



IMRICOR Q2 FY23 QUARTERLY ACTIVITIES REPORT AND APPENDIX 4C

HIGHLIGHTS:

- Consumable product revenues of US\$98,000 in Q2 FY23, a 53% increase quarter on quarter
- Following record procedures in Q1 2023, procedure volumes dropped by 12 in Q2 2023 compared to the previous quarter; lack of patients still impacting volume
- Restructuring of European sales team and approach are expected to increase number of active sites, pipeline sites, and overall procedure volume
- GE HealthCare and Imricor signed an MSA to make Imricor products work with GE HealthCare MRI systems
- GE HealthCare will pay Imricor to develop the needed hardware and software interfaces
- Upon the addition of GE HealthCare, Imricor's products will operate with the vast majority of 1.5T MRI systems sold in Imricor's target markets
- Cash balance of ~US\$1.5 million as at 30 June 2023

POST Q2

- Executed distribution agreement with Al Faisaliah Medical Systems (FMS), giving FMS exclusive right to market and sell Imricor's products in the Kingdom of Saudi Arabia (KSA)
- Balance sheet bolstered via advantageous A\$30 million equity funding facility, which can be drawn from at Imricor's discretion, secured from GEM Global
- Balance sheet further bolstered by US\$1 million secured via a private placement at a premium
- Commitment letter received from NDDF for US\$1 million term loan
- Current cash balance of ~US\$1.9 million, with undrawn A\$30m (~US\$20.4m) facility available

26 July 2023 – Minneapolis, MN United States (**27 July 2023** – Melbourne, Australia) – **Imricor Medical Systems, Inc. (Company or Imricor) (ASX: IMR)**, the global leader in real-time iCMR cardiac ablation products, releases its Appendix 4C Quarterly Cash Flow Report for the period ended 30 June 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. This process continued in Q2, and we believe further momentum will build through 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."



Procedure Volumes

Following a record quarter for procedure volume in Q1, procedure rates slowed this quarter. Lack of patients continues to be the major factor affecting volume, but atrial flutter patients are not being treated outside the iCMR lab at Imricor sites, and it is expected that the number of atrial flutter patients will increase as people return to more regular pre-COVID healthcare routines.

AI Product Update

The Company is planning the first integration of AI into NorthStar, targeting automatic heart chamber segmentation from 3D MRI images (“Automatic Segmentation”), a procedure that is performed manually today. The NorthStar development team, along with outside research partners, are working to integrate Automatic Segmentation into the next software release of NorthStar. Automatic segmentation, coupled with a physician’s ability to fine tune the result, is expected to save time during each procedure in the future.

European Sales Team Adjustments

The Company is currently restructuring its European sales team and approach, aiming to increase the activation rate of new iCMR labs at sites that have signed pricing agreements with Imricor but have not yet become active following the pandemic. The initiative is also directed toward growing the pipeline of new sites, and improving customer intimacy at this early commercialisation stage. Establishing more active sites is, in turn, expected to lead to an increase in overall procedures through 2H CY23, as well as build clinical momentum while VISABL-VT is enrolling patients in Europe.

Clinical Trials Update

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

As announced last quarter, the Haga Hospital in The Hague, Netherlands will be the first expected site to participate in the VISABL-VT trial.

After three rounds of questions from the Haga Hospital Ethics Committee since May and responses from the Imricor team and 3rd party equipment partners, the next Ethics Committee review date is set for 28 July. The Company does not expect to hear immediately from the Ethics Committee after its review, but based on the last round of questions, both the Imricor team and the Haga physicians are optimistic for a positive outcome, after which the VISABL-VT trial can commence.

The first patient to be enrolled in VISABL-VT is already identified, and a procedure date is tentatively set in August, pending Ethics Committee approval.

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)

As announced last 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, the contracting process at the first four sites identified to participate in the VISABL-AFL study progressed in the quarter. 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 2.0 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.

GE HealthCare Integration Update

The Company entered into a Master Services Agreement (MSA) with GE Precision Healthcare LLC (GE HealthCare), under the terms of which GE HealthCare will pay Imricor to develop the hardware and software interfaces required to make Imricor's real-time iCMR cardiac ablation solutions operate with GE HealthCare MRI systems.

The hardware interface will connect Imricor's Advantage-MR EP Recorder/Stimulator to GE HealthCare's 1.5T MRI platform, such that Imricor's catheters and other devices may be recognised and actively tracked by GE HealthCare MRI scanners. Similarly, the software interface will connect Imricor's NorthStar 3D mapping system to GE HealthCare MRI scanners.

The MSA is effective as of April 20, 2023, and has an initial term ending December 31, 2026. The hardware and software interface development projects are anticipated to be completed in Q4 2023.

With the addition of GE HealthCare MRI systems to the MRI systems from Philips and Siemens Healthineers, Imricor's products will operate with the vast majority of 1.5T MRI systems sold in the Company's target markets.

Significant Accomplishments After the Period

In July, subsequent to quarter end, Imricor took significant steps to expand its presence in the Middle East. The company signed a distribution agreement with Al Faisaliah Medical Systems (FMS) in the Kingdom of Saudi Arabia (KSA), granting FMS exclusive rights to market and sell Imricor's iCMR ablation products in the country. This milestone made KSA the first country in the Middle East to offer iCMR ablation products, catering to a market that performs nearly 50,000 cardiac ablation procedures annually.

