IMRICOR 1H 2024 Results

HIGHLIGHTS:

- Saudi FDA approval for Imricor capital equipment and consumable devices
- CE Mark approval for Vision-MR Diagnostic Catheter
- Amsterdam UMC recommences commercial cases using NorthStar 3D mapping system
- Dubrava University Hospital performs first iCMR procedures in Croatia
- Cardiovascular Institute Paris Sud (ICPS) commences cases for US FDA clinical trial
- Lausanne University Hospital (CHUV) completes construction of iCMR Lab and installation of Imricor equipment.
- Imricor wins tender to supply iCMR EP equipment and consumables to Semmelweis University Hospital in Hungary

Subsequent to quarter end:

- Semmelweis University Hospital completes installation and prepares for first cases in Hungary
- Johns Hopkins performs first iCMR guided ablation procedure on US soil
- Imricor successfully raises A$35 million in two-tranche placement

Webinar to be held today at 8:00am AEST / 5:00pm CDT. Click here to register.

27 August 2024 – Minneapolis, MN United States (**28 August 2024** – Melbourne, Australia) – **Imricor Medical Systems, Inc.** (**Company** or **Imricor**) (**ASX: IMR**), the global leader in real-time iCMR cardiac ablation products, today releases its 1H24 Financial Results for the period ended 30 June 2024 and provides an update on its operational performance.

Imricor's Chair and CEO, Steve Wedan, commented: "This year we are undertaking two global pivotal clinical trials: VISABL-AFL to support US FDA approval, which helps us access the world's biggest market at over US$4 billion annually; and VISABL-VT in Europe to prove the long-promised value of MRI guidance for complex arrhythmia treatment. Individually, each of these trials has the potential to transform Imricor, and to have them both occurring at the same time, along with the strongest balance sheet position in the Company's history, has the whole team highly energised."

VISABL-AFL Trial update

During the period, ICPS in France commenced enrolling patients to support the Company's FDA submission. Following the period end, Johns Hopkins also treated the first patient in the US. Lausanne University Hospital has now completed installation at their brand-new state of the art iCMR Lab, and patient recruitment is about to commence. The fourth site that will be joining the trial is Amsterdam UMC; however, Imricor staff and hospital staff are currently focussed on doing the world's first VT ablation in the iCMR at Amsterdam UMC before the focus shifts to enrolling patients for the VISABL-AFL trial.

Ventricular Tachycardia Ablation Trial Update

The VISABL-VT trial has been approved to commence at Amsterdam UMC. However, recent updates to the NorthStar 3D mapping system and the 3rd party defibrillator are being resubmitted for review and inclusion in the trial. These updates, whilst delaying the planned first case by approximately a month, make for a more robust trial experience for doctors and patients which is the top priority. The first VT patient is expected to be treated at Amsterdam UMC in early Q4.

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$8 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 are key drivers of Imricor's growth.

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 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 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.

The Company is pursuing the required regulatory approvals in the US and the other Middle East countries as well.

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.