ASX Announcement

BUSINESS UPDATE

- The Company's Notified Body TÜV SÜD has made significant progress toward finalising the CE mark process for the Vision-MR Ablation Catheter.
- The Company has received the Vision-MR Ablation Catheter design examination certificate and is awaiting the corresponding Quality Assurance System certificate.
- The certifier feedback and responses have been clarifications primarily asked of the internal TÜV SÜD lower level reviewers. The Company received no deficiencies during the certification process.
- Agreements are in place across four clinical sites which are ready to commence procedures once CE mark approval is received.
- Product inventory is in place in Imricor's European warehouse, ready for deployment, with sales expected to commence straight away following CE mark approval.
- Since the IPO, Imricor has expanded its workforce by 17 people, including senior appointments from high calibre organisations within the medical technology sector and the addition of nine people across assembly and manufacturing.
- Imricor updates revenue guidance for FY19 to be approximately US$640,000.

23 December 2019 – Minneapolis, United States – Imricor Medical Systems, Inc. (**Company** or **Imricor**) (**ASX:IMR**) is pleased to announce that its Notified Body has made significant progress toward CE mark approval for the Vision-MR Ablation Catheter. Notably, the Company has received the catheter's design examination certificate, and is awaiting the corresponding Quality Assurance System certificate for the CE mark certification process to be complete. The design examination certificate marks the successful completion of the catheter's design dossier review, while the Quality Assurance System certificate covers the scope extension to Imricor's existing Quality System to include manufacturing the catheter. The associated Quality System audit was completed in January of 2019 and successfully closed in March 2019. The Quality System has been recommended for certification and is currently with the final certifying reviewer.

It is important to note that during the certification review process, the Company received no deficiencies from TÜV SÜD.

Commenting on the current status, Imricor's Chair and CEO, Steve Wedan said "The speed of this process is frustrating, but we have been monitoring the progress closely, always offering to assist in any way we can. We look forward to getting the green light soon, and progressing with the execution of our well-established roll out plan, as set out in our Prospectus, that will simply be shifted in time due to the delays we have experienced with this certification.

"Across the company, we remain passionate about achieving great outcomes and delivering on the opportunity to make a meaningful impact on the lives of patients and their healthcare professionals."

Progress of iCMR Lab Rollout

As previously advised, CE mark approval will enable the Company to commence a controlled release of its approved products with the aim to have an initial 15 iCMR lab sites purchasing consumable products within the first half of 2020.

- Imricor has entered into agreements with four sites regarding the sale of its products. These sites have received Advantage-MR systems and are ready to commence procedures following CE mark approval and training.

- Across five sites, facilities for the performance of procedures are currently in place, with documentation that is in the final stages and expected to progress to completion once CE mark approval is received.

- Discussions are well progressed across an additional six sites and are expected to move to the documentation phase once CE mark approval is announced.

Further, Imricor has a solid pipeline of clinical sites it has targeted for the establishment of iCMR labs and sale of its products. This pipeline is expected to grow following CE mark approval, supported by a strengthened sales team and Imricor's collaborative relationship with Koninklijke Philips N.V. and Siemens Healthcare GmbH.

"Our strategy for the year ahead is well advanced, with target sites identified and greater clarity around potential lab adoption rates and timelines. We are seeing strong support across the healthcare sector and the list of potential lab sites continues to grow," Steve Wedan said.

"We have established inventory to ensure no delays in distribution once we have CE mark approval, with product in place in our European warehouse, ready for deployment. We have not been standing still as we wait out the certification process," he said.

Growth in Imricor's Workforce

Imricor has expanded its workforce by 17 people since midyear, including hires from high calibre organisations within the medical technology sector.

Recent appointments include a Director of Marketing who has over 20 years of industry experience including 13 years with Medtronic, most recently as Director of Heart Failure and International Marketing where he launched the company's MRI compatible pacemaker products.

A Clinical Account Manager joins Imricor from Boston Scientific, where he was a field clinical specialist and account manager in the electrophysiology and cardiac rhythm management field.

Imricor recently appointed a Regional Sales Manager – Benelux/West Germany, a seasoned sales professional with over 15 years of experience, most recently with Arthrex. Imricor also expects to appoint a Regional Sales Manager – Eastern Germany early in the first quarter of 2020.

Across assembly and manufacturing, Imricor has increased its workforce by a further nine people, supporting growth in production to facilitate product rollout following CE mark approval.

FY19 Outlook

Due to the delays of the CE mark certification process, Imricor does not expect to generate any material revenue from the sale of its consumable products in FY19, forecast in the Prospectus at US$4.974 million.

The revenue forecast for FY19 is also adjusted for the cancellation of Imricor's NIH contract for the development of an injection catheter for chemoablation. Imricor expects to finalise the cancelation of the contract in the coming days, reducing forecast FY19 revenue by US$418,000. The cancellation allows Imricor to focus its engineering resources on the development of its core pipeline products.

As previously advised, licence revenue of US$1.25 million included in the Prospectus forecast has been deferred to FY20.

As a result of the above Imricor expects revenue for FY19 to be approximately US$640,000.

Due to delays associated with CE mark approval, costs incurred by Imricor during FY19 will be lower than Prospectus forecasts, allowing however for increases in the Company's workforce and the establishment of inventory to enable immediate product distribution following CE mark approval.

Imricor will provide an outlook for FY20 as part of its FY19 results announcement.

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

ENDS

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 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 expects to sell 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.