# IMRICOR Q1 FY23 QUARTERLY ACTIVITIES REPORT AND APPENDIX 4C

**HIGHLIGHTS:**

- Consumable product revenues of US$64,000 in Q1 FY23, a 27% increase over last quarter
- Twice as many procedures performed in Q1 2023 compared to Q4 2022
- Imricor's NorthStar 3D mapping system added to the VISABL-VT study protocol and submitted for approval to commence the study at Haga Hospital in the Netherlands
- VISABL-VT study subsequently received the Netherlands CCMO (Central Committee on Research Involving Human Subjects) approval
- The last approval required to commence the study is a review by Haga Hospital's Ethics Committee which is scheduled to take place on 2 May
- Received approval from US FDA for an Investigational Device Exemption (IDE) to initiate a global clinical trial (VISABL-AFL) to support FDA approval of Imricor devices in the US
- Entered into a Master Services Agreement (MSA) with GE HealthCare in April, where GE HealthCare will pay Imricor to develop the hardware and software required to make NorthStar operate with the GE HealthCare MRI platform
- Cash of approximately US$4.5 million as at 31 March 2023

**26 April 2023** – Minneapolis, MN United States (**27 April 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 March 2023 and provides an update on its operational performance.

**Imricor's Chair and CEO, Steve Wedan, commented:** "In the first quarter of this year, we began rebuilding the momentum we previously enjoyed going into 2020. We are now focused on continuing to build that momentum, which is a process we believe will be greatly sparked by two significant upcoming events. First will be the initiation of our upcoming VISABL-VT trial in Europe, wherein we will demonstrate the first complex cardiac ablation procedures guided by real-time iCMR. Secondly, we will initiate our global VISABL-AFL trial that will set the stage for US FDA approval and our subsequent commercial launch into the over US$4 billion US cardiac ablation market.

"We are further energised by the prospects of delivering advanced artificial intelligence (AI) to iCMR guided procedures and also progressing a project to deliver iCMR guided pulsed field ablation (PFA) technology to the market. PFA is another technology to which we believe MRI will add significant value, and our NorthStar 3D mapping system, enabled with AI, will be the vehicle through which we plan to deliver that value."

## Record Procedure Volumes

As flagged in a recent business update from the Company, twice as many procedures were performed in Q1 2023 compared to the previous quarter. 28 procedures were performed in Q1, making it the highest volume quarter in the Company's history. This translated to consumable device revenue of US$64,000 for the period, noting that consumable device revenue lags procedure volume because devices are reordered after procedures are performed.

Notably, after the period, the Amsterdam University Medical Centre (AUMC) performed three iCMR ablation procedures in a single day in April. This is significant, as it demonstrates the efficiency possible with Imricor's procedures. In addition, the MRI system AUMC currently utilises for iCMR procedures is a shared resource, meaning cardiology has access only on certain days. Improved efficiency in the iCMR lab, even beyond three patients in a day, will improve procedure volume at that site. Meanwhile, the centre has a backlog of atrial flutter patients waiting for treatment in the iCMR lab. Looking ahead, AUMC is moving forward with plans for a new cardiology wing, which will feature a cardiology-owned dedicated iCMR lab. The project is expected to begin this year and be complete in 2025.

**Clinical Trials Update**

Ventricular Tachycardia (VT) –VISABL-VT Trial (EU)

Imricor completed the design, testing, and documentation of its NorthStar 3D mapping system, which allowed the Company to add NorthStar to the VISABL-VT study protocol. This, in turn, makes it possible for sites that utilise the Siemens MRI platform to participate in the study upon approval. The first such site is the Haga Hospital in The Hague, Netherlands. The Netherlands Central Committee on Research Involving Human Subjects (CCMO) has completed its review of the study protocol with positive results, and the Haga Hospital Ethics Committee will review it on 2 May. Upon approval by the Haga Hospital Ethics Committee, the VISABL-VT trial can begin at that site.

The VISABL-VT trial is a prospective, single-arm, multi-centre investigation of the safety and efficacy of radiofrequency (RF) ablation of ventricular tachycardia (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.

Atrial Flutter (AF) – VISABL-AFL Trial (US)

In the quarter, Imricor received an approved Investigational Device Exception (IDE) from the US Food and Drug Administration (FDA) to commence a global clinical trial to support FDA approval of Imricor's products in the US. The clinical trial is called VISABL-AFL.

Following the IDE approval, four sites are confirmed for the VISABL-AFL study, and these sites are currently engaged in the activation process, which includes site contracting and site approval. Two of the sites are in the US and two sites are in the EU. The Company's expectation is to begin enrolment in Q3 this year.

