



## ASX Announcement

### 2022 ANNUAL MEETING OF STOCKHOLDERS CHAIR'S ADDRESS

**3 May 2022 – 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 2022 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, 4 May 2022 at 9:00am Sydney time or Tuesday, 3 May 2022 at 6:00pm US Central Daylight Time

**URL:** [meetnow.global/MT5LJH7](https://meetnow.global/MT5LJH7)

ENDS

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

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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 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.



## **IMRICOR MEDICAL SYSTEMS INC.**

### **2022 ANNUAL MEETING OF STOCKHOLDERS**

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

I would like to commence today's meeting with an overview of the financial and operational performance of Imricor during 2021, as well as provide an update on our activities during the current year.

The foundations of our mission to change the standard of care for cardiac catheter ablation, and other life-changing and life-saving interventions, are based on three key drivers. First, we are growing the customer base of sites that have Interventional Cardiac Magnetic Resonance (iCMR) capabilities and are performing procedures with our products.

Secondly, we are working to increase the number of different types of ablation procedures, known as indications, doctors can perform with our products. This happens through product development – making the new devices needed for the procedures and working with third parties to develop other required equipment – and by gaining regulatory approval for the new indications.

Thirdly, we are working to broaden the geographic reach of our products by pursuing regulatory approvals outside of our core European markets, such as in the US, Australia and New Zealand.

While the challenges of the pandemic slowed our site rollout plans over the past year, they have not slowed our progress toward expanding our geographies beyond Europe (such as FDA approval), they have not slowed our progress toward expanding our indications for use (in particular delivering a solution for ventricular tachycardia ablation), nor have they slowed the product development that supports these initiatives while improving margins.

Since our IPO, and through the challenges of the last twelve months, we have maintained a very clear focus on our strategic plan, and we find ourselves well positioned as we enter 2022.

In 2021, we were pleased to announce that we contracted five new sites across Europe, bringing the total number of sites signed to fourteen at year end.

And although planned procedures were largely stalled throughout 2021, we still had a total of four sites that were operational, on and off. The Company announced first procedures at the South Paris Cardiovascular Institute and the recommencement of procedures at the Helios Leipzig Heart Centre, Dresden Heart Centre, and Maastricht University Medical Centre.

Following the end of the period, the Company announced the signing of Policlinico Casilino as its fifteenth site, and the commencement of first cases at Münster University Hospital in Münster, Germany. Since the time of that announcement, first cases have also commenced at Helios Hospital Berlin-Buch in Berlin, Germany.

Most recently, the Company announced that two additional sites, the Lausanne University Hospital (CHUV), in Switzerland and the Heart and Diabetes Centre NRW in Bad Oeynhausen, Germany are currently constructing Interventional Cardiac Magnetic Resonance (iCMR) labs.

So today, Imricor has six operational sites, two additional sites where installation is complete, and seven sites that are preparing for installation. In addition, we expect to add the two sites under construction to our list of contracted sites this year.



In the first half of the year, we appointed Regional Health Care Group as our local agent in Australia to help facilitate TGA approval in Australia and Medsafe approval in New Zealand.

So far, we have received Medsafe approval for all Imricor's products in New Zealand, and all our products are now registered in the WAND database for medical devices there. We have also received TGA approval for Imricor's Advantage-MR system. Achieving these approvals represents an important milestone in our geographic expansion plans.

We also entered into a *distribution agreement* with Regional Health Care Group, under the terms of which they are the exclusive distributors of Imricor's consumables, and non-exclusive distributors of Imricor's capital equipment, in both Australia and New Zealand.

We are working closely with Regional Health Care Group and our other 3<sup>rd</sup> party equipment partners to deliver iCMR ablation solutions in the ANZ region as soon as possible, once all devices are approved.

Our US expansion plans also progressed well in 2021, with the completion of our pre-submission meetings with the FDA, and the filing of our application for an Investigational Device Exemption to commence a clinical trial for iCMR atrial flutter ablation.

In September, the Company successfully raised 16.5 million Australian Dollars via an oversubscribed institutional placement; and in October the Company raised an additional 1 million Australian Dollars in an oversubscribed Security Purchase Plan.

The funds raised have been and will continue to be used to support the Company's product development pipeline, support clinical and regulatory efforts, and provide working capital support for general business activities.

