Equity Awards

In the event of a change in control, our Board of Directors has broad discretion under our 2019 Equity Incentive Plan to take various actions with respect to outstanding awards under the plan in connection with a change in control. The terms of individual award agreements or employment agreements may supersede the plan provisions to the extent they provide for different treatment of awards in a change in control.

Other Compensation and Benefits

Each of our named executive officers is eligible to participate in our employee benefit plans available in their jurisdiction, including our medical, dental, vision, life, disability, and other employee benefit plans, in each case on the same basis as all of our other employees. We pay some or all the premiums for medical, dental, vision, and life insurance for all of our employees, including our named executive officers. We generally do not provide perquisites or personal benefits to our named executive officers.

In addition, we provide our U.S. employees, including each of our named executive officers, the opportunity to participate in our 401(k) retirement plan. Under the terms of the plan, eligible U.S. employees may make elective deferrals of compensation on a pre-tax or after-tax (Roth) basis, up to the statutorily prescribed annual limits on contributions under the Internal Revenue Code of 1986, as amended (the “Code”). Individual contributions are allocated to each participant’s individual account and are then invested in selected investment alternatives according to the participants’ directions. The 401(k) plan is intended to be qualified under Section 401(a) of the Code with the 401(k) plan’s related trust intended to be tax exempt under Section 501(a) of the Code. As a tax-qualified retirement plan, contributions to the 401(k) plan (except for Roth contributions) and earnings on those contributions are not taxable to the employees until distributed from the 401(k) plan. As a safe harbor 401(k) plan, we make matching contributions equal to 100% of each participant's elective deferrals up to 3% of compensation, plus 50% of deferrals between 3% and 5% of compensation.

2019 Equity Incentive Plan

In February 2019, our Board of Directors adopted, and our stockholders approved, the 2019 Equity Incentive Plan (the "2019 Plan"). The 2019 Plan replaced the 2016 Stock Option Plan, with the company ceasing to grant new awards under the 2016 Stock Option Plan in February 2019. The predecessor to the 2016 Stock Option Plan was the 2006 Plan. We have no equity awards outstanding under either the 2016 Stock Option Plan or the 2006 Plan. Our Board of Directors has also adopted an Australian Sub-Plan to the 2019 Plan which applies to awards granted to participants who are resident in Australia.

Types of Awards. The 2019 Plan provides for the grant incentive stock options ("ISOs") within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended, nonstatutory stock options ("NSOs"), stock appreciation rights, restricted stock awards, restricted stock units, deferred stock units, performance awards, non-employee director awards, and other stock-based awards. ISOs may be granted only to employees. All other awards may be granted to employees, non-employee directors, and consultants.

Share Reserve. Subject to adjustment for certain changes in our capitalization, the maximum number of shares of common stock that were initially reserved and available for issuance under the 2019 Plan was 11,418,500 shares, which included any shares subject to options issued under our prior plans that subsequently expire or terminate without being exercised. On the first day of each of our fiscal years during the term of the 2019 Plan beginning in 2020, the number of shares available for issuance under the 2019 Plan automatically increases by an amount equal to the lesser of (i) five percent of the aggregate number of shares reserved under the 2019 Plan on the last day of the immediately preceding fiscal year, and (ii) such number of shares determined by our Board of Directors. The maximum aggregate number of shares that may be issued upon the exercise of ISOs under the 2019 Plan may not exceed the initial limit cumulatively increased on each January 1 beginning in 2020 by the lesser of the annual increase for such year or 1,500,000 shares, unless the increase is approved by our stockholders. As of April 21, 2026, the cumulative number of shares authorized for issuance under the 2019 Plan is 42,150,000 shares, of which 1,771,340 shares remained available for issuance.

Any shares of common stock related to awards granted under this Plan that terminate by expiration, forfeiture, cancellation, or otherwise without the issuance of the shares of common stock, will be available again for grant under this Plan. Shares of common stock subject to awards settled in cash will again be available for issuance pursuant to awards granted under the Plan. However, shares withheld to satisfy income or employment withholding taxes and shares used to pay the exercise or purchase price of a stock award under this plan will be counted against the shares authorized for issuance under the 2019 Plan and will not be available again for grant. The full number of shares subject to a stock-settled stock appreciation right or other stock-based award will be counted against the shares authorized for issuance under the 2019 Plan, regardless of the number of shares actually issued upon settlement. Shares issued under the 2019 Plan may be authorized and unissued shares or treasury shares.

Administration. Our Board of Directors, or a duly authorized committee of our Board of Directors, administers the 2019 Plan. Our Board of Directors may also delegate to one or more of its members or to one or more officers the authority to designate recipients and determine the size of awards, subject to certain limitations. Under the 2019 Plan, the plan administrator has the authority to, among other things, (i) designate eligible recipients to be selected as participants, (ii) determine the nature, extent, and terms of awards to be made to each participant, (iii) determine the time and duration of awards and the conditions upon which awards will become exercisable or vest, and (iv) establish rules and regulations for the administration of the 2019 Plan and to interpret the Plan and awards granted under (v) and make any other determination and take any other action it deems appropriate for the administration of the 2019 Plan. Our Board of Directors and Nomination and Remuneration Committee are each considered to be plan administrators for purposes of the 2019 Plan.

Stock Options. ISOs and NSOs are granted pursuant to stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for a stock option, within the terms and conditions of the 2019 Plan, provided that the exercise price of a stock option cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2019 Plan vest at the rate specified by the plan administrator. Options expire after 10 years from the grant date.

Tax Limitations on ISOs. The aggregate fair market value, determined at the time of grant, of our common stock with respect to ISOs that are exercisable for the first time by an option holder during any calendar year under all of our equity incentive plans may not exceed $100,000. Options or portions thereof that exceed such limit will be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our affiliates unless the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant and the term of the ISO does not exceed five years from the date of grant.

Restricted Stock Awards. Restricted stock awards are granted pursuant to restricted stock award agreements adopted by the plan administrator. Restricted stock awards are subject to such conditions or restrictions as the plan administrator may deem advisable, including a requirement that participants pay a stipulated purchase price for each share of common stock underlying a restricted stock award, and time-based restrictions on vesting or restrictions based upon the achievement of specific performance goals. Except as otherwise provided in an applicable award agreement, all outstanding unvested restricted stock awards held by the participant as of the effective date of termination of employment will be terminated and forfeited. Unless otherwise determined by the plan administrator and set forth in a participant's award agreement, participants holding a restricted stock award will be granted the right to exercise full voting rights with respect to such shares during the period of restriction and will have the same dividend rights as our other stockholders, provided that any such dividends as to a restricted stock award that is subject to vesting requirements will be subject to forfeiture and termination to the same extent as the restricted stock award to which such dividends relate.

Restricted Stock Unit Awards. Restricted stock unit awards are granted pursuant to restricted stock unit award agreements adopted by the plan administrator. Restricted stock unit awards are subject to such conditions or restrictions as the plan administrator may deem advisable, including a requirement that participants pay a stipulated purchase price for each share of common stock underlying a restricted stock unit, and time-based restrictions on vesting or restrictions based upon the achievement of specific performance goals. A restricted stock unit award may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the plan administrator, or in any other form of consideration set forth in the restricted stock unit award agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a restricted stock unit award. Except as otherwise provided in an applicable award agreement, all outstanding unvested restricted stock units held by the participant as of the effective date of termination of employment will be terminated and forfeited. Participants have no voting rights with respect to shares represented by restricted stock units until the date of the issuance of such shares.

Stock Appreciation Rights. Stock appreciation rights are granted pursuant to stock appreciation right agreements adopted by the plan administrator. The plan administrator determines the grant price for a stock appreciation right, which cannot be less than 100% of the fair market value of our common stock on the date of grant. Upon the exercise of a stock appreciation right, we will pay the participant an amount equal to the excess of the per share fair market value of our common stock on the date of exercise over the grant price, multiplied by the number of shares of common stock with respect to which the stock appreciation right is exercised. A stock appreciation right granted under the 2019 Plan vests at the rate specified in the stock appreciation right agreement as determined by the plan administrator. No stock appreciation right may be exercisable after 10 years from its grant date.

Performance Awards. The 2019 Plan permits the grant of performance-based stock and cash awards. The plan administrator can structure such awards so that stock or cash will be issued or paid pursuant to such award only after the achievement of certain pre-established performance goals during a designated performance period. The plan administrator will select one or more performance criteria for purposes of establishing the performance goals for a performance period. In evaluating performance, the plan administrator may include or exclude items such as changes in accounting principles, financing activities, restructuring or productivity initiatives, acquisitions, discontinued operations, and unusual or extraordinary corporate events, as determined by the plan administrator. The plan administrator may also amend or modify the vesting criteria and performance goals of any outstanding awards in recognition of unusual or nonrecurring events affecting the Company or changes in applicable laws, regulations, or accounting principles. Partial achievement of the specified criteria may result in the payment or vesting corresponding to the degree of achievement as specified in the award agreement.

Other Stock Awards. The plan administrator may grant other stock-based awards to eligible recipients, including the grant or offer for sale of unrestricted shares of common stock, in such amounts and subject to such terms and conditions as the plan administrator will determine. Such awards may involve the transfer of actual shares of common stock to participants as a bonus or in lieu of obligations to pay cash or deliver other property under the plan or under other plans or compensatory arrangements, or payment in cash or otherwise of amounts based on the value of shares of common stock. Each other stock-based award will be expressed in terms of shares of common stock or units based on shares of common stock, as determined by the plan administrator.

Changes to Capital Structure. In the event of any reorganization, merger, consolidation, recapitalization, liquidation, reclassification, stock dividend, stock split, combination of shares, rights offering, divestiture, or extraordinary dividend (including a spin off) or any other similar change in the corporate structure or shares of common stock of the Company, the plan administrator will make appropriate adjustment or substitutions to (i) the number and kind of securities or other property (including cash) available for issuance or payment under the 2019 Plan, and (ii) the number and kind of securities or other property (including cash) subject to outstanding awards and the exercise price of outstanding awards.

Change in Control. In the event of a change in control, our Board of Directors has discretion under the 2019 Plan to take various actions with respect to outstanding awards. The Board may require that shares of stock of a successor corporation be substituted for outstanding awards, with appropriate equitable adjustments to the number of shares and other terms. The Board may also provide that outstanding options become exercisable in full or in part, that restrictions or vesting applicable to restricted stock and restricted stock units lapse in full or in part, that performance periods and performance goals applicable to outstanding awards lapse or are deemed satisfied at target or another level, or that outstanding awards be canceled and terminated in exchange for cash or shares of stock of the successor corporation. The terms of individual award agreements or employment agreements may supersede the provisions above to the extent they provide for different treatment of awards in a change in control.

Transferability. A participant may not transfer stock awards under our 2019 Plan other than by will, the laws of descent and distribution, or as otherwise provided under our 2019 Plan.

Plan Amendment or Termination. Our Board of Directors has the authority to amend, suspend, or terminate the 2019 Plan, provided that such action does not materially impair a participant's rights under his or her outstanding awards without such participant's written consent and provided further that stockholder approval is required for certain types of amendments. The 2019 Plan will automatically terminate on the day before the tenth anniversary of the date our Board of Directors adopted the 2019 Plan, unless terminated sooner by the Board.

Policies and Practices Related to the Grant of Certain Equity Awards Close in Time to the Release of Material Nonpublic Information

With respect to the timing of equity awards, our practice is to grant annual equity awards to executive officers in accordance with the Remuneration Plan and to all other recipients in May of each year, with other grants as determined by the Nomination and Remuneration Committee. This timing is dependent upon a sufficient number of shares of our common stock reserved under our stockholder-approved equity plan. If there is an insufficient number of shares of our common stock reserved under our stockholder-approved equity plan, then the timing of our equity grants may be delayed until shortly after stockholder approval of a new equity plan or an increase in the share reserve under the existing plan. We intend not to grant stock options or similar awards in anticipation of the release of material nonpublic information that is likely to result in changes to the price of our common stock, such as a significant positive or negative earnings announcement, and not to time the public release of such information based on stock option grant dates.

Non-Executive Director Compensation

Under our Bylaws, our Board of Directors determines the total amount paid to all directors for their services. However, under the ASX Listing Rules, the total amount paid to all directors (excluding the salary of any executive director and excluding any equity securities issued to a director with the approval of stockholders under the ASX Listing Rules) for their services must not exceed in aggregate in any fiscal year, the amount approved by stockholders in a general meeting. This amount has been fixed at $400,000.

Our Board of Directors seeks to set non-executive director (“NED”) fees at levels that provides us with the ability to attract and retain NEDs of high caliber with relevant professional expertise and reflects the demands that are made on, and the responsibilities of, the NEDs, while incurring a cost that is acceptable to stockholders. As our operations are in the initial stages of commercialization, we have structured NEDs fees to include both cash remuneration and equity awards in order to maintain appropriate remuneration structures and preserve cash flow. Equity awards issued to NEDs do not have performance hurdles attached.

NEDs serving on our Board of Directors will receive $65,000 in annual fees. Committee chairs will receive an additional $10,000 in annual fees. Committee members will receive an additional $5,000 in annual fees. All fees for Australian NEDs are inclusive of superannuation. The Chairman, Mr. Steve Wedan, does not receive compensation for his service as a director. His compensation for service as an executive officer during 2025 is disclosed in the 2025 Summary Compensation Table and related narrative disclosure.

We generally provide for each of our NEDs with an opportunity to receive an annual equity-based award under our annual remuneration plan. Our Board of Directors is responsible for approving equity grants, subject to stockholder approval. Separately, NEDs appointed to our Board pursuant to our contractual obligations are non-independent non-executive directors. Non-independent non-executive directors are not eligible to receive compensation under our annual remuneration plan.

In May 2025, our Board of Directors granted to certain of our non-executive directors restricted stock awards with a grant date fair value equal to 50% of their 2025 fees. Mark Tibbles and Peter McGregor each received 41,280 shares, and Anita Messal received 38,700 shares. The shares underlying these awards vest in equal annual installments over four years from the grant date, subject to each director's continued service with the Company. The actual grant date fair values of these awards may vary from the planned allocation as a percentage of annual fees due to fluctuations in our stock price and, where applicable, currency translation adjustments occurring between the initial fair value measurement, stockholder approval at the Annual General Meeting, and the grant date.

The following table sets forth information concerning the compensation for all of our directors (except Mr. Wedan) for the year ended December 31, 2025:

Name		Fee Earned or Paid in Cash ($)	Stock Awards ($)[1]	Total ($)
Mark Tibbles	[2]	80,000	44,349	124,349
Peter McGregor	[3]	80,000	44,349	124,349
Anita Messal	[4]	75,000	41,577	116,577
Aldo Denti	[5]	10,151	-	10,151
Jeffrey Leighton	[6]	-	-	-

(1) Amounts do not reflect dollar amounts actually received by our NEDs and instead represent the aggregate grant date fair values of restricted stock awards granted in 2025.

(2) At December 31, 2025, Mr. Tibbles had 526,806 outstanding options to purchase shares of common stock.

(3) At December 31, 2025, Mr. McGregor had 246,906 outstanding options to purchase shares of common stock.

(4) At December 31, 2025, Ms. Messal had 38,340 outstanding options to purchase shares of common stock.

(5) Mr. Denti was appointed to the Board of Directors effective November 5, 2025, and accordingly received pro-rated board fees for the period from his appointment through the end of the fiscal year.

(6) Dr. Leighton is a non-independent non-executive director and therefore is not eligible to receive compensation under our annual remuneration plan.

Item 7. Certain Relationships and Related Transactions, and Director Independence.

Certain Relationships and Related Transactions

The following describes all transactions since January 1, 2024, to which we have been a party, in which the amount involved exceeded or will exceed $120,000 or 1% of the average of the Company's total assets at year-end for the last two completed fiscal years, and in which any of our directors, executive officers, or beneficial owners of more than 5% of our common stock, or an affiliate or immediate family member thereof, had or will have a direct or indirect material interest, other than compensation, termination, and change-in-control arrangements, which are described under Item 6. Executive Compensation.

Securities Purchase Agreement

On December 16, 2022, we entered into a Securities Purchase Agreement with K.A.H.R. Foundation, a beneficial owner of more than 5% of our common stock, for the issue of unsecured, unquoted convertible promissory notes, to be issued in two tranches, to raise a maximum aggregate amount of $5,000,000.

The first tranche was issued on December 23, 2022. The Company received $2,325,000 in gross proceeds from the issuance of the convertible note. The convertible note bears interest of 10% per annum, compounded annually. The interest accrued during the years ended December 31, 2025 and 2024 was $281,942 and $ 256,311, respectively. As of December 31, 2025 and 2024, cumulative accrued interest on the first tranche totaled $776,358 and $494,416, respectively. All or a portion of the principal is convertible into CHESS Depositary Interests ("CDIs") at a price of $0.2691 per share at the election of the holder following the 36-month anniversary of the closing date. All or a portion of accrued and unpaid interest is convertible into CDIs at a price of $0.2563 per share at the election of the holder during the same time frame. Accrued interest on the convertible notes is included in the fair value of the convertible notes on the consolidated balance sheets. The maximum number of CDIs to be issued upon conversion of the principal amount and interest is no more than 12,849,949 CDIs. As of December 31, 2025, 11,669,009 CDIs would be issued if the principal and accrued interest were converted.

The second tranche was issued on March 28, 2023. The Company received $2,675,000 of gross proceeds from the issuance of the convertible note. The second tranche is subject to the same terms as the first tranche. The interest accrued during the years ended December 31, 2025 and 2024 was $316,661 and $287,874, respectively. As of December 31, 2025 and 2024, cumulative accrued interest on the second tranche totaled $808,275 and $491,614, respectively. The maximum number of CDIs to be issued upon conversion of the principal and interest is no more than 14,784,350 CDIs. As of December 31, 2025, 13,094,172 CDIs would be issued if the principal and accrued interest were converted.

