IMRICOR BUSINESS UPDATE

Highlights:

- **VISABL-VT to commence upon identifying optimal first patient**
- **Previously scheduled first patient developed an infection days before procedure**
- **Haga physicians in second week of identifying new suitable patient for first-in-human iCMR-guided VT ablation procedure**
- **North Dakota Development Fund loan terms rejected by Imricor due to unacceptable terms**
- **North Dakota design and manufacturing expansion still progressing, aided by other North Dakota economic incentive programs**
- **CEO provides commentary on multiple material initiatives across the business**

19 September 2023 – Minneapolis, MN United States (**20 September 2023** – Melbourne, Australia) – **Imricor Medical Systems, Inc.** (**Company** or **Imricor**) (**ASX: IMR**) is pleased to provide the following business update.

VISABL-VT CLINICAL TRIAL

In an ASX Announcement released 31 July 2023, the Company announced Ethics Committee approval to commence the VISABL-VT trial at its first site, the Haga Hospital in The Hague, Netherlands.

Following the subsequent summer holiday breaks for doctors and medical staff at Haga Hospital, members of the Imricor clinical team travelled to the Netherlands during the week of 22 August to perform setup and training ahead of trial commencement. The first ventricular tachycardia (VT) ablation procedure was tentatively planned for the following week of 28 August, but the patient developed a serious infection prior to the procedure, and he is still being treated with antibiotics. For the past two weeks, new VT candidates have been screened, to identify an optimal candidate for the first-in-human iCMR-guided VT ablation. The hospital is widening its search area for potential appropriate VT patients, reaching out to nearby hospitals. Whilst the Company believes the first VT case will take place very soon, it cannot predict exactly when.

Imricor's Chair and CEO, Steve Wedan, commented: "Most importantly, our thoughts are with the person whom we thought would be our first VT ablation patient, as he recovers from his infection. We wish him a speedy and full recovery.

"In my experience, anytime physicians are performing a first-in-human procedure, they are very particular when it comes to patient selection. As cases progress, and routine workflows develop, this selectivity relaxes toward the full population of patients who meet the inclusion criteria.

"I would like to stress that the hardest part has been successfully completed in my opinion. Obtaining approval for such an ambitious and ground-breaking clinical trial, with such a large number of investigational devices, was the most significant Imricor milestone achieved in recent history. Now we will enrol patients and provide them with state-of-the-art, radiation-free iCMR-

guided ablation treatment. This is not like the first time we did *any* ablation inside the MRI in 2011. For VISABL-VT, we are simply ablating in a different area of the heart.

“Clinical trial enrolment is often unpredictable and can come in bursts, but as we enter the third week of patient selection, the entire Imricor team, along with the physicians and medical staff at Haga Hospital are extremely motivated and excited to commence the trial as soon as possible.”

The Company expects to expand the VISABL-VT trial to other sites in the Netherlands before the end of the year, with German sites expected to be added, upon approval by the German Competent Authority, BfArM. Currently, BfArM is reviewing the trial submission response, delivered on 10 September 2023, which included a report requested from Imricor’s 3rd party defibrillator partner, Mammendorfer Institut für Physik und Medizin, GmbH (MIPM).

NORTH DAKOTA EXPANSION FUNDING

Imricor has received and accepted a US $1.5 million loan under North Dakota Commerce Department’s Innovation Technology Loan Fund (LIFT), as announced on 22 December 2022. To date, only US $33,000 have been drawn from the LIFT funds, as the Company has been carefully considering options for available space, as well as the financing of capital improvements and capital equipment for its North Dakota expansion facility.

The Company also recently received a grant award of US$1.158 million from the North Dakota Department of Agriculture as part of the department’s Bioscience Innovation Grant (BIG) program. The grant funds will support the Company’s remaining US approval process, including the VISABL-AFL clinical trial and the subsequent FDA review.

