



## ASX Announcement

### 2021 ANNUAL MEETING OF STOCKHOLDERS CHAIR'S ADDRESS

**5 May 2021 – 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 2021 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:** Thursday, 6 May 2021 at 9:00am Sydney time or Tuesday, 5 May 2021 at 6:00pm US Central Daylight Time  
**URL:** <https://web.lumiagm.com>  
**Meeting ID:** 305-621-561

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.



## **IMRICOR MEDICAL SYSTEMS INC.**

### **2021 ANNUAL MEETING OF STOCKHOLDERS**

#### **CHAIR'S ADDRESS**

We commenced the year in a strong position, achieving two important milestones. The first of these was the granting of our CE mark certification, which enabled Imricor to commence selling its products in the European Union. CE mark was quickly followed by the first procedures using our products at the Dresden Heart Centre. 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.

At this time last year, however, the world changed rapidly as a result of the COVID-19 pandemic and the associated containment measures put in place by governments all over world.

For Imricor, these effects were felt most directly in the delays we experienced to our planned roll-out of new clinical sites and the broad suspension of elective medical procedures.

Due to the hospital closures associated with the strict COVID-19 containment measures implemented across our key geographies of Germany and the Netherlands, Imricor experienced delays in signing agreements with new clinical sites in 2020. We also saw lower procedure volumes as a result of restrictions on elective surgeries, which resulted in lower consumable sales.

Despite these constraints, we have been working closely with contracted sites to schedule installation and training, in preparation for the commencement of cases as COVID-19 restrictions ease. We have training and installation teams established in Europe that are supported by teams based in the United States, so that we can move quickly and efficiently.

We also made adjustments to our operations, redeploying some of our manufacturing personnel to product development to help build new devices for testing and for upcoming clinical trials.

While we are yet to see industry, events resume in a face-to-face format we have continued to participate in medical congresses, educational events, and training seminars online to support growing market awareness of our products.

As you can see on this chart, with the passing of the first COVID-19 wave last year, we made solid progress in signing agreements with new clinical sites, closing five new agreements in a six-week period during September and October. However, the second wave of COVID-19 in Europe, followed by an unanticipated resurgence late in 2020, slowed our progress.

Across our key target geographies of the Netherlands and Germany, containment measures have been both strict and prolonged. These countries implemented hard locks downs in mid-December causing further delays in our site roll out plans. However, the combination of early vaccinations and falling daily case rates resulted in restrictions easing in February and March. Elective procedures were once again allowed in certain geographies and we saw the first cases being carried out at one of our newest sites, the Maastricht University Medical Centre in the Netherlands in mid-February. In March cases started at the Leipzig Heart Centre for the first time since the clinical trial that resulted in CE mark certification.



This week we were pleased to announce that we added a second Helios hospital to our installed base, as Berlin-Buch joined the Helios Leipzig Heart Centre in adopting iCMR guided ablations. This makes Berlin-Buch the tenth site to establish an iCMR lab to perform ablations with Imricor's products.

While Europe continues a gradual recovery into a post COVID-19 era, we are very happy to be able to continue growing the number of centers enabled with Imricor's solution for the future of cardiac electrophysiology.

As you are likely aware, a new wave of COVID-19 in late March and early April resulted in the reinstatement of stricter containment measures in Europe, including the prohibition of elective procedures. Unfortunately, the vaccination program in the Netherlands has been disappointing, and Saxony, Germany, where Leipzig is has been particularly hard hit with new infections. As a result, elective procedures at both institutions are again on hold.

We are encouraged to see COVID-19 vaccinations presently gaining momentum across Europe, with over 20 per cent of the population in Germany and the Netherlands having now received at least one dose. As vaccinations continue to accelerate, we expect elective procedures to recommence this quarter.

In July 2020, we established our sales agreement with Philips to further fuel our pipeline. This agreement enables our capital product – the Advantage-MR EP Recorder/Stimulator System – to be sold as part of a Philips comprehensive iCMR lab installation package.

In effect, this enables the extensive Philips sales force to contribute to driving growth in site adoption, allowing us to focus on supporting product utilisation, growing our portfolio of consumable devices and expanding our indications for use.

In November, we commenced training the Philips European sales force on Imricor's technology and products, and that training will continue with another session this June. The sales force will become active in the field as COVID-19 restrictions allow and we expect this to drive a material increase in our installed base in 2021.

We continue to work very closely with Siemens and are currently working towards establishing a similar agreement. Notably, Imricor remains the exclusive provider of our consumable devices in Europe, and currently, we continue to supply capital equipment to Siemens sites.