The maturity date on the notes is the earliest occurrence of (i) a change-in-control event, at which time the Company would be required to pay the holder the greater of 125% of the then outstanding balance plus accrued and unpaid interest or the amount the holder would receive if the principal and accrued and unpaid interest had been converted to CDIs at a conversion price equal to the variable weighted average price ("VWAP") of the CDIs for the 10 day period ending on the change-in-control event date; or (ii) the four year anniversary of the closing date of each tranche.

On March 28, 2023 and December 23, 2022, pursuant to the Securities Purchase Agreement, the Company issued warrants exercisable for 1,043,699 and 907,141 CDIs, respectively, with an exercise price of $0.2563 per share. The warrants expire five years after the dates of issuance.

As of December 31, 2025 and 2024, the aggregate principal amount outstanding was $5,000,000 (representing the largest principal balance outstanding since January 1, 2024). During fiscal year 2025 and 2024, no principal or interest was repaid. As of December 31, 2025 and 2024, the aggregate 1,950,840 warrants remain outstanding.

In connection with the Securities Purchase Agreement, K.A.H.R. Foundation has the right to nominate one individual (the "Lender Nominee") to our Board of Directors, subject to customary background checks, regulatory approvals, and compliance with ASX Listing Rules. If stockholders fail to elect the initial Lender Nominee, the Company shall increase the Board size by one seat and appoint the nominee selected by K.A.H.R. Foundation to fill the vacancy. For so long as the convertible notes remain outstanding, if the Lender Nominee resigns or otherwise ceases to serve as a director, K.A.H.R. Foundation has the right to designate a successor, and the Company shall promptly appoint such successor to the Board. K.A.H.R. Foundation's nomination and appointment rights automatically terminate when the convertible notes are no longer outstanding, at which time the serving Lender Nominee shall resign from the Board immediately upon the Company's written request.

Dr. Jeffrey Leighton was appointed as a Class III director effective July 2024 pursuant to these nomination rights granted to the K.A.H.R. Foundation.

See Note 7 – Convertible Notes with Warrants (related party) to our audited consolidated financial statements included elsewhere in this Registration Statement for further information.

Participation in Institutional Placements

On February 9, 2024, we completed placements in which we issued 14,069,396 CDIs at $0.45 Australian dollars per CDI in the institutional placement, and 3,766,666 shares of common stock at $0.30 per share in the U.S. placement. An affiliate of K.A.H.R. Foundation participated in the U.S. placement and purchased 1,666,667 shares for the aggregate purchase price of $500,000.

On March 27, 2025, we completed a placement in which we issued 49,645,391 CDIs at $1.41 Australian dollars per CDI. Hart Capital Partners, a beneficial owner of more than 5% of our common stock, participated in the placement and purchased 2,943,262 CDIs for the aggregate purchase price of $4,149,999 Australian dollars (US$2,616,824). Greencape Capital, a beneficial owner of more than 5% of our common stock, participated in the placement and purchased 20,000,000 CDIs for the aggregate purchase price of $28,200,000 Australian dollars (US$17,781,792).

Director Independence

Our Board has determined that the following Board members can be considered independent:

- Mark Tibbles
- Peter McGregor
- Anita Messal
- Aldo Denti

We consider that a director is an independent director where that director is free from any business or other relationship that could materially interfere with, or be perceived to interfere with, the independent exercise of the director’s judgment. While we are not currently seeking a listing on Nasdaq, the New York Stock Exchange (“NYSE”), or any other U.S. securities exchange and do not intend to do so in the foreseeable future, we have assessed the independence of our directors with respect to the definition of independence prescribed by Nasdaq and the SEC. Although we may seek a listing on Nasdaq or NYSE in the future, there is no guarantee that we will do so or that we will achieve a listing on Nasdaq, NYSE, or any other exchange in any particular timeframe or at all.

Our Board of Directors undertook a review of its composition, the composition of its committees and the independence of our directors and considered whether any director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. Based upon information requested from and provided by each director concerning his background, employment, and affiliations, including family relationships, our Board of Directors has determined that each of Mr. Tibbles, Mr. McGregor, Ms. Messal, and Mr. Denti, representing four of our six directors, do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the rules of Nasdaq.

In making these determinations, our Board of Directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our Board of Directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director, and the transactions involving them described in the section titled "Certain Relationships and Related Transactions."

Corporate Governance

The roles of Chair of the Board and Chief Executive Officer of the Company are currently performed by Mr. Steve Wedan. Our Board of Directors does not have a policy requiring the separation of the roles of Chair of the Board and Chief Executive Officer, as the Board believes it is in the best interests of the Company and our stockholders to make this determination based on the Company's specific circumstances and needs at any particular point in time.

The Board considers Mr. Wedan to presently be the most appropriate person to serve as Chair given the size of the Board and the Company's stage of development. Mr. Wedan's role as both Chief Executive Officer and founder of the Company provides him with unique insights into our operations, clinical programs, and strategic direction, which enhances the Board's ability to fulfill its oversight responsibilities effectively. The combined role also provides a single point of leadership for Imricor so that the company maintains a unified message and strategic direction.

To enhance the independent oversight function of the Board while maintaining this structure, Mr. Tibbles serves as Lead Independent Director, presiding over meetings of the non-executive directors and serving as a liaison between the non-executive directors and management on sensitive matters. The Board recognizes that different board leadership structures may be appropriate for the Company as it continues to grow and evolve. The Board evaluates its leadership structure on an annual basis to ensure it remains appropriate for the Company's specific characteristics and circumstances. As stated in our Board Charter, the Board is free to select its Chairman and Imricor's Chief Executive Officer in the manner it considers in the best interests of the company at any given point in time.

Board Committees

Our Board of Directors has an Audit and Risk Committee, and Nomination and Remuneration Committee, each of which has the composition and the responsibilities described below. Formal charters can be viewed on the Company's website at http://www.imricor.com/corporate-governance/.

Audit and Risk Committee

The members of our Audit and Risk Committee are Mr. Tibbles, Mr. McGregor, and Ms. Messal. Mr. McGregor qualifies as a financial expert as defined in the Nasdaq rules, given he has over 30 years of experience in senior finance and management roles as described in Item 5. Directors and Executive Officers. Mr. McGregor is the chair of the Audit and Risk Committee. The purpose of the committee is to assist the Board in fulfilling its responsibilities in relation to financial reporting processes, audit processes, risk management systems, and compliance frameworks. The Audit and Risk Committee also assists with:

- reviewing the consolidated financial statements and any accompanying reports with management and the external auditor and if considered appropriate, to recommend their approval to the Board;
- the appointment, reappointment, or replacement of the external auditor and the rotation of the audit engagement partner;
- the remuneration and other contractual terms of the external auditor;
- the effectiveness and independence of the external auditor;
- assessing any proposal for the external auditor to provide non-audit services and whether it might compromise the independence of the external auditor;
- establishing procedures for the consideration of any complaints received by us regarding accounting, internal control, and auditing matters.
- overseeing the establishment, methodology, and implementation of the risk management procedures, including processes to ensure that there are reviews of internal control procedures and the operational effectiveness of the procedures related to risk and control;
- review and approve transactions that have or will have a material direct or indirect interest between us and our directors, officers, and related parties; and
- reviewing the procedures in place to ensure compliance with laws and regulations that are material to us, including any specific compliance requirements under the terms of any regulatory approvals granted in connection with the business.

Our Audit and Risk Committee operates under a written charter, which has been prepared having regard to the recommendations set out in the ASX Corporate Governance Principles and Recommendations.

Nomination and Remuneration Committee

The members of our Nomination and Remuneration Committee are Mr. Tibbles, Mr. McGregor, and Ms. Messal. Mr. Tibbles is the chair of our Nomination and Remuneration Committee. The purpose of the committee is to assist the Board in reviewing and approving remuneration and incentive policies and practices. The Nomination and Remuneration Committee also:

- establishes processes for the identification of suitable candidates for appointment to the Board;
- establishes processes for reviewing the performance of individual Directors, the Board as a whole, and Board committees;
- determines executive remuneration policy and non-executive director remuneration policy;
- reviews all equity-based incentive plans and makes recommendations to the Board regarding their adoption and implementation; and
- ensures that our remuneration policies are balanced and do not reward behavior that is inconsistent with our values.

Our Nomination and Remuneration Committee operates under a written charter, which has been prepared having regard to the recommendations set out in the ASX Corporate Governance Principles and Recommendations.

Code of Business Conduct

Our Board of Directors has adopted a code of business conduct that applies to all of our employees, officers, and directors, including those officers responsible for financial reporting. Our code of business conduct is available on our website at http://www.imricor.com/.

Item 8. Legal Proceedings.

From time to time, we may become involved in litigation relating to claims arising out of our operations in the normal course of business. No legal proceedings, government actions, administrative actions, investigations, or claims are currently pending against us or our officers and directors in which we are adverse.

Item 9. Market Price of and Dividends on the Registrant's Common Equity and Related Stockholder Matters.

Market Information

Our securities began trading on the Australian Securities Exchange on August 30, 2019, under the ticker "IMR". Prior to such time, there was no public market for our securities. There is no principal market in the U.S. for our CDIs or shares of our common stock.

Rule 144

In general, under Rule 144 under the Securities Act, a person who acquires our common stock in a transaction not registered under the Securities Act and has beneficially owned such shares for at least one year would be entitled to sell such shares during any three-month period subject to certain restrictions, including volume limitations and manner of sale requirements.

Under Rule 144(b)(1) of the Securities Act, a person who is not deemed to have been an affiliate of ours at any time during the three months preceding a sale and who has beneficially owned the shares proposed to be sold for at least one year is entitled to sell such shares without complying with the volume and manner of sale restrictions of Rule 144, provided current public information about us is available.

We have not previously filed a registration statement under the Securities Act. Shares sold pursuant to exemptions from registration are designated as "restricted" securities as defined by the Securities Act. As of April 21, 2026, out of a total of 535,000,000 shares of common stock authorized, 320,947,028 shares of common stock are issued as restricted securities and can only be sold or otherwise transferred pursuant to a registration statement under the Securities Act or pursuant to an available exemption from registration. 16,227,895 (5.1%) shares are held by affiliates (directors, officers, and 10% holders), with the balance of 304,719,133 (94.9%) shares being held by non-affiliates.

Holders

As of April 21, 2026, we had 320,947,028 shares of common stock outstanding, held of record by 140 stockholders. The holders included CHESS Depositary Nominees Pty Limited ("CDN"), which held 269,075,509 shares of our common stock. CDN, a subsidiary of ASX Limited, acts as our Australian depositary nominee and issues depository interests, in the form of CDIs, to the CDI holders; of which there were approximately 2,488 registered owners of our CDIs, a substantial majority of whom are non-U.S. holders. There were no shares of preferred stock outstanding.

Dividends

Subject to the prior rights of holders of all outstanding classes of stock, the holders of common stock shall be entitled to receive any dividends as may be declared from time to time by the Board of Directors from any assets legally available. The right to such dividends shall not be cumulative, and no right shall accrue by reason of the fact that dividends are not declared in any prior period. However, we have never paid cash dividends on any of our capital stock, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. We do not intend to pay cash dividends to holders of our common stock in the foreseeable future.

Equity Compensation Plan Information

The following table provides information about the common stock that may be issued upon the exercise of options, warrants, and rights under all our existing equity compensation plans as of December 31, 2025:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	33,907,621 [1]	0.58	581,340 [2]
Equity compensation plans not approved by security holders	-	-	-
Total	33,907,621	0.58	581,340

(1) All stock options issued under the 2019 Plan, as described under Item 6. Executive Compensation.

(2) Represents shares available for issuance under the 2019 Plan.

Item 10. Recent Sales of Unregistered Securities.

Since April 21, 2023, we have issued the following securities pursuant to exemptions from registration under the Securities Act.

Issuances Exempt Under Rule 701

The offers, sales, and issuances of the securities described below were deemed to be exempt from registration under the Securities Act pursuant to Rule 701 promulgated under the Securities Act, as offers and sale of securities made pursuant to certain compensatory benefit plans and contracts relating to compensation in accordance with Rule 701.

Stock Options

From April 21, 2023 to April 21, 2026, we granted stock options to purchase an aggregate of 24,496,120 shares of common stock at exercise prices ranging from $0.19 to $1.28 per share to a total of 49 employees, consultants, and directors under our 2019 Equity Incentive Plan. The stock options are subject to varying time-based vesting schedules over periods ranging from one to four years or performance-based vesting conditions as determined by our Board of Directors. Of these options, options to purchase 625,234 shares have been forfeited or expired without being exercised, and options to purchase 23,870,886 shares remain outstanding.

From April 21, 2023 to April 21, 2026, 356,150 shares of common stock have been issued upon the exercise of stock options granted under our 2019 Equity Incentive Plan at exercise prices ranging from $0.31 to $0.52 per share, for cash consideration in the aggregate amount of $182,836. After deducting issuance costs of $1,914, we received net proceeds of $180,922.

Restricted Stock Awards

From April 21, 2023 to April 21, 2026, we granted an aggregate of 965,295 restricted stock awards (“RSAs”) in the form of CDIs to certain directors pursuant to the 2019 Equity Incentive Plan as compensation for director services. Specifically, 528,089 RSAs were granted on May 12, 2023, 315,946 RSAs were granted on May 15, 2024, and 121,260 RSAs were granted on May 14, 2025. The shares underlying these awards vest in equal annual installments over four years from the grant date, subject to each director's continued service with the Company

Issuances Exempt Under Section 4(a)(2) or Regulation S

The offers, sales, and issuances of the securities described below were deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder as transactions by an issuer not involving a public offering or Regulation S as an offering made outside the United States. The Company took appropriate measures to confirm that the recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof. Each of the recipients of securities in these transactions was an accredited investor, as such term is defined in Rule 501(a) of Regulation D, or a sophisticated person and had adequate access, through employment, business, or other relationships, to information about us. Appropriate legends or notices were affixed to the securities issued in reliance on Regulation S to ensure compliance with Regulation S restrictions.

On July 18, 2023, we completed a U.S. private placement in which the securities were sold to an accredited U.S. investor. We issued 2,857,143 shares of common stock at $0.35 per share. In conjunction with the placement, we issued 428,571 warrants to purchase shares of common stock at $0.60 per share. The warrants have a 10-year term and are exercisable immediately upon issuance. We raised gross proceeds of $1,000,000. After deducting issuance costs of $18,234, we received net proceeds of $981,766.

On August 15, 2023, we completed a placement in which securities were sold to accredited U.S. investors and investors in Australia and New Zealand. We issued 2,127,056 CDIs at $0.61 Australian dollars per CDI for Australian and New Zealand investors and 2,564,103 shares of common stock at $0.39 per share for U.S investors. In conjunction with the placement, we issued 319,068 warrants to purchase CDIs to Australian and New Zealand investors at $1.00 Australian dollars per CDI and 384,616 warrants to purchase common stock to U.S investors at $0.60 per share. The warrants have a 10-year term and are exercisable immediately upon issuance. We raised gross proceeds of $1,829,736. After deducting issuance costs of $12,797, we received net proceeds of $1,816,939.

In September and October 2023, we issued a total of 961,868 CDIs at prices ranging from $0.47 to $0.60 Australian dollars per CDI. We received gross proceeds of $280,629. After deducting issuance costs of $2,582, we received net proceeds of $278,047.

On October 24, 2023, we completed a placement in which securities were sold to accredited U.S. investors and investors in Australia and New Zealand. We issued 7,126,000 CDIs at $0.50 Australian dollars per CDI for Australian and New Zealand investors and 1,406,250 shares of common stock at $0.32 per share for U.S investors. In conjunction with the placement, we issued 1,781,500 warrants to purchase CDIs to Australian and New Zealand investors at $0.95 Australian dollars per CDI and 351,563 warrants to purchase common stock to U.S investors at $0.60 per share. The warrants have a 10-year term and are exercisable immediately upon issuance. We raised gross proceeds of $2,737,151. After deducting issuance costs of $60,194, we received net proceeds of $2,676,957.

In February and April 2024, we completed a capital raising consisting of an institutional placement, a U.S. placement, and an accelerated pro-rata non-renounceable entitlement offer in which securities were sold to accredited U.S. investors and investors in Australia. On February 9, 2024, we issued 14,069,396 CDIs at $0.45 Australian dollars per CDI in the institutional placement (including the institutional component of the entitlement offer), and 3,766,666 shares of common stock at $0.30 per share in the U.S. placement. Under the retail component of the entitlement offer, we issued 1,419,069 CDIs on February 27, 2024, and 14,378,862 CDIs on April 5, 2024, each at $0.45 Australian dollars per CDI. We raised gross proceeds of $9,848,560. After deducting issuance costs of $637,942, we received net proceeds of $9,210,618.

In July and September 2024, we completed a two-tranche placement in which securities were sold to accredited U.S. investors and investors in Australia, Hong Kong, and New Zealand. In the first tranche on July 25, 2024, we issued 49,514,682 CDIs at $0.52 Australian dollars per CDI to investors in Australia, Hong Kong, and New Zealand. In the second tranche on September 5, 2024, we issued 17,550,154 CDIs at $0.52 Australian dollars per CDI to investors in Australia and New Zealand and 242,857 shares of common stock at $0.35 per share to accredited U.S. investors. We raised gross proceeds of $23,057,731. After deducting issuance costs of $1,266,522, we received net proceeds of $21,791,209.

On February 6, 2025, a total of 163,935 CDI options were exercised at an exercise price of $0.61 Australian dollars per CDI for total proceeds of $62,410. After deducting issuance costs of $991, we received net proceeds of $61,419.

