



## IMRICOR Q4 FY22 QUARTERLY ACTIVITIES REPORT AND APPENDIX 4C

### HIGHLIGHTS:

- Q4 consumable product revenues of US\$50,000, down 56% compared to Q3 2022 and 42% compared to Q4 2021 on a reported basis; adjusted for currency fluctuations sales were down 54% and 32%, respectively. Procedure volumes were flat in the quarter, but consumable product revenues were down as device re-orders expected in December were pushed into the following period. December was a particularly slow month for procedures due to year-end holidays.
- Received first of two required approvals to commence “Vision-MR Ablation of VT” or VISABL-VT clinical trial.
- Successfully received a positive outcome from the Notified Body in Europe (TÜV SÜD) following a technical review of Imricor’s Vision-MR Diagnostic Catheter.
- NorthStar-MR, Imricor’s 3D mapping system, successfully used in first human experience in Netherlands
- Signed two new sites and expanded the Company’s geographical footprint into Croatia
- Entered into an agreement with US-based existing investor, The K.A.H.R. Foundation and its affiliates, for a convertible note to raise a maximum of US\$5 million
- Secured a US\$1.5 million loan under the North Dakota Commerce Department’s Innovation Technology Loan Fund (LIFT) program, with favourable terms
- Significant 2023 milestones include commencing the VISABL-VT clinical trial in Europe and receiving Investigational Device Exemption (IDE) approval to begin a clinical trial in the US
- As at 31 December 2022, Imricor had cash of approximately US\$5.7 million

**19 January 2023** – Minneapolis, MN United States (**20 January 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 31 December 2022 and provides an update on its operational performance.

**Imricor’s Chair and CEO, Steve Wedan, commented:** “We entered 2023 with great momentum toward delivering VT indications in Europe and FDA approval in the US. Importantly, our new NorthStar-MR 3D Mapping System is minimising our reliance on 3<sup>rd</sup> party mapping systems, allowing us to better control the timelines associated with both of these strategic goals.

“Whilst procedure volumes were limited in Q4 by lingering impacts of the pandemic and MRI availability at sites where cardiology departments do not yet own their own MRI, we expect both of these effects to diminish as time passes and we steadily activate more sites. More active sites also expands our installed base of customers who can perform VT ablations once the indication is approved. We are building the foundation for the future of iCMR ablations and Imricor, and we expect 2023 to be a pivotal year.”



## **Milestones Expected in 2023**

- Commencement of the VISABL-VT trial. This is significant as it demonstrates the expansion of iCMR ablations beyond atrial flutter and is expected to catalyse the market for growth. Critically, VT ablations performed in MRI are expected to improve patient outcomes.
- Receive Investigational Device Exception (IDE) from US Food and Drug Association (FDA), allowing Imricor to commence an atrial flutter (AFL) clinical trial in the US. This is significant because the US is expected to be a major market for Imricor's products.
- Steady growth in number of active sites, meaning ones that are installed, trained and able to perform procedures. Along with more active sites, procedure volumes will grow.

## **Procedure Volumes**

Atrial flutter procedure rates were flat in the last quarter of 2022 compared to Q3 2022. Customer physicians are reporting that fewer patients presented with standalone atrial flutter in the second half of 2022, compared to their experiences prior to the pandemic. Instead, more patients are presenting with a combination of atrial flutter and atrial fibrillation. It is unclear if the effect is a temporary result of the pandemic.

December was a particularly slow month for procedures, due to people being off for end-of-year holidays. The holiday effect is exasperated at sites where the MRI is a borrowed resource, due to a lack of schedule flexibility. As previously outlined, emphasis is now on signing sites where the MRI lab is owned and controlled by the cardiology department so access to the lab is not limited.

## **VISABL-VT Ethics Committee Approval**

The Company received the first of two required approvals to commence its "Vision-MR Ablation of VT" or VISABL-VT clinical trial.

The next and final step required to commence the trial is to receive approval from the German Federal Institute for Drugs and Medical Devices (BfArM). Under the new European Medical Device Regulations (EU-MDR) regime, BfArM will not begin a review of a clinical trial until they receive a positive approval from a local Ethics Committee, which VISABL-VT has successfully received.

