



2023 ANNUAL MEETING OF STOCKHOLDERS CHAIR'S ADDRESS

11 May 2023 – Minneapolis, United States (**12 May 2023** – Melbourne, Australia) – **Imricor Medical Systems, Inc. (Company or Imricor) (ASX:IMR)** is pleased to provide the Chair's address to be delivered at the 2023 Annual Meeting of Stockholders today.

The Annual Meeting will be held as a virtual meeting, details of which are provided below:

Date: Thursday, 11 May 2023 at 5:00pm Minneapolis Time or Friday, 12 May 2023 at 8:00am Sydney Time

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

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IMRICOR MEDICAL SYSTEMS INC.

2023 ANNUAL MEETING OF STOCKHOLDERS

CHAIR'S ADDRESS

I would like to commence today's meeting with an overview of the strategic and operational performance of Imricor during 2022, as well as provide an update on our activities during the current year.

Our Mission

As I have talked about in the past, 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 number customer sites that have Interventional Cardiac Magnetic Resonance (iCMR) capabilities and who are performing procedures with our products.

Secondly, we are working to increase the number of different types of ablation procedures, known as indications, that doctors can perform with our products.

And 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, New Zealand, and the Middle East.

These value drivers are unchanged, but I want to break them down in terms of priority because they are not all independent. Progress in some areas can promote better success in others, especially in this post-pandemic world.

Key Message

The key message, here, is that the primary drivers of value today are the second and third items I just mentioned: expanding indications, and expanding geographies.

Expanding indications is by far the largest value driver we have available to us. Having lost some momentum while our customers were effectively shut down during the pandemic, many doctors and hospitals now want to see that Imricor's iCMR ablation solution is not stuck in the past and will, indeed, expand beyond atrial flutter and address complex ablation procedures like ventricular tachycardia and atrial fibrillation where MRI is expected to add great value. This year is when people expect to see clinical trials, and they are eagerly awaiting the early results. I call this catalyst number one.

Expanding geographies is the next most important thing we can do. As we relaunch iCMR ablations into a post-pandemic world, we need to regain the momentum that was lost. One way to do that is to expand into geographies where we didn't have a presence before, and thus help rebuild the excitement across the entire world of electrophysiology and interventional medicine. I call this catalyst number two.

Catalysts number one and number two drive everything else forward, what I'm calling Additional Drivers of Value on this slide. The catalysts create demand for iCMR sites and promote the growth of our installed base. They provide the critical need and desire for hospitals to establish cardiology-owned dedicated iCMR labs. Obviously, catalyst number 1 (expanding indications) inherently increases the number of procedures performed at each iCMR site, and this volume and workflow comfort helps iCMR ablations become the clinical routine at the site. And, finally,



expanding indications gives both Imricor and our MRI partners good messaging to drive additional growth.

2022 Highlights

In 2022, we were pleased to announce that we contracted three new sites across Europe.

At the end of the prior year, we had four sites that were performing procedures (as I said last year) “on and off” with the pandemic. We ended 2022, on the other hand, with nine active sites, each of which is working to build real-time iCMR ablation of atrial flutter into their routine clinical workflows.

I have also touched on, recently, new challenges on the back end of COVID, particularly in the areas of MRI availability at sites where the MRI is a shared resource, and also in the number of patients who are presenting to their cardiologist today with stand-alone atrial flutter. In response to the problem of availability of a shared MRI, our sales team is focusing on new sites that are building cardiology-owned dedicated iCMR labs. This is a longer process than retrofitting a shared MRI resource so that ablations are possible there, since new construction is required, but we believe now is the time to grow the installed base for sustained unlimited access to iCMR labs for our doctors, just like they have access to their x-ray labs.

Regarding patient populations presenting to their doctors in late 2022 and so far early this year, patients who presumably did not get their atrial flutter treated during the pandemic have now found that it has progressed to also include other arrhythmias. This means that (currently) our iCMR treatment is not available for those patients and conventional ablation has to be used. Just two weeks ago, one of our sites screened over 30 atrial flutter referrals to find patients who could be treated in the iCMR lab, but none had standalone atrial flutter. Clinical market research shows that in the past over 20% of arrhythmia patients in Europe suffered from standalone atrial flutter. It's expected that these numbers will be true again in the future as things normalise, but for now, the medical community is still working hard to catch up after so many patients didn't get treated during COVID. Keep in mind, though, that while patients with combination arrhythmias can't be treated in the iCMR lab today, that will not be the case forever. As we expand our indications and product offering, more and more patients with various arrhythmias will be able to have their ablations performed in the iCMR lab. This reinforces the importance of catalyst number one: expanding those indications.

And nearly every other 2022 highlight on this slide, which I talked about at our year-end results briefing, represents progress toward expanding indications.

NorthStar 3D electroanatomical mapping system

I have mentioned, several times over the past 6 months, the importance of our new NorthStar 3D electroanatomical mapping system, and I want to highlight it again here today. Having developed (and now growing) our own 3D mapping system adds so much value to Imricor in several key ways.

First, owning and controlling the development of NorthStar allows us to scope out and realise our vision of the future for iCMR procedures, and it allows us to move at our own pace toward that future. For instance, NorthStar currently interfaces with Siemens MRI scanners, and we are working with GE HealthCare and Philips to interface it to their MRI platforms as well. In the end, we see NorthStar as the central component of every iCMR practice, and we want our customers to have the same experience no matter which MRI system they have in their iCMR lab.