On March 25, 2025, a total of 340,000 CDI options were exercised at an exercise price $0.61 Australian dollars per CDI for total proceeds of $130,842.

On March 27, 2025, we completed a placement in which securities were sold to investors in Australia. We issued 49,645,391 CDIs at $1.41 Australian dollars per CDI. We raised gross proceeds of $44,139,201. After deducting issuance costs of $1,311,624, we received net proceeds of $42,827,577.

On October 24, 2025, a total of 144,526 CDI options were exercised at an exercise price of $0.61 Australian dollars per CDI for total proceeds of $57,120. After deducting issuance costs of $960, we received net proceeds of $56,160.

Item 11. Description of Registrant's Securities to be Registered.

The following summary describes our capital stock, including our common stock being registered hereby. This summary does not purport to be complete and is qualified in its entirety by the provisions of our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws, copies of which have been filed as exhibits to this Registration Statement.

General

Our authorized capital stock consists of 535,000,000 shares of common stock, par value $0.0001 per share, and 25,000,000 shares of preferred stock, par value $0.0001 per share. Of the total shares of common stock authorized, 500,000,000 are classified as Class A common stock and 35,000,000 are classified as Class B common stock. We have no shares of preferred stock or Class B common stock outstanding.

In connection with our IPO certain of our stockholders were required by ASX to enter into an escrow agreement under which the stockholder agreed, among other things, to certain restrictions and prohibitions from engaging in transactions for a period of time. The Class A common stock shall automatically and without further action be converted into shares of Class B common stock, on a one-for-one basis, if the Board of Directors determines, in its sole discretion, that the stockholder breached or violated any term of such stockholder's escrow arrangement or breached the ASX Listing Rules relating to the restricted common stock. Any shares of Class A common stock converted to Class B common stock shall automatically and without further action be converted back into shares of Class A common stock, on a one-for-one basis, upon the earlier to occur of the expiration of the escrow period or the breach of the ASX Listing Rules relating to shares being remedied. All escrow periods have now expired, and no Class A common stock was, or will in the future, be converted to Class B common stock. Unless the context requires otherwise, all references to our common stock refer to our Class A common stock.

Common Stock

Outstanding Shares

As of April 21, 2026, we had 320,947,028 shares of Class A common stock outstanding.

Voting Rights

Each holder of Class A common stock is entitled to one vote for each share on each matter properly submitted to a vote of the stockholders, including the election of directors. Holders of Class B common stock have no voting rights except as otherwise required by law. Our stockholders do not have cumulative voting rights in the election of directors. For all matters submitted to a vote of the stockholders other than the election of directors, the affirmative vote of a majority of the shares present in person, by remote communication, or represented by proxy at the meeting and entitled to vote on the subject matter will be required to take such actions. Directors are elected by a plurality of the votes of the shares present in person, by remote communication, or represented by proxy at the meeting and entitled to vote generally on the election of directors.

Dividends

Subject to the rights of any preferred stock that may be issued from time to time, holders of Class A common stock are entitled to share, on a per share basis, in such dividends and other distributions of cash, property or shares as may be declared by our Board of Directors out of funds legally available. Holders of Class B common stock are not entitled to share in any dividends or other distributions of cash, property, or shares.

Liquidation

In the event of our liquidation, dissolution or winding up, and subject to the rights of any preferred stock that may be issued from time to time, holders of Class A and Class B common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after payment of all our debts and other liabilities.

Rights, Preferences, and Privileges

Holders of Class A common stock and Class B common stock have no preemptive, subscription, redemption, sinking fund, registration, or conversion rights. The rights, preferences, and privileges of holders of Class A and Class B common stock are subject to, and may be adversely affected by, the rights of holders of shares of any series of preferred stock that our Board of Directors may designate and issue in the future.

Fully Paid and Nonassessable

All outstanding shares of Class A common stock are fully paid and nonassessable.

Restrictions on Alienability

Under the Delaware General Corporation Law, shares are generally freely transferable subject to restrictions imposed by U.S. federal or state securities laws, by our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws, or by an agreement signed with the holders of the shares at issue. Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws do not impose any specific restrictions on transfer.

Anti-Discrimination Provisions

Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws do not contain provisions that discriminate against any existing or prospective holder of common stock as a result of such stockholder owning a substantial number of securities. All holders within a particular class of common stock have uniform voting, dividend, and liquidation rights regardless of the number of shares they own. However, we are subject to the provisions of Section 203 of the Delaware General Corporation Law, which may, unless certain criteria are met, prohibit certain interested stockholders (defined as stockholders owning 15% or more of our outstanding voting stock) from merging or engaging in various other business combinations with us for a prescribed period.

Listing

Our common stock is currently listed on the ASX, under the ticker “IMR”.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A., 150 Royall Street, Canton, Massachusetts 02021, United States. For holders of CDIs, the CDI registry is maintained by Computershare Investor Services Pty Limited, GPO Box 2975, Melbourne, Victoria 3001, Australia.

CDIs

In order for our shares of Class A common stock in the form of CHESS Depositary Interests (“CDIs”) to trade electronically on the Australian Securities Exchange (“ASX”), we participate in the electronic transfer system known as the Clearing House Electronic Subregister System (“CHESS”) operated by ASX Settlement Pty Limited (“ASX Settlement”). ASX Settlement provides settlement services for ASX markets to assist participants and issuers to understand the rules and procedures governing settlement facilities. The ASX Settlement Operating Rules form part of the overall listing and market rules which we are required to comply with as an entity listed on ASX.

CHESS is an electronic system which manages the settlement of transactions executed on ASX and facilitates the paperless transfer of legal title to ASX quoted securities. CHESS cannot be used directly for the transfer of securities of companies domiciled in certain jurisdictions outside of Australia, such as the United States. Accordingly, to enable our shares of Class A common stock to be cleared and settled electronically through CHESS, we have issued and will continue to issue depositary interests called CDIs.

CDIs confer upon the CDI holder the beneficial ownership in the shares of Class A common stock, with one CDI representing an interest in one share. The legal title to such shares is held by CHESS Depositary Nominees Pty Limited ("CDN"), a subsidiary of ASX Limited, which acts as our Australian depositary nominee and issues the CDIs. CDI holders are entitled to receive all direct economic and other benefits of the underlying shares of Class A common stock.

A holder of CDIs who does not wish to have their trades settled in CDIs may request that their CDIs be converted into shares of Class A common stock on a 1-for-1 basis, in which case legal title to the shares of Class A common stock will be transferred to the holder of CDIs.

There are a number of differences between holding CDIs and shares of Class A common stock. The major differences are that:

- CDI holders do not have legal title in the underlying shares of Class A common stock to which the CDIs relate (the legal title is held by CDN as summarized above); and
- CDI holders are not able to vote personally as stockholders at a meeting of Imricor. Instead, CDI holders are provided with a voting instruction form which enables them to instruct CDN in relation to the exercise of voting rights.

Alternatively, CDI holders can transmute their CDIs into shares of our common stock in sufficient time before the relevant meeting, in which case they will be able to vote personally as our stockholders.

Preferred Stock

Our Board of Directors is authorized to issue up to 25,000,000 shares of preferred stock in one or more series, to fix number of shares to be included in each series, and establish the voting powers, designation, preferences, and rights of each series and any of its qualifications, limitations, or restrictions, subject to the limitations of Delaware law and, to the extent applicable, the ASX Listing Rules. Our Board of Directors is also authorized to increase or decrease the number of shares in any series after issuance, provided that the number of shares does not fall below the outstanding shares of that series without any further vote or action by the Company's stockholders unless required by applicable law or the ASX Listing Rules. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring, discouraging, or preventing a change in control of Imricor and may adversely affect the market price of our common stock and the rights of the holders of common stock.

Anti-Takeover Provisions

Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws include a number of provisions that may deter or impede hostile takeovers or changes of control or management. These provisions include:

Issuance of undesignated preferred stock. Our Board of Directors is authorized to issue up to 25,000,000 shares of preferred stock in one or more series, to fix the number of shares to be included in each series, and establish the voting powers, designation, preferences, and rights of each series and any of its qualifications, limitations, or restrictions, subject to the limitations of Delaware law and, to the extent applicable, the ASX Listing Rules. The existence of authorized but unissued shares of preferred stock enables our Board of Directors to make it more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest, or otherwise.

Classified Board of Directors. Our Amended and Restated Certificate of Incorporation provides for a classified Board of Directors divided into three classes, with each class serving a three-year term. This staggered director election structure means that a majority of our Board of Directors cannot be replaced in any single annual meeting. This provision may discourage a potential acquiror from launching a proxy contest, since it would be difficult for the acquiror to obtain control of our Board of Directors without the cooperation of management.

Director Removal and Vacancy Provision. Our Certificate of Incorporation provides that directors may only be removed with cause by the affirmative vote of holders of at least 66 2/3% of our outstanding voting stock. Additionally, any vacancies on the Board of Directors are filled by majority vote of the remaining directors, not by stockholders. The number of directors constituting our Board of Directors may be set only by resolution adopted by a majority vote of the authorized number of directors. These provisions prevent a stockholder from increasing the size of our Board of Directors and gaining control of our Board of Directors by filling the resulting vacancies with its own nominees.

No Cumulative Voting. Our Amended and Restated Certificate of Incorporation does not provide for cumulative voting rights in the election of directors. Accordingly, stockholders do not have cumulative voting rights in the election of directors. This provision prevents a minority stockholder from accumulating votes and potentially electing one or more directors of its choosing.

Stockholder action; special meetings of stockholders. Our Amended and Restated Certificate of Incorporation provides that stockholders may only take action at annual or special meetings of stockholders and may not take action by written consent or electronic transmission. Additionally, special meetings of stockholders may only be called by the Chairperson of the Board, the Chief Executive Officer, or a majority of our Board of Directors. These restrictions prevent stockholders from taking action without the notice and procedural requirements of a stockholder meeting and limit the ability of a potential acquiror to take action with stockholder support without calling a stockholder meeting.

Advance notice requirements for stockholder proposals and director nominations. Our Amended and Restated Bylaws require stockholders to provide advance written notice (between 90 and 120 days before the anniversary of the preceding annual meeting of stockholders) of any proposals they intend to bring before an annual meeting of stockholders or any director nominees they intend to propose. These provisions may make it more difficult for our stockholders to bring matters before our annual meeting of stockholders or to nominate directors at annual meetings of stockholders.

Exclusive Forum Selection. Our Amended and Restated Certificate of Incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for: (1) any derivative action or proceeding brought on behalf of the Company; (2) any action asserting a claim of breach of a fiduciary duty owed by any director, officer, or other employee of the Company to the Company or the Company's stockholders; and (3) any action asserting a claim against the Company arising pursuant to any provision of the Delaware General Corporation Law, our Amended and Restated Certificate of Incorporation, or our Amended and Restated Bylaws. Stockholders are deemed to have consented to this sole and exclusive forum provision by purchasing or acquiring any interest in our capital stock. The exclusive forum provision does not apply to any actions brought to enforce a duty or liability created by the Securities Act, the Securities Exchange Act, or any other claim for which the U.S. federal courts have exclusive jurisdiction, nor does it prevent stockholders from bringing claims in any other forum to the extent permitted by applicable law. This provision may discourage certain stockholder challenges to business combinations or control transactions.

We designed these provisions to enhance the likelihood of continued stability in the composition of our Board of Directors and its policies, to discourage certain types of transactions that may involve an actual or threatened acquisition of us, and to reduce our vulnerability to an unsolicited acquisition proposal. We also designed these provisions to discourage certain tactics that may be used in proxy fights. However, these provisions could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our Board of Directors and management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the Delaware General Corporation Law ("DGCL"), which prohibits a Delaware corporation from engaging in a business combination with any interested stockholder for a period of three years following the time that such stockholder became an interested stockholder, unless:

- prior to such time the Board of Directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- at or subsequent to such time the business combination is approved by the Board of Directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

In general, Section 203 of the DGCL defines business combination to include the following:

- any merger or consolidation of the corporation or any subsidiary thereof and any other corporation, whether or not such other corporation is incorporated in the State of Delaware, involving the interested stockholder;
- any sale, lease, pledge, or other disposition (in one transaction or a series of transactions) of assets representing 10% or more of either (i) the aggregate market value of all assets of the corporation (determined on a consolidated basis) or (ii) the aggregate market value of all outstanding stock of the corporation, involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of any class or series of stock or securities of the corporation or any subsidiary thereof beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit, directly or indirectly, of any loans, advances, guarantees, pledges, or other financial benefits by or through the corporation.

In general, Section 203 of the DGCL defines an "interested stockholder" as an entity or person who, together with the entity's or person's affiliates and associates, beneficially owns, or is an affiliate of the corporation and within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation. A Delaware corporation may "opt out" of these provisions with an express provision in its certificate of incorporation. We have not opted out of these provisions, which may, as a result, discourage or prevent mergers or other takeover or change of control attempts of us.

Item 12. Indemnification of Directors and Officers.

General Corporation Law of the State of Delaware

Section 145(a) of the DGCL provides that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation) by reason of the fact that the person is or was a director, officer, employee, or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee, or agent of another corporation, partnership, joint venture, trust, or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit, or proceeding if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe the person's conduct was unlawful. The termination of any action, suit, or proceeding by judgment, order, settlement, conviction, or upon a plea of nolo contendere or its equivalent, shall not, of itself, create a presumption that the person did not act in good faith and in a manner which the person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that the person's conduct was unlawful.

Section 145(b) of the DGCL states that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending, or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that the person is or was a director, officer, employee, or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee, or agent of another corporation, partnership, joint venture, trust, or other enterprise against expenses (including attorneys' fees) actually and reasonably incurred by the person in connection with the defense or settlement of such action or suit if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation and except that no indemnification shall be made in respect of any claim, issue, or matter as to which the person shall have been adjudged to be liable to the corporation unless and only to the extent that the Delaware Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, the person is fairly and reasonably entitled to indemnity for such expenses as the Delaware Court of Chancery or such other court shall deem proper.

Section 145(c) of the DGCL provides that to the extent that a present or former director or officer of a corporation has been successful on the merits or otherwise in defense of any action, suit, or proceeding referred to in subsections (a) and (b) of Section 145, or in defense of any claim, issue, or matter therein, such person shall be indemnified against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection therewith.

Section 145(d) of the DGCL states that any indemnification under subsections (a) and (b) of Section 145 (unless ordered by a court) shall be made by the corporation only as authorized in the specific case upon a determination that indemnification of the present or former director, officer, employee, or agent is proper in the circumstances because the person has met the applicable standard of conduct set forth in subsections (a) and (b) of Section 145. Such determination shall be made with respect to a person who is a director or officer at the time of such determination (1) by a majority vote of the directors who are not parties to such action, suit or proceeding, even though less than a quorum, (2) by a committee of such directors designated by majority vote of such directors, even though less than a quorum, (3) if there are no such directors, or if such directors so direct, by independent legal counsel in a written opinion or (4) by the stockholders.

Section 145(f) of the DGCL states that the indemnification and advancement of expenses provided by, or granted pursuant to, the other subsections of Section 145 shall not be deemed exclusive of any other rights to which those seeking indemnification or advancement of expenses may be entitled under any bylaw, agreement, vote of stockholders or disinterested directors, or otherwise, both as to action in such person's official capacity and as to action in another capacity while holding such office.

Section 145(g) of the DGCL provides that a corporation shall have the power to purchase and maintain insurance on behalf of any person who is or was a director, officer, employee, or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee, or agent of another corporation, partnership, joint venture, trust, or other enterprise, against any liability asserted against such person and incurred by such person in any such capacity or arising out of such person's status as such, whether or not the corporation would have the power to indemnify such person against such liability under the provisions of Section 145.

Section 145(j) of the DGCL states that the indemnification and advancement of expenses provided by, or granted pursuant to, Section 145 shall, unless otherwise provided when authorized or ratified, continue as to a person who has ceased to be a director, officer, employee, or agent and shall inure to the benefit of the heirs, executors and administrators of such a person.

Section 102(b)(7) of the DGCL permits a corporation to provide in its certificate of incorporation that a director or officer of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director or an officer, except for liability for any breach of the director's or officer's duty of loyalty to the corporation or its stockholders, for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, for unlawful payments of dividends or unlawful stock purchases or redemptions in the case of a director, for any transaction from which the director or officer derived an improper personal benefit or in the case of an officer any action by or in the right of the corporation. No such provision shall eliminate or limit the liability of a director or officer for any act or omission occurring prior to the date when such provision becomes effective.

Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

As permitted under Delaware law, Imricor indemnifies certain officers and directors for certain events or occurrences that happen by reason of their relationship with, or position held at, Imricor. The Company's Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws provide for the indemnification of its directors, officers, employees, and other agents to the maximum extent permitted by Delaware General Corporation Law.

Indemnification Agreements

Imricor has entered into indemnification agreements with its directors and certain officers to this effect, including advancement of expenses incurred in legal proceedings to which the director or officer was, or is threatened to be made, a party by reason of the fact that such director or officer is or was a director, officer, employee, or agent of Imricor, provided that such director or officer acted in good faith and in a manner that the director or officer reasonably believed to be in, or not opposed to, the Company's best interests.

Insurance Policy

We have purchased an insurance policy that purports to insure our directors and officers against certain liabilities incurred by them in the discharge of their functions as directors and officers.

The foregoing description of Section 145 of the DGCL, Section 102(b)(7) of the DGCL, our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws is only a summary and is qualified in its entirety by the full text of each of the foregoing.

We have been advised that it is the position of the SEC that insofar as the foregoing provisions may be invoked to disclaim liability for damages arising under the Securities Act, that such provisions are against public policy as expressed in the Securities Act and are therefore unenforceable.

Item 13. Financial Statements and Supplementary Data.

