



ASX Announcement

27 October 2021

IMRICOR 3Q FY21 QUARTERLY ACTIVITIES REPORT AND APPENDIX 4C

Highlights

- Signed a new purchase agreement in October with Semmelweis University Heart and Vascular Centre in Budapest, Hungary
- Successfully raised A\$16.5 million via an institutional placement at \$1.00 per CDI
- Successfully raised A\$1 million in October via an oversubscribed security purchase plan (SPP) offered to eligible CHESS Depository Interest (CDI) holders in Australia and New Zealand
- Received TGA approval for the Advantage-MR system in Australia and Medsafe approval for all Imricor products in New Zealand
- Entered into a Sales Distribution Agreement with MiRTLE Medical, LLC (MiRTLE), maker of an MRI-compatible 12 lead ECG system
- Entered into a Sales Distribution Agreement with NordicNeuroLab AS (NordicNeuroLab), a leading maker of MRI compatible in-room monitors
- As at 30 September 2021, Imricor maintained a cash balance of approximately **US\$20.202**.

27 October 2021 – Minneapolis, United States – Imricor Medical Systems, Inc. (Company or Imricor) (ASX:IMR) the global leader in realtime iCMR cardiac ablation products, today releases its Appendix 4C Quarterly Cash Flow Report for the period ending 30 September 2021 and provides an update on financial and operational performance.

New Site Signing

Following the end of the quarter, Imricor signed a new purchase agreement with Semmelweis University Heart and Vascular Centre in Budapest, Hungary (Semmelweis). Semmelweis is the eleventh site to sign with Imricor and expands Imricor's geographical presence into a new region.

Planning is underway at Semmelweis for procedures to commence before the end of 2021 in an existing Cardiovascular Magnetic Resonance (CMR) suite that will be outfitted to be their iCMR lab.



Procedures

Procedure volume continues to be slow, as expected, due to the lingering effects of the COVID-19 pandemic. Four sites are currently active, with six additional sites slated to begin procedures in Q4 2021 or Q1 2022.

Institutional Placement & Security Purchase Plan

In September the Company successfully raised A\$16.5 million via an institutional placement. In October the Company raised an additional A\$1 million in an oversubscribed Security Purchase Plan (SPP).

The funds raised will be used to support the Company's product development pipeline, support clinical and regulatory requirements, and provide working capital support for general business activities.

Maintaining Progress on Growth Opportunities

Imricor has continued to progress in the execution of its growth strategy across key areas.

1. *Grow installed base*

Over the last quarter, Imricor has focused greatly on growing the Company's installed base by engaging with various key opinion leaders across multiple regional conferences including AIAC National Conference in Italy, DGK Heart Days 2021 in Germany, and the European Society of Cardiology Congress 2021 which was held virtually.

In addition, direct in-person visits with potential customers increased through the quarter as COVID-19 restrictions eased. The establishment of Semmelweis as Imricor's eleventh site was a direct result of such meetings.

In addition, Imricor has expanded its strategic partnerships through two new Sales Distribution Agreements with NeuroNordicLab and MiRTLE.

Headquartered in Norway, NeuroNordicLab are a leading maker of MRI compatible in-room monitors. Under the terms of the Sales Distribution Agreement, Imricor will be a non-exclusive distributor of NeuroNordicLab's *InroomViewingDevice*, a high quality 40" MRI-compatible monitor for use in the magnet room of an iCMR lab.

MiRTLE, maker of an MRI-compatible 12-lead ECG system, have been a great strategic partner of Imricor's since 2017. Under the terms of the new Sales Distribution Agreement, Imricor will be a non-exclusive distributor of MiRTLE's 12-lead ECG system. The sale of MiRTLE's 12-lead ECG system is very important in Imricor's strategic plan of enabling iCMR cardiac ablations of complex arrhythmias such as ventricular tachycardia (VT).

Entering both agreements streamlines the sales process for all parties and strengthens the range of 3rd party iCMR lab equipment Imricor offers to its customers. This, in turn, promotes the growth of Imricor's installed base.

