IMRICOR 1H22 RESULTS – PROCEDURES RAMPING UP, VT TRIAL GATHERING MOMENTUM

HIGHLIGHTS:

- Consumable product revenues of US$229 thousand in 1H22, up 159% compared to 1H21 and 12% compared to 2H21
- 1 new site signed in the first half, bringing total sites to 15
- Signed an agreement with Siemens enabling the ability to deploy Imricor's upcoming 3D mapping system across all newer Siemens MRI scanners, and allowing the participation of Siemens sites in upcoming ventricular tachycardia (VT) trials
- Second generation ablation catheter submitted for approval in Europe – designed to support current ablations as well as future indications including VT
- Completed preclinical work to support a submission for approval to initiate a VT clinical trial in Europe
- Director of Finance Jonathon Gut appointed Chief Financial Officer, replacing the retiring Lori Milbrandt in July
- Cash of approximately US$9.1 million as at 30 June 2022
- An investor webinar will be held at 9.15am **AEST** today, 31 August 2022. Click here to register

30 August 2022 – Minneapolis, MN United States – **Imricor Medical Systems, Inc.** (**Company** or **Imricor**) (**ASX:IMR**), the global leader in real-time iCMR cardiac ablation products, today releases its financial results for the half year ending 30 June 2022.

Commenting on the first half, Imricor Chair and CEO Steve Wedan said: "As we entered 2022, we were still impacted by the pandemic, but we also saw positive signs of recovery. In April, we experienced a tangible shift, and we were able to begin the process of commencing procedures across sites who had not yet started, as well as sites who had been on hold during the pandemic. In addition, we saw movement in our new site sales pipeline, including the activation of two new iCMR lab construction projects that had been on hold.

"Also importantly, we continued progressing toward our VT clinical trial in Europe across many areas including product development, business development, clinical, and regulatory."

Operations Update

During the first half, The Company executed two agreements with Siemens to enable its 3D mapping system. The first agreement was an Access-i License Agreement, which provides Imricor the ability to interface its new 3D mapping system to Siemens MRI scanners via the Access-i software interface available on newer Siemens scanners. The second agreement is a Local Coil Agreement, which allows Imricor catheters to be recognised across newer Siemens MRI scanners. Both agreements have an initial term ending 31 December 2026 and shall be automatically extended by periods of 12 months thereafter, unless terminated by either party.

Importantly, both agreements open the door for Siemens sites to participate in upcoming VT trials.

On the regulatory front, during the half, the Company's second-generation Vision-MR Ablation Catheter was submitted for the initial indication of treating Type 1 atrial flutter (AFL). The review is expected to take 12 months and will rely on previous clinical trial results of the first-generation catheter.

The second generation will replace its predecessor upon approval and will be used in the VT clinical trial, such that once the clinical trial is completed, data can be submitted for further review to expand the catheter's indications to VT.

Ventricular Tachycardia (VT)

The Company has completed its preclinical work to support a submission for approval to initiate a VT clinical trial in Europe.

In the second half, the Company expects to apply for approval to initiate the VT clinical trial, receive such approval, and commence the trial.

Sales Update/Consumable Product Revenue

While we expect 2H to be particularly strong in consumable device revenue, 1H still delivered $229,000 in consumable device revenues as pandemic effects wound back. This was up 159% on 1H21 primarily due to the re-commencing of procedures at existing customers and product ordered to treat first patients at new sites during 1H.

We had six sites which were operational and able to perform procedures at the end of June, with another three where installation was complete, but, procedures had not commenced. One of these three sites commenced procedures in July, and two additional sites are expected to perform first procedures and subsequently increase volumes following the end of the European summer holiday season in August.

Outlook

Imricor Chair and CEO Steve Wedan said: "We turned a corner in the first half of the year, as we largely put the pandemic behind us. Today, we continue to gain momentum as we move into September, especially as the European summer holiday season winds down. We will see more procedures than ever in the second half, and we will once again see new sites being added to our contracted customer base.

"Finally, after years of faithful commitment by the entire Imricor team, we look forward with great anticipation to the world's first VT ablation guided by real-time iCMR commencing in the second half."

Imricor background and strategy

Imricor is leading the new field of *real-time iCMR cardiac ablations* – that is, cardiac ablations guided by real-time magnetic resonance imaging (MRI), rather than by conventional x-ray fluoroscopy. iCMR (*interventional cardiac magnetic resonance*) is the term used to describe such interventional procedures performed in conjunction with MRI. The goal is to provide faster, safer, and more effective treatments of cardiac arrhythmias compared to conventional means.

Imricor is the only company in the world that provides MRI-compatible consumable devices, such as single-use ablation catheters, required to perform cardiac ablations in an iCMR lab.

Benefits of real-time iCMR cardiac ablations are derived from the superior imaging capabilities of MRI compared to x-ray, especially when it comes to imaging the heart and vascular structures which are largely invisible to x-rays. Real-time iCMR also reduces repeated exposure to dangerous x-ray radiation.

Imricor's strategy to grow the field of real-time iCMR cardiac ablations worldwide is built on two actions: to increase the number of iCMR sites across the world and to increase the number of procedures doctors can perform at each iCMR site using Imricor's consumable products.

Key drivers to growing the number of iCMR sites include:

- Existing iCMR sites commencing procedures and presenting/publishing on their experiences
- Growing the Company's footprint across different countries and regions, enabling access for those seeking care and creating competitive pressures between hospitals
- Showing progress toward performing complex ablation procedures, such as ventricular tachycardia (VT) ablations, which increases the utility and demand for iCMR ablations
- Engaging with new physicians to educate them on the benefits of iCMR ablations
- Working with MRI manufacturers to help drive adoption
- Expanding regulatory approval beyond Europe, including the US and ANZ.

Key drivers to increasing the number of iCMR ablation procedures doctors can perform include:

- Development of additional consumable products required for new procedures such as VT ablations
- Partnering with 3rd parties to deliver auxiliary equipment needed for new procedures
- Demonstrating clinical effectiveness through clinical trials
- Receiving regulatory approval to market devices for the new indications

As of today, the Company's additional consumables are in final testing before regulatory submission, and the Company has partnered with all 3rd parties required to deliver the needed auxiliary equipment for VT ablations. Further, the Company made significant progress toward initiating a VT clinical trial, as evidenced by the completion of the preclinical work mentioned previously. This, in turn, progresses the Company's overall regulatory approval process.

Investor Webinar

An investor webinar will be held to discuss the 1H22 results. Please find the details below:

Presenting: Executive Chair, President and CEO, Steve Wedan and CFO, Jonathon Gut.

Time: 9:15am AEST on Wednesday, 31 August 2022
(6:15pm CDT on Tuesday, 30 August 2022)

To register for the session and for more information on the conference click here:

https://us02web.zoom.us/webinar/register/WN_cqM_OICrSdyraUqsoQZ2MQ

Investors can submit questions prior to the webinar to simon@nwrcommunications.com.au or do so via the Q&A function on Zoom.

ENDS

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

Media and Investor Relations Contact:

Simon Hinsley
simon@nwrcommunications.com.au
+61 401 909 653

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.

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.