INDEX TO FINANCIAL STATEMENTS

Audited Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Imricor Medical Systems, Inc. (the "Company") as of December 31, 2025 and 2024, the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2025, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BDO USA, P.C.

We have served as the Company's auditor since 2022.

Minneapolis, Minnesota

February 24, 2026

IMRICOR MEDICAL SYSTEMS, INC.
CONSOLIDATED BALANCE SHEETS
As of December 31, 2025 and 2024

	2025	2024
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 19,502,348	$ 15,707,739
Marketable securities	21,277,609	-
Accounts receivable	240,866	345,342
Inventory	1,096,065	1,502,048
Prepaid expenses and other current assets	799,786	794,308
Total Current Assets	42,916,674	18,349,437
ACCOUNTS RECEIVABLE, LONG TERM	95,673	141,430
PROPERTY AND EQUIPMENT, NET	1,538,460	1,878,751
INVENTORY, LONG TERM	415,383	327,721
OTHER ASSETS	186,291	208,212
OPERATING LEASE RIGHT OF USE ASSETS	604,256	718,379
TOTAL ASSETS	$ 45,756,737	$ 21,623,930
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 496,073	$ 334,870
Accrued expenses	1,619,954	1,493,095
Current portion of convertible notes (related party)	11,745,700	-
Option liabilities	3,157,717	-
Current portion of contract liabilities	34,035	59,519
Current portion of operating lease liabilities	317,153	259,292
Current portion of financing obligation	-	209,137
Total Current Liabilities	17,370,632	2,355,913
LONG-TERM LIABILITIES		
Convertible notes, net of current portion (related party)	13,268,500	19,869,700
Option liabilities	-	3,135,000
Warrant liabilities	1,828,677	1,532,067
Contract liabilities, net of current portion	1,085,753	1,098,533
Operating lease liabilities, net of current portion	634,043	875,553
Other long-term liabilities	45,828	134,197
Total Liabilities	34,233,433	29,000,963
COMMITMENTS AND CONTINGENCIES (NOTE 6)		
STOCKHOLDERS' EQUITY (DEFICIT)		
Preferred stock, $0.0001 par value: 25,000,000 shares authorized and 0 shares outstanding as of both December 31, 2025 and 2024	-	-
Common stock, $0.0001 par value: 535,000,000 shares authorized as of both December 31, 2025 and 2024 and 320,947,028 and 270,175,766 shares issued and outstanding as of December 31, 2025 and 2024, respectively	32,096	27,018
Additional paid-in capital	179,089,487	134,875,666
Accumulated deficit	(167,598,279)	(142,279,717)
Total Stockholders' Equity (Deficit)	11,523,304	(7,377,033)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 45,756,737	$ 21,623,930

See accompanying notes to the consolidated financial statements

IMRICOR MEDICAL SYSTEMS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
For the Years Ended December 31, 2025 and 2024

	2025	2024
REVENUES	$ 292,309	$ 959,424
COSTS AND EXPENSES		
Cost of goods sold	2,325,837	1,883,542
Sales and marketing	4,300,264	2,272,044
Research and development	11,155,766	8,180,184
General and administrative	5,301,396	4,920,466
Total Costs and Expenses	23,083,263	17,256,236
LOSS FROM OPERATIONS	(22,790,954)	(16,296,812)
OTHER INCOME (EXPENSE)		
Interest income	1,180,294	257,718
Government grant income	658,546	325,332
Foreign currency exchange gain	1,509,925	197,867
Interest expense	(4,169)	(20,065)
Change in fair value of convertible notes (related party)	(5,144,500)	(11,416,400)
Change in fair value of option liabilities	(396,491)	(1,842,240)
Change in fair value of warrant liabilities	(296,610)	(879,551)
Other Expense	(34,603)	(18,680)
Total Other Income (Expense)	(2,527,608)	(13,396,019)
NET LOSS	$ (25,318,562)	$ (29,692,831)
EARNINGS PER SHARE:		
Basic and diluted loss per common share	$ (0.08)	$ (0.13)
Basic and diluted weighted average shares outstanding	308,748,911	223,999,081

See accompanying notes to the consolidated financial statements

IMRICOR MEDICAL SYSTEMS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
For the Years Ended December 31, 2025 and 2024

	Common Stock		Additional	Accumulated	Total Stockholders'
	Shares	Amount	Paid-in Capital	Deficit	Equity (Deficit)
BALANCES, December 31, 2023	168,918,134	$ 16,893	$ 103,816,628	$ (112,586,886)	$ (8,753,365)
Stock-based compensation expense	-	-	68,769	-	68,769
Issuance of common stock and restricted stock, net of issuance costs of $1,905,897	101,257,632	10,125	30,990,269	-	31,000,394
Net loss	-	-	-	(29,692,831)	(29,692,831)
BALANCES, December 31, 2024	270,175,766	$ 27,018	$ 134,875,666	$ (142,279,717)	$ (7,377,033)
Stock-based compensation expense	-	-	589,611	-	589,611
Issuance of common stock and restricted stock, net of issuance costs of $1,313,030	49,766,651	4,977	42,821,194	-	42,826,171
Exercise of options, net of issuance costs of $3,866	1,004,611	101	803,016	-	803,117
Net loss	-	-	-	(25,318,562)	(25,318,562)
BALANCES, December 31, 2025	320,947,028	$ 32,096	$ 179,089,487	$ (167,598,279)	$ 11,523,304

See accompanying notes to the consolidated financial statements

IMRICOR MEDICAL SYSTEMS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
For the Years Ended December 31, 2025 and 2024

	2025	2024
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (25,318,562)	$ (29,692,831)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation and amortization	798,715	748,165
Stock-based compensation expense	589,611	68,769
Loss (gain) on disposal of property and equipment	25,673	(2,423)
Change in inventory reserves	400,167	60,866
Amortization of right-of-use assets	196,542	172,872
Services performed in exchange for property and equipment	-	(100,000)
Foreign currency exchange gain	(1,509,925)	(197,867)
Change in fair value of convertible notes (related party)	5,144,500	11,416,400
Change in fair value of option liabilities	396,491	1,842,240
Change in fair value of warrant liabilities	296,610	879,551
Changes in assets and liabilities		
Accounts receivable	151,580	66,277
Inventory	(129,846)	453,877
Prepaid expenses and other assets	16,443	210,586
Accounts payable and other liabilities	41,739	(1,746,136)
Accrued expenses	126,859	702,373
Lease liabilities	(269,490)	(237,019)
Contract liabilities	(38,264)	(219,610)
Net Cash Flows used in Operating Activities	(19,081,157)	(15,573,910)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(434,287)	(77,976)
Proceeds from sale of property and equipment	-	3,000
Purchases of marketable securities	(28,683,359)	-
Proceeds from maturity of marketable securities	7,405,750	-
Net Cash Flows used in Investing Activities	(21,711,896)	(74,976)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of common stock and restricted stock	44,139,201	32,906,291
Issuance costs of common stock and restricted stock	(1,313,030)	(1,905,897)
Proceeds from exercise of options, net of expenses	429,343	-
Payment on promissory note	-	(386,452)
Payments on finance lease liability	-	(65,999)
Proceeds from financing obligation	-	344,050
Payments on financing obligation	(209,137)	(557,779)
Net Cash Flows provided by Financing Activities	43,046,377	30,334,214
Net change in cash and cash equivalents	2,253,324	14,685,328
Cash and cash equivalents - beginning of year	15,707,739	831,522
Effect of foreign currency exchange rate changes on cash and cash equivalents	1,541,285	190,889
Cash and cash equivalents - end of year	$ 19,502,348	$ 15,707,739
Supplemental cash flow disclosure		
Cash paid for interest	$ 4,169	$ 22,855
Noncash investing and financing activities		
Transfer from inventory to property and equipment	$ 48,000	$ 175,207
Property and equipment obtained in exchange for services	$ -	$ 100,000
Property and equipment included in accounts payable	$ 1,810	$ -
Operating lease right of use assets in exchange for operating lease liability	$ 82,419	$ -
Fair value adjustment for for liability-classified options and warrants exercised	$ 373,774	$ -

See accompanying notes to the consolidated financial statements

NOTE 1 – Summary of Significant Accounting Policies

Nature of Operations and Basis of Presentation

Imricor Medical Systems, Inc. is a U.S.-based medical device company that, along with its wholly-owned subsidiary, Imricor B.V. (together, "Imricor" and the "Company"), seeks to address the current issues with traditional x-ray-guided ablation procedures through the development of Magnetic Resonance Imaging ("MRI") guided technology. Incorporated in the State of Delaware in 2006, the Company's principal focus is the design, manufacturing, sale, and distribution of MRI-compatible products for use in Interventional Cardiac Magnetic Resonance ("iCMR") guided ablation procedures. Imricor's technology utilizes an intellectual property ("IP") portfolio that includes technology developed in-house, as well as IP originating from Johns Hopkins University, Koninklijke Philips N.V., and livetec Ingenieurbuero, GmbH. The Company is headquartered in Burnsville, Minnesota, where it has development and manufacturing facilities. The Company's primary product offering is the Vision-MR Ablation Catheter, which is specifically designed to work under real-time MRI guidance, with the intent of enabling higher success rates along with a faster and safer treatment compared to conventional procedures using x-ray guided catheters. Historically, Imricor generated revenue from licensing some of its IP for use in implantable devices and performing contract research but expects to generate most of its future revenue from the sale of the MRI-compatible products it has developed for use in cardiac catheter ablation procedures (comprising single-use consumables and capital equipment). The Company has obtained CE mark approval to place its key products on the market in the European Union under the European Union's Medical Device Regulation ("EU MDR"), including the Advantage-MR EP Recorder/Stimulator System, Vision-MR Ablation Catheter, Vision-MR Diagnostic Catheter, and NorthStar Mapping System.

The Company has prepared the accompanying consolidated financial statements and notes in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The consolidated financial statements include the accounts of Imricor Medical Systems, Inc. and its wholly-owned subsidiary, Imricor B.V. All intercompany transactions and balances have been eliminated in consolidation.

The Company's consolidated financial statements and notes are presented in United States dollars, unless otherwise noted, which is also the functional currency.

Cash and Cash Equivalents

Cash and cash equivalents consist of funds in depository accounts, money market funds, and time deposits. The Company considers cash invested in highly liquid financial instruments with original maturities of three months or less at the date of purchase to be cash equivalents. The Company holds cash with high quality financial institutions and, at times, such balances are in excess of federal insurance limits.

Cash and cash equivalents consisted of the following as of December 31:

	2025	2024
Cash and cash equivalents		
Cash	$ 1,637,496	$ 517,765
Money market funds	7,472,940	14,251,177
Time deposits	10,391,912	938,797
Total cash and cash equivalents	$ 19,502,348	$ 15,707,739

NOTE 1 – Summary of Significant Accounting Policies (cont.)

Marketable Securities

The Company's marketable securities consist of investments in U.S. Treasury bills with original maturities greater than three months from the date of purchase. These securities are classified as held-to-maturity debt securities because the Company has the positive intent and ability to hold them to maturity. Held-to-maturity securities are recorded at amortized cost, adjusted for any allowance for credit losses, with securities having remaining maturities of less than one year classified as current on the consolidated balance sheets.

The Company evaluates held-to-maturity securities for expected credit losses using a qualitative assessment methodology. As of December 31, 2025, no allowance for credit losses was required. U.S. Treasury bills are backed by the full faith and credit of the U.S. government and are considered to have minimal credit risk.

The Company excludes accrued interest from the amortized cost basis of held-to-maturity debt securities. Accrued interest totaled $117,949 as of December 31, 2025. Accrued interest is included in prepaid expenses and other current assets on the consolidated balance sheets. The Company recognizes interest income through accretion of the discount from the purchase price to par value over the holding period. Discount accretion is recognized in interest income on the consolidated statements of operations.

The following table summarizes the gross unrealized gains and losses related to the Company's held-to-maturity marketable securities as of and for the year ended December 31:

	2025			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized (losses)	Fair Value
Marketable securities				
U.S. Treasury bills	$ 21,277,609	$ 98,006	$ -	$ 21,375,615
Total marketable securities	$ 21,277,609	$ 98,006	$ -	$ 21,375,615

The Company held no marketable securities as of December 31, 2024. Fair value is measured using Level 2 inputs (prices for similar assets or liabilities that are directly or indirectly observable in the marketplace). All held-to-maturity U.S. Treasury bills had remaining maturities of less than one year as of December 31, 2025. Purchases and maturities of held-to-maturity securities are presented within cash flows from investing activities in the consolidated statements of cash flows.

Accounts Receivable and Customer Concentrations

Accounts receivable are unsecured, are recorded net of amounts expected for credit losses, and do not bear interest except if a revenue transaction has a significant financing component. The Company reviews the allowance for credit losses by considering factors such as historical experience, current economic conditions that may affect a customer's ability to pay, and reasonable and supportable forecasts. Payment is generally due 30 days from the invoice date. When all collection efforts have been exhausted, the account is written off against the related allowance. To date the Company has not experienced any significant write-offs or significant deterioration of its accounts receivable aging, and therefore, no allowance for credit losses was considered necessary as of December 31, 2025 or 2024.

As of December 31, 2025 and 2024, the Company had total current and long-term accounts receivable of $336,539 and $486,772, respectively, of which $95,673 and $141,430 was included in long-term accounts receivable as of December 31, 2025 and 2024, respectively. Accounts receivable includes unbilled receivables of $45,757 and $44,424 as of December 31, 2025 and 2024, respectively, which represents the current portion of minimum royalties due to the Company during the following year. The long-term accounts receivable relates to minimum royalties due to the Company beyond twelve months from the respective balance sheet date.

NOTE 1 – Summary of Significant Accounting Policies (cont.)

The following table sets forth information related to accounts receivable for the years ended December 31:

	2025	2024
Balance at January 1	$ 486,772	$ 578,411
Decrease from accounts receivable collected	(189,855)	(396,445)
Increase for accounts receivable not yet collected	39,622	304,806
Balance at December 31	$ 336,539	$ 486,772

During the year ended December 31, 2025, the Company had sales from 2 customers that accounted for 40% and 39% of revenue and accounts receivable from 3 customers that represented 65%, 19%, and 15% of the accounts receivable balance. During the year ended December 31, 2024, the Company had sales from 4 customers that accounted for 19%, 17%, 16%, and 15% of revenue and accounts receivable from 4 customers that represented 45%, 17%, 13%, and 12% of the accounts receivable balance.

Inventory

Inventories are stated at the lower of cost or net realizable value, with cost determined on the first-in, first-out ("FIFO") method. The establishment of allowances for excess and obsolete inventories is based on historical usage and estimated exposure on specific inventory items. Inventories are as follows:

	2025	2024
Inventory - Current Portion		
Raw materials	$ 292,566	$ 501,766
Work in process	103,215	228,396
Finished goods	700,284	771,886
Total Inventory - Current Portion	1,096,065	1,502,048
Inventory - Long-term		
Raw materials	415,383	231,721
Finished goods	-	96,000
Total Inventory - Long-term	415,383	327,721
Total Inventory	$ 1,511,448	$ 1,829,769

The Company utilizes significant estimates in determining the realizable value of its inventory, including the future revenue forecasts that will result in product sales. These estimates have a corresponding impact on the inventory values recorded as of December 31, 2025 and 2024. Management continually evaluates the likelihood of future sales based on current economic conditions, expiration timing of products, and product design changes prior to sale of product on hand. If actual conditions are less favorable than those the Company has projected, it may need to increase its reserves for excess and obsolete inventories. Any increases in the Company's reserves will adversely impact its results of operations. The establishment of a reserve for excess and obsolete inventory establishes a new cost basis in the inventory. Future sales of inventory on hand at December 31, 2025 will result in recognition of cost of sales based on initial inventory costs, net of reserves taken for expected realization values. For the years ended December 31, 2025 and 2024, the Company recorded inventory reserves of $400,167 and $60,866, respectively.

NOTE 1 – Summary of Significant Accounting Policies (cont.)

Property and Equipment

Property and equipment are stated at cost. Additions and improvements that extend the lives of assets are capitalized, while expenditures for repairs and maintenance are expensed as incurred. Depreciation is computed using the straight-line method over the estimated useful lives of the assets. Amortization of leasehold improvements is computed on a straight-line basis over the shorter of the estimated useful lives of the related assets or life of the lease.

The standard estimated useful lives of property and equipment are as follows:

	Years
Office furniture and equipment	5
Lab and production equipment	5
Computer equipment	3 - 5
MRI scanner	7
Leasehold improvements	Lesser of useful life or remaining lease term

The Company reviews property and equipment and right of use assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If the impairment tests indicate that the carrying value of the asset, or asset group, is greater than the expected undiscounted cash flows to be generated by such asset or asset group, further analysis is performed to determine the fair value of the asset or asset group. To the extent the fair value of the asset or asset group is less than its carrying value, an impairment loss is recognized equal to the amount the carrying value of the asset or asset group exceeds its fair value. The Company generally measures fair value by considering sale prices for similar assets or asset groups, or by discounting estimated future cash flows from such assets or asset groups using an appropriate discount rate. Considerable management judgment is necessary to estimate the fair value of assets or asset groups, and accordingly, actual results could vary significantly from such estimates. Assets to be disposed of would be reported at the lower of the carrying amount or fair value less costs to sell. To date, the Company has not recognized any impairment loss for property and equipment and right of use assets.

Leases

At the inception of a contract, the Company determines whether the contract is or contains a lease based on all relevant facts and circumstances. Leases with a term greater than 12 months are recognized in the consolidated balance sheets as right of use ("ROU") assets and corresponding current and non-current lease liabilities. Amounts expected to be paid within 12 months are classified as current lease liabilities, with the remainder classified as non-current lease liabilities. The Company has elected not to recognize leases with terms of 12 months or less on the consolidated balance sheets. Lease payments for short-term leases are recognized as an expense on a straight-line basis over the lease term. The Company includes lease option extensions in the assessment of the lease arrangement when it is reasonably certain the option will be exercised.