The VISABL-AFL trial is a prospective, single-arm, multi-centre global investigational study of the safety and efficacy of type I atrial flutter ablation procedures performed with the Vision-MR Ablation Catheter (second generation) and Osypka HAT 500 RF generator and irrigation pump. The sample size is 91 patients, with an interim analysis after 76 patients have achieved the seven-day follow-up. Final follow-up is 3 months.

## NorthStar's Expansion to Other MRI Platforms

Also flagged in the recent business update, Imricor participated in a multi-day in-person meeting of the *Sensing and Image-Guided Neurological therapies, cardiac Electrophysiology and Tumour treatments* (SIGNET) consortium at the Amsterdam University Medical Centre in the Netherlands. An overview of SIGNET can be found here: https://itea4.org/project/signet.html.

Imricor's SIGNET involvement is the mechanism through which the Company and Philips will collaborate to develop the software necessary for Imricor's NorthStar 3D mapping system to operate with the Philips MRI platform.

In addition, the Company entered into a Master Services Agreement (MSA) with GE Precision Healthcare LLC (GE HealthCare) in April. Under the terms of the MSA, GE HealthCare will pay Imricor to develop the hardware and software required to make NorthStar operate with the GE HealthCare MRI platform. The deliverables for payment are milestone based, with certain compatibility test reports being the final deliverable. Imricor will retain ownership of all technology and equipment developed during the project.

NorthStar is currently operational with the Siemens MRI platform. Once NorthStar is also operational on the Philips and GE Healthcare MRI platforms, the system will work with the vast majority of MRI systems sold in Imricor's target markets. It is the Company's goal that customers will encounter a consistent NorthStar 3D mapping system experience, no matter which of the three major MRI platforms they utilise in their iCMR lab.

## Capital Management and Balance Sheet

As of January 2023, North Dakota LIFT loan proceeds of US$1.5 million are fully available to the Company, subject to use of funds limitations outlined on the North Dakota Department of Commerce's LIFT program website.

As a follow-up to the LIFT loan, the Company is now in the review process for an application with the North Dakota Development Fund (NDDF) for a US$3 million capital loan to further bolster Imricor's manufacturing initiatives in the state of North Dakota. The Company expects a decision from the NDDF Board on 11 May.

In addition, the Company continues to pursue various potential means of increasing its cash position across many fronts including sales, licensing, grant funding, and investment.

## Appendix 4C Cashflow for 1Q FY23

During the quarter ended 31 March 2023 (Q1 2023), Imricor reported net cash outflows from operating activities of US$3.388 million. Receipts from customers during the period were US$0.125 million comprising the rental of capital equipment (US$0.011 million) and consumable product sales (US$0.114 million).

Payments made in relation to operating costs of US$3.990 million were up compared to the prior quarter of US$3.630 million due to an increase in inventory purchases during the quarter and the payment of certain annual R&D software licenses.

Receipts from government grants and tax incentives of US$0.474 million were related to the final payment of certain COVID-19 relief programs the Company qualified for.

Net cash outflows from investing activities were US$0.093 million during the period.

Net cash inflows from financing activities were US$2.317 in the period, largely comprising net proceeds from the convertible note issued in March 2023.

At 31 March 2023, Imricor maintained a cash balance of US$4.521 million. Payments made to related parties as described in Item 6.1 on the Appendix 4C were for directors' fees.

**Annual General Meeting (AGM)**

Imricor will hold its Annual Meeting of Stockholders on Friday, 12 May 2023 at 8:00 am Sydney time (on Thursday, 11 May 2023, at 5:00 pm U.S. Central Daylight Time).

This is a completely virtual Annual Meeting. Stockholders can watch and participate in the Annual Meeting virtually via the online platform by visiting www.meetnow.global/MDVKVKA on your smartphone, tablet or computer. You will need the latest versions of Chrome, Safari, Edge or Firefox. Please ensure your browser is compatible.

Further details are provided to stockholders in Imricor's Notice of Annual Meeting released to the ASX on 6 April 2023.

**Imricor background and strategy**

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 strategy to grow the field of real-time iCMR cardiac ablations worldwide is built on two actions: to increase the number of iCMR sites across the world and to increase the number of procedures doctors can perform at each iCMR site using Imricor's consumable products.

Key drivers to growing the number of iCMR sites include:

- Existing iCMR sites commencing procedures and presenting/publishing on their experiences
- Growing the Company's footprint across different countries and regions, enabling access for those seeking care and creating competitive pressures between hospitals
- Showing progress toward performing complex ablation procedures, such as ventricular tachycardia (VT) ablations, which increases the utility and demand for iCMR ablations
- Engaging with new physicians to educate them on the benefits of iCMR ablations
- Working with MRI manufacturers to help drive adoption

- Expanding regulatory approval beyond Europe, including the US and ANZ.