## **Diagnostic Catheter Technical Review Complete**

Pleasingly, the Company's Notified Body in Europe (TÜV SÜD) signed off on the technical review component of the Vision-MR Diagnostic Catheter. Following a successful Quality Management System audit scheduled for Q1 CY2023, and the issuance of certificates, the Vision-MR Diagnostic Catheter can be sold to EU clinical customers.

Importantly, the Vision-MR Diagnostic Catheter is a simplified, lower-cost version of the Vision-MR Ablation Catheter, which will contribute to increased margins for the Company. Currently, two ablation catheters are sold in a kit for the price of one ablation catheter plus one diagnostic catheter.



### 3D NorthStar-MR First-in-Human Experience

Staff at Haga Hospital in The Hague, Netherlands successfully treated two atrial flutter patients in the iCMR in December, while evaluating the Imricor's prototype NorthStar-MR 3D Mapping System. These procedures were the first human clinical procedures for which NorthStar-MR was evaluated. The feedback was extremely positive.

NorthStar-MR currently operates with Siemens MRI scanners, and it is the Company's goal to include NorthStar-MR as a supplement to the VISABL-VT trial submission, such that Siemens iCMR sites can participate in the trial. It is also the Company's goal to apply NorthStar-MR to MRI systems from GE Healthcare and Philips, ultimately providing the same user experience for physicians no matter which MRI platform they utilise. The company is currently in discussions with GE and Philips.

### Signed Two New Sites

Two new sites signed agreements with Imricor during the quarter. The first site is the Heart and Diabetes Centre Nordrhein-Westfalen (HDZ-NRW) in Bad Oeynhausen, Germany. The second site is the Clinical Hospital Dubrava, in Zagreb, Croatia, which is the Company's first site in Croatia.

### New Funding Secured

During the quarter, the Company completed two deals to secure further working capital in addition to the A\$2.92m placement completed in the September quarter. The Company continues to explore other economic incentive programs that offer attractive terms.

#### Convertible Note

Imricor entered into a Securities Purchase Agreement with The K.A.H.R. Foundation and its affiliates for the issue of unsecured, unquoted convertible notes to be issued in two tranches to raise a maximum aggregate amount of US\$5 million.

#### LIFT Loan

Imricor secured a US\$1.5 million loan under the North Dakota Commerce Department's Innovation Technology Loan Fund (LIFT) program. The LIFT Promissory Note from the Bank of North Dakota, dated 6 January 2023, has been fully executed, and the funds are now available.

The key terms of the LIFT loan are as follows:

<b>Principal Amount:</b>	US\$1,500,000.00
<b>Interest Rate:</b>	0% for the first three years of the loan 2% for the next two years of the loan An interest rate equal to a standard Bank of North Dakota loan for all subsequent years
<b>Term:</b>	5 years
<b>Prepayment Penalty:</b>	None



<b>Repayment Terms:</b>	Years 1 to 3: No payments required Years 4 and 5: Monthly interest payments required Principal due at maturity
<b>Security:</b>	Unsecured
<b>Fees:</b>	None
<b>Program and Loan Conditions:</b>	There are certain limited LIFT program conditions and loan conditions, but no revenue conditions or other conditions that are outside the control of Imricor. There are also customary events of default.

### Appendix 4C Cashflow for Q4 FY22

During the quarter ended 31 December 2022 (Q4 2022), Imricor reported net cash outflows from operating activities of US\$3.256 million. Receipts from customers during the period were US\$0.103 million comprising contract receipts (US\$0.048 million), the rental of capital equipment (US\$0.007 million) and consumable product sales (US\$0.048 million).

Payments made in relation to operating costs of US\$3.631 million were down compared to the prior quarter of US\$4.990 million primarily due to the payment of annual corporate insurance premiums during the prior period. Adjusted for the payment of those insurance premiums, payments made in relation to operating costs during the prior quarter were US\$3.859 million which represents a decrease in the current quarter of approximately US\$0.228 million, or 6%.

