

IMRICOR - FY2024 RESULTS

HIGHLIGHTS:

Regulatory

- First module submitted and returned by US FDA with no deficiencies
- NorthStar submitted for CE Mark approval in Europe
- First MRI guided ablation on US soil performed at Johns Hopkins as part of VISABL-AFL
- Saudi FDA approval received, registration completed in Qatar opening Middle East
- CE Mark approval of MR Vision diagnostic catheter
- VISABL-AFL global pivotal trial commences enrolment in France, US and Switzerland

Commercial

- Global rollout underway with new site activations in France, Netherlands, Croatia and Switzerland.
- Installation complete in Hungary, first procedures being scheduled
- First purchase orders received from Qatar initiating expansion into Middle East
- Completed all technical goals to allow NorthStar to operate on the Philips platform
- Licence agreement signed with ADIS, a Swiss-based AI company, to add AI modules into NorthStar
- Added sales resources in Europe, growing US team, beginning training to prepare for US commercial launch

Financial

- Group revenue of US\$959k + 56% on prior year
- Operating costs well contained down 1% to \$17.3m including R&D investment
- Fourth quarter cash burn of \$3.8m in line with guidance
- Strong balance sheet US\$15.7m cash in place to fund major milestones in 2025

An investor webinar will be held at 9.00am AEDT on Thursday 27th February 2025. <u>Click here to register</u>

27 February 2025 – Melbourne, Australia (26 February 2025 – Minneapolis, MN United States) – Imricor Medical Systems, Inc. (Company or Imricor) (ASX: IMR), today releases its financial results for the full year ending 31 December 2024.

Commenting on the year, Imricor Chair and CEO, Steve Wedan said: "2024 was a year of significant progress across Imricor, and a turning point for all of us in so many ways. Looking forward, there is no time to pause and appreciate the magnitude of what we have accomplished, because our work is not done."

"We have started 2025 with excellent momentum. A strong balance sheet has allowed us to make measured investments towards several functions, and these are already having a material impact across the business.

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"We are advancing iCMR applications, driving towards US commercialisation, expanding in the Middle East, and once again growing our European pipeline to pre-pandemic levels.

"The milestones ahead of us in 2025 are truly groundbreaking. Within Imricor, you can feel the excitement, whilst externally, you can feel the anticipation. It is a special time, and we are genuinely eager to deliver on our mission and on the promise of MRI-guided interventional medicine."

Commenting on the outlook, Mr. Wedan said, "The stage is set for Imricor to have a breakout year in 2025. For any medical device company, to have just a single device approved by the US FDA is a significant achievement and the culmination of years of work and thousands of pages of supporting documentation.

"Imricor is doing this on a large scale with over a dozen products across capital equipment, consumable devices, and NorthStar. This set of approvals will establish the platform for commercial sales in the US, a market that accounts for half of the \$10 billion global market, where reimbursement is over four times higher than in some European countries.

"The US is also our home market where we have excellent data on hospitals that already have access to a CMR, as well as having our own iCMR in Minneapolis, where doctors can visit and experience the technology first hand. In healthcare, data is king, and Imricor will have the clinical data coming out of two global trials, VISABL-VT and VISABL-AFL. From these data, we expect proof points will build further interest and excitement in the space, which in turn helps grow the pipeline and establish new iCMR labs."

Imricor background

Imricor is leading the new field of *real-time iCMR cardiac ablations* – that is, cardiac ablations guided by real-time magnetic resonance imaging (MRI), rather than by conventional x-ray fluoroscopy. iCMR (*interventional cardiac magnetic resonance*) is the term used to describe such interventional procedures performed in conjunction with MRI. The goal is to provide faster, safer, and more effective treatments of cardiac arrhythmias compared to conventional means. Imricor is the only company in the world that provides MRI-compatible consumable devices, such as single-use ablation catheters, required to perform cardiac ablations in an iCMR lab.

Benefits of real-time iCMR cardiac ablations are derived from the superior imaging capabilities of MRI compared to x-ray, especially when it comes to imaging the heart and vascular structures which are largely invisible to x-rays. The goal of MRI guidance is to enable faster, more effective, and less expensive treatment of cardiac arrhythmias, all in a setting that is free of dangerous x-ray radiation exposure for patients, physicians, and other medical personnel.

Imricor's target market of cardiac ablations is estimated to be US\$10 billion worldwide.

Executing the VISABL-VT and VISABL-AFL trials, as well as re-establishing the iCMR-guided atrial flutter ablation market in Europe, post-pandemic, and expanding into new geographies like the United States, Australia, New Zealand, and the Middle East are key drivers of Imricor's growth.



For more information on the Company's FY24 Results, refer to the Investor Presentation released to the ASX today, 27 February 2025.

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 a leading developer of innovative MRI-compatible medical devices which can be used to carry out real-time iCMR cardiac ablation procedures. Headquartered in the US, Imricor seeks to make a meaningful impact on patients, healthcare professionals, and healthcare facilities around the world by increasing the success rates and bringing down the overall costs of cardiac ablation procedures.

Imricor's Products

Imricor is a pioneer and leader in developing MRI-compatible products for cardiac catheter ablation procedures, and believes it is the first company in the world to bring commercially viable and safe MRI-compatible products to the cardiac catheter ablation market.

The Vision-MR Ablation Catheter is the Company's 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 European Union and the Kingdom of Saudi Arabia (KSA) with an indication for treating type 1 atrial flutter. Imricor intends to seek approval for expanded indications in the future. The Company is also pursuing the required regulatory approvals to place its key products on the market in Australia, the U.S., and the other Middle East countries.

The Company has also obtained approval within the EU and KSA for the sale of the Advantage-MR EP Recorder/Stimulator System and other consumable products, such as the Vision-MR Diagnostic Catheter (pending in KSA) and Vision-MR Dispersive Electrode.

Imricor sells its capital and consumable products to hospitals and clinics for use in Interventional Cardiac Magnetic Resonance Imaging (iCMR) labs, in which ablation procedures using the Vision-MR Ablation Catheter can be performed. An iCMR lab is an interventional lab that is fitted with MRI equipment for use in cardiac diagnostic and interventional procedures. The installation of iCMR labs is driven primarily by MRI equipment vendors working collaboratively with Imricor. Vendors such as Koninklijke Philips N.V., Siemens Healthcare GmbH, and GE HealthCare help to target certain sites and support the design and construction of iCMR labs for those sites.

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. 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.