



## ASX Announcement

### 2020 ANNUAL MEETING OF STOCKHOLDERS CHAIR'S ADDRESS

**12 May 2020 – Minneapolis, United States – Imricor Medical Systems, Inc. (Company or Imricor) (ASX:IMR)** is pleased to provide the Chair's address to be delivered at the 2020 Annual Meeting of Stockholders today.

Due to restrictions on travel and public gatherings associated with COVID-19, this will be held as a virtual meeting, details of which are provided below:

**Date:** Wednesday, 13 May 2020 at 9:00am Sydney time or Tuesday, 12 May 2020 at 6:00pm US Central Daylight Time

**URL:** <https://web.lumiagm.com>

**Meeting ID:** 382-686-529

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.

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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 expects to sell 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 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.



**IMRICOR MEDICAL SYSTEMS INC.**  
**2020 ANNUAL MEETING OF STOCKHOLDERS**  
**CHAIR'S ADDRESS**

2019 and the early part of 2020 were transformative periods for Imricor. In August last year we listed on the Australian Securities Exchange, raising capital for growth and commercialisation pending the CE marking of our consumable products. The remainder of 2019 was focused on pushing through the CE mark process which was significantly delayed due to the well-known stresses placed on our notified body, TÜV SÜD, as a result of the new EU Medical Device Regulations.

However, on January 23<sup>rd</sup>, we were pleased to finally receive CE mark approval, and we moved swiftly to commercial launch. Our first procedures were performed at the Dresden Heart Centre in late January. This was an exciting moment for me personally and a tremendous milestone for Imricor, as these were the first iCMR-guided ablations to be performed anywhere in the world with market approved devices.

Contributing significantly to the speed at which the Dresden Heart Centre got started, was a new imaging technique our engineers and scientists developed in the latter part of 2019, which we call Active Catheter Imaging. This technique uses native MR imaging to easily identify the location of the ablation catheter within the patient without the use of a mapping system or active tracking and has opened the door for more clinical sites like Dresden to more quickly commence atrial flutter ablations guided by real time iCMR.

Active Catheter Imaging has proven to be highly effective in procedures undertaken at the Dresden Heart Centre, and feedback from physicians performing these procedures has been excellent. Further, anecdotal outcomes support reduced atrial flutter procedure times compared to traditional atrial flutter procedures in a conventional lab.

It has therefore been highly disappointing for all of us that following the strength of our initial commercial launch, the COVID-19 pandemic has led to hospital restrictions banning outside personnel and postponing most elective procedures, effectively stalling our lab roll out plans.

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At this time, hospital operations appear to be normalising somewhat in Germany and the Netherlands, and we have plans to re-start procedures in Dresden and also to ramp up our next three sites within the next several weeks.

Across the medical community we are seeing strong interest in our products and the opportunity to undertake MR guided ablation procedures. Thanks to our sales and marketing teams, who adapted but did not stop in response to COVID-19, our pipeline is growing strongly, and we are expanding our list of targeted sites every week.

As an example, in early April we successfully hosted our first online educational seminar, led by Dr Thomas Gaspar and Dr Stefan Ulbrich of the Dresden Heart Centre. The doctors described their experiences performing ablations in the iCMR lab and answered questions from attending physicians. You can find a recording of this webinar on Imricor's YouTube channel.

As another example, last month we signed a Master Purchasing Agreement with Sana, the largest Group Purchasing Organisation in Germany. The Sana network includes 600 cooperating hospitals and medical institutions across Germany and Switzerland. Importantly for us, approximately 80 of these sites perform cardiac ablations and are potential customers.

Under this agreement, Imricor's products are included in Sana's catalogue of approved materials, with pricing set for any site that is part of the GPO.

We have found that in establishing new sites, contract negotiations can be a time consuming component of the process. The agreement with Sana will streamline this process as well as facilitate access to approximately 80 sites for sales and marketing activities, supporting the future success of our roll out strategy.

