

IMRICOR 1H 2023 RESULTS

HIGHLIGHTS:

- Consumable product revenues of US\$161,000
- 44 procedures performed across 9 active sites in Europe; fewer patients with standalone atrial flutter identified as major contributor to low procedure volume, expected to increase with time
- Received approval from US FDA to commence the VISABL-AFL clinical trial aimed at supporting FDA approval of Imricor's products in the US
- GE HealthCare and Imricor signed an MSA to make Imricor products work with GE HealthCare MRI systems
- Cash balance of ~US\$1.5 million as at 30 June 2023
- An investor webinar will be held at 9.00am AEST on 24 August 2023. [Click HERE to register](#)

POST 1H:

- Executed distribution agreement with Al Faisaliah Medical Systems (FMS), giving FMS exclusive right to market and sell Imricor's products in the Kingdom of Saudi Arabia (KSA)
- Balance sheet bolstered via advantageous A\$30 million equity funding facility secured from GEM Global Yield LLC SCS, which can be drawn from at Imricor's discretion
- Successfully executed two placements raising a total of A\$4.29 million¹ (US\$2.84m¹)
- Commitment letter received from NDDF for US\$1 million term loan
- Received approval to commence VISABL-VT clinical trial at Haga Hospital in the Netherlands
- Current cash balance of ~US\$2.6 million, with undrawn A\$30m (~US\$20m) facility available

23 August 2023 – Minneapolis, MN United States (**24 August 2023** – Melbourne, Australia) – **Imricor Medical Systems, Inc. (Company or Imricor) (ASX: IMR)**, the global leader in real-time iCMR cardiac ablation products, is pleased to announce its results for the six months ended 30 June 2023.

Imricor's Chair and CEO, Steve Wedan, commented: *"The first half of 2023 was a time of building momentum through many efforts that are not always obvious from the outside but are critical to our success as we aim to fulfil our mission of changing a clinical standard of care worldwide.*

"More recently, we've been able to announce the outcomes of many of these internal initiatives, including our clinical trial approvals, the development of our NorthStar 3D mapping system, our

¹ Figures in this announcement include amounts transacted in both A\$ and US\$, which have been converted to the currency presented based on a foreign exchange rate of A\$1.00 to US\$0.6475 (being the exchange rate published by the Reserve Bank of Australia on 14 August 2023).



expansion into the Middle East, the addition of GE HealthCare to our targeted MRI platform set, and the bolstering of our balance sheet.

“Looking forward, we are fast approaching some of the most significant milestones in the Company’s history - milestones such as performing the first ventricular tachycardia ablation guided by real-time iCMR, and initiating a clinical trial aimed at supporting FDA approval in the US. We also intend to continue building momentum in our market development and sales efforts, growing our installed base of active sites, and increasing procedure volumes and revenue.”

Clinical Trials Update

Ventricular Tachycardia (VT) –VISABL-VT Trial (EU)

During the first half of FY23, the Company made several advancements toward commencing its VISABL-VT clinical trial, aimed at supporting expanded indications for real-time iCMR ablation of ventricular tachycardia (VT). Following the period, the Company received approval to commence the VISABL-VT clinical trial at Haga Hospital in The Hague, Netherlands. On-site training and other preparations for the first procedure at Haga Hospital began on Monday this week, as medical personnel returned from summer holiday breaks. Once the study is initiated at Haga Hospital, additional sites in the Netherlands are expected to be added, followed by German sites upon approval by the German Competent Authority, BfArM.

Atrial Flutter (AF) – VISABL-AFL Trial (US)

Imricor received an approved Investigational Device Exception (IDE) from the US Food and Drug Administration (FDA) to commence a global clinical trial to support FDA approval of Imricor’s products in the US. The clinical trial is called VISABL-AFL.

The contracting process at the first four sites identified to participate in the VISABL-AFL study is progressing. Two sites are in the US and two sites are in the EU. The Company’s expectation is to begin enrolment in Q3 this year.

Procedure Volumes

A total of 44 procedures were performed in the period across 9 active sites, providing a baseline for future procedure rate tracking. A decrease in patients with stand-alone atrial flutter following the pandemic continues to be the major factor affecting volume, and it is expected that the number of atrial flutter patients will increase at each site, as people return to more regular pre-COVID healthcare routines.

AI Product Update

The Company is planning the first integration of AI into NorthStar², targeting automatic heart chamber segmentation from 3D MRI images (“Automatic Segmentation”), a procedure that is performed manually today. The NorthStar development team, along with outside research partners, are working to integrate Automatic Segmentation into the next software release of

² NorthStar is investigational and has not yet received regulatory approval in any jurisdiction



NorthStar. Automatic Segmentation, coupled with a physician's ability to fine tune the result, is expected to save time during each procedure in the future.