Receipts from government grants and tax incentives of US\$0.276 million were related to certain COVID-19 relief programs the Company qualified for. The Company received the final payment of US\$0.474 million from the program in January 2023.

Net cash inflows from investing activities were US\$0.023 million during the period.

Net cash inflows from financing activities were US\$1.974 in the period, largely comprising net proceeds from the convertible note issued in December 2022.

At 31 December 2022, Imricor maintained a cash balance of US\$5.688 million. Payments made to related parties as described in Item 6.1 on the Appendix 4C were for directors' fees.

### 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.

## 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 December 2022

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$USD'000</b>	<b>Year to date (12 months) \$USD'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	103	703
1.2 Payments for		
(a) research and development	(506)	(2,924)
(b) product manufacturing and operating costs	(316)	(1,459)
(c) advertising and marketing	(293)	(935)
(d) leased assets	-	-
(e) staff costs	(1,993)	(9,212)
(f) administration and corporate costs	(522)	(3,537)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	9	19
1.5 Interest and other costs of finance paid	(14)	(73)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	276	299
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(3,256)</b>	<b>(17,119)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	35	(167)
(d) investments	-	-
(e) intellectual property	(12)	(65)
(f) other non-current assets	-	-

Consolidated 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	-	1
	(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)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>23</b>	<b>(231)</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	2,016
3.2	Proceeds from issue of convertible debt securities	2,325	2,325
3.3	Proceeds from exercise of options	-	31
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(64)	(103)
3.5	Proceeds from borrowings	-	839
3.6	Repayment of borrowings	(287)	(663)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	100
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>1,974</b>	<b>4,545</b>

<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of period	6,940	18,516
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,256)	(17,119)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	23	(231)

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$USD'000</b>	<b>Year to date (12 months) \$USD'000</b>
4.4	Net cash from / (used in) financing activities (item 3.10 above)	1,974	4,545
4.5	Effect of movement in exchange rates on cash held	7	(23)
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>5,688</b>	<b>5,688</b>

<b>5.</b>	<b>Reconciliation of cash and cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>Current quarter \$USD'000</b>	<b>Previous quarter \$USD'000</b>
5.1	Bank balances	5,688	6,940
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>5,688</b>	<b>6,940</b>

**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

<b>Current quarter \$USD'000</b>
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 amount at quarter end \$USD'000	Amount drawn at quarter end \$USD'000
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
7.4 <b>Total financing facilities</b>	-	-

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.

As announced on 19 December, 2022, Imricor entered into a Securities and Purchase Agreement with The K.A.H.R. Foundation for the issue of unsecured, unquoted convertible notes to be issued in two tranches to raise a maximum of US\$5,000,000. The first tranche of the convertible notes was issued on 23 December, 2022 and the Company received US\$2,325,000 (as reported in item 3.2). The second tranche is subject to shareholder approval, which the company expects to request in Q1 2023, and would provide US\$2,675,000 of additional funding.

As announced on 22 December, 2022, Imricor was awarded a US\$1,500,000 loan through the North Dakota Commerce Department. Imricor finalized terms of the loan with the Bank of North Dakota on 11 January, 2022 and has full access to the funding subject to the use of funds limitations outlined on the Department of Commerce's LIFT program website.

<b>8. Estimated cash available for future operating activities</b>	<b>\$USD'000</b>
8.1 Net cash from / (used in) operating activities (item 1.9)	(3,256)
8.2 Cash and cash equivalents at quarter end (item 4.6)	5,688
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	5,688
8.5 <b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	1.7

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: Imricor expects net operating cash outflows will increase from the current quarter primarily due to planned increases in spending on research and development, driven by the planned start of a clinical trial for ventricular tachycardia. 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. Imricor is taking steps to raise further capital to fund its operations. These steps include obtaining shareholder approval for the second tranche of the convertible note discussed in item 7.6, pursuing economic incentive programs from regional agencies, and other capital raising initiatives.

- 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 on the basis of 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: 20 January 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 – eg 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.