On 19 July, 2023, the Company announced that it had received a commitment letter from the North Dakota Development Fund (NDDF), approving a US$1 million term loan to Imricor for financing capital equipment. As detailed in the announcement, the NDDF loan was subject to certain terms and conditions, and “the Company notes that the terms are not yet agreed upon, and Imricor may decide to not accept the loan.” Today, the Company advises that it has rejected the NDDF terms, and it will not accept the NDDF loan.

Imricor’s Chair and CEO, Steve Wedan, commented: “We remain excited about the prospect of growing our manufacturing and design capabilities in North Dakota, and while an NDDF loan could have been a useful component to support our strategy there, ultimately, the terms were not acceptable, and we are pursuing other means of driving the project forward. We thank the North Dakota Development Fund for their consideration.”

GROWING VALUE ACROSS MANY FRONTS

Imricor’s Chair and CEO, Steve Wedan, continued: “We are not just sitting around waiting for the first VT case or for more North Dakota incentives to materialise. Many exciting things are happening across the Company, each of which grow Imricor’s value as we execute our strategic plan.

“Last week, our clinical team was in Baltimore at Johns Hopkins University submitting the IRB approval packet and advancing the contract documents for the VISABL-AFL clinical trial intended to support FDA approval in the US. Yesterday, the team was in Philadelphia at the University of Pennsylvania advancing VISABL-AFL there. Meanwhile, the Ethics Committee and Competent

Authority approval processes for VISABL-AFL are underway in Switzerland at the Lausanne University Hospital (CHUV) and in France at the Cardiovascular Institute of South Paris (ICPS). We expect to commence the trial in Q4.

“We are closing in on a Joint Development Agreement with a software development company specialising in artificial intelligence (AI), with the goal of augmenting NorthStar with advanced AI aimed at delivering even more MRI value through NorthStar. We will provide further details once we finalise the agreement.

“With regard to NorthStar, the Imricor team is creating the required pre-approval documentation and scheduling pre-submission consultations with regulators to advance the approval of NorthStar for sale. We are excited for NorthStar to be progressing toward approval and we are not the only ones who are excited about NorthStar. We recently hosted a team from a large medical device company at our iCMR Design Center, where we demonstrated NorthStar’s unique ability to natively communicate in real-time with an MRI scanner, as well as with our catheter devices through our Advantage-MR EP Recorder/Stimulator. This makes NorthStar the central hub of an iCMR lab for a wide variety of interventional MRI procedures (even beyond ablation). No other 3D mapping system on the market can do that. We are creating significant value with NorthStar.

“In Europe, we have three sites nearing activation, and we are working with them to schedule installation and training. Some activations have been slowed by the lack of availability of the Philips’ iSuite 3D mapping system, which is one reason we are working to replace iSuite with NorthStar for use on the Philips MRI platform. Some other sites have been slowed because they need to update their Siemens software’s operating system and licenses. Nonetheless, our process of activating sites and growing procedure numbers is moving, and we expect the commencement of VISABL-VT will help spark the processes across many hospitals.

“In Australia, we received a small set of questions from TGA, and we have submitted our responses to our Australian sponsor who will submit them to TGA. We expect to receive TGA approval soon. We already have strong interest from a leading Australian hospital, which we look forward to progressing.

“In the Middle East, we recently signed a distributor in the Kingdom of Saudi Arabia, and they are shepherding our devices through regulatory approval there, with results expected in Q4.

“Finally, we have many activities happening in-house, including our manufacturing team aiming to reduce the time-and-material cost of the Vision-MR ablation catheter by as much as 20% in the near future and to cut it in half in the longer term as part of the North Dakota manufacturing expansion. Our quality team continues to excel on many fronts, including passing (sometimes surprise) regulatory audits. Successful audits are required to maintain our certifications. And our regulatory group is driving approval processes for all Imricor products across four continents, each with many different and sometimes dynamic regulatory expectations.

“There is a significant work underway within the Company, from big visible things like clinical trials, to lots of little things behind the scenes, each of which are growing our value and moving us closer to our mission of changing the standard of care for interventional medicine.”

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 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 pursuing the required regulatory approvals to place its key products on the market in Australia, the U.S., and the Middle East.

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.