ROU assets and the corresponding lease liabilities are recorded based on the present value of lease payments to be made over the lease term. The discount rate used to calculate the present value is the rate implicit in the lease, or if not readily determinable, the Company's incremental borrowing rate. The Company's incremental borrowing rate is the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term, an amount equal to the lease payments in a similar economic environment. Certain adjustments to the ROU asset may be required for items such as initial direct costs or incentives received. See Note 5 for additional disclosure on leases.

For all asset classes of its leases, the Company has elected to account for the lease and non-lease components together for all classes of underlying assets.

NOTE 1 – Summary of Significant Accounting Policies (cont.)

Research and Development Costs

The Company expenses research and development costs as incurred.

Nonmonetary Transaction

The Company had a nonmonetary exchange with a vendor whereby the vendor provided equipment to the Company in exchange for space to display the vendor's product at the Company's booths at two tradeshows during the year ended December 31, 2024. The Company is using the equipment for research and development activities. The transaction was recorded with an addition of $100,000 to Property and equipment on the consolidated balance sheets and an equal reduction to sales and marketing expense on the consolidated statements of operations.

Other Assets

Other assets on the consolidated balance sheets include security deposits related to the Company's operating leases, an equity investment, a derivative asset, and a prepaid expense. The balance is made up of the following as of December 31:

	December 31, 2025	December 31, 2024
Security deposit	$ 60,488	$ 52,597
Equity investment	69,560	69,560
Derivative asset	56,243	56,243
Prepaid expense	-	29,812
	$ 186,291	$ 208,212

The equity investment of $69,560 is held at cost. There have been no impairment losses or observable price changes recognized for the years ended December 31, 2025 and 2024.

Patents

Expenditures for patent costs are charged to operations as incurred.

Income Taxes

Income taxes are recorded under the liability method. Deferred income taxes are provided for temporary differences between financial reporting and tax bases of assets and liabilities. Deferred tax assets are reduced by a valuation allowance to the extent the realization of the related deferred tax asset is not assured.

The Company recognizes the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting the more-likely-than not threshold, the amount recognized in the consolidated financial statements is the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement with the relevant tax authority.

Loss per Share

Basic loss per share is computed by dividing net loss by the weighted average shares outstanding during the reporting period. The weighted average common shares outstanding were 308,748,911 and 223,999,081 for the years ended December 31, 2025 and 2024, respectively.

NOTE 1 – Summary of Significant Accounting Policies (cont.)

Dilutive net income (loss) per share assumes the exercise and issuance of all potential common stock equivalents in computing the weighted-average number of common shares outstanding, unless their effect is antidilutive. The computation of dilutive net income (loss) per share attributable to common stockholders assumes the potential dilutive effect of potential common stock, which includes common stock consisting of (a) stock options and warrants using the treasury stock method, and (b) convertible notes using the if-converted method. The effects of including incremental shares associated with stock options, warrants, and convertible notes outstanding are anti-dilutive due to the net loss incurred and are not included in the diluted weighted average number of shares of common stock outstanding for the years ended December 31, 2025 and 2024.

The table below provides potentially dilutive securities not included in the calculation of the diluted net loss per share for the years ended December 31 because to do so would be anti-dilutive:

	2025	2024
Exercise of stock options	38,959,160	31,255,170
Conversion of convertible notes (related party)	24,763,181	22,427,625
Exercise of warrants	5,216,158	5,216,158
Total	68,938,499	58,898,953

Foreign Currency Exchange Gains (Losses)

As of December 31, 2025, the Company had cash accounts denominated in Euros and Australian dollars, accounts payable that are denominated in Australian dollars and Euros, lease liabilities denominated in Euros, and accounts receivable denominated in Euros and Hungarian forint. As of December 31, 2024, the Company had cash accounts denominated in Euros and Australian dollars, accounts payable that were denominated in Australian dollars, Euros, and Hungarian forint, lease liabilities denominated in Euros, and accounts receivable denominated in Euros and Hungarian forint. These assets and liabilities have been remeasured into U.S. dollars at year-end exchange rates. Foreign currency exchange gains of $1,509,925 and $197,867 for the years ended December 31, 2025 and 2024, respectively, are included in the consolidated statements of operations within other expense.

The increase in foreign currency exchange gain for the year ended December 31, 2025 compared to the year ended December 31, 2024 primarily reflects the effect of changes in the Australian dollar exchange rate on the Company's cash balances denominated in that currency. Consistent with this, the effect of foreign currency exchange rate changes on cash and cash equivalents reported in the consolidated statements of cash flows was $1,541,285 for the year ended December 31, 2025; this amount includes $819,371 of realized gains as of December 31, 2025.

Revenue Recognition

In order for an arrangement to be considered a contract, it must be probable that the Company will collect the consideration to which it is entitled for goods or services to be transferred. The Company then assesses the goods or services promised within the contract to determine whether each promised good or service is a performance obligation. Performance obligations are promises in a contract to transfer a distinct good or service to the customer that (i) the customer can benefit from on its own or together with other readily available resources, and (ii) is separately identifiable from other promises in the contract.

The Company determines the transaction price based on the amount of consideration the Company expects to receive for providing the promised goods or services in the contract. Consideration may be fixed, variable, or a combination of both.

NOTE 1 – Summary of Significant Accounting Policies (cont.)

At contract inception for arrangements that include variable consideration, the Company estimates the probability and extent of consideration it expects to receive under the contract utilizing either the most likely amount method or expected amount method, whichever best estimates the amount expected to be received. The Company then considers any constraints on the variable consideration and includes in the transaction price variable consideration to the extent it is deemed probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

The Company's product revenue is derived from sales of both capital equipment and single-use consumables used in iCMR-guided cardiac ablation procedures. Capital equipment includes the Company's systems such as the Advantage-MR EP Recorder/Stimulator System and NorthStar Mapping System as well as related third-party equipment, while consumables primarily comprise the Company's catheters, including the Vision-MR Ablation Catheter and Vision-MR Diagnostic Catheter, and related accessories.

For equipment and consumable product sales that contain a single performance obligation, the Company recognizes revenue when control is transferred to the customer. This occurs at a point in time when title to the goods and risk of loss transfers. The transaction price is based on invoice price, net of any variable consideration.

When accounting for a contract that contains multiple performance obligations, the Company must develop judgmental assumptions to determine the estimated standalone selling price ("SSP") for each performance obligation identified in the contract. The Company utilizes the observable SSP when available, which represents the price charged for the promised product or service when sold separately. When the SSP for the Company's products or services are not directly observable, the Company determines the SSP using relevant information available and applies suitable estimation methods including, but not limited to, the cost-plus margin approach. The Company then allocates the transaction price to each performance obligation based on the relative SSP and recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) control is transferred to the customer and the performance obligation is satisfied.

Revenue from service contracts is recognized over the contract period on a straight-line basis, as the customer benefits from the services throughout the service contract period.

Revenue is derived from both domestic and foreign countries. Sales tax and value added taxes in foreign jurisdictions that are collected from customers and remitted to governmental authorities are accounted for on a net basis and therefore are excluded from net sales. Product sales include shipment and handling fees charged to customers. Shipping and handling costs associated with outbound freight after control over a product has transferred to a customer are accounted for as a fulfillment cost and are included in cost of goods sold.

As of December 31, 2025, $129,794 of a contract's transaction price was allocated to an unsatisfied performance obligation. The Company expects to recognize the revenue related to these performance obligations during 2026.

Royalties

On June 1, 2012, the Company licensed certain intellectual property to a customer which included a royalty of 3% of product sales, subject to a minimum of $50,000 per year through 2028. The minimum guaranteed royalties were recognized upon the execution of the license agreement as these proceeds were not variable consideration. The remaining minimum royalty payments to be received, less the portion which represents future interest expected to be received within 12 months is included in Accounts receivable and the amounts expected to be received in future periods beyond 12 months are included in Accounts receivable, long term. Any royalties received in the future which are more than the minimum guaranteed royalty will be recognized when they are earned.

NOTE 1 – Summary of Significant Accounting Policies (cont.)

Consulting Revenue

The Company recognizes revenue for consulting over time using the "as invoiced" practical expedient, except for in certain instances where billings are made in advance of the satisfaction of performance obligations.

The Company did not recognize any consulting revenue during the year ended December 31, 2025. During the year ended December 31, 2024, the Company recognized consulting revenue of $115,749, including $60,000 related to work performed to develop a prototype version of the Company's catheter that is compatible with a GE Healthcare MRI system and $55,749 related to work performed with a research institution utilizing the Company's MRI scanner.

Contract Liabilities

In 2013, the Company licensed certain intellectual property to a customer in exchange for an upfront non-refundable license fee and milestone payments, which can total up to $7,000,000. The Company collected $6,000,000 of these milestone payments, including the non-refundable license fee, on or before October 2016. A total of $373,333 of this amount is deferred as of December 31, 2025 and 2024. The customer sold the portion of the business which held this license in May 2018, and the license has been assigned to the purchaser. The project is still on hold with no plans to work on final development during the next 12 months, and therefore, the contract liability is included in long-term liabilities as of December 31, 2025 and 2024.

The Company invoices its customers for product revenue and consulting revenue based on the billing schedules in its sales arrangements. Service contracts are billed in advance, prior to the services having been performed, and the associated deferred revenue is recognized over the term of the service contract period.

Amounts received prior to satisfying the above revenue recognition criteria are recorded as contract liabilities in the accompanying consolidated balance sheets, with the contract liabilities to be recognized beyond one year being classified as non-current contract liabilities. As of December 31, 2025 and 2024, the Company had total current and long-term contract liabilities of $1,119,788 and $1,158,052, respectively, of which $1,085,753 and $1,098,533 was included in long-term liabilities as of December 31, 2025 and 2024, respectively. As of December 31, 2025, the Company expects to recognize the balance included in long-term liabilities at an indeterminable time. The decrease in contract liabilities is due to recognition of revenue for completion of performance obligations that were included in contract liabilities at the beginning of the period.

The following table sets forth information related to the contract liabilities for the years ended December 31:

	2025	2024
Balance at January 1	$ 1,158,052	$ 1,377,662
Decrease from revenue recognized for completion of performance obligations that were included in contract liabilities at the beginning of the period included in:		
Product revenue	-	(166,046)
Service revenue	(49,529)	(24,879)
Consulting revenue	-	(55,749)
Increase for revenue deferred as the performance obligation has not been satisfied related to:		
Service revenue	11,265	27,064
Balance at December 31	$ 1,119,788	$ 1,158,052

NOTE 1 – Summary of Significant Accounting Policies (cont.)

Derivative Asset, Option Liabilities, and Warrant Liabilities

The Capital Commitment Agreement ("Agreement") with GEM Global Yield LLC SCS ("GGY") (discussed further in Note 9) meets the definition of a derivative and was recorded upon issuance within other assets on the consolidated balance sheets at fair value. The derivative asset is revalued at each balance sheet date, with changes in fair value recorded on the consolidated statements of operations as other income or expense. The Company estimates the fair value of the asset using the Monte Carlo Simulation model.

Also in connection with the Agreement with GGY, the Company issued 5,700,000 options which were determined to qualify as liabilities in accordance with Accounting Standards Codification ("ASC") 480-10, Distinguishing Liabilities from Equity and ASC 815-40, Derivatives and Hedging. Additionally, the Company issued warrants in connection with the equity raises in August and October 2023 (Note 10), where 2,100,568 warrants were determined to qualify as liabilities due to the exercise price being denominated in a currency other than the Company's functional currency. The result of this accounting treatment is that the options and warrants are recorded upon issuance as a liability on the consolidated balance sheets at fair value and are revalued at each balance sheet date, with the change in fair value recorded in the consolidated statements of operations as other income or expense. The Company estimates the fair value of the liability using the Black-Scholes pricing model.

See **Notes 9 and 10** for further details and assumptions used in the Black-Scholes pricing model and Monte Carlo Simulation model.

S*tock-Based Compensation*

The Company measures and records compensation expense using the applicable accounting guidance for share-based payments related to equity awards granted to directors and employees. The fair value of stock options, including performance awards, without a market condition is estimated at the date of grant, using the Black-Scholes option-pricing model. The fair value of stock options with a market condition is estimated at the date of grant using the Monte Carlo Simulation model. The Black-Scholes and Monte Carlo Simulation valuation models incorporate assumptions as to stock price volatility, the expected life of options or awards, a risk-free interest rate, and dividend yield.

The Company's policy is to account for forfeitures as they occur and compensation expense is recognized on a straight-line basis over the vesting period for awards with service and market conditions; for awards with performance conditions, expense is recognized over the requisite service period for awards for which the performance condition is considered probable of being achieved. Compensation expense is recognized for all awards over the vesting period to the extent the employees or directors meet the requisite service requirements, whether or not the award is ultimately exercised. Conversely, when an employee or director does not meet the requisite service requirements and forfeits the award prior to vesting, any compensation expense previously recognized for the award is reversed.

See **Note 10** for further details and assumptions used in the Black-Scholes pricing model.

Fair Value Measurement

ASC 820, Fair Value Measurements, ("ASC 820") provides guidance on the development and disclosure of fair value measurements. Under this accounting guidance, fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability.

NOTE 1 – Summary of Significant Accounting Policies (cont.)

The accounting guidance classifies fair value measurements in one of the following three categories for disclosure purposes:

Level 1: Quoted prices in active markets for identical assets or liabilities.
Level 2: Inputs other than Level 1 prices for similar assets or liabilities that are directly or indirectly observable in the marketplace.
Level 3: Unobservable inputs which are supported by little or no market activity and values determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

The Company evaluates assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level at which to classify them for each reporting period. This determination requires significant judgments to be made by the Company.

The carrying value of financial assets and liabilities recorded at fair value is measured on a recurring or nonrecurring basis. Financial assets and liabilities measured on a non-recurring basis are those that are adjusted to fair value when a significant event occurs. The Company had no financial assets or liabilities carried and measured on a nonrecurring basis during the reporting periods. Financial assets and liabilities measured on a recurring basis are those that are adjusted to fair value each time a consolidated financial statement is prepared. The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis, based on the fair value hierarchy:

	As of December 31, 2025			
	Level 1	Level 2	Level 3	Total
Other Assets				
Derivative asset	$ -	$ -	$ 56,243	$ 56,243
Total Other Assets	$ -	$ -	$ 56,243	$ 56,243
Current Liabilities				
Current portion of convertible notes (related party)	$ -	$ -	$ 11,745,700	$ 11,745,700
Option liabilities	$ -	$ -	$ 3,157,717	$ 3,157,717
Total Current Liabilities	$ -	$ -	$ 14,903,417	$ 14,903,417
Long-term Liabilities				
Convertible notes, net of current portion (related party)	$ -	$ -	$ 13,268,500	$ 13,268,500
Warrant liabilities	$ -	$ -	$ 1,828,677	$ 1,828,677
Total Long-term Liabilities	$ -	$ -	$ 15,097,177	$ 15,097,177

	As of December 31, 2024			
	Level 1	Level 2	Level 3	Total
Other Assets				
Derivative asset	$ -	$ -	$ 56,243	$ 56,243
Total Other Assets	$ -	$ -	$ 56,243	$ 56,243
Long-term Liabilities				
Convertible notes, net of current portion (related party)	$ -	$ -	$ 19,869,700	$ 19,869,700
Option liabilities	$ -	$ -	$ 3,135,000	$ 3,135,000
Warrant liabilities	$ -	$ -	$ 1,532,067	$ 1,532,067
Total Long-term Liabilities	$ -	$ -	$ 24,536,767	$ 24,536,767

The convertible notes (related party) (Note 7), the derivative asset and option liabilities (Note 9), and the warrant liabilities (Note 10) are recognized at fair value on a recurring basis at December 31, 2025 and 2024 and are all classified as Level 3. There have been no transfers between levels. The Company estimates the fair value of the asset or liabilities using the Monte Carlo Simulation model or Black-Scholes pricing model.

See **Notes 7, 9, and 10** for further details and assumptions used in the respective pricing model.

As of December 31, 2025 and 2024, the recorded values of cash and cash equivalents, prepaid expenses, accounts payable, and accrued expenses and other liabilities approximate their fair values due to the short-term nature of these items.

NOTE 1 – Summary of Significant Accounting Policies (cont.)

Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Bioscience Innovation Grant

In August 2023, the Company received a $1,158,000 grant from the North Dakota Department of Agriculture as part of the department's Bioscience Innovation Grant ("BIG") program. The grant money is obtained by submitting requests for reimbursement of specific expenses incurred to support the remaining approval process of the Company's products in the US. The grant program ended on June 30, 2025.

The Company has elected to account for the reimbursement as a government grant. U.S. GAAP does not currently include grant accounting guidance that is in effect related to transfers of assets from governments to business entities, therefore, the Company has elected to follow the grant accounting model in International Accounting Standard ("IAS") 20, Accounting for Government Grants and Disclosure of Government Assistance. In accordance with IAS 20, the Company cannot recognize any income from the grant until there is reasonable assurance (similar to the "probable" threshold in U.S. GAAP) that any conditions attached to the grant will be met and that the grant will be received. Once it is reasonably assured that the grant conditions will be met and that the grant will be received, grant income is recorded on a systematic basis over the periods in which the Company incurred the reimbursable expenses for which the grant is intended to compensate. Income from the grant can be presented as either other income or as a reduction in the expenses for which the grant was intended to compensate.

As of December 31, 2025 and 2024, BIG benefits of $0 and $177,057, respectively, were included in Prepaid expense and other current assets on the consolidated balance sheets. Income of $658,456 and $325,332 for the years ended December 31, 2025 and 2024, respectively, was included in government grant income on the consolidated statements of operations.