We have also executed other strategic agreements in 2020 and early 2021. The most recent of these was in March this year with the Regional Health Care Group out of Sydney, expanding Imricor's reach to Australia in New Zealand. Under the agreement, Regional Health Care Group will be the exclusive distributor of Imricor's consumable products in Australia & NZ and the non-exclusive distributor of Imricor's capital equipment. Importantly they will help facilitate the necessary regulatory approvals and support of Imricor's products in Australia and New Zealand. We expect first approvals by year-end 2021.

Developing our product lines to support our expanded indications and margin improvements is a key growth driver of our future growth.

The ablation market has tremendous growth potential, with a key avenue being through expanding the approved indications for our products to procedures in the left side of the heart, including ventricular tachycardia and atrial fibrillation. We believe the benefits of MRI guidance



will help further fuel this growth. It is the opportunity to perform ventricular tachycardia and atrial fibrillation ablations in the iCMR lab that is significantly adding to clinical interest in our products.

Our strategy around expanding indications is supported by our research and development pipeline, in particular the transseptal puncture kit required to undertake these procedures. We remain on track to begin clinical trials for expanded indications using our steerable sheath and transseptal needle during 2021.

I am happy to report that our diagnostic catheter has been submitted for CE mark certification and will deliver material improvements in gross margin once approved. The diagnostic catheter is a simplified version of our next-generation ablation catheter which is currently in development. We expect CE mark approval late this year or early in 2022.

As mentioned earlier, we currently have signed purchase agreements in place across ten sites in Germany, The Netherlands and France. The Leipzig Heart Centre, a Philips site, and Dresden Heart Centre, which is a Siemens site, have been established as training Centres of Excellence for sites that follow, supporting our future roll out plans.

Training and installation are completed at six of our contracted sites and they are ready to commence, or recommence, procedures as restrictions ease.

We are working closely with remaining sites to schedule training and installation, and the commencement of procedures, in anticipation of COVID restrictions easing soon.

In addition, our pipeline remains very strong; and our agreement with Philips, along with our collaborative relationship with Siemens, better enable us to develop a long-term pipeline that is aligned with capital cycles at clinical sites.

In the short term, we have several agreements that are well advanced, and as such, we expect to start gaining traction again this quarter, as evidenced by the Berlin-Buch signing. We further expect site adoption to accelerate in the second half of 2021.

Another key driver of our future growth is geographic expansion.

Our strategy to gain FDA approval in the United States is progressing well. We have now completed our third pre-submission meeting with the FDA, and we are confident our clinical trial study design is fit for purpose. The next steps are to lodge a submission for an Investigational Device Exemption (IDE) from the FDA, with lodgement expected in July. Once the IDE is approved, the clinical trial to support FDA approval will commence. We are targeting late 2021 to early 2022 to undertake the clinical trial.

As mentioned earlier, we have appointed a local agent Regional Health Care Group to facilitate TGA approval and the eventual distribution of our products in Australia. We do not expect clinical trials to be a requirement for TGA approval, and we are hoping for approval before the end of the year.

Despite disruptions associated with the COVID-19 pandemic, we continued to grow our workforce across all functional areas and have been fortunate to welcome a number of talented individuals from high calibre organisations within the medical technology sector to further build our organisational strength.





In December, we promoted our Vice President of Operations, Greg Stenzel, to Chief Operating Officer. Greg has over 20 years of medical device experience and has been a key member of the Imricor team since 2007. Greg is leading the execution of our strategic plan across most functional areas of the business, providing me with greater capacity to help drive an acceleration in site adoption across Europe in 2021.

We have continued to selectively expand the capacity and capability of our personnel to support our commercialization and growth strategies. Today we employ a workforce of over 70, more than triple our size since our IPO in August 2019.

We are fortunate to have a team of very talented people who importantly, have really leaned into the challenges that COVID-19 has thrown at us, remaining focused on our future success and on delivering great outcomes for patients and healthcare professionals.

While the COVID-19 pandemic has disrupted our early commercialization plans, I am very pleased with our positioning as we move into 2021.

Our focus remains on site adoption across Europe, and we expect to gain momentum in the second quarter as Covid restrictions ease and to deliver an acceleration in adoption during the last half of the year.

We will continue to pursue opportunities to grow our pipeline of potential sites, working collaboratively with Philips and Siemens to drive adoption and grow market awareness and education through our direct sales and marketing activities.

With the Philips sales force to become active in the field as COVID-19 restrictions ease, and with further expansion of our team to occur in 2021, we expect this relationship to significantly enhance our pipeline and further accelerate our adoption plans as we move forward.

As mentioned earlier, we will continue our R&D focus on products to expand our indications and deliver margin improvements while also pursuing regulatory approvals in Australia and the United States, supported by our strategy around clinical trials.

It is important to reiterate that while we have experienced delays due to COVID-19, the outlook for Imricor is exciting, particularly as we pursue opportunities to expand our future indications and geographic reach to drive accelerated growth. We have great opportunities ahead of us and look forward to keeping you updated on our progress throughout the year.

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.