It is also true that it is hard to have a relevant and competitive electrophysiology ablation product offering without an associated 3D mapping system. Just look at medical device giant Medtronic's acquisition of Affera announced in early 2022, a deal worth US\$925 million, including US\$250 million in milestone payments, to fill the what Medtronic's CEO called their "gap in mapping and navigation" (<https://www.fiercebiotech.com/medtech/jpm22-medtronic-makes-925m-offer-for-affera-aiming-to-break-into-advanced-cardiac-mapping>).

And building on that point, NorthStar is the world's only 3D electroanatomical mapping system that works directly and natively with MRI scanners. It controls the MRI. It receives MR images in real time from the MRI. It displays everything in 3-dimensional space for the user, and it brings together everything needed for a procedure: actively tracked devices, ablation parameters, intracardiac electrogram data, electroanatomical mapping, and more. NorthStar is the central hub that brings it all together.

Lastly (and so importantly), while we have shown that you can do cardiac ablations in the iCMR lab, we are now, through NorthStar, going to deliver the why. Imagine a future iCMR practice where patients are scanned by MRI, using NorthStar, and internal NorthStar AI helps diagnose the patient's condition and inform therapy decisions. And then imagine NorthStar as it helps guide the therapy by being that central hub of the procedure like I just mentioned. Imagine NorthStar with AI-enabled automatic anatomy segmentation and tissue substrate analysis, helping to streamline and individualise treatments for each patient. And then imagine NorthStar with AI-enabled 3D lesion assessment and other therapy verification tools to help physicians know that they got the job done permanently and without complication in the first procedure. This is the promise of MRI guided interventions, and as we see it, the embodiment of this promise will be NorthStar. It is the future we are developing, and it is what excites me every day when I go to work.

Business Update and Outlook

Let's now take a look at where we are and what we're planning next.

Clinical Trial Update

As you all know, we have two major trials that we are preparing to commence in the coming months.

The first is our ventricular tachycardia ablation trial in Europe (the VISABL-VT trial). We have submitted the VISABL-VT protocol and device data for approval to begin in both Germany and the Netherlands. It is a big trial in terms of the number of investigational devices – again, because when you do anything in the iCMR lab, everything you use has to be MRI compatible, so all the devices are new. There are also several 3rd party devices, such as the defibrillator from our partner, MIPM out of Germany. The reviews have been accordingly long, but the process is not stalled or blocked, it just takes time.

In Germany, we are awaiting documentation from MIPM and Philips to submit the full response to the German Competent Authority's questions, and in the Netherlands, we were awaiting the outcome of the Ethics Committee review at Haga Hospital that took place on May 2nd. This morning, we received the Ethics Committee's response, which included several questions that our team is currently assessing in detail and assigning to individual responsible parties. There are no show-stoppers or critical concerns, but we (and our 3rd party partners) will have to draft thorough responses, which will take a few weeks. At this point, we think the start of the VISABL-VT trial will commence in Q3, and we are doing everything we can to prepare the sites so they can begin as soon as possible.



For US FDA approval, we have received our IDE (investigational device exemption) to commence the worldwide VISABL-AFL trial. We also expect to start enrolling patients for this trial in Q3, and we are working through the site contracting and site approval processes needed.

These two trials embody the most obvious examples of catalysts one and two: expanding indications and expanding geographies. We're moving as quickly as possible, but also with great care and precision. We always know that our primary objective is to safely and effectively treat patients. Regulatory burden can be frustrating, especially when it comes to timelines, but everyone involved is working in the best interest of patients. When your loved one is receiving life-saving medical treatment, it is good to know how rigorous of a process it is for new technology to be used.

Other 2023 Updates

We have a few other notable events that have happened so far this year as well. First, we have seen an increase in procedure volumes in the first quarter compared to the last quarter of 2022. This is due to a lot of diligent work by our sales and clinical teams, and I want to thank them for their efforts.

We also entered into a Master Service Agreement with GE HealthCare. With this agreement, GE HealthCare will pay us to develop the hardware and software interfaces to make our products, including NorthStar as I mentioned, operate with the GE HealthCare MRI platform.

In March, we hosted our second Real-time iCMR Ablation Global Summit. We hosted our first summit in 2021 in Amsterdam, and this year we gathered potential new customers in Munich to hear presentations from our current users and to engage with our team and each other to learn more about the new field of iCMR ablations. We have found these summits to be very effective, and we will continue holding them, perhaps even more often in the future.

The sales and marketing team also organised and participated in several medical and scientific congresses such as SCMR, EHRA, DGK, and next week HRS. These are important meetings for us as we rebuild momentum and continue building brand awareness ahead of our VISABL-VT and VISABL-AFL trials.

There are many other great things on the horizon for 2023, and I look forward to telling you about them as they happen.

Path to Significant Scale

In summary, our path to scaling the business is unchanged, and you've likely seen this slide before. Our opportunity remains significant, and we are progressing every day to realise that opportunity.

Focus on the Year Ahead

In terms of focus for the year ahead, this is another familiar slide from our 2022 year-end results briefing. We're still focused on the things that drive value growth, and with these things we hope to make 2023 a breakout year for Imricor.

In closing, if there is just one idea that I want you to take away from my message today, it's this:



The post pandemic medical world is a bit different than it was before the pandemic, but the value MRI brings to cardiac ablations is unchanged, and we are closer than ever to delivering that value - certainly much closer than we were in 2019.

We have an exciting year ahead of us, and I can't wait for us all to share in the upcoming successes.





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 real-time iCMR cardiac 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 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.

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.