



IMRICOR Q1 CY24 QUARTERLY ACTIVITIES REPORT AND APPENDIX 4C

HIGHLIGHTS:

- Reactivation of customer sites under way with momentum building
- April month to date consumable revenue already exceeding Q1 consumable revenue with more site activations to come during Q2
- Johns Hopkins IRB approved VISABL-AFL Trial for US FDA submission
- US FDA granted IDE approval for NorthStar 3D mapping system in VISABL-AFL trial
- Saudi FDA approval received, with first sales expected 2H CY24
- CE Mark approval in Europe for Vision-MR Diagnostic Catheter
- CHUV Hospital in Switzerland received ethics approval to join VISABL-AFL trial to support US FDA approval
- ICPS Hospital in France received ethics approval to join VISABL-AFL trial to support US FDA approval
- Cash costs in Q2 are expected to decrease ~30% (\$3.5 million) in Q2, as Q1 included non-recurring items
- North Dakota's Pioneer Capital remain highly engaged with in person meetings scheduled for Q2.

Subsequent to quarter end:

- Amsterdam UMC restarted MRI guided ablation procedures using Imricor catheters and NorthStar 3D mapping system
- Dubrava University Hospital in Croatia ordered first catheters – procedures to commence in May with installation complete
- ICPS Hospital in France received final French Competent Authority approval to join VISABL-AFL trial to support US FDA approval
- Successfully completed A\$15 million Institutional Placement and Entitlement offer fully subscribed
- Webinar to be held today at 9:00am AEST / 6:00pm CDT. [Click here](#) to register.

29 April 2024 – Minneapolis, MN United States (**30 April 2024** – Melbourne, Australia) – **Imricor Medical Systems, Inc. (Company or Imricor) (ASX: IMR)**, the global leader in real-time iCMR cardiac ablation products, today releases its Appendix 4C Quarterly Cash Flow Report for the period ended 31 March 2024 and provides an update on its operational performance.

Imricor's Chair and CEO, Steve Wedan, commented: "We have been laying the foundations for Imricor and our customers to move this new field forward. Each new site we activate provides near term capital and consumable revenue to Imricor. More importantly however, these same sites will then perform more complex procedures like VT and atrial fibrillation (AF)



ablations, which have a greater need for MRI guidance along with higher procedure volumes and higher revenue for Imricor.

“We are very excited to commence the US FDA trial and for the first VT patient to be treated this quarter. I would like to thank our staff for their hard work and commitment to our mission as well as our shareholders who have supported our long-term vision which is now becoming a reality in 2024.”

European Commercialisation Update

In CY23, the Company’s sales and marketing team engaged closely with European customers to refresh their iCMR infrastructure and to train new medical personnel, as needed, all in anticipation of establishing consistent procedure volumes at active sites and increasing the number of active sites in CY24.

The Company is delivering on this promise, as demonstrated by the consistent schedule of procedures at the Leipzig Heart Center during the period, as well as the reactivation of Amsterdam UMC in April.

Also in April, Dubrava University Hospital (Dubrava) issued their first purchase order for Imricor catheters and other disposables. Dubrava previously ordered the required capital equipment from Imricor, and the lab installation has been completed. The MRI software upgrades required for real-time imaging were installed by Siemens over the last week of April, and procedures at Dubrava are expected to commence in May.

Also in the period, Semmelweis University Heart and Vascular Centre in Budapest, Hungary, published a tender for the acquisition of iCMR lab infrastructure. Imricor is the only company globally able to bid because it produces the MRI compatible equipment requested in the tender. Procedures are expected to commence at Semmelweis in late Q2 or early Q3.

Finally, Imricor’s Vision-MR Diagnostic Catheter received CE mark certification in the period. The diagnostic catheter is the first Imricor device to receive approval under the new, stricter European Union Medical Device Regulations (EU MDR). The Vision-MR Diagnostic Catheter is a lower-cost non-ablating catheter which can replace the second ablation catheter in atrial flutter procedures, thereby increasing margins.

Ventricular Tachycardia Ablation Trial Update

The VISABL-VT trial is awaiting final Ethics Committee approval at Amsterdam UMC. The trial already has Dutch Competent Authority approval, with final Ethics Committee approval is expected in the next few weeks. The first VT patient is expected to be treated at Amsterdam UMC in the current quarter.

US Commercialisation Update

The Company’s path to opening the US market, accounting for about half of the US\$8 billion global market, is via US Food and Drug Administration (FDA) approval. The FDA approval process across Imricor’s many products involves multiple parallel paths, depending on the regulatory classification and the information required to demonstrate safe and effective use of each device.



A major milestone required for FDA approval is the successful execution of a pivotal clinical trial (named “Vision-MR Ablation of Atrial Flutter” or VISABL-AFL) to provide the clinical evidence required for Imricor’s higher-classification products, in particular the Vision-MR Ablation Catheter and HAT 500 Ablation Generator.

