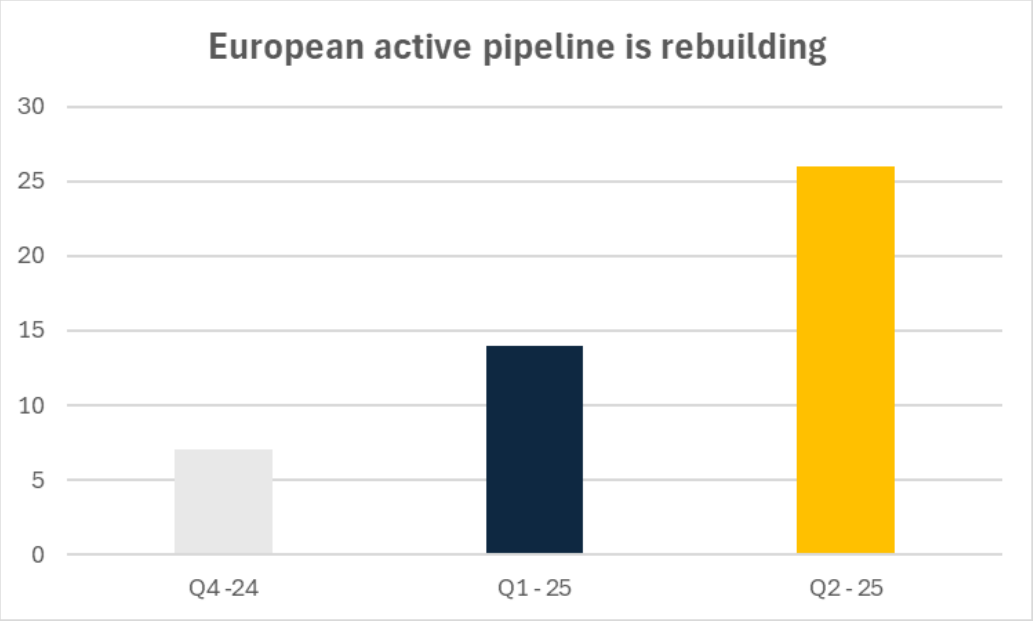
IMRICOR PROVIDES REGULATORY PROGRESS AND BUSINESS UPDATE

10th July 2025 – Melbourne, Australia (**9th July 2025** – Minneapolis, MN United States) – **Imricor Medical Systems, Inc.** (**Company** or **Imricor**) (**ASX: IMR**) provides the following update regarding regulatory and commercial progress across the world.

Europe

- Imricor has now received regulatory approval for NorthStar, as well the 2nd generation ablation catheter and 2nd generation capital equipment, all under today's more stringent European Medical Device Regulation (EU-MDR).
- The company is currently phasing out the 1st generation devices and has commenced the commercial launch of the 2nd generation products from July 1st 2025.
- Investments in sales and marketing are beginning to pay dividends, with the number of hospitals in the active European pipeline increasing from 7 to 26 over the past six months. This growing momentum reinforces our confidence in sustained regional growth as more iCMR labs come online.



United States

- NorthStar 510(k) Premarket Notification was submitted **today** to the US FDA. The submission maintains the prioritisation of the US commercialisation plan of NorthStar, with approval still expected in CY 2025.
- Approval of NorthStar will mark the commercial entry point for Imricor in the US and enable Imricor's sales team to initiate site engagement and pipeline development.

- Multiple pieces of capital equipment and various consumable devices remain on track for submission and approval by the end of the calendar year or shortly into next year in line with guidance (see table below).
- FDA has communicated that the reviewer of the Company's 2nd Premarket Approval (PMA) module is no longer with the agency and a new reviewer has been appointed. The PMA submission relates **only** to the ablation catheter and the RF generator, meaning most products are unaffected.
- VISABL-AFL Clinical trial enrolment has been slower than anticipated during the summer months in the US and Europe, but is expected to ramp up again.
- Imricor **today** submitted an updated PMA schedule, called a "PMA Shell," to the FDA, targeting final clinical trial data submission to the FDA following submission of the 3rd PMA module in 1H 2026.