Three important financing agreements were made post quarter end which provide the company significant runway to execute on its strategy. Imricor secured up to A\$30 million through a Security Subscription Facility (SSF) with GEM Global ("GGY"). This financing option allows Imricor to draw down funds as needed, providing financial flexibility to achieve upcoming milestones that are expected to positively impact the company's valuation and attractiveness as an investment proposition.



Additionally, the company raised US\$1 million (approximately A\$1.45 million) from a US investor through a private placement, issuing Class A Common Stock (Shares) subject to a 12-month holding lock. After the lock period, the investor can convert the Shares to CHESSE Depository Interests (CDIs) for trading on the ASX. The investor also received a 10-year warrant to purchase an additional 428,571 Shares at US\$0.60 (approximately A\$0.87) per Share.

Furthermore, the North Dakota Development Fund (NDDF) has approved a US\$1 million term loan for Imricor, which is currently in the negotiation stage for final terms and documentation.

Appendix 4C Cashflow for Q2 FY23

During the quarter ended 30 June 2023 (Q2 2023), Imricor reported net cash outflows from operating activities of US\$2.710 million. Receipts from customers during the period were US\$0.691 million comprising:

- the downpayment received on research equipment sold to a US customer (US\$0.593 million);
- rental of capital equipment (US\$0.008 million);
- consumable product sales (US\$0.073 million); and
- the sale of service agreements (US\$0.017 million)

Payments made in relation to operating costs of US\$3.409 million were down compared to the prior quarter of US\$3.990 million primarily due to a decrease in inventory purchases during the quarter and the prior quarter including payment of certain annual R&D software licenses.

Net cash outflows from investing activities were US\$0.011 million during the period.

Net cash outflows from financing activities were US\$0.287 in the period, largely comprising the repayment of the D&O insurance premiums financed in August 2022.

At 30 June 2023, Imricor maintained a cash balance of US\$1.509 million. Payments made to related parties as described in Item 6.1 on the Appendix 4C were for directors' fees.

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, ANZ, and the Middle East.

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.

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About Imricor

Imricor Medical Systems, Inc. (ASX:IMR) is a leading developer of innovative MRI-compatible medical devices which can be used to carry out real-time iCMR cardiac ablation procedures. Headquartered in the US, Imricor seeks to make a meaningful impact on patients, healthcare professionals, and healthcare facilities around the world by increasing the success rates and bringing down the overall costs of cardiac ablation procedures.



Imricor's Products

Imricor is a pioneer and leader in developing MRI-compatible products for cardiac catheter ablation procedures, and believes it is the first company in the world to bring commercially viable and safe MRI-compatible products to the cardiac catheter ablation market.

The Vision-MR Ablation Catheter is the Company's prime product offering, specifically designed to work under real-time MRI guidance, with the intent of enabling higher success rates along with a faster and safer treatment compared to conventional procedures using x-ray guided catheters. The Vision-MR Ablation Catheter has been approved in the European Union 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")

30 June 2023

Consolidated statement of cash flows	Current quarter \$USD'000	Year to date (6 months) \$USD'000
1. Cash flows from operating activities		
1.1 Receipts from customers	691	816
1.2 Payments for		
(a) research and development	(354)	(945)
(b) product manufacturing and operating costs	(161)	(664)
(c) advertising and marketing	(278)	(563)
(d) leased assets	-	-
(e) staff costs	(2,087)	(4,230)
(f) administration and corporate costs	(529)	(997)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	17	30
1.5 Interest and other costs of finance paid	(9)	(19)
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	(2,710)	(6,098)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(9)	(74)
(d) investments	-	-
(e) intellectual property	(2)	(30)
(f) other non-current assets	-	-

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Consolidated statement of cash flows		Current quarter \$USD'000	Year to date (6 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	(11)	(104)
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
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(24)	(90)
3.5	Proceeds from borrowings	33	33
3.6	Repayment of borrowings	(296)	(588)
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	(287)	2,030
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	4,521	5,688
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,710)	(6,098)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(11)	(104)

Consolidated statement of cash flows		Current quarter \$USD'000	Year to date (6 months) \$USD'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(287)	2,030
4.5	Effect of movement in exchange rates on cash held	(4)	(7)
4.6	Cash and cash equivalents at end of period	1,509	1,509

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	1,509	4,521
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)	1,509	4,521

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.

After quarter end, Imricor secured up to A\$30 million through a Security Subscription Facility from GEM Global Yield LLC SCS, the details of which were included in our announcements dated 6 July 2023 and 7 July 2023. Also after quarter end, Imricor raised US\$1 million from a US investor via a private placement, the details of which were included in our announcement dated 18 July.

8. Estimated cash available for future operating activities	\$USD'000
8.1 Net cash from / (used in) operating activities (item 1.9)	(2,710)
8.2 Cash and cash equivalents at quarter end (item 4.6)	1,509
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)	2,976
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	1.1

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 a significant customer prepayment (recorded in item 1.1). 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.

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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 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 Share Subscription Facility described in item 7.6 is available to provide cash to fund operations.

- 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 July 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.