



IMRICOR Q3 FY23 QUARTERLY ACTIVITIES REPORT AND APPENDIX 4C

HIGHLIGHTS:

- Granted approval for VISABL-VT trial to commence at Haga Hospital in the Netherlands by Competent Authority and local Medical Ethics Review Committee
- Granted approval for VISABL-VT trial to commence across Germany by Competent Authority, pending local Medical Ethics Review Committees
- Trial to commence upon finding optimal patient, which is well advanced
- Grant awarded of US\$1.158 million from the North Dakota Department of Agriculture as part of the department's Bioscience Innovation Grant (BIG) program to fund FDA trial (VISABL-AFL)
- Successfully raised A\$4.29 million¹ (US\$2.84 million¹) from a small number of US, Australian, and New Zealand investors
- Consumable product revenues of US\$102,000 in Q3 2023, a 5% increase quarter-on-quarter and an 11% decrease versus the prior corresponding periods ("pcp") reported basis; adjusted for currency fluctuations sales were up 4% and down 16%, respectively
- As at 30 September 2023, Imricor had cash of approximately US\$1.4 million

POST PERIOD HIGHLIGHTS:

- Commenced activation of new iCMR site in Zagreb, Croatia with procedures expected in Q4 2023
- Current cash of US\$3.5 million after securing US\$2.7 million through placement and draw from Security Subscription Facility
- Letter of Intent received from the Pioneer Capital Fund to invest US\$8 million in Imricor in exchange for equity at a target price of US\$0.60 (A\$0.95) per share

30 October 2023 – Minneapolis, MN United States (**31 October 2023** – 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 30 September 2023 and provides an update on its operational performance.

Imricor's Chair and CEO, Steve Wedan, commented: "This was a huge quarter for the future of Imricor and for the field of iCMR-guided interventions, with the approval to commence a major global clinical trial aiming to expand the kinds of heart diseases our products can treat, as well as the progress toward commencing a second global clinical trial aiming to open the world's largest market for our products, the United States.

"As we rebuild our commercial efforts and re-develop the European market – often meaning working with hospitals and our MRI partners to update MRI software and operating systems that became outdated during the pandemic – we are establishing ourselves and our customers to drive this exciting new field of medicine forward."

¹ Figures in this announcement include amounts transacted in both A\$ and US\$, which have been converted to the currency presented based on a foreign exchange rate of A\$1.00 to US\$0.6475 (being the exchange rate published by the Reserve Bank of Australia on 14 August 2023).



Ventricular Tachycardia (VT) Update

During the quarter, Imricor received approval from the Medical Ethics Review Committee, Leiden The Hague Delft (METC LDD) to begin the VISABL-VT trial at Haga Hospital in The Hague, Netherlands. Approval was also granted from the German Federal Institute for Drugs and Medical Devices (BfArM) to commence the VISABL-VT clinical trial at sites within Germany, pending local Ethics Committee approval at the German sites.

First patient enrolment at Haga Hospital is expected upon finding and scheduling an optimal first-in-man patient by the medical team. Meanwhile, Ethics Committee submissions are progressing at the German Heart Centre of the Charité in Berlin and the Amsterdam University Medical Centre. Both of these institutions are higher-volume VT centres than Haga Hospital, and both are on schedule for their approvals and trial participation beginning in early Q1 2024.

The VISABL-VT trial is a prospective, single-arm, multi-centre investigation of the safety and efficacy of radiofrequency (RF) ablation of VT associated with ischemic cardiomyopathy performed with the Vision-MR Ablation Catheter 2.0 in the iCMR environment. The study calls for treating 64 patients and includes a six-month follow-up for each patient. The study is intended to support CE mark certification of the Vision-MR Ablation Catheter 2.0 for treating VT.

US FDA Update

During the quarter, Imricor's clinical team visited the Johns Hopkins University in Baltimore to submit the IRB (Institutional Review Board) approval packet and advance the contract documents for the VISABL-AFL clinical trial, with the aim of supporting FDA approval in the United States.

Simultaneously, the Ethics Committee and Competent Authority approval processes for VISABL-AFL are moving forward in Switzerland at Lausanne University Hospital (CHUV) and in France at the Cardiovascular Institute of South Paris (ICPS).

After the period, Imricor's clinical team returned on two occasions to Johns Hopkins University for installation and procedure training. The Company anticipates the initiation of the trial in Q4 2023.

Operations Update

Imricor is on the verge of finalizing a Joint Development Agreement with a specialized software development company in the field of artificial intelligence (AI). The objective is to enhance NorthStar with advanced AI capabilities, further enriching the value of MRI technology provided by NorthStar.

The Imricor team is also diligently preparing the necessary pre-approval documentation and arranging pre-submission consultations with regulatory authorities to expedite the approval process for NorthStar's sale. Notably, NorthStar garnered substantial interest during a recent demonstration at Imricor's iCMR Design Center, where it showcased its unique capacity to seamlessly communicate in real-time with MRI scanners and Imricor's catheter devices through the Advantage-MR EP Recorder/Stimulator. This positions NorthStar as the central hub with a 3D user interface for guiding interventional MRI procedures, extending its capabilities beyond cardiac ablation. This distinctive feature places NorthStar in a league of its own, as no other 3D



mapping system worldwide offers comparable functionality. Imricor is actively creating substantial value with NorthStar.

