

# **IMRICOR Q4 CY24 QUARTERLY ACTIVITIES REPORT AND APPENDIX 4C**

# **HIGHLIGHTS:**

## Regulatory

- US FDA review of Imricor's first module completed successfully
- Successful onsite audit by European notified body to support registration and commercial launch of Gen 2.0 catheter and MR Advantage EP Recorder/Stimulator
- Submitted NorthStar for CE Mark in Europe
- Submitted for CE Mark approval to bring catheter shaft manufacturing in house

## Commercial

- NorthStar completed technical objectives to operate on the Philips MRI platform
- First MRI guided ablation in Switzerland performed at the CHUV
- Signed license agreement with ADIS for AI integration into NorthStar
- Successful entry into Middle East following first sales in Qatar
- Two additional sales resources hired in Europe focusing on Germany, Netherlands, and the Nordics
- Two capital sales specialists hired in the US preparing for the commercial launch following US FDA approval expected in the second half of 2025

### Financial

- Consumables revenue of \$255k up over 840% on Q4 2023
- Total revenue of \$280k (did not include the capital sale in Qatar which will be recognised upon installation)
- Cash receipts of US\$290k up 52% on pcp
- Operating cash outflows in Q4 were well contained at US\$3.48m
- Cash balance of US\$15.7m as at 31 December 2024
- Investor webinar to be held following release of CY24 result in February; registration details to follow.

22 January 2025 – Minneapolis, MN United States (23 January 2025 – Melbourne, Australia) – Imricor Medical Systems, Inc. (Company or Imricor) (ASX: IMR) today releases its Appendix 4C Quarterly Cash Flow Report for the period ended 31 December 2024 and provides an update on its operational performance.

**Imricor's Chair and CEO, Steve Wedan, commented:** "We finished the quarter with a lot of momentum and excitement in the business, and this has continued into 2025. We set and achieved ambitious goals for the Company in 2024, and I am immensely proud of everyone at Imricor. I am also grateful for their brilliance, dedication, creativity, and hard work. Together, with our world-class physician partners, we are moving this new field forward. We are now doubling down on our ambition for 2025, with some of the most significant milestones in Imricor's 19-year history right around the corner."

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# **Business update**

# **Regulatory progress**

Imricor has made significant regulatory progress in Europe and the United States in 2024. NorthStar is emerging as a key piece of the infrastructure to not only support MRI guided ablations, but any MRI guided intervention. Beyond this, there are plans to increase NorthStar's utility for diagnostic purposes, which could significantly expand the addressable market for Imricor. NorthStar has been submitted for CE Mark approval in Europe and the FDA submission will follow in 2025.

Imricor has developed an entire platform of technologies to enable cardiac ablations, and other interventions, to be conducted under MRI guidance. These technologies are made up of capital equipment, consumable devices, and software. Given the substantial number of devices to be reviewed, Imricor has been fortunate to work with the FDA under a modular review process. The collaboration between Imricor staff and the FDA has kept communication lines open, and valuable feedback has seen the first module, a large and complex one, be submitted and returned successfully and ahead of expectations. As our participating hospitals continue to enrol patients in our VISABL-AFL clinical trial, the team is making excellent progress behind the scenes to advance the final submissions which will include the safety and efficacy data from the trial.

In Europe, following the successful onsite audit by Imricor's Notified Body, TÜV SÜD, Imricor is preparing for the launch of the Gen 2.0 suite of products following registration under the new and more stringent European MDR framework. Once the products are registered under MDR, Imricor plans to submit the Gen 2.0 catheter for approval to TGA in Australia as previously communicated to investors.

# **Commercial progress**

After receiving regulatory approval in Qatar and the Kingdom of Saudi Arabia earlier this year, Imricor made its first sale in Qatar during the quarter. In 2025, Imricor expects further sales in Saudi Arabia where approximately 50,000 cardiac ablations are performed each year and where Imricor is well aligned to the growth objectives of Saudi Vision 2030's Health Sector Transformation Program.

In Switzerland, MRI guided ablations are underway at the prestigious Lausanne University Hospital (CHUV).

In Amsterdam, the team have been preparing for the groundbreaking first VT case whilst also hosting physicians from other European hospitals to observe atrial flutter cases in preparation for commencing their own programs.

The quarter's revenue of \$280k was mostly made up of consumable revenue with the capital sale made in Qatar to be recognised in future quarters following installation. This was a pleasing result given several of Imricor's active sites are performing procedures towards the VISABL-AFL trial which are currently non-revenue generating.

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On the manufacturing front, during the quarter Imricor submitted for European approval to bring catheter shaft manufacturing in-house. Imricor previously outsourced catheter shaft manufacturing, and the operations team worked throughout 2024 to bring this process inside the Company. Manufacturing catheter shafts in-house is expected to significantly improve gross margins on the catheters as the business scales. It is also expected to alleviate long lead times while improving quality. Completing and submitting this critical work by year-end was a remarkable achievement, led by our operations team under the direction of Vic Fabano.

# VT update

Imricor was started 19 years ago to enable complex cases like VT and Afib ablations under iCMR guidance. The Company's current hospital customers that have built, or are building, iCMR labs are doing atrial flutter cases as a stepping stone to VT and Afib ablations in the future. Amsterdam UMC is a useful case study to both highlight the commitment to this new field but also some of the short-term challenges they face. Amsterdam UMC is currently building a brand-new heart centre that has an iCMR lab as the central piece. The heart centre will be one of the largest in the Netherlands and perform over 7,500 interventional cardiology, electrophysiology, and structural heart procedures per year.