GE HealthCare Integration Update

The Company entered into a Master Services Agreement (MSA) with GE Precision Healthcare LLC (GE HealthCare), under the terms of which GE HealthCare will pay Imricor to develop the hardware and software interfaces required to make Imricor's real-time iCMR cardiac ablation solutions operate with GE HealthCare MRI systems.

The hardware interface will connect Imricor's Advantage-MR EP Recorder/Stimulator to GE HealthCare's 1.5T MRI platform, such that Imricor's catheters and other devices may be recognised and actively tracked by GE HealthCare MRI scanners. Similarly, the software interface will connect Imricor's NorthStar 3D mapping system to GE HealthCare MRI scanners.

The MSA is effective as of April 20, 2023, and has an initial term ending December 31, 2026. The hardware and software interface development projects are anticipated to be completed in Q4 2023.

With the addition of GE HealthCare MRI systems to the MRI systems from Philips and Siemens Healthineers, Imricor's products will operate with the vast majority of 1.5T MRI systems sold in the Company's target markets.

Distribution Agreement

In July, Imricor took significant steps to expand its presence in the Middle East. The company signed a distribution agreement with Al Faisaliah Medical Systems (FMS) in the Kingdom of Saudi Arabia (KSA), granting FMS exclusive rights to market and sell Imricor's iCMR ablation products in the country. This milestone is expected to make KSA the first country in the Middle East to offer iCMR ablation products, catering to a market that performs nearly 50,000 cardiac ablation procedures annually.

Capital Management and Balance Sheet

Imricor has secured significant financing agreements to support its strategic initiatives. Firstly, a Security Subscription Facility (SSF) with GEM Global Yield LLC SCS (GGY) provides Imricor with access to up to A\$30 million, enabling flexible funding for achieving upcoming milestones and enhancing its investment appeal. This financing option allows Imricor to draw down funds as needed, providing financial flexibility to achieve upcoming milestones that are expected to positively impact the company's valuation and attractiveness as an investment proposition.

Additionally, the company successfully raised US\$2.84 million¹ (approximately A\$4.29 million¹) from Australian, New Zealand, and US investors through two private placements. Australian and New Zealand investors obtained CDIs, while US investors acquired Class A Common Stock. The shares of Class A Common Stock are subject to a 12-month holding lock, after which they can be converted into CDIs for trading on the ASX. Investors also received 10-year warrants as part of the placements. Both placements were executed without assistance from a broker to minimise fees and to maximise proceeds available to apply to the business.

Furthermore, the North Dakota Development Fund (NDDF) has approved a US\$1 million term loan for Imricor, which is currently in the negotiation stage for final terms and documentation.



The company is actively exploring additional attractive economic incentive programs from government agencies.

Investor Webinar

An investor webinar will be held to discuss the 1H23 results. Please find the details below:

Presenting: Executive Chair, President and CEO, Steve Wedan and CFO, Jonathon Gut.

Time: 9:00am AEST on Thursday, 24 August 2023

To register for the session and for more information on the conference click here:

https://us02web.zoom.us/webinar/register/WN_LVifah87TrmcVgv6vHc1hA

Investors can submit questions prior to the webinar to simon@nwrcommunications.com.au or do so via the Q&A function on Zoom.

Imricor Background and Strategy

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. Real-time iCMR also reduces repeated exposure to dangerous x-ray radiation.

Imricor's strategy to grow the field of real-time iCMR cardiac ablations worldwide is built on two actions: to increase the number of iCMR sites across the world and to increase the number of procedures doctors can perform at each iCMR site using Imricor's consumable products.

The near-term keys to executing this strategy include:

- Progressing the VISABL-VT clinical trial
- Progressing the VISABL-AFL clinical trial
- Gaining regulatory approval for NorthStar, and integrating it with all three major MRI platforms from Siemens Healthineers, GE HealthCare, and Philips
- Engaging with key opinion leaders to expand the breadth of presentations and publications on real-time iCMR guided ablations
- Growing the Company's footprint across different countries and regions, enabling access for those seeking care and creating competitive pressures between hospitals

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 with an indication for treating type 1 atrial flutter. Imricor intends to seek approval for expanded indications in the future. The Company is also in the early stages of pursuing the required regulatory approvals to place its key products on the market in Australia and the U.S.

The Company has also obtained approval within the EU for the sale of the Advantage-MR EP Recorder/Stimulator System and its consumable product, the 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. and Siemens Healthcare GmbH 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.