



ASX Announcement

## RELEASE OF FINANCIAL RESULTS FOR FIRST HALF OF 2020

**24 August 2020 – Minneapolis, United States – Imricor Medical Systems, Inc. (Company or Imricor) (ASX:IMR)** the global leader in MRI-guided cardiac ablation products, today releases its Appendix 4D half year report for the six months to 30 June 2020.

### Highlights during the first half of 2020

- CE mark approval received in January for the Vision-MR Ablation Catheter and Vision-MR Dispersive Electrode, enabling Imricor to market and sell these consumable products in the European Union for use in atrial flutter procedures.
- Commencement of procedures at the Dresden Heart Centre in late January, followed by the Haga Hospital and Amsterdam University Medical Centre in June as hospitals eased restrictions associated with the COVID-19 pandemic.
- Five sites, including the Leipzig Heart Centre, have labs in place and are expected to sign contracts and/or commence procedures within the next four to six weeks, assuming no further COVID-19 related disruptions in these regions. Training and installation across these sites is currently either scheduled, or in the process of being scheduled.
- A further 14 sites are well progressed and in the third stage of Imricor's five-stage sales process, supporting an acceleration of lab rollouts during the last quarter of 2020, assuming no further COVID-19 related disruptions to European medical facilities.
- A strong and growing pipeline of potential clinical sites with opportunities further enhanced by the recent agreement with Philips, enabling the sale of Imricor's capital products as part of the Philips comprehensive iCMR installation package.
- Entered into a Master Purchasing Agreement with Sana, the largest Group Purchasing Organisation in Germany, streamlining the future establishments of new sites and facilitating access for sales and marketing purposes to approximately 80 sites in Germany and Switzerland currently performing cardiac catheter ablations.
- Active Catheter Imaging successfully implemented for atrial flutter procedures, enabling accelerated adoption at certain sites utilising existing equipment without reliance on third-party active tracking and mapping systems.
- On track to commence clinical trials during 2021 to support expanded indications.
- Continued expansion of the Imricor workforce, building further strength to deliver growth strategies including a number of hires from high calibre organisations within the medical technology sector.
- Achieved strong progress across a number of initiatives to support future growth despite the impact of the COVID-19 pandemic.

Imricor's Chair and CEO, Steve Wedan said: "Having commenced our long-awaited commercial launch at the Dresden Heart Centre, we were deeply disappointed by the impact COVID-19 had on our European lab rollout plans, as hospitals restricted access to outside personnel and



postponed elective procedures. Clearly, we are thrilled to have recommenced these activities, successfully launching the Haga Hospital and Amsterdam University Medical Centre in June, with more sites expecting to commence procedures in the coming weeks. We have recently seen a moderate rise in daily COVID case numbers across Germany and while there has been no increase in hospital restrictions, we remain in close contact with doctors at these locations.

“The benefits of undertaking cardiac catheter ablation procedures guided by MRI, combined with ease of adoption and early clinical success is driving strong and growing support for Imricor’s products across the medical profession. In particular we are seeing increased focus on the future deployment of our technology for more complex cardiac ablation procedures, further enhancing the opportunity to deliver meaningful and positive impacts on the health of people suffering from heart arrhythmias.

“As such we are seeing strong growth in our pipeline of potential new sites, buoyed by our early commercial success, education and growing awareness of Imricor’s products supported by early adopters of our technology and our ongoing collaborative relationships with leading MRI vendors, Siemens and Philips.

“Our recent capital sales agreement with Philips is an exciting milestone, allowing Philips to deploy their extensive sales force across Europe to drive iCMR lab adoption and enabling us to focus on supporting product utilisation, growing our portfolio of consumable devices and expanding our indications for use.

“This agreement further enhances our expectations regarding an acceleration in lab adoption during the last quarter of 2020, assuming no further COVID-19 related disruptions to European hospitals.

“Although the COVID-19 pandemic stalled our lab roll out plans, we continued to work hard across the business to build the foundations for our future success. Development of our pipeline products to deliver improvements in gross margin, and most importantly, products to enable expanded indications has progressed well. We expect to achieve commercialisation of our diagnostic catheter in mid-2021 and to commence clinical trials to support expanded indications during 2021.

“Our regulatory strategy regarding these products is well advanced and we are continuing to progress towards regulatory approval in the United States and Australia, further supporting our future growth.

“We have exciting opportunities ahead of us as we accelerate our lab roll out plans and continue our focus on enabling physicians with MRI-compatible products as we work together to establish a new standard of care in cardiac catheter ablation procedures.”

Further information is provided in Imricor’s HY20 Investor Presentation released today and the business update released on 28 July 2020.

## **Financial Performance**

During the six months to 30 June 2020, Imricor delivered revenue of US\$0.277 million (HY19 US\$0.055 million). Product revenue of US\$0.170 million was generated from the sale of Imricor’s consumable products, significantly impacted by the COVID-19 pandemic and stalling of Imricor’s lab roll out plans, along with a temporary suspension in procedure volumes at Dresden Heart



Centre. Consulting revenue of US\$0.1 million in the period related to the termination of a Joint Research Agreement which resulted in the recognition of a previously recorded contract liability.

For the half year period, Imricor reported a net loss of US\$5.798 million (HY19 US\$5.050 million). Operating expenses increased to US\$5.639 million (HY19 US\$3.071 million) driven by further investment in sales and marketing, research and development and staff costs across a number of functional areas as the Company expanded its workforce to deliver future growth, as well as increased costs associated with becoming a public company.

Cash outflows from operating activities were US\$5.737 million (HY19 US\$3.046 million). The Company completed an AU\$20.3 million institutional placement in February 2020, raising net proceeds of US\$12.653 million. At 30 June 2020 Imricor maintained a cash balance of US\$11.425 million.

### **Investor Briefing**

Imricor's Chair and CEO, Steve Wedan and CFO, Lori Milbrandt will today provide a briefing on the half year results to investors via a live webcast as detailed below:

**Date:** Tuesday 25 August 2020 (AEST) / Monday 24 August 2020 (CDT)  
**Time:** 9:00am (AEST) / 6:00pm (CDT)  
**Webcast:** <https://s1.c-conf.com/DiamondPass/10009134-invite.html>

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

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

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### **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 CHES Depository 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.