In Australia, Imricor has addressed inquiries from the Therapeutic Goods Administration (TGA) and is anticipating TGA approval in the near future. The company has already garnered strong interest from a prominent Australian hospital and is eager to advance discussions.

Finally, Imricor is actively engaged in various in-house initiatives. These include efforts by the manufacturing team to reduce the time-and-material costs of the Vision-MR ablation catheter, with a short-term goal of achieving up to a 20% reduction and a longer-term aspiration of halving the costs as part of the North Dakota manufacturing expansion. The quality team continues its relentless pursuit of enhancing the quality system and the products it yields.

Market Development

A key focus for the European sales team continues to be the activation of sites. Activation of a new iCMR site at Dubrava Hospital in Zagreb, Croatia commenced after the period with procedures expected to begin in Q4. Activations of additional sites are expected to commence in Q4 and beyond.

In addition, several sites are in the process of what the Company calls “re-activation.” Re-activation is the process of a site updating their MRI system and/or software to allow for the use of Imricor’s new NorthStar 3D mapping system.

Appendix 4C Cashflow for Q3 FY23

During the quarter ended 30 September 2023 (Q3 2023), Imricor reported net cash outflows from operating activities of US\$3.675 million. Receipts from customers during the period were US\$0.254 million comprising:

- contract receipts (US\$0.099 million);
- rental of capital equipment (US\$0.008 million);
- consumable product sales (US\$0.073 million); and
- the sale of service agreements (US\$0.074 million)

Payments made in relation to operating costs of US\$3.949 million were up compared to the prior quarter of US\$3.409 million primarily due to the payment of annual corporate insurance premiums during the period. Adjusted for these annual premiums, payments made in relation to operating costs were US\$3.139 million which represents a decrease of approximately US\$0.270 million, or 8%, compared to the prior quarter.

Net cash outflows from investing activities were US\$0.020 million during the period.

Net cash inflows from financing activities were US\$3.562 million in the period, largely comprising net proceeds from the placements completed in July and August 2023 as well as the proceeds from an insurance premium financing arrangement the Company entered into during the quarter. These proceeds are reported in item 3.5 and will be repaid in ten equal instalments, with the final payment due 30 June 2024.

At 30 September 2023, Imricor maintained a cash balance of US\$1.371 million.



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. Real-time iCMR also reduces repeated exposure to dangerous x-ray radiation.

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 Contact:

Simon Hinsley
simon@nwrcommunications.com.au
+61 401 909 653

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 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 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")

30 September 2023

Consolidated statement of cash flows	Current quarter \$USD'000	Year to date (9 months) \$USD'000
1. Cash flows from operating activities		
1.1 Receipts from customers	254	1,070
1.2 Payments for		
(a) research and development	(367)	(1,312)
(b) product manufacturing and operating costs	(176)	(840)
(c) advertising and marketing	(202)	(765)
(d) leased assets	-	-
(e) staff costs	(2,007)	(6,237)
(f) administration and corporate costs	(1,197)	(2,194)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	22	52
1.5 Interest and other costs of finance paid	(2)	(21)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	474
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(3,675)	(9,773)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(3)	(77)
(d) investments	-	-
(e) intellectual property	(17)	(47)
(f) other non-current assets	-	-

For personal use only

Consolidated statement of cash flows		Current quarter \$USD'000	Year to date (9 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	(20)	(124)
3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	3,018	3,018
3.2	Proceeds from issue of convertible debt securities	-	2,675
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(14)	(104)
3.5	Proceeds from borrowings	598	631
3.6	Repayment of borrowings	(40)	(628)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	Net cash from / (used in) financing activities	3,562	5,592
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	1,509	5,688
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,675)	(9,773)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(20)	(124)

Consolidated statement of cash flows		Current quarter \$USD'000	Year to date (9 months) \$USD'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	3,562	5,592
4.5	Effect of movement in exchange rates on cash held	(5)	(12)
4.6	Cash and cash equivalents at end of period	1,371	1,371

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	1,371	1,509
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)	1,371	1,509

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
-
-

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

For personal use only

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)	(3,675)
8.2 Cash and cash equivalents at quarter end (item 4.6)	1,371
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)	2,838
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	0.8

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 planned start of our clinical trials for ventricular tachycardia in Europe and atrial flutter in the United States will likely increase spending on research and development compared to the current period. Any significant decrease in future net operating cash outflows would be reliant upon future increases in receipts from customers.

- 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. After quarter end, Imricor completed a placement to raise A\$4.28 million with existing and new investors, the details of which were included in our announcement dated 23 October. Further, Imricor is taking steps to raise further capital to fund its operations. These steps include pursuing economic incentive programs from regional agencies and other capital raising initiatives.

Additionally, the Security Subscription Facility Imricor secured from GEM Global Yield LLC SCS in July 2023 is available to provide cash of up to A\$29.7 million to fund operations (full details included in our announcements dated 6 July 2023 and 7 July 2023). After quarter end, Imricor drew A\$145,822 from the facility, the details of which were included in our announcement dated 23 October.

- 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: 31 October 2023

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

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

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.

For personal use only