Key drivers to increasing the number of iCMR ablation procedures doctors can perform include:

- Development of additional consumable products required for new procedures such as VT ablations
- Partnering with 3rd parties to deliver auxiliary equipment needed for new procedures
- Demonstrating clinical effectiveness through clinical trials
- Receiving regulatory approval to market devices for the new indications

As of today, the Company's additional consumables are in final testing before regulatory submission, and the Company has partnered with all 3rd parties required to deliver the needed auxiliary equipment for VT ablations. Further, the Company made significant progress toward initiating a VT clinical trial, as evidenced by the progress made toward the approval of study submissions mentioned previously. This, in turn, progresses the Company's overall regulatory approval process.

**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** | **Quarter ended ("current quarter")** |
| 633 106 019 | 31 March 2023 |

| **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 | 125 | 125 |
| 1.2 | Payments for | | |
| | (a) research and development | (591) | (591) |
| | (b) product manufacturing and operating costs | (503) | (503) |
| | (c) advertising and marketing | (285) | (285) |
| | (d) leased assets | - | - |
| | (e) staff costs | (2,143) | (2,143) |
| | (f) administration and corporate costs | (468) | (468) |
| 1.3 | Dividends received (see note 3) | - | - |
| 1.4 | Interest received | 13 | 13 |
| 1.5 | Interest and other costs of finance paid | (10) | (10) |
| 1.6 | Income taxes paid | - | - |
| 1.7 | Government grants and tax incentives | 474 | 474 |
| 1.8 | Other (provide details if material) | - | - |
| **1.9** | **Net cash from / (used in) operating activities** | **(3,388)** | **(3,388)** |

| | | | |
|---|---|---|---|
| **2.** | **Cash flows from investing activities** | | |
| 2.1 | Payments to acquire or for: | | |
| | (a) entities | - | - |
| | (b) businesses | - | - |
| | (c) property, plant and equipment | (65) | (65) |
| | (d) investments | - | - |
| | (e) intellectual property | (28) | (28) |
| | (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** | **(93)** | **(93)** |

| | | | |
|---|---|---|---|
| **3.** | **Cash flows from financing activities** | | |
| 3.1 | Proceeds from issues of equity securities (excluding convertible debt securities) | - | - |
| 3.2 | Proceeds from issue of convertible debt securities | 2,675 | 2,675 |
| 3.3 | Proceeds from exercise of options | - | - |
| 3.4 | Transaction costs related to issues of equity securities or convertible debt securities | (66) | (66) |
| 3.5 | Proceeds from borrowings | - | - |
| 3.6 | Repayment of borrowings | (292) | (292) |
| 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** | **2,317** | **2,317** |

| | | | |
|---|---|---|---|
| **4.** | **Net increase / (decrease) in cash and cash equivalents for the period** | | |
| 4.1 | Cash and cash equivalents at beginning of period | 5,688 | 5,688 |
| 4.2 | Net cash from / (used in) operating activities (item 1.9 above) | (3,388) | (3,388) |
| 4.3 | Net cash from / (used in) investing activities (item 2.6 above) | (93) | (93) |

| 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) | 2,317 | 2,317 |
| 4.5 | Effect of movement in exchange rates on cash held | (3) | (3) |
| **4.6** | **Cash and cash equivalents at end of period** | **4,521** | **4,521** |

| **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 | 4,521 | **5,688** |
| 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)** | **4,521** | **5,688** |

| **6.** | **Payments to related parties of the entity and their associates** | Current quarter $USD'000 |
|---|---|---|
| 6.1 | Aggregate amount of payments to related parties and their associates included in item 1 | 59 |
| 6.2 | Aggregate amount of payments to related parties and their associates included in item 2 | - |

*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**<br>*Note: the term "facility' includes all forms of financing arrangements available to the entity.*<br>*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 | - |
| 7.2 | Credit standby arrangements | - | - |
| 7.3 | Other (please specify) | - | - |
| 7.4 | **Total financing facilities** | 1,500 | - |

| | | |
|---|---|---|
| 7.5 | **Unused financing facilities available at quarter end** | 1,500 |

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) | (3,388) |
| 8.2 | Cash and cash equivalents at quarter end (item 4.6) | 4,521 |
| 8.3 | Unused finance facilities available at quarter end (item 7.5) | 1,500 |
| 8.4 | Total available funding (item 8.2 + item 8.3) | 6,021 |
| 8.5 | **Estimated quarters of funding available (item 8.4 divided by item 8.1)** | 1.8 |

*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: Imricor expects net operating cash outflows to increase from the current quarter primarily due to the current period including receipt of the final COVID-19 relief program payment (recorded in item 1.7). Additionally, 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. 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.

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: 27 April 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 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.