



## ASX Announcement

### RELEASE OF FINANCIAL RESULTS FOR FY2020

**24 February 2021 – Minneapolis, United States – 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 full year to 31 December 2020.

#### Highlights:

- Imricor has signed purchasing agreements across nine sites in Germany, The Netherlands and France.
- In recent months Imricor has experienced delays in signing agreements with new clinical sites due to extended hospital closures associated with COVID-19 containment measures across the key target geographies of Germany and The Netherlands, however a number of agreements are well advanced with execution pending the easing of existing COVID-19 restrictions.
- Imricor's strong and growing pipeline is further supported by collaborative relationships with Philips and Siemens, with the company well positioned as COVID-19 restrictions ease to quickly deliver an acceleration in lab adoption in 2021.
- The Company is working closely with contracted sites to schedule installation, training and the commencement of cases as COVID-19 restrictions ease.
- Imricor continues to make solid progress on other key growth strategies including FDA approval in the United States, TGA approval in Australia, the development of products to enable expanded indications and the development of an MRI-compatible myocardial biopsy system with the potential to establish Imricor's first product line expansion beyond cardiac ablation.
- The Company incurred a net loss of US\$12.4 million for FY20, with revenue of US\$0.7 million, impacted by low procedure volumes due to the COVID-19 pandemic.
- At 31 December 2020, Imricor maintained a cash balance of US\$25.140 million which supports the progress of its commercialisation plans and growth strategy.

Imricor Chair and CEO Steve Wedan said: "COVID-19 related restrictions on hospital access and elective procedures had a significant impact on Imricor's commercialisation plans during 2020. On a positive note, vaccinations are underway across Europe and falling daily case numbers are expected to deliver relief in terms of government restrictions in coming weeks, evidenced by the fact that we commenced procedures yesterday at one of our newest sites, the Maastricht University Medical Centre+ in the Netherlands.

"Looking ahead, we expect to see the signing of new agreements recommence in the second quarter and accelerate in the second half of this year. Our training and installation teams in Europe are supported by US-based teams, providing capacity to drive towards an installed base by the end of 2021 that is aligned with our pre-COVID-19 expectations.



“While recognising the pressures still faced by the medical community, we have maintained close engagement with sites to progress the signing of agreements and also to schedule training and installation in anticipation of reduced restrictions.

“Interest in Imricor’s products remains strong, driven by early clinical success, growing market awareness and the opportunity to establish a new standard of care in the treatment of heart arrhythmias. In particular, we are seeing increased focus on more complex cardiac ablation procedures, where our technology has the potential to address significant unmet needs in the market.

“While our commercialisation plans have been delayed, we have retained a strong focus on progressing our future growth initiatives, through expanding our approved indications and geographic reach. We continue to make excellent progress in the development of our products to enable this, with a focus on more complex procedures requiring access to the left side of the heart, such as ventricular tachycardia and atrial fibrillation. These products are expected to be ready for clinical trial in 2021.

“Our strategy on FDA approval in the United States is progressing well and we continue to target a clinical trial during 2021-2022. Further, we expect to appoint a local agent to facilitate TGA approval in Australia very soon.

“We have made good progress on strategies that will improve our gross margin in future years, with the development of our second-generation ablation catheter and diagnostic catheter. We expect these products to be available for commercial release by the end of 2021 or early 2022, pending CE mark approval.

“Our pipeline of potential clinical sites continues to grow, supported by our strategic relationships with leading MRI vendors Philips and Siemens. With a sales and distribution agreement in place enabling Philips to sell our capital equipment as part of an overall iCMR package, the expansion of the trained Philips sales force will support significant growth in this pipeline over the coming year. We continue to work collaboratively with Siemens as we progress towards a similar agreement.

“We have an exciting year ahead, as we move through COVID-19 and accelerate lab adoption, deliver significant progress across our growth strategies and further advance opportunities for expansion beyond cardiac ablation, including the current development of an MRI-compatible myocardial biopsy system. We see 2021 as an important year that will strongly position the company for success in the coming years.”

Further detail in relation to Imricor’s business activities is contained in the December 2020 quarterly update dated 27 January 2021 and in the investor presentation released today.



## Investor Conference Call

Imricor's Chair and CEO, Steve Wedan and CFO, Lori Milbrandt will provide a briefing on the FY20 results to investors via a live webcast as detailed below:

**Date:** Thursday 25 February 2021 (AEDT) / Wednesday 24 February 2021 (CDT)  
**Time:** 9:00am (AEDT) / 4:00pm (CDT)  
**Webcast:** <https://s1.c-conf.com/diamondpass/10012222-f8ijlc.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.

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

ENDS

### 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.

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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.

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