		Imricor product suite regulatory status	Approved	Status	Comment
Europe	CE Mark	NorthStar	✓		Company has made excellent regulatory progress with all 2nd Generation products and NorthStar receiving CE Mark ahead of plan
		Advantage-MR EP Recorder/Stimulator	✓		
		Vision-MR Diagnostic Catheter	✓		
		Vision-MR Diagnostic Cable	✓		
		Vision-MR Ablation Catheter 2.0	✓		
		Vision-MR Ablation Cable Set 2.0	✓		
		NavTrac-MR Cable	✓		
		Vision-MR Dispersive Electrode	✓		
US	FDA	NorthStar		✓	In US, NorthStar and various pieces of capital equipment and consumables remain on target for approval under 510(k) pathway in line with previous expectations
		Advantage-MR EP Recorder/Stimulator		✓	
		Vision-MR Diagnostic Catheter		✓	
		Vision-MR Diagnostic Cable		✓	
		Vision-MR Dispersive Electrode		✓	
		NavTrac-MR Steerable Introducer and Dilator		✓	
		NavTrac-MR Cable		✓	
		NavTrac Steerable Introducer and Dilator (x-ray use)		✓	
		Vision-MR Ablation Catheter 2.0		→	PMA approval of ablation catheter and RF Generator is behind schedule with final module submission targeting 1H 2026
		Vision-MR Ablation Cable Set 2.0		→	
		RF5000 Ablation Generator, Pump, and Remote		→	

Key ✓ on track
→ behind schedule

Commercial Impact and Outlook

As announced on 23 December, 2024, "*the Company believes NorthStar's release in the EU is a top priority, and that its US approval and release should also be prioritised above the approval and release of the Company's consumable ablation tools. This allows for faster EU iCMR lab adoption and earlier US iCMR lab adoption, providing a larger installed base for the Company's ablation tools sooner*."

The strategic choice to prioritise NorthStar approval and commercialisation ahead the ablation catheter means that the PMA approval process delays are not expected to have a material impact on the Company's commercial trajectory.

With NorthStar approval and capital equipment sales activities beginning by the end of CY 2025, the Company expects the natural sales cycle to align well with the anticipated PMA approval timeline for the catheter and generator. This synchronisation supports an uninterrupted path to revenue generation and scaling in the US.

Imricor's Chair and CEO, Steve Wedan, commented: "We continue to march towards commercialising Imricor's groundbreaking technology across the globe. In Europe the regulatory approvals are now in place, the commercial launch is fully underway, and the sales team are growing and progressing the pipeline. We are conducting our global sales training this week at our home office in Burnsville, and I am delighted with the calibre of talent that has joined the company, most of whom have 15+ years' experience in electrophysiology and ablation. This is the right team, and the results are evident in the growing momentum of our sales pipeline.

"In the US, we continue to advance the entire platform through the various regulatory pathways with our FDA. The timelines associated with each of these pathways can be somewhat unpredictable, of course. For instance, we were pleasantly surprised at the faster-than-expected approval of the first PMA module. We were also pleased to receive CE mark for NorthStar ahead of our expectations. However, we were disappointed in the loss and replacement of the second PMA module's reviewer, and we were disappointed to find clinical trial enrolment slow this summer. But even with these ups and downs, we are moving with great speed in the right direction, and our regulatory and clinical teams continue to shepherd our broad multi-device platform technology onto global markets with great urgency and skill. The EU market is primed, and the US market is quickly following."

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 striving to make interventional medical procedures better, safer, and more cost effective by making it possible for these procedures to be performed under real-time magnetic resonance imaging (MRI) guidance, rather than under x-ray fluoroscopy guidance, thus taking advantage of MRI's superior imaging capabilities.

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 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, the Kingdom of Saudi Arabia (KSA), and New Zealand 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 the U.S. and the other Middle East countries.

The Company has also obtained approval within the EU and KSA for the sale of the Advantage-MR EP Recorder/Stimulator System and other consumable products, such as the Vision-MR Diagnostic Catheter (pending in KSA) and 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., Siemens Healthcare GmbH, and GE HealthCare 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.