During the period, the Company achieved many key milestones toward FDA approval, including:

- **Approval** from Johns Hopkins Hospital’s Institutional Review Board, in Baltimore, USA, to commence VISABL-AFL (the final approval required at Johns Hopkins)
- **Approval** from Lausanne University Hospital (CHUV) Ethics Committee, in Switzerland, to commence VISABL-AFL (the first of two approvals required at CHUV)
- **Approval** from the Cardiovascular Institute of South Paris (ICPS) Ethics Committee, in France, to commence VISABL-AFL (the first of two approvals required at ICPS)
- **Approval** of an Investigational Device Exemption (IDE) for Imricor’s NorthStar 3D mapping system to be added to the VISABL-AFL trial

After the period, the Company further received the **second** and final **approval** by the French Competent Authority to commence VISABL-AFL at ICPS. Swiss Competent authority approval for CHUV is expected in the coming weeks.

With the successful completion of these multiple milestones, VISABL-AFL is fully cleared to commence at Johns Hopkins and ICPS, with CHUV to follow soon. Patient recruitment is underway at Johns Hopkins, while installation planning is taking place at ICPS, and patient enrolment will commence shortly thereafter.

Amsterdam UMC is also expected to join the VISABL-AFL trial, and the required Ethics Committee submission will take place once the Amsterdam UMC Ethics Committee approves the VISABL-VT trial in the coming weeks.

All 91 patients in the VISABL-AFL trial are expected to be treated by year-end CY24, opening the door for FDA approval of Imricor’s platform of capital and consumable devices in CY25.

Middle East Commercialisation Update

Imricor has achieved a significant milestone in market development, solidifying its presence in the Middle East.

In the period, Imricor received Medical Device Marketing Authorization (MDMA) from the Saudi Food & Drug Authority (SFDA), opening commercialisation efforts in Saudi Arabia through its exclusive distributor, Al Faisaliah Medical Systems (FMS). FMS, with a strong track record and expansive distribution network, is positioned to propel Imricor’s technology in a market where approximately 50,000 cardiac ablation procedures are conducted annually, aligned with the growth objectives of Saudi Vision 2030’s Health Sector Transformation Program.

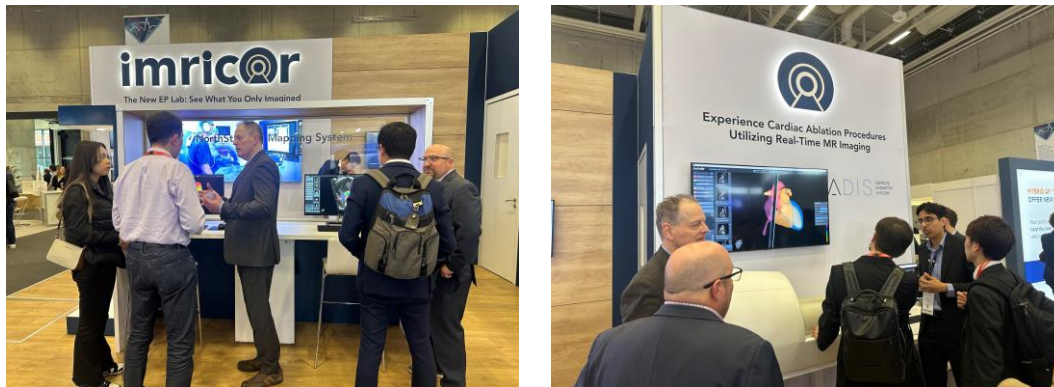
SFDA approval also opens the door for commercialisation efforts in Qatar. Late last year, the Company entered into a 5-year Distribution Agreement with East Agency WWL, a prominent distributor in Qatar, granting exclusive rights for the distribution of Imricor’s innovative iCMR family of ablation products in the country.



These developments underscore Imricor's commitment to strategic market expansion and sustained growth.

Market Development Update

Imricor participated in the European Heart Rhythm Association's annual congress in Berlin, and the Sales team reported the most traffic and interest since before the pandemic. Imricor invited partner ADIS to join in the booth presentation, showcasing the iCMR simulator with Imricor catheters and a NorthStar 3D mapping system front end. Physicians were able to guide a real catheter within the simulator and view it in NorthStar as if they were doing a real procedure.



Imricor's Sales Team introducing physicians to MRI-guided ablation technology at EHRA 2024

The Heart Rhythm Society's annual congress in Boston will take place in May. Imricor's participation, along with ADIS and the simulator, will be similar.

Appendix 4C Cashflow for Q1 CY24

During the quarter ended 31 March 2024, Imricor reported net cash outflows from operating activities of US\$4.7 million. Receipts from customers during the period were US\$0.1 million.