Lastly, we have continued to promote iCMR site adoption and indication expansion through strategic partnership agreements. The Company entered into two new sales distribution agreements in the year, with NordicNeuroLab and MiRTLE Medical. In late November we announced a small but strategic investment in MiRTLE, further deepening our relationship with the company.

In March of this year, the Company announced a new Development Agreement that was signed with Mammendorfer Institut für Physik und Medizin GmbH (MIPM) an established German manufacturer of MRI compatible monitoring equipment, to provide MRI-compatible defibrillators, the last piece of third-party equipment needed for realtime iCMR ablations of VT. I will discuss these agreements in greater detail in a moment.

But first, moving onto the next slide, we'll focus on the current status of our site expansion plans.

As mentioned earlier, Imricor signed five new agreements in the year. These sites include:

Helios Hospital Berlin-Buch, the second Helios hospital added to our installed base.

And Semmelweis University Heart and Vascular Centre, which is our first site to be established in Hungary. I should note that the iCMR program at Semmelweis is being led by Dr. Béla Merkely the receiver of the prestigious Széchenyi Prize last year. A prize that honours the greatest scientists in Hungary alive today.

In Germany we added The German Heart Centre Berlin and Charité Medical University Virchow-Klinikum Campus, both in Berlin. These are two sites that have well-established facilities and programs like the MRI Core Lab at the Charité and the CMR-Academy at the German Heart Center Berlin.





And lastly, the Henry Dunant Hospital Centre, which is one of the largest and most technologically advanced hospital centres in Southeast Europe, became our latest site, and the first Imricor hospital in Greece.

Most recently, we signed our first site in Italy, Policlinico Casilino in Rome. As you may have read in our first quarter 2022 update recently, this site will be influential in generating interest for iCMR ablations in Italy.

Imricor now has a total of fifteen sites signed across Germany, The Netherlands, France, Hungary, Greece and Italy. And this year, we will continue to grow our number of iCMR sites, as the effects of the pandemic continue to diminish.

For example, I already mentioned the CHUV in Lausanne Switzerland, and the Bad Oeynhausen Heart and Diabetes Centre NRW, who are constructing new iCMR facilities.

Imricor and the CHUV have had a research collaboration agreement in place since 2019. And that site is expected to be a research and training centre of excellence, where other physicians can learn iCMR ablation techniques. Meanwhile, the electrophysiology department at The Heart and Diabetes Centre NRW in Bad Oeynhausen, is lead by Professor Philipp Sommer, who is a world-renowned key opinion leader in the field of electrophysiology and an Imricor medical advisor. Professor Sommer's iCMR lab is expected to be operational in the fourth quarter of 2022, while the CHUV iCMR lab will be completed in early 2023.

As stated earlier in the presentation, to promote iCMR site adoption and indication expansion, the Company entered into two new sales distribution agreements in the year, with NordicNeuroLab and MiRTLE Medical.

Headquartered in Norway, NordicNeuroLab are a leading maker of MRI compatible in-room monitors. Under the terms of our Sales Distribution Agreement with them, Imricor is a non-exclusive distributor of NordicNeuroLab's *InroomViewingDevice*, a high quality 40" MRI-compatible monitor for use in the magnet room of an iCMR lab.

MiRTLE, maker of an MRI-compatible 12-lead ECG system, have been a great strategic partner of Imricor's since 2017. Under the terms of our Sales Distribution Agreement with MiRTLE, Imricor will be a non-exclusive distributor of MiRTLE's 12-lead ECG system. The sale of MiRTLE's 12-lead ECG system is very important in Imricor's strategic plan of enabling iCMR cardiac ablations of complex arrhythmias such as ventricular tachycardia (or VT).

Entering both agreements streamlines the sales process for all parties and strengthens the range of 3<sup>rd</sup> party iCMR lab equipment Imricor offers to our customers. In the case of the MiRTLE partnership, it also strengthens our ability to expand our indications to VT ablation. This, in turn, promotes the growth of Imricor's installed base.

In late November we announced a small but strategic investment in MiRTLE, further deepening our relationship with the company. As part of the investment, we received about 2% equity in MiRTLE, along with three ECG systems (each with a list price of \$125,000 US Dollars) for use in our planned VT clinical trial and for customer demonstration purposes. We also received board observation rights and the right of first negotiation for an acquisition of MiRTLE through November 2024.