Recently Adopted Accounting Pronouncements

The Company considers the applicability and impact of all Accounting Standard Updates ("ASUs"). ASUs not discussed below were assessed and determined to be either not applicable or are expected to have minimal impact on the Company's consolidated financial statements and related notes.

In November 2023, the Financial Accounting Standards Board ("FASB") issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. The amendments in ASU 2023-07 improve the disclosures about a public entity's reportable segments and address requests from investors for additional, more detailed information about a reportable segment's expenses. The Company adopted this standard as of January 1, 2025. Adoption of the ASU did not materially impact the Company's consolidated financial statements. See Note 12 for further details.

NOTE 1 – Summary of Significant Accounting Policies (cont.)

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* which requires more detailed income tax disclosures. The guidance requires entities to disclose disaggregated information about their effective tax rate reconciliation as well as expanded information on income taxes paid by jurisdiction. The disclosure requirements will be applied on a prospective basis, with the option to apply them retrospectively. The standard is effective for fiscal years beginning after December 15, 2024. The Company adopted this standard as of January 1, 2025, prospectively. Adoption of the ASU did not materially impact the Company's consolidated financial statements. See Note 11 for further details.

In May 2024, the FASB issued ASU 2024-01, *Compensation – Stock Compensation (Topic 718): Scope Application of Profits Interest Awards*, which adds an example that illustrates how an entity applies the scope guidance to determine whether a profits interest award should be accounted for as a share-based payment arrangement under ASC 718 or another accounting standard. The standard is effective for fiscal years beginning after December 15, 2024. The Company adopted this standard as of January 1, 2025. The adoption of ASU 2024-01 did not materially impact the Company's consolidated financial statements.

Recent Accounting Pronouncements

In November 2024, the FASB issued ASU 2024-03, *Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220-40)*. The amendment requires disaggregated disclosure of income statement expenses for public business entities ("PBEs"). The ASU does not change the expense captions an entity presents on the face of the income statement; rather, it requires disaggregation of certain expense captions into specified categories in disclosures within the footnotes to the consolidated financial statements. The standard is effective for fiscal years beginning after December 15, 2026. Early adoption is permitted. The Company is evaluating the disclosure requirements related to the new standard.

In November 2024, the FASB issued ASU 2024-04, *Debt – Debt with Conversion and Other Options (Subtopic 470-20)*, which amends ASC 470-20 to clarify the circumstances in which an entity is required to account for a settlement of a debt instrument as an induced conversion. The standard is effective for fiscal years beginning after December 15, 2025. Early adoption is permitted for all entities that have adopted the amendments in Update 2020-06. The Company is evaluating the disclosure requirements related to the new standard.

In July 2025, the FASB issued ASU 2025-05, *Financial Instruments – Credit Losses (Topic 326)*: Measurement of Credit Losses for Accounts Receivable and Contract Assets, which provides a practical expedient for entities estimated expected credit losses on current accounts receivable and current contract assets arising from transactions under Topic 606. The practical expedient permits an entity to assume current conditions as of the balance sheet date that do not change for the remaining life of the current accounts receivable and current contract assets. The standard is effective for fiscal years beginning after December 15, 2025, with early adoption permitted. The Company is currently assessing the potential impact of adopting this new guidance on our consolidated financial statements and related disclosures.

In December 2025, the FASB issued ASU 2025-11, *Interim Reporting (Topic 270): Narrow-Scope Improvements*, which clarifies interim disclosure requirements and the applicability of Topic 270, resulting in a consolidated list of all interim disclosures required by GAAP. The amendments include a disclosure principle that requires entities to disclose events since the end of the last annual reporting period that have a material impact on the entity. The standard is effective for interim periods within fiscal years beginning after December 15, 2027, for public business entities, with early adoption permitted. The Company is currently assessing the potential impact of adopting this new guidance on our interim consolidated financial statements and related disclosures.

NOTE 2 – Liquidity

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business.

At each reporting period, the Company evaluates whether conditions or events raise substantial doubt about its ability to continue as a going concern for one year after the date that the consolidated financial statements are available to be issued. In performing this evaluation, management considers the Company's current financial condition, results of operations, cash flows, contractual obligations, and its ability to obtain additional financing if needed.

As disclosed in the Company's financial statements for the year ended December 31, 2024, management concluded that substantial doubt existed about the Company's ability to continue as a going concern due to recurring operating losses, negative cash flows from operations, and the need to secure additional financing to fund operations beyond the then-current cash runway. Since December 31, 2024, the Company completed an equity raise which resulted in net proceeds of $42,827,577 (see Note 10), which has materially improved its liquidity and extended its projected cash runway.

For the year ended December 31, 2025, the Company incurred net losses of $25,318,562, and negative cash flows from operating activities of $19,081,157. As of December 31, 2025, the Company had working capital of $25,546,042. Current liabilities include the current portions of the Company's convertible notes (related party) and option liabilities, which are recorded at fair value in accordance with ASC 825 and ASC 815, respectively, and their carrying amounts may differ significantly from the contractual principal and interest or other cash obligations associated with settling these instruments. See Note 7 for disclosure of the contractual principal and interest outstanding on the Company's convertible notes (related party) as of December 31, 2025.

Management has evaluated the principal conditions affecting the Company's liquidity, including recurring operating losses, negative cash flows, and contractual obligations due within the next 12 months. Based on this evaluation, management has concluded that the Company's existing working capital is sufficient to fund its operations for at least the 12-month period following the date these consolidated financial statements are available to be issued.

NOTE 3 – Accrued Expenses

As of December 31, accrued expenses consisted of the following:

	December 31, 2025	December 31, 2024
Compensation	$ 917,553	$ 896,715
Other accruals	702,401	596,380
	$ 1,619,954	$ 1,493,095

NOTE 4 – Property and Equipment

As of December 31, property and equipment consisted of the following:

	December 31, 2025	December 31, 2024
Office furniture and equipment	$ 329,106	$ 249,399
Lab and production equipment	2,563,189	2,416,607
Computer equipment	303,145	241,067
MRI scanner	1,200,000	1,200,000
Leasehold improvements	1,641,837	1,641,837
	6,037,277	5,748,910
Less: accumulated depreciation and amortization	(4,498,817)	(3,870,159)
	$ 1,538,460	$ 1,878,751

Depreciation and amortization expense was $798,715 and $748,165 for the years ended December 31, 2025 and 2024, respectively.

NOTE 5 – Leases

Operating Leases

The Company leases office, manufacturing, and laboratory space in Burnsville, Minnesota under operating leases expiring at various dates through 2030. The Company's office and manufacturing facility (Gateway) lease commenced in March 2007, was originally set to expire in July 2014, and has been amended and extended over time, most recently in 2022, resulting in a current lease term through March 2027. The Company's office and laboratory facility (Design Center) lease commenced in January 2019, was originally set to expire in March 2026, and was amended in 2020 to extend the term through May 2030. Neither facility lease includes renewal or extension rights. For each facility lease, the landlord provided leasehold improvement incentives that reduced the Company's initial right-of-use asset. Both facility lease agreements require the Company to pay a pro rata portion of the lessor's actual operating expenses, which are considered variable lease costs.

The Company has also entered into operating leases for vehicles with contractual terms expiring at various dates through November 2028. Vehicle lease payments are fixed and do not include renewal or purchase options, and related costs are included in operating lease expense.

As the leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the lease commencement date in determining the present value of the lease payments. As of December 31, 2025 and 2024, the weighted average remaining lease term on operating leases was 3.6 and 4.5 years, respectively, and the weighted average discount rate was 5.8% and 5.6%, respectively. For the years ended December 31, 2025 and 2024, the operating cash outflows from operating leases was $328,728 and $307,842 respectively.

NOTE 5 – Leases (cont.)

As of December 31, 2025, maturities of the Company's operating lease liabilities are as follows:

2026	$ 363,140
2027	247,023
2028	191,217
2029	178,359
2030	75,228
Total lease payments	1,054,967
Less: interest	(103,771)
Present value of lease liabilities	951,196
Less: current portion	(317,153)
Operating lease liability, net of current portion	$ 634,043

The cost components of the Company's operating leases for office and manufacturing space, which were included in general and administrative expenses on the consolidated statements of operations, were as follows for the years ended December 31, 2025 and 2024:

	December 31, 2025	December 31, 2024
Operating lease cost	$ 228,426	$ 228,426
Variable lease cost	173,807	156,450
	$ 402,233	$ 384,876

Finance Lease Liability

The Company had a finance lease agreement related to its MRI scanner under which the Company obtained ownership of the scanner at the end of the lease term. During the year ended December 31, 2024, the Company paid $67,159 under this finance lease, of which $1,160 represented interest, and as of December 31, 2024, there were no remaining payments outstanding.

NOTE 6 – Commitments and Contingencies

Vendor concentration

Certain components and products that meet the Company's requirements are available only from a single supplier or a limited number of suppliers. The inability to obtain components and products as required, or to develop alternative sources, if and as required in the future, could result in delays or reductions in product shipments, which in turn could have a material adverse effect on the Company's business, financial condition, and results of operations. The Company believes that it will be able to source alternative suppliers or materials if required to do so.

For the year ended December 31, 2025, the Company had accounts payable to two vendors that each accounted for 12% of the total outstanding balance. For the year ended December 31, 2024, the Company had accounts payable to two vendors that accounted for 14% and 13% of the total outstanding balance.

NOTE 6 – Commitments and Contingencies (cont.)

Purchase Commitments

At December 31, 2025 and 2024, the Company had $218,912 and $366,675, respectively, in outstanding firm purchase commitments for raw materials inventory and prototype components used in research and development activities. As of December 31, 2025, payment of the purchase commitments is expected to be made within one year. During the years ended December 31, 2025 and 2024, the Company purchased $324,805 and $109,767, respectively, under firm purchase commitments outstanding at the beginning of the respective year.

Financing Obligation

The Company entered into an agreement to finance a portion of an annual insurance premium for the policy period beginning August 2024. The financing obligation was to be paid in 10 monthly installments of $35,665 beginning in September 2024, and the stated interest rate was 7.91%. As of December 31, 2025, there were no payments remaining to be paid.

Retirement Plan

The Company maintains retirement plans for its employees in which eligible employees can contribute a percentage of their compensation. The Company contributed $333,897 and $269,541 to these plans during the years ended December 31, 2025 and 2024, respectively.

Employment Agreements

The Company has employment agreements with the CEO and certain senior executives of the Company. The agreements require severance of twelve and six months, respectively, of current annual salary and medical insurance in the event employment is terminated without cause.

NOTE 7 – Convertible Notes with Warrants (related party)

On December 16, 2022, the Company entered into a Securities Purchase Agreement with K.A.H.R. Foundation, a beneficial owner of more than 5% of the Company's common stock as of the agreement date (see Note 13), for the issuance of unsecured, unquoted convertible promissory notes, to be issued in two tranches, to raise a maximum aggregate amount of $5,000,000.

The first tranche was issued on December 23, 2022. The Company received $2,325,000 in gross proceeds from the issuance of the convertible note. The convertible note bears interest of 10% per annum, compounded annually. The interest accrued during the years ended December 31, 2025 and 2024 was $281,942 and $256,311, respectively. As of December 31, 2025 and 2024, cumulative accrued interest on the first tranche totaled $776,358 and $494,416, respectively. All or a portion of the principal is convertible into CHESS Depositary Interests ("CDIs", as described further in Note 10) at a price of $0.2691 per share at the election of the holder following the 36 month anniversary of the closing date. All or a portion of accrued and unpaid interest is convertible into CDIs at a price of $0.2563 per share at the election of the holder during the same time frame. Accrued interest on the convertible notes is included in the fair value of the convertible notes on the consolidated balance sheets. The maximum number of CDIs to be issued upon conversion of the principal amount and interest is no more than 12,849,949 CDIs. As of December 31, 2025, 11,669,009 CDIs would be issued if the principal and accrued interest were converted.

NOTE 7 – Convertible Notes with Warrants (related party) (cont.)

The second tranche was issued on March 28, 2023. The Company received $2,675,000 of gross proceeds from the issuance of the convertible note. The second tranche is subject to the same terms as the first tranche. The interest accrued during the years ended December 31, 2025 and 2024 was $316,661 and $287,874, respectively. As of December 31, 2025 and 2024, cumulative accrued interest on the second tranche totaled $808,275 and $491,614, respectively. The maximum number of CDIs to be issued upon conversion of the principal and interest is no more than 14,784,350 CDIs. As of December 31, 2025, 13,094,172 CDIs would be issued if the principal and accrued interest were converted.

The maturity date on the notes is the earliest occurrence of (i) a change-in-control event, at which time the Company would be required to pay the holder the greater of 125% of the then outstanding balance plus accrued and unpaid interest or the amount the holder would receive if the principal and accrued and unpaid interest had been converted to CDIs at a conversion price equal to the variable weighted average price ("VWAP") of the CDIs for the 10 day period ending on the change-in-control event date; or (ii) the four year anniversary of the closing date of each tranche.

On March 28, 2023 and December 23, 2022, pursuant to the Securities Purchase Agreement, the Company issued warrants exercisable for 1,043,699 and 907,141 CDIs, respectively, with an exercise price of $0.2563 per share. The warrants expire five years after the dates of issuance.

The Company accounts for its convertible promissory notes under ASC 815, Derivatives and Hedging ("ASC 815"). Under 815-15-25, the election can be made at the inception of a financial instrument to account for the instrument under the fair value option under ASC 825. The Company has made such election for its convertible promissory notes. Using the fair value option, the convertible promissory notes are required to be recorded at its initial fair value on the date of issuance, and each balance sheet date thereafter. Changes in the estimated fair value of the notes are recognized as a non-cash item in the change in fair value of convertible notes (related party) in the consolidated statements of operations.

The convertible notes (related party) were recorded as a liability on the consolidated balance sheets at the dates of issuance. The following table provides a summary of change in fair value of the two tranches of the convertible notes (related party) for the years ended December 31:

	Total	Tranche 1	Tranche 2
Fair value at December 31, 2023	$ 8,453,300	$ 3,964,800	$ 4,488,500
Fair value change in convertible notes (related party)	11,416,400	5,305,100	6,111,300
Fair value at December 31, 2024	$ 19,869,700	$ 9,269,900	$ 10,599,800
Fair value change in convertible notes (related party)	5,144,500	2,475,800	2,668,700
Fair value at December 31, 2025	$ 25,014,200	$ 11,745,700	$ 13,268,500

As of December 31, 2025, the Company had total convertible notes (related party) of $25,014,200 of which $13,268,500 was included in long-term liabilities as of December 31, 2025. The entire convertible notes (related party) balance was included in long-term liabilities as of December 31, 2024.

NOTE 7 – Convertible Notes with Warrants (related party) (cont.)

The fair value of the convertible notes is measured in accordance with ASC 820 "Fair Value Measurement" using the "Monte Carlo Method" modeling incorporating the following inputs:

	December 31, 2025	December 31, 2024
Expected dividend yield	0%	0%
Expected stock-price volatility	66.0% - 72.1%	88.1% - 89.4%
Risk-free interest rate	3.42% - 3.43%	4.16% - 4.17%
Stock price	$1.0210	$0.8416
Conversion price	$0.2691	$0.2691

Significant assumptions used to determine the fair value of the convertible note include the estimated probability of a change in control event, which is based on management's expectation of future transactions; the volatility of the stock price, which is estimated based on the Company's own historical volatility; and the credit spread, which is based on the Company's estimate of its credit rating derived from the Company's financial condition and market yields for similar instruments issued by companies with comparable credit ratings.

The Company evaluated the warrants under ASC 480, "Distinguishing Liabilities from Equity" and ASC 815. The warrants do not meet the characteristics for liability classification under either provision and as such are classified as equity under ASC 815. Given that the convertible notes were subject to fair value remeasurement, the fair value of the convertible notes was carved out from gross proceeds and the remainder of the gross proceeds of the first and second tranches of $127,900 and $541,200, respectively, was allocated to warrants. The warrants were recorded as Additional paid-in capital on the consolidated balance sheets at the dates of issuance. No subsequent remeasurement of the warrants is required.

NOTE 8 – Promissory Notes

LIFT Loan

On January 6, 2023, the Company obtained a $1,500,000 loan from the Bank of North Dakota under the North Dakota Commerce Department's Innovation Technology Loan Fund ("LIFT"). The loan matures in five years and has an interest rate of 0% for the first three years and 2% for the next two years of the loan, with monthly interest payments due. The outstanding loan balance is due at maturity on January 6, 2028. The Company had an 18-month draw period through July 2024, during which it drew $33,219. The balance was paid in full during the year ended December 31, 2024, and no amounts were outstanding under the LIFT loan as of December 31, 2025 or 2024.

The loan included certain restrictions on the use of the funds. The Company could use the funding only to conduct applied research, experimentation, or operational testing within the state of North Dakota. The funds could not be used for capital or building investments or for general corporate purposes to support existing operations outside the state of North Dakota.

NOTE 8 – Promissory Notes (cont.)

GGY Promissory Note

As part of the Agreement with GGY (discussed further in Note 9), the Company entered into a promissory note to pay GEM Yield Bahamas Limited a fee equal to two percent of the capital commitment facility, being $600,000 Australian dollars ($399,660 U.S. dollars at issuance date). The fee was payable, whether or not any draw down notices were delivered, within the first year of the Agreement's term. In the event the fee was not paid in full within the first year, interest would accrue on the unpaid portion at the Mortgage Free Business Finance Rate published by Westpac Banking Corporation, compounded monthly. The promissory note was revalued at each reporting date. The Company paid the remaining balance on the note, along with accrued interest of $3,103, during the year ended December 31, 2024.