Payments made in relation to operating costs of US\$5.0 million increased compared to the prior quarter of US\$3.2 million, primarily due to the payment of regulatory review expenses following receipt of CE Mark on the diagnostic catheter and the payment for certain 3rd party equipment inventory where commitments to purchase were made in a prior period. The Company expects this increase to be limited to Q1 CY24, with payments for the quarter ending 30 June expected to decrease below \$3.6 million.

Receipts from government grants and tax incentives of US\$0.2 million were related to the Bioscience Innovation Grant program, which is administered by the North Dakota Department of Agriculture, and serve as reimbursement for specific expenses incurred to support the approval process of the Company's products in the United States.

Net cash inflows from financing activities were US\$5.1 million in the period, comprising net proceeds from the placements and institutional entitlement offer completed in February 2024.



At 31 March 2024, Imricor maintained a cash balance of US\$1.2 million. After the period, the Company completed the placement of the shortfall securities pursuant to the entitlement offer announced on 2 February 2024. This resulted in gross proceeds of approximately US\$4.2 million and brings pro forma cash balance at 31 March to US\$5.4 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.

Media and Investor Relations Contacts:

Simon Hinsley
Executive Director, NWR
simon@nwrcommunications.com.au
+61 401 909 653

Nick Corkill
VP Corporate Strategy, Imricor
nick.corkill@imricor.com
+61 450 475 633

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

Imricor's CHES Depository 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.

Appendix 4C

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

Name of entity

Imricor Medical Systems, Inc.

ABN

633 106 019

Quarter ended ("current quarter")

31 March 2024

Consolidated statement of cash flows	Current quarter \$USD'000	Year to date (3 months) \$USD'000
1. Cash flows from operating activities		
1.1 Receipts from customers	109	109
1.2 Payments for		
(a) research and development	(1,171)	(1,171)
(b) product manufacturing and operating costs	(1,066)	(1,066)
(c) advertising and marketing	(168)	(168)
(d) leased assets	-	-
(e) staff costs	(1,959)	(1,959)
(f) administration and corporate costs	(639)	(639)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	6	6
1.5 Interest and other costs of finance paid	(8)	(8)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	167	167
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(4,729)	(4,729)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(1)	(1)
(d) investments	-	-
(e) intellectual property	(40)	(40)
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$USD'000	Year to date (3 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	(41)	(41)
3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	5,603	5,603
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	(306)	(306)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	(246)	(246)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	65	65
3.10	Net cash from / (used in) financing activities	5,116	5,116
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	832	832
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(4,729)	(4,729)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(41)	(41)

Consolidated statement of cash flows		Current quarter \$USD'000	Year to date (3 months) \$USD'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	5,116	5,116
4.5	Effect of movement in exchange rates on cash held	(10)	(10)
4.6	Cash and cash equivalents at end of period	1,168	1,168

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	1,168	832
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)	1,168	832

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**

59

-

*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. Financing facilities

Note: the term "facility" includes all forms of financing arrangements available to the entity.

Add notes as necessary for an understanding of the sources of finance available to the entity.

	Total facility amounts at quarter end \$USD'000	Amount drawn at quarter end \$USD'000
7.1 Loan facilities	1,500	33
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
7.4 Total financing facilities	1,500	33

7.5 **Unused financing facilities available at quarter end** 1,467

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.

Imricor was awarded a US\$1,500,000 loan through the North Dakota Commerce Department, the details of which were included in our announcement dated 22 December 2022. Imricor has full access to the funding subject to the use of funds limitations outlined on the Department of Commerce's LIFT program website.

8. Estimated cash available for future operating activities	\$USD'000
8.1 Net cash from / (used in) operating activities (item 1.9)	(4,729)
8.2 Cash and cash equivalents at quarter end (item 4.6)	1,168
8.3 Unused finance facilities available at quarter end (item 7.5)	1,467
8.4 Total available funding (item 8.2 + item 8.3)	2,635
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	0.6

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?

Answer: The current period included the payment of certain one-time or infrequent expenses which elevated the current quarter's net operating cash outflows. Imricor expects the net operating cash outflows for the quarter ending 30 June 2024 to decrease from the current quarter.

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- 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?

Answer: Yes, Imricor completed the issuance of shortfall securities pursuant to a pro-rata non renounceable entitlement offer on 2 April 2024, resulting in gross proceeds of A\$6.47 million.

Additionally, Imricor continues to pursue an investment from the North Dakota Pioneer Capital Fund in accordance with the Letter of Intent to Invest received on 12 October 2023 (additional details included in the Cleansing Notice and Excluded Information announcement dated 25 October 2023).

Finally, the Security Subscription Facility Imricor secured from GEM Global Yield LLC SCS in July 2023 is available to provide cash of up to A\$29.6 million to fund operations (full details included in our announcements dated 6 July 2023 and 7 July 2023).

- 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: Yes, Imricor expects to continue its operations and to meet its business objectives based on its capital raising plans summarised in 8.6.2.

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: 30 April 2024

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

Notes

1. 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.

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