Following the model of the online seminar I mentioned earlier, we are extending this style of physician engagement to relevant hospitals within the Sana GPO as well as high volume sites across the countries we have identified in phase one of our roll out plan.

These seminars provide an effective alternative, in the COVID-19 environment, to educational programs we would typically deliver at congresses such as the European Heart Rhythm Association and the Heart Rhythm Society. This enables us to support continued advancement in patient care and develop greater awareness of Imricor's products, despite the social and travel restrictions in place today.



Our research and development pipeline, focussed on the expansion of our products for use in iCMR ablation procedures, remains a clear priority.

Our diagnostic catheter's development, along with regulatory strategy are well advanced. As a scaled down version of our ablation catheter, the diagnostic catheter will provide material improvements in our gross margin and is targeted for release in mid-2021, pending CE mark approval.

We are currently in the prototype phase for our steerable sheath and transseptal needle which, in the future, will enable access to the left side of the heart via the intra-atrial septum. At this stage we are developing our regulatory strategy and aim to have these products ready for clinical trial during 2021.

Further, we are developing improvements to our ablation catheter which, while relatively minor, will deliver enhanced manoeuvrability when used for future indications other than atrial flutter.

The delivery of these pipeline products is critical to our growth strategy of expanding indications for our ablation catheter to procedures in the left side of the heart, including atrial fibrillation and ventricular tachycardia and will remain a key focus in the year ahead.

We also continue to pursue expansion in geographies outside of the European Union.

In Australia we are in the late stages of appointing a local agent to facilitate TGA approval, and our strategy on FDA approval in the United States is progressing well. We are targeting discussions with the FDA in the coming months with the aim of undertaking an IDE clinical trial during 2021-2022.

Our workforce continued to expand throughout 2019 and into 2020 as we focused on expanding capability across the company, particularly within sales, marketing and manufacturing to support our commercialisation and growth strategies. We have been fortunate to welcome a number of talented individuals from high calibre organisations within the medical technology sector to the Imricor team. Our people, long-standing and new alike, are all passionate about achieving great outcomes for patients and their healthcare professionals. Each person on our team plays a crucial role in our achievements, and I thank each of them for their dedication and determination.



I'd also like to take this opportunity to highlight our Board of Directors. During 2019, and in preparation for our IPO, we were fortunate to welcome Doris Engibous and Peter McGregor to the Board. Doris has over 40 years of experience in the medical device industry, including executive roles in early commercialisation stage medical technology companies. She brings deep industry experience to the Board and we greatly value her contribution.

Peter, our Australia based Director, has over 30 years of experience across investment and institutional banking and has held CFO roles in large ASX listed entities. His deep financial and commercial expertise combined with his extensive experience as a company director brings a valuable contribution to the Imricor Board.

Mark Tibbles, our longest standing non-executive director, brings a breadth of experience in entrepreneurial business and venture investing in the medical device space. Mark has helped guide the Company toward and through our IPO, and continues to bring unique value to the Board.

In addition, we as a Board are fortunate to have the ongoing support of our Board advisors, Tom Borillo and Professor Neils Kuster who have deep expertise and experiences in sales and technology respectively. As former Board members, Tom and Neils combine their specialities with a strong knowledge of the Imricor business and the markets in which we operate.

Across the Board, along with high standards of governance, there is a deep commitment to the success of Imricor and the delivery of value for our stockholders and CDI holders. I thank each of my fellow directors for their commitment and support.

While we are extremely disappointed that COVID-19 has temporarily stalled our roll out plans, I remain very pleased with the position we are in. We have adapted well across all functional areas, with little negative effect aside from site installations, and we are well positioned to swiftly recommence roll out plans once hospital restrictions are lifted. Having completed in February an institutional placement, we maintain a robust balance sheet with capacity to manage the financial impacts of the current situation, with available cash at March 31<sup>st</sup> of US\$13.3 million.

On behalf of the Board and management of Imricor, I would like to thank our stockholders and CDI holders for your ongoing support. I look forward to sharing the next exciting phase of the Imricor journey with you.