We are very pleased to have had the opportunity to deepen our relationship with MiRTLE through this investment, and it is a great example of our planned, purposeful de-risking of our strategic goals... in this case, the goal of expanding our indications for use.

As I mentioned earlier, in March this year, we signed a Development Agreement with MIPM, headquartered in Mammendorf, Germany. MIPM is an established manufacturer of MRI compatible monitoring equipment and has recently developed an MRI-compatible defibrillator in



consultation with Imricor. The defibrillator was tested earlier this year at Imricor's iCMR Design Center as part of preclinical work being performed by the Company. MIPM personnel also participated in the preclinical study. An MRI-compatible defibrillator is the last piece of third-party equipment needed for realtime iCMR ablations of VT.

So in summary, the business has completed nine strategic partnership agreements and we are very thrilled to be in a position where we have accessibility to all third-party equipment needed to expand into our next indication of VT ablations.

On this slide we highlight that our research and development pipeline remains a clear priority to drive future growth through expanded indications as well as gross margin improvement.

We have begun pre-clinical trials for VT ablation using our second generation ablation catheter, our steerable sheath, and transseptal needle.

We are also progressing well with our diagnostic catheter which will deliver material improvements in gross margin. We expect this device will receive CE mark certification this year, our first device to be certified under the new Medical Device Regulations in Europe.

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

As you can see on this slide, atrial flutter procedures, our current approved indication in Europe, accounts for around 23% of the ablation market. This provides us with a significant immediate opportunity, as well as a significant opportunity to grow through expanding our approved indications to other arrhythmias. As I've mentioned, ventricular tachycardia ablation, or VT, is our next targeted indication. While VT is shown on graph as only representing 8% of ablation procedures, there are great opportunities to expand this market by delivering the advantages of ablating in the iCMR lab using our products.

The size and forecast growth of the ablation market, as well as the ability of our technology to deliver solutions that will expand this market, underpins our future growth strategy. And this is overlaid by the fact that we are the only company globally, to offer cardiac catheter ablation devices for use in the MRI environment.

Today, we are successfully managing a recovery from the effects of the pandemic, and now more than ever, things are going very well.

Since the last time I spoke to you, we have been moving new sites through our sales process and adding them to our contracted customer base. We've been busy scheduling installations, performing installations, and commencing or re-commencing procedures at sites where procedures were prohibited during the pandemic.

In addition, our sales team is engaging closely with our customer sites to promote increased procedure volumes, and we are essentially getting back to the way things are supposed to work in the field.

As we exited the first quarter of 2022, we observed renewed energy from hospitals and physicians, and we are continuing to gain traction.

These things are happening not only due to the diminishing effects of the pandemic, but also due to purposeful actions taken by our team.

Looking ahead, we will grow our installed base throughout 2022. Our team is engaging more than ever with electrophysiologists to drive awareness and demand for iCMR, and we continue to work collaboratively with Philips and Siemens to drive site adoption.



An example of this was our first “Realtime iCMR Ablations Global Summit” which we hosted on March 12<sup>th</sup> in Amsterdam. Fifteen doctors attended the one and a half day summit in person, as well as representatives from both Siemens and Philips. These people gave up their weekend to learn about Imricor and iCMR ablations, and the group was extraordinarily engaged. Professor Hindricks from the Leipzig Heart Center, who was one of the presenters, contracted COVID the day before the summit, so he drove back to Leipzig from Amsterdam and still gave his presentation virtually from his home the next morning, while he was clearly not feeling well at all. What we’re doing is that important to these key opinion leaders.

Another example was our participation in the European Heart Rhythm Association’s annual congress in April. We were unsure if the congress would be well attended, and we were pleasantly surprised to find that it was. Our sales team generated 14 new site leads over the three days. Things are getting back to normal.

And I am very excited to say that we are completing our VT preclinical work, preparing to submit for trial approval, and finalising our preparations to begin.

Starting the VT trial this year is expected to be a significant catalyst for new site interest and engagement. As I’ve discussed in the past, the promise and potential of iCMR ablations are centered around complex ablation procedures like VT. Atrial flutter is where you start, but VT is where we expect to make a real impact, along with other complex ablation procedures that will follow.

In closing, I’ll say this: we did what we needed to do in 2021 to continue making progress under very difficult circumstances. And now, in 2022, we have hit the ground running, and we’re moving at full speed to fulfil our mission of changing the standard of care for interventional medicine.

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