In the short term, whilst the team await completion of the iCMR lab, an MRI has been made available by the radiology department for procedures 1-2 days per month. In order to take the significant next step and do the world's first VT procedure under iCMR guidance, the electrophysiologist will be travelling to Imricor's iCMR lab in Minneapolis to intensively use the Gen 2.0 catheter and new tools developed for VT, and to refine and practice new associated workflows to ensure the first-in-human procedure is a success on his return to Amsterdam. The plan is to then take full control of the radiology MRI scanner for the team to perform several atrial flutter cases and then the first VT case. Imricor will provide updates on this exciting event in the near term.

# Appendix 4C Cashflow for Q4 CY24

During the quarter ended 31 December 2024, Imricor reported net cash outflows from operating activities of US\$3.48 million. Receipts from customers during the period were US\$0.3 million.

Payments made in relation to operating costs of US\$3.9 million decreased compared to the prior quarter of US\$4.5 million, primarily due to the prepayment of annual D&O insurance premiums during the prior quarter.

At 31 December 2024, Imricor maintained a cash balance of US\$15.7 million.

Payments made to related parties as described in Item 6.1 on the Appendix 4C were for directors' fees.

# Imricor background

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. The goal of MRI guidance is to enable faster, more effective, and less expensive treatment of cardiac arrhythmias, all in a setting that is free of dangerous x-ray radiation exposure for patients, physicians, and other medical personnel.

Imricor's target market of cardiac ablations is estimated to be US\$8 billion worldwide.

Executing the VISABL-VT and VISABL-AFL trials, as well as re-establishing the iCMR-guided atrial flutter ablation market in Europe, post-pandemic, and expanding into new geographies like Australia, New Zealand, and the Middle East are key drivers of Imricor's growth.

### 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 and the Kingdom of Saudi Arabia (KSA) 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 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**

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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 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.

# Appendix 4C

# Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity	
Imricor Medical Systems, Inc.	
ABN	Quarter ended ("current quarter")
633 106 019	31 December 2024

Con	solidated statement of cash flows	Current quarter \$USD'000	Year to date (12 months) \$USD'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	290	840
1.2	Payments for		
	(a) research and development	(995)	(3,668)
	(b) product manufacturing and operating costs	(125)	(1,396)
	(c) advertising and marketing	(224)	(938)
	(d) leased assets	-	-
	(e) staff costs	(2,083)	(8,188)
	(f) administration and corporate costs	(502)	(2,706)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	163	258
1.5	Interest and other costs of finance paid	(8)	(20)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	313
1.8	Other (provide details if material)	-	-
1.9	Net cash from / (used in) operating activities	(3,484)	(15,505)

2.	Cash flows from investing activities	
2.1	Payments to acquire or for:	
	(a) entities	-
	(b) businesses	-
	(c) property, plant and equipment	(50)
	(d) investments	-
	(e) intellectual property	(16)
	(f) other non-current assets	-

Con	solidated statement of cash flows	Current quarter \$USD'000	Year to date (12 months) \$USD'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant, and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	Net cash from / (used in) investing activities	(66)	(193)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	32,886
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(34)	(1,892)
3.5	Proceeds from borrowings	-	344
3.6	Repayment of borrowings	(168)	(1,007)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	65
3.10	Net cash from / (used in) financing activities	(202)	30,396

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	19,615	832
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,484)	(15,505)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(66)	(193)

solidated statement of cash flows	Current quarter \$USD'000	Year to date (12 months) \$USD'000
Net cash from / (used in) financing activities (item 3.10 above)	(202)	30,396
Effect of movement in exchange rates on cash held	(155)	178
Cash and cash equivalents at end of period	15,708	15,708
	Net cash from / (used in) financing activities (item 3.10 above) Effect of movement in exchange rates on cash held <b>Cash and cash equivalents at end of</b>	Net cash from / (used in) financing activities (item 3.10 above)(202)Effect of movement in exchange rates on cash held(155)Cash and cash equivalents at end of15,708

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$USD'000	Previous quarter \$USD'000
5.1	Bank balances	15,708	19,615
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	15,708	19,615

# 6. Payments to related parties of the entity and their associates

- 6.1 Aggregate amount of payments to related parties and their associates included in item 1
- 6.2 Aggregate amount of payments to related parties and their associates included in item 2

Current quarter \$USD'000 79 -

\*Payments listed in 6.1 represent board fees.

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments

- 7.2 Credit standby arrangements
- 7.3 Other (please specify)
- 7.4 Total financing facilities

Total facility amounts at quarter end \$USD'000	Amount drawn at quarter end \$USD'000
-	-
-	-
-	-
-	-

-

### 7.5 Unused financing facilities available at quarter end

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

8.	Estimated cash available for future operating activities	\$USD'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(3,484)
8.2	Cash and cash equivalents at quarter end (item 4.6)	15,708
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	15,708
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	4.5

Note: if the entity has reported positive net operating cash flows in item 1.9 answer item 8.5 as 'N/A". Otherwise, a figure for the estimated quarters of funding must be included in item 8.5.

### 8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answe	er:
8.6.2	Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?
Answe	er:

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer:

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 about must be answered.

#### **Compliance statement**

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Date: 23 January 2025

Authorised by: the Board (Name of body or officer authorising release – see note 4)

#### Notes

- This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
- 2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, AASB 107: Statement of Cash Flows apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
- 3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
- 4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – e.g., Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
- 5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's Corporate Governance Principles and Recommendations, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.