NOTE 9 – Capital Commitments

On July 6, 2023, the Company entered into a Capital Commitment Agreement ("Agreement") with GEM Global Yield LLC SCS ("GGY"), under the terms of which GGY has agreed to provide the Company with up to $30 million Australian dollars through a Security Subscription Facility (the "Facility") over a 3-year term. The Agreement allows the Company to draw down funds during the 3-year term by giving GGY 15 Australian Securities Exchange ("ASX") trading days' notice to subscribe for CDIs, subject to share lending arrangement(s) being in place. The number of CDIs which GGY may subscribe for is capped at 700% of the average daily number of CDIs traded on the ASX during the 15 trading days prior to the relevant drawdown notice, subject to certain adjustments. The subscription price of the CDIs to be issued to GGY is the higher of (i) 90% of the average closing bid price of the Company's CDIs over the 15 consecutive trading days after the Company gives the drawdown notice, subject to certain adjustments; or (ii) a fixed floor price nominated by the Company in the drawdown notice. The Company controls the timing of drawdowns under the Facility and has no minimum drawdown obligation. The issue of CDIs to GGY pursuant to any drawdown notice will also be conditional on the Company having sufficient placement capacity under ASX Listing Rules 7.1 or 7.1A (as applicable) or obtaining any requisite securityholder approval for the issue.

The Agreement meets the definition of a derivative in accordance with ASC 815 and is measured at fair value. Any changes in fair value of such instruments are recorded in other income (expense) in the consolidated statements of operations. There was no change in fair value of the derivative asset for the years ended December 31, 2025 or 2024.

The derivative asset's fair value was calculated using the Monte Carlo Simulation model utilizing the following assumptions:

Expected stock-price volatility		104.1%
Risk-free interest rate		4.03%
Stock price (in Australian dollars)	$	0.5700

These key assumptions used in the valuation have remained unchanged since December 31, 2023 and were also used in determining the fair value of the derivative asset as of December 31, 2025 and 2024.

NOTE 9 – Capital Commitments (cont.)

Pursuant to the terms of the Agreement, the Company issued options to purchase 5,700,000 CDIs with an exercise price of $0.61 Australian dollars per CDI and a 3-year term.

No CDI Options were exercised during the year ended December 31, 2024. A summary of activity related to the CDI Options during the year ended December 31, 2025 is as follows:

CDI Options outstanding at December 31, 2024	5,700,000
Exercise of CDI Options	(648,461)
CDI Options outstanding at December 31, 2025	5,051,539

The following table provides a summary of the change in fair value of the CDI Options for the years ended December 31, 2025 and 2024:

Fair value at December 31, 2023	$	1,292,760
Fair value change in CDI Options		1,842,240
Fair value at December 31, 2024		3,135,000
Exercise of CDI Options		(373,774)
Fair value change in CDI Options		396,491
Fair value at December 31, 2025	$	3,157,717

As of December 31, 2025, the fair value of the CDI Options of $3,157,717 is classified as short-term option liabilities on the consolidated balance sheets. As of December 31, 2024, the fair value of the CDI Options of $3,135,000 is classified as long-term option liabilities on the consolidated balance sheets.

The CDI Options' fair value was calculated using the Black-Scholes option pricing model utilizing the following assumptions:

	December 31, 2025	December 31, 2024
Expected dividend yield	0%	0%
Expected stock-price volatility	59.2%	85.4%
Risk-free interest rate	3.97%	3.97%
Stock price	$ 1.0240	$ 0.8455
Conversion price	$ 0.4083	$ 0.3792

The fair value of CDI Options was determined using the Black-Scholes option pricing model with assumptions consistent in methodology to those used for stock options, except that the contractual life of the options is used as the expected term and volatility of the stock price is estimated based on the Company's own historical volatility.

Since issuance, the Company has drawn $444,922 Australian dollars on the Facility, and $29,555,078 Australian dollars is available as of December 31, 2025. Converted to U.S. dollars using the exchange rate of $1 Australian dollar to $0.67 U.S. dollar as of December 31, 2025, these amounts are $297,786 and $19,781,214, respectively.

NOTE 10 – Stockholders' Equity

Capital Stock Authorized

As of both December 31, 2025 and 2024, the Board of Directors of the Company had authorized 560,000,000 shares of capital stock, consisting of 535,000,000 shares of common stock and 25,000,000 shares of preferred stock.

Common Stock

The Australian Securities Exchange ("ASX") uses an electronic system called CHESS for the clearance and settlement of trades on the ASX. The State of Delaware does not recognize the CHESS system of holding securities or electronic transfers of legal title to shares. To enable companies to have their securities cleared and settled electronically through CHESS, depositary instruments called CHESS Depositary Interests ("CDIs") are issued. CDIs are units of beneficial ownership in shares and are traded in a manner similar to shares of Australian companies listed on the ASX. The legal title to the shares is held by a depositary, CHESS Depositary Nominees Pty Ltd ("CDN"), which is a wholly-owned subsidiary of the ASX, and is an approved general participant of ASX Settlement. One share of common stock is equivalent to one CDI.

In February 2024, the Company completed a placement and institutional entitlement offer with a mix of U.S. and Australian investors which consisted of 3,766,666 shares of common stock at $0.30 per share for U.S. investors and 14,069,396 CDIs at $0.45 Australian dollars per share for Australian investors for proceeds of $4,823,937, net of expenses.

The Company also completed a retail entitlement offer with Australian investors, which consisted of 1,419,069 CDIs at $0.45 Australian dollars per share for proceeds of $389,888, net of expenses in February 2024, and 14,378,862 CDIs at $0.45 Australian dollars per share, for proceeds of $3,996,793, net of expenses, in April 2024.

In July and September 2024, the Company completed a two-tranche placement with a mix of Australian and U.S. investors, which consisted of 67,064,836 CDIs at $0.52 Australian dollars per share and 242,857 shares of common stock at $0.35 per share for U.S. investors for proceeds of $21,791,209, net of expenses.

In February 2025, a total of 163,935 CDI Options were exercised at $0.61 Australian dollars per share for total proceeds of $61,419, net of expenses.

In March 2025, the Company completed an equity raise with Australian investors which consisted of 49,645,391 CDIs at $1.41 Australian dollars per share for proceeds of $42,827,577, net of expenses.

In March 2025, a total of 340,000 CDI Options were exercised at $0.61 Australian dollars per share for total proceeds of $130,842, net of expenses.

In September 2025, a total of 356,150 options to purchase common stock were exercised at prices ranging from $0.31 to $0.52 per share for total proceeds of $180,922, net of expenses.

In October 2025, a total of 144,526 CDI Options were exercised at $0.61 Australian dollars per CDI for total proceeds of $56,160, net of expenses.

NOTE 10 – Stockholders' Equity (cont.)

Dividend Rights

Subject to the prior rights of holders of all classes of stock at the time outstanding having prior rights as to dividends, the holders of the common stock shall be entitled to receive, out of any assets of the Corporation legally available therefore, any dividends as may be declared from time to time by the Board of Directors. The right to such dividends shall not be cumulative, and no right shall accrue by reason of the fact that dividends are not declared in any prior period.

Voting Rights

The holder of each share of common stock shall have the right to one vote for each such share, and shall be entitled to notice of any stockholders' meeting in accordance with the Bylaws of the Corporation, and shall be entitled to vote upon such matters and in such manner as may be provided by law.

Stock Option Plans

The Company and its stockholders adopted a stock incentive plan (the "2006 Plan") in 2006. The 2006 Plan, as amended on January 26, 2011 by the stockholders, reserved 10,918,500 shares of the Company's common stock for the granting of incentive and nonqualified stock options to employees, directors and consultants. On May 22, 2016, the Company replaced the 2006 Plan with the 2016 Stock Option Plan (the "2016 Plan"), as the 2006 Plan was expiring. The terms of the 2016 Plan were the same as the 2006 Plan. In August 2018, the Board of Directors approved an increase of 500,000 shares to the option pool. On February 14, 2019, the Board of Directors terminated the 2016 Plan and approved the 2019 Equity Incentive Plan (the "2019 Plan"), reserving 11,418,500 shares of the Company's common stock for the granting of incentive and nonqualified stock options, or other stock-based awards, to employees, directors and consultants. On June 4, 2019, the Board of Directors approved an increase of 2,000,000 shares to the option pool and provided that on the first day of each of the Company's fiscal years during the term of the 2019 Plan beginning in 2020, the number of shares of Common Stock available for issuance from time to time under the 2019 Plan will be increased by an amount equal to the lesser of (i) five percent (5%) of the aggregate number of shares reserved under this Plan on the last day of the immediately preceding fiscal year, and (ii) such number of shares determined by the Board (the "Annual Increase"). On April 20, 2020, the Board of Directors approved an increase of 3,470,925 shares to the option pool, which was approved by the stockholders at the Annual Meeting on May 12, 2020. On January 14, 2021, the Board of Directors approved an increase of 844,471 shares to the option pool. On April 6, 2022, the Board of Directors approved an increase of 848,695 shares to the option pool. On April 4, 2023, the Board of Directors approved an increase of 7,929,130 shares to the option pool, which was approved by the stockholders at the Annual General Meeting on May 11, 2023. On February 14, 2024, the Board of Directors approved an increase of 6,488,279 shares to the option pool, which was approved by stockholders at the Annual Meeting on May 15, 2024. On February 17, 2025, the Board of Directors approved an increase of 7,650,000 shares to the option pool, which was approved by the shareholders at the Annual Meeting on May 14, 2025.

NOTE 10 – Stockholders' Equity (cont.)

Options are granted at a price equal to the closing sale price of a CDI as of the date of grant, converted from Australian dollars to U.S. dollars using the prevailing exchange rate. Generally, vesting terms of outstanding options range from immediate to four years. In addition, some options have been issued to the executive management team that vest upon completion of certain milestones, performance requirements, and market conditions; as of December 31, 2025, 24,914,305 of these options are issued and outstanding. For these performance-based awards, expense is recognized when it is probable the performance condition will be achieved. If at any point the Company determines that the performance condition is improbable, any previously recognized expense is reversed. Adjustments for forfeitures are recorded as they occur. In no event are the options exercisable for more than ten years after the date of grant. The Company issues new shares of common stock when stock options are exercised.

Information regarding the Company's stock options is summarized below:

	Number of Option Shares	Weighted-Average Exercise Price	Aggregate Intrinsic Value
Options outstanding - December 31, 2024	25,555,170	$ 0.42	
Exercised	(356,150)	0.51	
Forfeited	(41,250)	0.30	
Expired	(34,100)	0.50	
Granted	8,783,951	1.06	
Options outstanding - December 31, 2025	33,907,621	$ 0.58	$ 15,944,060
Options exercisable - December 31, 2025	6,767,066	$ 0.66	$ 2,788,732
Weighted average fair value of options granted during the year ended December 31, 2025		$ 0.82	

	Number of Option Shares	Weighted-Average Exercise Price	Aggregate Intrinsic Value
Options outstanding - December 31, 2023	16,895,981	$ 0.47	
Exercised	-	-	
Forfeited	(148,750)	0.53	
Expired	(115,050)	0.82	
Granted	8,922,989	0.32	
Options outstanding - December 31, 2024	25,555,170	$ 0.42	$ 12,066,510
Options exercisable - December 31, 2024	6,349,658	$ 0.67	$ 1,585,640
Weighted average fair value of options granted during the year ended December 31, 2024		$ 0.24	

As of December 31, 2025, the Company had 581,340 shares available for grant under the Plan.

The weighted average remaining contractual life of options outstanding and exercisable was 7.37 and 4.29 years, respectively, as of December 31, 2025.

The intrinsic value of options exercised during the years ended December 31, 2025 and 2024 was $138,476 and $0, respectively.

NOTE 10 – Stockholders' Equity (cont.)

The fair value of option awards granted was determined using the Black-Scholes option pricing model utilizing the following assumptions:

	2025	2024
Expected life (in years)	5.32 - 6.82	5.32 - 6.32
Volatility	85.13% - 88.03%	90.19% - 91.69%
Risk-free interest rate	3.67% - 4.38%	4.05% - 4.35%
Dividend yield	0%	0%

The Company reviews its current assumptions on a periodic basis and adjusts them as necessary to determine the option valuation. The expected term reflects our estimate of the period over which the stock options will remain outstanding before exercise or expiration. As we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term, the expected term of stock option awards granted has been determined using the simplified method, which is the average of the weighted-average vesting period and the contractual term. Volatility is based on the Company's own historical volatility as well as historic volatilities of traded shares from a selected publicly traded peer group, believed to be comparable after consideration of size, maturity, profitability, growth, risk and return on investment. The risk-free interest rate is based on the yield of constant maturity U.S. treasury bonds with a remaining term equal to the expected life of the awards at the grant date. The expected dividend yield is zero, as the Company has not paid or declared any dividends to common stockholders and does not expect to pay dividends in the foreseeable future. The Company's policy is to account for forfeitures as they occur and records stock-based compensation expense only for those awards that are expected to vest.

Total stock-based compensation expense resulting from options is charged to the Company's consolidated statements of operations as follows:

	December 31, 2025	December 31, 2024
Cost of goods sold	$ 26,117	$ 11,191
Sales and marketing	90,642	(593)
Research and development	169,103	24,362
General and administrative	213,621	(27,115)
	$ 499,483	$ 7,845

The negative sales and marketing and general and administrative stock-based compensation expense on the consolidated statements of operations during the year ended December 31, 2024 is due to a change in probability of achievement for certain performance grants that were previously considered probable. This change resulted in the reversal of expense already taken until achievement becomes probable, in accordance with ASC 718, Stock Compensation. No income tax benefits were recognized related to this compensation expense due to the full valuation allowance provided on the Company's deferred income tax assets.

NOTE 10 – Stockholders' Equity (cont.)

As of December 31, 2025, the total unrecognized compensation cost related to unvested stock options then outstanding was $10,959,913. Future stock-based compensation expense is expected to be as follows for the years ending December 31:

2026	$	501,151
2027		345,470
2028		168,735
2029		41,592
Total related to options expected to vest		1,056,948
Performance grants not probable of achievement		9,902,965
Total unrecognized compensation expense	$	10,959,913

The performance grants not probable of achievement are generally related to the receipt of regulatory approvals or sales milestones predicated on the receipt of regulatory approvals not yet received. Under current U.S. GAAP, these milestones are generally not considered probable until the regulatory approval is obtained.

Issuance of additional options subsequent to December 31, 2025 could affect future expected amounts.

Restricted Stock

On May 15, 2024, the Company granted 315,946 shares of restricted stock to its three independent board directors. The restricted stock vests annually over four years on the anniversary of the grant date, provided that the participant continuously provides services to the Company through the applicable vesting date. The fair market value on the date of grant was $0.30 per share.

On May 14, 2025, the Company granted 121,260 shares of restricted stock to its three independent board directors. The restricted stock vests annually on the anniversary of the grant date, provided that the participant continuously provides services to the Company through the applicable vesting date. The fair market value on the date of grant was $1.07 per share.

A summary of activity related to time-based nonvested restricted stock grants during 2025 and 2024 is as follows:

	Nonvested Restricted Shares		Weighted Average Grant Date Fair Value
Outstanding as of December 31, 2023	751,812	$	0.22
Granted	315,946		0.30
Vested	(206,597)		0.22
Forfeited	-		-
Outstanding as of December 31, 2024	861,161	$	0.25
Granted	121,260		1.07
Vested	(285,583)		0.24
Forfeited	-		-
Outstanding as of December 31, 2025	696,838	$	0.39

NOTE 10 – Stockholders' Equity (cont.)

Total stock-based compensation expense resulting from grants of restricted stock was $90,128 and $60,924 for the years ended December 31, 2025 and 2024, respectively, and is included in general and administrative expenses on the consolidated statements of operations. No income tax benefits were recognized related to this compensation expense due to the full valuation allowance provided on the Company's deferred income tax assets.

As of December 31, 2025, the total unrecognized compensation cost related to unvested restricted stock was $206,980. Future unrecognized stock-based compensation expense is expected to be as follows for the years ended December 31 thereafter:

2026	$	88,593
2027		65,160
2028		41,327
2029		11,900
Total	$	206,980

Issuance of additional shares of restricted stock subsequent to December 31, 2025 could affect future expected amounts.

Warrants

As part of the convertible notes (related party) issuances in 2022 and 2023 and the equity raises in 2023, the Company issued warrants to purchase common stock or CDIs which are summarized below:

	Number of Warrants		Weighted-Average Exercise Price
Warrants outstanding - December 31, 2023	5,216,158	$	0.4742
Warrants issued	-		-
Warrants exercised	-		-
Warrants expired/forfeited	-		-
Warrants outstanding - December 31, 2024	5,216,158	$	0.4742
Warrants issued	-		-
Warrants exercised	-		-
Warrants expired/forfeited	-		-
Warrants outstanding - December 31, 2025	5,216,158	$	0.4742
Warrants exercisable - December 31, 2025 and 2024	5,216,158	$	0.4742

The warrants issued in connection with the equity raises were evaluated under ASC 480 and ASC 815. Of the 3,265,318 warrants issued in connection with the equity raises, 2,100,568 were determined to qualify as liabilities due to the exercise price being denominated in a currency other than the Company's functional currency, while the remaining 1,164,750 do not meet the characteristics for liability classification under either provision and as such are classified as equity under ASC 815. The warrants expire ten years after the dates of issuance. In addition, the Company has 1,950,840 warrants outstanding that were issued in connection with the convertible notes (related party) issuances, which are classified as equity under ASC 815. See Note 7 for further details.

NOTE 10 – Stockholders' Equity (cont.)

