



ASX Announcement

28 April 2021

BUSINESS UPDATE AND MARCH 2021 QUARTERLY APPENDIX 4C

- Cases commenced in Q1 at Leipzig Heart Centre and Maastricht University Medical Centre. Subsequent COVID-19 containment measures have temporarily halted procedures again.
- The Company is progressing toward purchase agreements with a number of new sites and is working closely with contracted sites to progress installation, training and the commencement of cases as COVID-19 restrictions ease.
- Imricor continues to make solid progress on other key growth strategies including FDA approval in the United States and TGA approval in Australia.
- The Company has appointed a local agent in Australia to help facilitate approval from the TGA and has entered into a distribution agreement whereby they will be the exclusive distributor of Imricor's consumable products and a non-exclusive distributor of Imricor's capital equipment.
- With a significant pipeline of new sites, further supported by Philips and Siemens, Imricor is well positioned as COVID-19 restrictions ease to deliver an acceleration in lab adoption in 2021.
- As at 31 March 2021, Imricor maintained a cash balance of approximately **US\$20.68 million**.

28 April 2021 – Minneapolis, United States – Imricor Medical Systems, Inc. (Company or Imricor) (ASX:IMR) the global leader in MRI-guided cardiac ablation products, today releases its Appendix 4C Quarterly Cash Flow Report for the period ending 31 March 2021 and provides an update on financial and operational performance.

Progress of iCMR Lab Rollout

While COVID-19 has slowed the roll-out of new labs, Imricor has been working to ensure that the foundations are laid for our future success and that the Company is well positioned to deliver on its strategy as restrictions ease.

In Germany, the authorities continue to take a regional approach to the implementation of COVID-19 containment measures. These measures were recently updated and are expected to remain in force until June. In the Netherlands, it is expected that lockdown measures will be eased from this week. Notwithstanding these restrictions, Imricor is working closely with contracted sites to progress installation, training, and the commencement of cases as soon as allowed.

Imricor currently has nine clinical sites contracted and expects to see the signing of new agreements recommence in the second quarter and accelerate in the second half of this year. The Company maintains a strong focus on progressing these agreements as expediently as possible.



Imricor Chair and CEO Steve Wedan said: “While Covid still presents challenges, we are progressing through the second quarter as expected, with Europe experiencing a gradual recovery and ever-increasing vaccinations. Where needed, containment measures to suppress a third wave are in place and may persist until June. However, many of the measures are applied regionally based on incidence rates, and our team is working in the context of each local situation to sign new sites and commence procedures when and where possible.”

Maintaining Progress on Growth Opportunities

Imricor has continued to achieve solid progress in the execution of its growth strategy across a number of other areas.

1. Expanding geographies

Imricor’s strategy on FDA approval in the United States continues to progress well. The Company has completed its third pre-submission meeting with the FDA and is confident in its clinical trial study design. The next steps are to submit for an Investigational Device Exemption (IDE) from the FDA (targeting July), and then once the IDE is approved, commence the clinical trial.

Imricor continues to target a clinical trial during 2021-2022 to support FDA approval.

In Australia, Imricor has appointed a local agent, Regional Health Care Group (RHCG), to facilitate TGA approval. Imricor has entered into a distribution agreement with RHCG, whereby they will be the exclusive distributor of Imricor’s consumable products in Australia and New Zealand and a non-exclusive distributor of Imricor’s capital equipment. It is not expected that a clinical trial will be required to support TGA approval.

2. Expanding indications and Opportunities beyond cardiac ablation

Imricor’s research and development pipeline, focused on the expansion of products for use in iCMR ablation procedures, remains a clear priority. Early clinical success and ongoing physician engagement has driven increased appetite across the medical profession for products that enable the treatment of expanded indications under MRI with a focus on more complex procedures requiring access to the left side of the heart such as ventricular tachycardia and atrial fibrillation.

The Company is currently in the prototype phase for its steerable sheath and transseptal needle which, in the future, will enable access to the left side of the heart via the intra-atrial septum. It is anticipated that these products will be ready for clinical trial during 2021.

Development of a prototype system of devices that can biopsy the inner walls of the heart while using MRI imaging to guide the procedure, under Imricor’s contract with the US National Institutes of Health (NIH), is progressing well. This has the potential to mark Imricor’s first product line expansion beyond cardiac ablation.

3. Gross margin improvement

Development of Imricor’s diagnostic catheter is also progressing well with the Company aiming for commercial release late in 2021 or early 2022, pending CE mark approval. Submission for CE mark approval is scheduled for next week. The diagnostic catheter will utilise technological advancements incorporated in Imricor’s next-generation ablation catheter – currently under



development – to provide physicians with a consistent product line for use in procedures and Imricor with the benefits of lower production costs.

The diagnostic catheter is expected to deliver a material improvement in gross margin through its inclusion in the two-catheter set¹ required for completion of atrial flutter ablation procedures.

Appendix 4C Cashflow for Q1 2021

During the quarter ended 31 March 2021 (Q1 2021) net cash outflows from operating activities were US\$4.069 million. Receipts from customers during the period were US\$0.234 million comprising the sale of third-party equipment used in conjunction with the Advantage-MR System, service agreements, consumable product sales and proceeds from the contract with the NIH. Revenue and associated cash receipts in Q1 2021 continued to be impacted by the COVID-19 pandemic.

