



ASX Announcement

23 February 2022

IMRICOR ANNOUNCES FINANCIAL RESULTS FOR FY2021

Imricor Medical Systems, Inc. (Company or Imricor) (ASX:IMR), the global leader in realtime iCMR cardiac ablation products, today released its financial results for the full year to 31 December 2021.

Highlights

- Added five new sites in Europe, totalling 14 sites across Germany, The Netherlands, France, Hungary, and Greece
- Commenced first cases at the South Paris Cardiovascular Institute, and re-commenced procedures across three other sites
- Entered into an exclusive distribution agreement with Regional Health Care Group (RHCG) for the sale of consumables and a non-exclusive distribution agreement for the sale of capital equipment in Australia and New Zealand
- Received TGA approval for Advantage-MR system in Australia and Medsafe approval for all Imricor products in New Zealand
- Successfully raised A\$16.5 million via an institutional placement at \$1.00 per CHES Depositary Interest (CDI) and raised an additional A\$1.0 million via an oversubscribed Security Purchase Plan (SPP) offered to eligible CDI holders in Australia and New Zealand
- Entered into a Sales Distribution Agreement with NordicNeuroLab AS (NordicNeuroLab)
- Entered into a Sales Distribution Agreement and completed a strategic investment in MiRTLE Medical, LLC (MiRTLE)
- At 31 December 2021, Imricor maintained a cash balance of US\$18.516 million which supports the progress of its commercialisation plans and growth strategy

Imricor Chair and CEO Steve Wedan said: “Over the past twelve months, Imricor has made solid progress on a range of objectives that support the Company’s strategic plan to grow the installed base of iCMR sites across Europe, increase procedure rates, grow the geographies in which we can sell, and expand the medical indications our products can support.

“Despite continued restrictions during the second half of the year, we were pleased to add five new sites, two of which are in new country markets for Imricor. The Company now has a total of fourteen sites, four of which are operational and performing procedures.



You will see a steady stream of announcements as the rest of the sites become operational and begin performing procedures.”

Executing on Strategy

During 2021, and despite the COVID-19 impacts seen in Imricor’s core geographies during the period, the Company has delivered strong outcomes on a significant number of initiatives that support its strategic plan.

1. *Grow installed base*

Since receiving CE Mark approval in early 2020, Imricor now has 14 sites across five European countries, including Germany, The Netherlands, France, Hungary, and Greece, with plans to expand into other European regions.

To support this growth, the Company engaged with various key opinion leaders across multiple global and regional conferences including Heart Rhythm 2021 in the US, AIAC National Conference in Italy, DGK Heart Days 2021 in Germany, and the European Society of Cardiology Congress 2021 which was held virtually.

Growth was also supported through a new strategic partnership that makes it easier for hospitals to outfit an iCMR lab. The Company signed a Sales Distribution Agreement with NordicNeuroLab in the second half of the year. NordicNeuroLab is a leading maker of MRI compatible in-room monitors. Under the terms of the agreement, Imricor now acts as a non-exclusive distributor for NordicNeuroLab’s *InroomViewingDevice* monitor, allowing the Company to provide these monitors to iCMR lab customers.

2. *Expanding geographies*

The Company’s activities to expand its geographic reach into the US, Australia, and New Zealand are progressing as planned.

In the US, the Company completed its submission for an Investigational Device Exemption (IDE) to commence a clinical trial. US sites are currently being selected for participation in the trial, and the Company is targeting the end of 2023 for FDA approval of atrial flutter ablation.

In Australia and New Zealand, the Company entered into a Distribution Agreement with RHCG. Soon after the agreement, Imricor’s Advantage-MR EP Recorder/Stimulator system received TGA approval in Australia, and all Imricor products were approved by Medsafe and registered in the WAND database for medical devices in New Zealand. Both approvals are significant milestones in Imricor’s geographic expansion plans.

The Company’s Vision-MR Ablation Catheter is under review with the TGA, and Imricor is working closely with its local agent and distributor, RHCG, to develop its sales strategy across the ANZ region.

3. *Expanding indications*

The Company’s plans for expanding indications to ventricular tachycardia (VT) ablations remain on track for approval at the end of 2023.



Preclinical studies to support a VT ablation clinical trial in Europe are expected to commence in March, while the trial, itself, is on track to commence in the second half of 2022.

The strategy of expanding indications was supported by a key strategic partnership with MiRTLE Medical, maker of an MRI-compatible 12-lead ECG system, which is required for a VT ablation procedure. In September, the Company expanded beyond its technical collaboration with MiRTLE by entering into a Sales Distribution Agreement, under the terms of which Imricor became a non-exclusive distributor of the MiRTLE system. In November, Imricor further expanded its partnership with MiRTLE by completing a strategic investment in the business. Under the terms of the investment, the Company acquired approximately two per cent of the equity in MiRTLE, along with three ECG systems, for US\$200,000. The cash purchase price was funded from the Company's existing cash reserves.

Executing this strategic investment with MiRTLE further de-risks Imricor's strategic plan to deliver iCMR-based ventricular tachycardia and other ablation procedures for which 12-lead ECG capabilities are required.

Capital Management

In September, the Company successfully raised A\$16.5 million via an institutional placement, with an additional A\$1.0 million raised via the oversubscribed SPP.

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

Summary

Imricor remains focused on successfully executing the Company's strategic plan by growing our installed base, expanding our geographies and indications, as well as delivering on higher ASPs and improved margins through the development of new products.

The Company currently has 14 labs signed in key European markets and has a strong pipeline of sites in advanced stages of the sales process.

Four of these sites have re-commenced procedures as COVID-19 restrictions have eased, and more sites are expected to commence procedures in the coming months.

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



Investor Conference Call

Imricor's Chair and CEO, Steve Wedan and CFO, Lori Milbrandt will host a market briefing today via a live webcast as detailed below:

Date: Thursday 24th February 2022 (AEDT) / Wednesday 23rd February 2022 (CDT)

Time: 9:00am (AEDT) / 4:00pm (CDT)

Webcast: <https://s1.c-conf.com/diamondpass/10019050-sm2kl1.html>

Participants will be required to register for access to the webcast. An archive of the webcast will be available on Imricor's website after the event.

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 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.