2. Expanding geographies

Since receiving CE Mark approval in early 2020, Imricor now has presence in eleven sites across four European countries, including Germany, The Netherlands, France, and Hungary with plans to expand into other European regions in the coming months.

The Company's activities to expand its geographic reach into the US, Australia, and New Zealand are progressing as planned.

In the US, the Company completed its pre-submission meetings with the FDA and is preparing its submission for an Investigational Device Exemption (IDE) to commence a clinical trial. US sites are currently being selected for participation in the trial, and the Company is targeting the end of 2023 for FDA approval of atrial flutter ablation.

In Australia, Imricor achieved an important milestone in its geographic expansion plans with the Company's Advantage-MR EP Recorder/Stimulator system receiving Australian TGA approval in early August. The Company's Vision-MR Ablation Catheter is now also under review with the TGA.

In New Zealand, Imricor's products have been registered in Medsafe's WAND database for medical devices and are approved for sale.

Imricor is working closely with its local agent and distributor, Regional Health Care Group, to develop its sales strategy and deliver training programs across the ANZ region.

3. Expanding indications

The Company's plans for expanding indications to ventricular tachycardia (VT) ablations remain on track for approval at the end of 2023. While COVID-19 restrictions have resulted in some modifications to path toward gaining approval, the Company has established a plan for a pre-clinical study followed by a European VT clinical trial to achieve this goal. The pre-clinical study is still on track for Q4, 2021, with the clinical trial expected to commence in 2022.

Appendix 4C Cashflow for 3Q FY21

During the quarter ended 30 September 2021 (Q3 2021) net cash outflows from operating activities were US\$4.651million. Receipts from customers during the period were US\$0.366 million comprising contract receipts (US\$0.202 million), the sale and rental of capital equipment (US\$0.082 million), consumable product sales (US\$0.063 million) and the sale of service agreements (US\$0.019 million). Revenue and associated cash receipts in Q3 2021 continued to be impacted by the COVID-19 pandemic.

Payments made in relation to operating costs of US\$5.017 million were relatively consistent with the prior quarter of US\$4.943 million.

Net cash outflows from investing activities were US\$0.057 million during Q3 2021. Net cash inflows from financing activities were US\$11.314 million in the period, largely comprising net proceeds from the institutional placement completed in September 2021.

At 30 September 2021, Imricor maintained a cash balance of US\$22.202 million.



Payments made to related parties as described in item 6.1 on the Appendix 4C were for director fees.

ENDS

Authorised for release by Steve Wedan, Executive Chair, President, and CEO.

Further Information

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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 MRI-guided cardiac catheter 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 catheter 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.

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Foreign Ownership Restrictions

Imricor's CHESSE 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.

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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 2021

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	366	738
1.2 Payments for		
(a) research and development	(1,195)	(2,632)
(b) product manufacturing and operating costs	(293)	(1,279)
(c) advertising and marketing	(231)	(703)
(d) leased assets	-	-
(e) staff costs	(2,328)	(7,164)
(f) administration and corporate costs	(966)	(2,362)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	13	17
1.5 Interest and other costs of finance paid	(17)	(140)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(4,651)	(13,525)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(44)	(424)
(d) investments	-	-
(e) intellectual property	(13)	(54)
(f) other non-current assets	-	-

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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	(57)	(478)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	12,063	12,063
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	17	92
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(614)	(691)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	(152)	(376)
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	11,314	11,088

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	15,607	25,140
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(4,651)	(13,525)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(57)	(478)

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)	11,314	11,088
4.5	Effect of movement in exchange rates on cash held	(11)	(23)
4.6	Cash and cash equivalents at end of period	22,202	22,202

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	22,202	15,607
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)	22,202	15,607

**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**

60

-

*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 Total financing facilities	-	-

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.

8. Estimated cash available for future operating activities	\$USD'000
8.1 Net cash from / (used in) operating activities (item 1.9)	(4,651)
8.2 Cash and cash equivalents at quarter end (item 4.6)	22,202
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	22,202
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	4.8

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:

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:

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:

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: 28 October 2021

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.