Payments made in relation to operating costs of US\$4.303 million were up on the prior quarter primarily due to increased staff costs, along with increases in product development and inventory purchases.

Net cash outflows from investing activities were US\$0.211 million during Q1 2021. Net cash outflows from financing activities were US\$0.161 million in the period. This included the payment of some residual costs incurred from Imricor's A\$28.45 million institutional placement completed in November 2020 and A\$1.55 million SPP completed in December 2020.

As at 31 March 2021, Imricor maintained a cash balance of US\$20.682 million.

Annual meeting of stockholders

Imricor will hold its annual meeting of stockholders on Thursday, 6 May 2021 at 9:00am Sydney time or Wednesday, 5 May 2021 at 6:00pm US Central Daylight Time. Due to restrictions on travel and public gatherings associated with COVID-19 this will be held as a virtual meeting and will include the facility for investors to ask questions during the meeting. Further information on participating at the meeting is included in the proxy statement dispatched to investors and in the virtual meeting guide available on Imricor's website at <https://imricor.com/investors/>.

ENDS

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

¹ Currently priced by Imricor as though comprising an ablation and diagnostic catheter, however currently comprising two ablation catheters.



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.

Foreign Ownership Restrictions

Imricor's CHES Depository Interests (**CDIs**) are issued in reliance on the exemption from registration contained in Regulation S of the US Securities Act of 1933 (**Securities Act**) for offers which are made outside the US. Accordingly, the CDIs have not been, and will not be, registered under the Securities Act or the laws of any state or other jurisdiction in the US. As a result of relying on the Regulation S exemption, the CDIs are 'restricted securities' under Rule 144 of the Securities Act. This means that you are unable to sell the CDIs into the US or to a US person for the foreseeable future except in very limited circumstances after the expiration of a restricted period, unless the re-sale of the CDIs is registered under the Securities Act or an exemption is available. To enforce the above transfer restrictions, all CDIs issued bear a 'FOR US' designation on the Australian Securities Exchange (**ASX**). This designation restricts any CDIs from being sold on ASX to US persons. However, you are still able to freely transfer your CDIs on ASX to any person other than a US person. In addition, hedging transactions with regard to the CDIs may only be conducted in accordance with the Securities Act.

Forward-Looking Statements

This announcement contains or may contain forward-looking statements that are based on the Company's management's beliefs, assumptions and expectations and on information currently available to management. All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements. These include, without limitation, EU commercial market acceptance and EU sales of our product as well as our expectations with respect to our ability to develop and commercialise new products. Management believes that these forward-looking statements are reasonable when made. You should not place undue reliance on forward-looking statements because they speak only as of the date when made. Imricor does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. Imricor may not actually achieve the plans, projections or expectations disclosed in forward-looking statements. Actual results, developments or events could differ materially from those disclosed in the forward-looking statements.

Annexure

The quarter ended 31 March 2021 is a period covered by the Uses of Funds statement as outlined in Imricor's prospectus dated 14 August 2019. A summary of expenditure to date is outlined below:

Use of funds	Prospectus dated 14 August 2019 & Pre-Quotation Disclosure released at the time of admission (US\$m)	Actual Expenditure since admission on 30 August 2019 to 31 March 2021 (US\$m)
Sales and marketing	1.475	2.290
Clinical and regulatory	5.418	7.118
Costs of the Offer	1.198	1.325
Other working capital ^(a)	1.536	6.210
All other ^(a)	-	5.339
Total	9.627	22.282

- (a) Actual expenditure exceeds prospectus expectations as the prospectus anticipated that revenue from the commercialisation of Imricor's products would be used to fund other working capital as well as investments in inventory and operations, capital equipment and repayment of debt. This revenue was however not realised due to the delay in CE Mark approval and subsequent delay in commercial launch due to COVID-19.

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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")

31 March 2021

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	234	234
1.2 Payments for		
(a) research and development	(475)	(475)
(b) product manufacturing and operating costs	(568)	(568)
(c) advertising and marketing	(144)	(144)
(d) leased assets	-	-
(e) staff costs	(2,455)	(2,455)
(f) administration and corporate costs	(602)	(602)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	4	4
1.5 Interest and other costs of finance paid	(63)	(63)
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	(4,069)	(4,069)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(192)	(192)
(d) investments	-	-
(e) intellectual property	(19)	(19)
(f) other non-current assets	-	-

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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	(211)	(211)

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	-	-
3.3	Proceeds from exercise of options	25	25
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(77)	(77)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	(109)	(109)
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	(161)	(161)

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	25,140	25,140
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(4,069)	(4,069)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(211)	(211)

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)	(161)	(161)
4.5	Effect of movement in exchange rates on cash held	(17)	(17)
4.6	Cash and cash equivalents at end of period	20,682	20,682

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	20,682	25,140
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)	20,682	25,140

6. Payments to related parties of the entity and their associates

- 6.1 Aggregate amount of payments to related parties and their associates included in item 1
- 6.2 Aggregate amount of payments to related parties and their associates included in item 2

**Current quarter
\$USD'000**

-

-

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments

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)	(4,069)
8.2 Cash and cash equivalents at quarter end (item 4.6)	20,682
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	20,682
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	5.1

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:

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: 29 April 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.