Any subsequent changes in fair value of warrants classified as a liability have been recorded in change in fair value of warrant liabilities in the consolidated statements of operations. The following table provides a summary of change in fair value of the warrants classified as a liability for the year ended December 31, 2025 and 2024:

Fair value at December 31, 2023	$ 652,516
Fair value change in warrants	879,551
Fair value at December 31, 2024	1,532,067
Fair value change in warrants	296,610
Fair value at December 31, 2025	$ 1,828,677

As of December 31, 2025 and 2024, the fair value of the warrants of $1,828,677 and $1,532,067, respectively, are classified as warrant liabilities on the consolidated balance sheets.

The fair value of the warrants was determined using the Black-Scholes option pricing model utilizing the following assumptions:

	December 31, 2025	December 31, 2024
Expected dividend yield	0%	0%
Expected stock-price volatility	85.3% - 85.5%	85.9% - 86.1%
Risk-free interest rate	4.60%	4.37%
Stock price	$1.0240	$0.8455
Conversion price	$0.6358 - $0.6693	$0.5906 - $0.6217

The fair value of warrants was determined using the Black-Scholes option pricing model with assumptions consistent in methodology to those used for stock options, except that the contractual life of the warrant is used as the expected term.

NOTE 11 – Income Taxes

As of December 31, 2025, the Company had generated approximately $116,363,000 of net operating losses ("NOL") for federal tax purposes. As a result of the Tax Cuts and Jobs Act, for U.S. income tax purposes, NOLs generated prior to December 31, 2017 can still be carried forward for up to 20 years, while NOLs generated after December 31, 2017 carryforward indefinitely, but are limited to 80% utilization against taxable income. Of the total federal NOL of $116,363,000, $18,662,000 will begin to expire in 2028 through 2037, and $97,701,000 will not expire but will only offset 80% of future taxable income.

As of December 31, 2025, the Company had also generated approximately $36,931,000 of state NOLs. The state NOLs can be carried forward for up to 15 years and are limited to 80% utilization against taxable income. The state NOLs will begin to expire in 2026 through 2039 if they are not used.

As of December 31, 2025, the Company had approximately $2,458,000 of federal research and development ("R&D") credit carryforwards available for federal tax purposes. As of December 31, 2025, the Company also had approximately $1,293,000 of state R&D credit carryforwards available for Minnesota. The federal R&D credits carryforwards will begin to expire in 2028 through 2037, and the state R&D credits carryforwards will begin to expire in 2028 through 2039, if they are not used.

NOTE 11 – Income Taxes (cont.)

In assessing the realizability of deferred tax assets as of December 31, 2025 and 2024, the Company determined it is more likely than not that its net deferred tax assets will not be realized and the Company continues to maintain a valuation allowance for the full amount of the deferred tax assets.

Pursuant to Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"), annual use of the Company's NOLs and R&D credit carryforwards may be limited if there is a cumulative change in ownership of greater than 50% within a three-year period. The amount of annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. If sufficiently limited, the related tax assets would be removed from the deferred tax asset schedule with a corresponding reduction in the valuation allowance.

In 2023, the Company completed an analysis of past equity offerings, and other transactions that had an impact on the Company's ownership structure, for potential ownership changes under Sections 382 and 383 of the Code and concluded that the Company experienced ownership changes in 2009, 2011 and 2020. The analysis determined that there were limitations on the amount of pre-ownership change NOL carryforwards that can be utilized annually to offset future taxable incomes.

In 2024 and 2025, the Company completed an analysis of equity offerings during the respective years, and other transactions that have an impact on the Company's ownership structure, for potential ownership changes under Sections 382 and 383 of the Code and concluded no ownership changes were experienced during either year. The Company may experience subsequent ownership changes as a result of future equity offerings or other changes in the ownership of Company stock, some of which are beyond the Company's control. Similar provisions of state tax law may also apply to limit the use of accumulated state tax attributes.

The Company conducts intensive research and experimentation activities, generating R&D tax credits for Federal and state purposes under Section 41 of the Code. The Company has not performed a formal study validating these credits claimed in the tax returns. Once a study is prepared, the amount of R&D tax credits available could vary from what was originally claimed on the tax returns.

Net loss from operations before income tax expense (benefit) for the year ended December 31:

	2025	2024
U.S.	$ (25,036,699)	$ (29,692,831)
Foreign	(281,863)	-
Total	$ (25,318,562)	$ (29,692,831)

NOTE 11 – Income Taxes (cont.)

Income tax expense (benefit) consists of the following for the years ended December 31:

	2025	2024
Current:		
Federal	$ -	$ -
State	-	-
Foreign	-	-
	-	-
Deferred:		
Federal	(5,271,000)	(6,686,000)
State	(121,000)	(260,000)
Foreign	(73,000)	-
	(5,465,000)	(6,946,000)
Deferred tax asset valuation allowance	5,465,000	6,946,000
Total provision (benefit)	$ -	$ -

The Company paid no income taxes during the years ended December 31, 2025 and 2024 due to net operating losses.

The provision for income taxes differs from the tax computed using the statutory U.S. federal income tax rate of 21% for the year ended December 31, 2025, as a result of the following items:

	2025	
	Amount	Percent
U.S. federal statutory income tax rate	$ (5,317,000)	21.0%
Domestic federal		
Tax Credits		
Research and development credits, net	(480,000)	1.9%
Other	50,000	-0.2%
Nontaxable and nondeductible items	41,000	-0.2%
Changes in valuation allowance	5,296,000	-20.9%
Changes in tax rates enacted in the current period	-	0.0%
Other	251,000	-1.0%
Domestic state and local income taxes, net of federal effect	(39,000)	0.2%
Foreign tax effects	59,000	-0.2%
Changes in unrecognized tax benefits	139,000	-0.5%
Net deferred tax assets (liabilities)	$ -	0.00%

State and local income taxes relate primarily to Minnesota income taxes, net of federal effect. Minnesota comprises substantially all of the state tax effect for the year ended December 31, 2025.

NOTE 11 – Income Taxes (cont.)

The provision for income taxes differs from the tax computed using the statutory U.S. federal income tax rate of 21% for the year ended December 31, 2024, as a result of the following items:

	2024
Tax at U.S. statutory rate	$ (6,235,000)
State tax expense, net of federal benefit	(393,000)
Permanent items and other	(87,000)
R&D credits, net	(205,000)
Fair value change in convertible notes (related party)	(194,000)
Change in tax rate	168,000
Change in valuation allowance	6,946,000
Income tax expense	$ -

Components of deferred income taxes are as follows as of December 31:

	2025	2024
Deferred tax assets:		
Net operating loss carryforwards	$ 27,368,000	$ 22,204,000
Research and development credit carryforwards	3,480,000	3,010,000
Section 174 Capitalization of R&D	2,080,000	3,333,000
Stock-based compensation	237,000	360,000
Accrued expenses	213,000	291,000
Deferred revenue	246,000	254,000
Fixed assets	447,000	352,000
Fair value change of financial instruments	5,503,000	4,330,000
Prepaid expenses and other assets	55,000	-
Gross deferred tax assets	39,629,000	34,134,000
Valuation allowance	(39,472,000)	(34,007,000)
Deferred tax assets, net	157,000	127,000
Deferred tax liabilities:		
Prepaid expenses and other assets	-	47,000
Foreign currency exchange	157,000	80,000
Gross deferred tax liabilities	157,000	127,000
Net deferred tax assets (liabilities)	$ -	$ -

Due to net losses since inception and the uncertainty of realizing the deferred tax assets, the Company has a full valuation allowance against its net deferred tax assets. To the extent that the Company generates positive income and expects, with reasonable certainty, to continue to generate positive income, the Company may release all, or a portion of, the valuation allowance in a future period. This release would result in the recognition of all, or a portion of, the Company's deferred tax assets, resulting in a decrease to income tax expense for the period such release is made.

The following table sets forth information related to the valuation allowance as of and for the years ended December 31:

	2025	2024
Balance at January 1	$ 34,007,000	$ 27,061,000
Additions charged to income tax benefit	5,465,000	6,946,000
Balance at December 31	$ 39,472,000	$ 34,007,000

NOTE 11 – Income Taxes (cont.)

The following table sets forth information related to the unrecognized tax benefits as of and for the years ended December 31:

	2025	2024
Balance at January 1	$ 810,000	$ 723,000
Additions based on current year tax positions	139,000	87,000
Balance at December 31	$ 949,000	$ 810,000

The Company's unrecognized tax benefits are netted against the underlying deferred tax assets. As of December 31, 2025 and 2024, none of the unrecognized tax benefits, if recognized, would affect the effective tax rate due to the full valuation allowance maintained against the Company's deferred tax assets.

The Company files income tax returns in the U.S. federal jurisdiction and various state and foreign jurisdictions. The tax years from 2008 through December 31, 2025 remain subject to examination by all major taxing authorities due to the net operating loss carryforwards. The Company is not currently under examination by any taxing jurisdiction. The Company has elected to record the income taxes and any related interest and penalties as income tax expense in the Company's consolidated statements of operations.

Changes in tax laws and rates may affect recorded deferred tax assets and liabilities and the Company's effective tax rate in the future. On July 4, 2025, the One, Big, Beautiful Bill Act (the "Act") was signed into law. The Act contains significant tax law changes with various effective dates affecting business taxpayers, including making permanent the current 21% U.S. federal corporate income tax rate and modifying the timing of certain tax deductions, such as depreciation expense, research and development expenditures, and interest expense. The Company implemented the provisions of the Act in its income tax accounting for the year ended December 31, 2025. The enactment of the Act did not have a material effect on the Company's consolidated financial statements for the current period, and the Company does not currently expect the provisions of the Act to have a material impact on its effective tax rate in future periods.

NOTE 12 – Segment Information

The Company sells capital equipment, which includes both Imricor-developed and third-party equipment, and consumable products, for use in iCMR labs, and capital equipment maintenance service agreements.

Operating segments are defined as components of an enterprise about which separate discrete financial information is available for evaluation by the Chief Operating Decision Maker ("CODM") when making decisions regarding resource allocation and assessing performance. The Company's CODM is its Chief Executive Officer, who reviews consolidated financial results when making resource allocation decisions or evaluating Company performance. The Company manages its business on a consolidated basis and operates as one reportable segment, and the CODM's primary measure of segment profit or loss is net loss.

For the Company's single reportable segment, the total amounts of segment profit or loss and segment assets are the same as net loss and total assets, respectively, presented in the accompanying consolidated financial statements.

NOTE 12 – Segment Information (cont.)

The following table summarizes the significant expense categories reviewed by the CODM for the years ended December 31:

	2025	2024
Revenues		
Equipment revenue	$ 37,798	$ 305,891
Consumable revenue	170,578	460,693
Service revenue	83,933	77,091
Consulting revenue	-	115,749
Total Revenues	292,309	959,424
Costs and expenses		
Cost of goods sold	2,325,837	1,883,542
Sales expenses	2,577,864	1,147,455
Marketing expenses	1,722,401	1,124,589
Clinical research expenses	2,335,524	1,409,113
Regulatory affairs and quality assurance expenses	3,169,087	2,514,980
Other research and development expenses	5,651,154	4,256,091
General and administrative expenses	5,301,396	4,920,466
Total Costs and Expenses	23,083,263	17,256,236
Loss from Operations	(22,790,954)	(16,296,812)
Other income (expense)		
Interest income	1,180,294	257,718
Foreign currency exchange gain	1,509,925	197,867
Other expense	(5,217,827)	(13,851,604)
Total Other Income (Expense)	(2,527,608)	(13,396,019)
Net loss	$ (25,318,562)	$ (29,692,831)

Other segment items within net loss correspond to the consolidated statements of operations line items for interest expense, government grant income, change in fair value of convertible notes (related party), change in fair value of option liabilities, change in fair value of warrant liabilities, and other expense.

Revenues by region were as follows:

	December 31,	
	2025	2024
Europe	$ 292,309	$ 688,209
U.S.	-	115,749
Middle East	-	155,466
Total revenue by geography	$ 292,309	$ 959,424

NOTE 12 – Segment Information (cont.)

The following table provides revenue by country based on the location where services are provided and products are sold for more than 10% of the total revenue for the years ended December 31:

	December 31, 2025	December 31, 2024
Netherlands	$ 156,112	$ 98,237
Germany	112,859	167,320
Hungary	23,338	178,187
Switzerland	-	166,046
Qatar	-	155,466
U.S.	-	115,749
Other countries	-	78,419
	$ 292,309	$ 959,424

Product revenue by type were as follows:

	December 31, 2025	December 31, 2024
Equipment revenue	$ 37,798	$ 305,891
Consumable revenue	170,578	460,693
Total product revenue	$ 208,376	$ 766,584

Property and equipment is held in the following countries:

	December 31, 2025	December 31, 2024
U.S.	$ 1,121,585	$ 1,198,383
Germany	175,111	206,084
Other foreign countries	241,764	474,284
	$ 1,538,460	$ 1,878,751

No individual country other than the U.S. and Germany accounted for more than 10% of the total net book value.

See Note 1 for further details on the Company's products and services, geographic areas, and major customers.

NOTE 13 – Related Party Transactions

K.A.H.R. Foundation is considered a related party based on its ownership interest in the Company, its position as the sole holder of the Company's unsecured, unquoted convertible promissory notes and related warrants issued under the Securities Purchase Agreement dated December 16, 2022, and its contractual right to designate a member of the Company's Board of Directors. See Note 7 for further details on the convertible notes and warrants. Pursuant to the Securities Purchase Agreement, K.A.H.R. Foundation has the right, for so long as the convertible notes are outstanding, to designate one individual to serve as a member of the Company's Board of Directors (the "Lender Nominee"). Dr. Jeffrey Leighton has served as the Lender Nominee since July 2024.

In February 2024, an affiliate of K.A.H.R. Foundation purchased 1,666,667 shares of common stock in the Company's U.S. placement for an aggregate purchase price of $500,000, on the same terms as other investors in the offering. See Note 10 for further information regarding this placement.

NOTE 14 – Subsequent Events

For the year ended December 31, 2025, the Company evaluated, for potential recognition and disclosure, events that occurred through the date the consolidated financial statements were available for issuance, February 24, 2026.

In January 2026, the Company received 510(k) clearance under the premarket notification process from the U.S. Food and Drug Administration ("FDA") for its Vision-MR Diagnostic Catheter and its NorthStar Mapping System. At December 31, 2025, the related performance-based stock options associated with these regulatory milestones were assessed as not probable of achievement under ASC 718, as discussed in Note 10, and, accordingly, no stock-based compensation expense was recognized for these awards as of that date. The January 2026 FDA clearances caused the related performance conditions to be satisfied and certain performance-based stock options to vest, and the Company expects to recognize approximately $773,000 of additional stock-based compensation expense during 2026 in connection with these awards.

Item 14. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 15. Financial Statements and Exhibits.

(a) Financial Statements

The following audited consolidated financial statements of the Company are included in a separate section of this Registration Statement commencing on the page numbers specified below:

INDEX TO FINANCIAL STATEMENTS

Audited Financial Statements

(b) Exhibits

Exhibit Number	Description
3.1+	Amended and Restated Certificate of Incorporation
3.2+	Amended and Restated Bylaws
4.1+	Form of Warrant to Purchase Class A Common Stock issued July 14, 2023
4.2+	Form of Warrant to Purchase Class A Common Stock issued between August 14, 2023, and October 23, 2023
4.3+	Form of Warrant to Purchase CDIs issued between August 15, 2023, and October 23, 2023
10.1+*	2025 Remuneration Plan
10.2+	Securities Purchase Agreement between the Company and K.A.H.R. Foundation dated December 16, 2022
10.3+	Capital Commitment Agreement between the Company and GEM Global Yield LLC SCS dated July 6, 2023
10.4+*	Lease Agreement between the Company and Kraus-Anderson, Incorporated, dated July 15, 2007
10.5+*	First Amendment to Lease Agreement between the Company and Kraus-Anderson, Incorporated, dated March 23, 2009
10.6+*	Second Amendment to Lease Agreement between the Company and Kraus-Anderson, Incorporated, dated October 18, 2012
10.7+*	Third Amendment to Lease Agreement between the Company and Kraus-Anderson, Incorporated, dated June 14, 2019
10.8+	Fourth Amendment to Lease and Expansion Agreement between the Company and Kraus-Anderson, Incorporated, dated October 19, 2021
10.9+*	Lease between the Company and MSP Industrial Portfolio Owner, LLC dated August 1, 2018
10.10+*	First Amendment to Lease between the Company and MSP Industrial Portfolio Owner, LLC dated February 21, 2020
10.11+	Second Amendment to Lease between the Company and MSP Industrial Portfolio Owner, LLC dated May 19, 2020
10.12+	Amended and Restated Employment Agreement between the Company and Steve Wedan dated April 11, 2019
10.13+	Employment Agreement between the Company and Gregg Stenzel dated October 23, 2019
10.14+	Employment Agreement between the Company and Jonathon Gut dated February 20, 2024
10.15+	Form of Indemnification Agreement for directors and executive officers
10.16+	2019 Equity Incentive Plan
10.17+	Form of Stock Option Award Agreement for 2019 Plan
10.18+	Form of Restricted Stock Award Agreement for 2019 Plan
10.19+	2019 Equity Incentive Plan Australia Subplan
10.20+	Form of Stock Option Award Agreement for 2019 Plan Australia Subplan
10.21+*	Patent License Agreement between the Company and Koninklijke Philips N.V. dated December 1, 2023
10.22+*	Licensing Agreement between the Company and livetec Ingenieurbuero GmbH dated November 6, 2023
21.1+	Subsidiaries of the registrant

+Previously filed

*Confidential portions of this exhibit have been redacted in compliance with Item 601(b)(10) of Regulation S-K

SIGNATURES

Pursuant to the requirements of Section 12 of the Securities Exchange Act of 1934, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized.

IMRICOR MEDICAL SYSTEMS, INC.

Date: April 24, 2026

By: /s/ *Steven Wedan*
Steven Wedan
Chief Executive Officer