ASX Announcement

25 August 2021

IMRICOR ANNOUNCES FINANCIAL RESULTS FOR HY2021

Highlights

- The Company incurred a net loss of US$9.962 million for HY21, with revenue of US$0.366 million, impacted by low procedure volumes due to the COVID-19 pandemic
- Signed one new purchase agreement at Helios Berlin Buch, totalling to 10 sites across Germany, The Netherlands and France
- Commenced first cases at the South Paris Cardiovascular Institute, and re-commenced procedures across multiple sites in Germany and The Netherlands following a temporary halt due to the introduction of COVID-19 containment measures
- Remain on schedule with key growth strategy of geographic expansion, including FDA approval in the United States and TGA approval in Australia
- Remain on schedule with key growth strategy of expanding indications for ventricular tachycardia (VT) by year-end 2023
- Entered into an exclusive distribution agreement with Regional Health Care Group for consumables and a non-exclusive distribution agreement for sale of capital equipment in Australia and New Zealand
- Received TGA approval for Advantage-MR system in Australia and Medsafe approval for all Imricor products in New Zealand
- At 30 June 2021, Imricor maintained a cash balance of US$15.607 million which supports the progress of its commercialisation plans and growth strategy

Imricor Medical Systems, Inc. (**Company** or **Imricor**) (**ASX:IMR**) the global leader in MRI-guided cardiac ablation products, today released its financial results for the half year to 30 June 2021.

Imricor Chair and CEO Steve Wedan said: “We have made strong progress, delivering on a range of objectives that were outlined at the time of our Initial Public Offering which will support the Company’s growth and drive long-term value creation for investors.

“While the operating environment in the first half has presented challenges due to the impact of the COVID-19 pandemic in our core European markets, Imricor is well positioned to leverage its achievements to date as business conditions improve.

“We currently have 10 sites signed, and we are in active discussions with 48 additional hospitals, of which nine are in the final two stages of the sales process.

“As restrictions eased across our key geographies, iCMR guided atrial flutter ablations procedures commenced smoothly at multiple sites including Helios Leipzig Heart Centre, Dresden Heart Centre and Maastricht University Medical Centre. In addition, South Paris Cardiovascular Institute

has also recently undertaken its first procedures. Additional sites are scheduling procedures as we head into September."

Delivering on IPO objectives

Over the past 18 months, Imricor has delivered strong outcomes on a significant number of important initiatives, outlined at the time of the Company's Initial Public Offering (IPO), that will support the delivery of the Company's strategy of growing the installed base of iCMR sites across its target geographies, growing procedure rates and expanding the indications that Imricor's products can support.

These key achievements include:

- CE mark approval received in January 2020 for the Vision-MR Ablation Catheter and the Vision-MR Dispersive Electrode;
- While the COVID-19 pandemic has impeded Imricor's site expansion program over the past 18 months, the Company has signed 10 sites across Germany, The Netherlands & France, and is in active discussions with 48 additional hospitals, including nine who are in the latter stages of the sales process;
- The Company's geographic expansion strategy is well progressed and on schedule, with sales commenced in three priority countries in Europe and strong progress on regulatory approvals being made in key new markets including the US, Australia and New Zealand
- Expanding indications to ventricular tachycardia (VT) ablations is on track, with VT clinical trials commencing in 2022 to support approvals in Europe by the end of 2023, with ANZ and the US to follow shortly afterwards
- Product development and line expansion is well progressed, including commercial release of the diagnostic catheter, pending CE mark approval, expected by early 2022, and clinical trials for the steerable sheath and transseptal needle planned as part of the VT indication expansion;

Despite the impact of COVID-19 on the Company's site expansion program, Imricor has concluded a number of new agreements during this time and ensured that, by maintaining close engagement with prospective sites, it is well positioned to accelerate its expansion program as conditions ease.

Expanding indications and geographic reach

Throughout the pandemic, Imricor has focused resources on advancing future growth initiatives, through expanding the Company's approved indications and geographic reach.

The Company's plans to expand indications to ventricular tachycardia ablations are on track. A pre-clinical trial study is scheduled for the fourth quarter of 2021, with a European clinical trial expected to commence in 2022, and approval expected at the end of 2023.

The Company's plans for securing FDA approval in the United States are progressing well. In April, pre-submission meetings with the FDA were completed, and the Company is now preparing to submit documentation for an Investigational Device Exemption (IDE) to commence a clinical trial. The Company is currently working through a process to identify suitable sites for participation in the trial and targets the end of 2023 for FDA approval of atrial flutter ablation. VT indications in the US are expected to follow shortly thereafter by initiating a VT clinical trial soon after the European trial begins, or potentially combining them into a worldwide trial if FDA timing allows.

In March, Imricor entered into a Distribution Agreement with Regional Health Care Group (RHCG) in Australia and New Zealand. Under the terms of the agreement, RHCG will be the exclusive distributor of Imricor's consumable products, and non-exclusive distributor of Imricor's capital

equipment. RHCG will also help facilitate the necessary regulatory approvals and support of Imricor's products.

In Australia, Imricor's Advantage-MR System received TGA approval toward the end of the period and the Vision-MR Ablation Catheter is now under review with the TGA. In New Zealand, all Imricor products have been approved by Medsafe and have now been registered in the WAND database for medical devices. Both of these approvals are significant milestones in Imricor's geographic expansion strategy, and also create the opportunity for select Australian and New Zealand sites to participate in the Company's VT ablation clinical trial which is anticipated to commence in 2022.

Summary

Imricor is focused on managing a recovery from the effects of the pandemic.

The Company currently has ten labs signed in key European markets, with four of these having commenced or re-commenced procedures. Importantly, while site adoption has been slowed by the COVID-19 pandemic, Imricor's pipeline of new sites remains strong with many sites at advanced stages in the sales process.

Irmicor's geographic expansion plans are proceeding well, with sales expected to commence in Australia and New Zealand in the near term, while the overall path to the US FDA approval is on track for the end of CY2023.

The Company's plans to expand indications are also on track, with ventricular tachycardia (VT) clinical trials to commence in 2022, supported by further system developments and integrations that enable a seamless transition into VT ablation procedures.

Imricor is targeting a large addressable market, estimated to be over US$6 billion worldwide with growth supported by several key drivers, including increased incidence of cardiac disease, a shift towards minimally invasive procedures and the cost effectiveness of catheter ablation treatment options.

The solid outcomes and progress that Irmicor has delivered on its key priorities from the time of the IPO position the Company well for the period ahead, ensuring that as conditions recover, the Company can leverage its strong product and expanding geographic platforms for the benefit of shareholders.

Investor Conference Call

Imricor's Chair and CEO, Steve Wedan and CFO, Lori Milbrandt will host a market briefing via a live webcast as detailed below:

Date: **Thursday 26 August 2021 (AEST) / Wednesday 25 August 2021 (CDT)**

Time: **9:00am (AEST) / 6:00pm (CDT)**

Webcast: **https://s1.c-conf.com/diamondpass/10015521-fs63h9.html**

Participants will be required to register for access to the webcast. An archive of the webcast will be available on Imricor's website after the event.

ENDS

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

Further Information

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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 MRI-guided cardiac catheter 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 catheter 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.