**ASX Announcement**

**28 July 2021**

# IMRICOR Q2 FY21 QUARTERLY ACTIVITIES REPORT AND APPENDIX 4C

## Highlights

- Cases have re-commenced at Helios Leipzig Heart Centre, Dresden Heart Centre, Maastricht University Medical Centre, and have commenced at the South Paris Cardiovascular Institute following a temporary halt due to the introduction of COVID-19 containment measures.
- The Company is progressing toward purchase agreements with several 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 progress its key growth strategy of expanding geographies including FDA approval in the United States and TGA approval in Australia.
- Imricor continues to progress its key growth strategy of expanding indications for ventricular tachycardia (VT) ablations.
- Imricor's partner, Mirtle Medical, received CE Mark certification for its MRI compatible 12-lead ECG system in May.
- Active Catheter Imaging (ACI) is now available on the Philips platform.
- As at 30 June 2021, Imricor maintained a cash balance of approximately **US$15.607 million.**

**28 July 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 30 June 2021 and provides an update on financial and operational performance.

## Progress of iCMR Site Adoption and Cases Commencing

One new site, Helios Hospital Berlin-Buch, was added in the quarter. While the Company's pipeline remains strong, the process of signing new iCMR sites was slower than expected, due to the prolonged effects of COVID-19 through the second quarter, the slower than expected vaccination rates in June and July, and the backlog of non-COVID patients.

In what may be seen as a leading indicator for Imricor's sales recovery in Europe, iCMR guided atrial flutter ablations have re-commenced at Helios Leipzig Heart Centre, Dresden Heart Centre, and Maastricht University Medical Centre. In addition, first cases

commenced at the South Paris Cardiovascular Institute. Over the next quarter the Company expects cases to commence at Haga Hospital, Amsterdam University Medical Centre, Münster University Hospital, and the Helios Hospital Berlin-Buch.

The Company is maintaining a focus on progressing new agreements as expediently as possible, while maintaining a sensitivity to the unique pressures placed on hospitals by the pandemic. As of July, with the easing of restrictions, Imricor's sales team has been able to return to in-person engagement with hospitals, helping to advance sales processes.

As a result of the backlog of non-COVID patients, Imricor expects utilisation of its products at installed sites to be lower than normal for the remainder of 2021, anticipating 1 to 2 procedures per week per site on average from the conclusion of the summer holiday period at the end of August.

**Maintaining Progress on Growth Opportunities**

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

***1. Go to Market Strategies – Heart Rhythm 2021***

Imricor has secured a significant presence at Heart Rhythm 2021 which is being held in Boston this week.

The Heart Rhythm 2021 conference is held by the Heart Rhythm Society (HRS), a leading resource on cardiac pacing and electrophysiology. Participation in the conference is enabling Imricor to further grow awareness by engaging with key opinion leaders throughout the conference schedule.

This is the first in-person electrophysiology congress Imricor has been able to participate in since the start of the pandemic and since the company launched its products in February 2020.

Imricor Chair and CEO Steve Wedan said "Heart Rhythm 2021 is an exciting opportunity for Imricor to significantly grow awareness of our solution for iCMR-guided cardiac ablations. In addition to our large booth presence at the conference, we are hosting a Rhythm Theater session where doctors who perform our procedures will share their experiences and views of the future with conference participants."

In addition, Imricor and Philips partnered to deliver Active Catheter Imaging (ACI) on the Philips platform, something previously only available on the Siemens platform. ACI is a guidance technique that allows Imricor's catheters to be actively visualised in real-time MRI video during the procedure. ACI eliminates the need for a mapping system for atrial flutter ablations, opening the door to increase the rate of site adoption.

***2. Expanding geographies***

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. Short-term COVID-19 supply chain delays for prototype materials pushed out the IDE submission date to September, but the overall path to approval is still on track. US sites are currently being selected for participation in the trial, and the Company continues to target the end of 2023 for FDA approval of atrial flutter ablation.

In Australia and New Zealand, the submissions for the Company's various products have now been made to the regulatory authorities, TGA (Australia) and Medsafe (New Zealand). In New Zealand, Imricor's products have been registered in Medsafe's WAND database for medical devices and are approved for sale. In Australia, the submission to TGA is under review. Imricor is working closely with its local agent and distributor, Regional Heath Care Group, to develop its sales strategy and deliver training programs across the 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 the path toward gaining approval, the Company has established a plan for a pre-clinical study followed by a worldwide VT clinical trial to achieve this goal. The pre-clinical study is scheduled for Q4, 2021, with the clinical trial expected to commence in 2022. The worldwide clinical trial is intended to result in approvals in the US, Europe, Australia, and New Zealand.

In a related milestone, Mirtle Medical, a medical device company that Imricor entered into a development agreement with in 2017, received CE mark certification for their MRI compatible 12-lead ECG system in May.

Mirtle's 12-lead ECG system, which interfaces with Imricor's Advantage-MR EP Recorder/Stimulator, is an important component for VT ablation procedures and for the upcoming VT ablation clinical trials and indication expansion.

"There is tremendous enthusiasm for VT ablations guided by MRI with our products, and this kind of complex ablation procedure – one that suffers from limitations with conventional means – is precisely why Imricor was founded," noted Mr Wedan. "All of the behind-the-scenes accomplishments of our team are making this possible. These accomplishments include the product development of a second-generation ablation catheter, a steerable sheath, a transseptal needle, and added features to the Advantage-MR system to incorporate 12-lead ECG and a new ablation generator. We are delivering on our plan to expand our indications and grow the field of iCMR ablations well beyond atrial flutter."

## Appendix 4C Cashflow for 21 2021

During the quarter ended 30 June 2021 (Q2 2021) net cash outflows from operating activities were US$4.805 million. Receipts from customers during the period were US$0.138 million comprising the sale of service agreements, consumable product sales

and proceeds from the contract with the NIH. Revenue and associated cash receipts in Q2 2021 continued to be impacted by the COVID-19 pandemic.

Payments made in relation to operating costs of US$4.943 million were up on the prior quarter primarily due to increased product development costs, along with increases in administration and advertising and marketing costs.

Net cash outflows from investing activities were US$0.210 million during Q1 2021. Net cash outflows from financing activities were US$0.650 million in the period.

At 30 June 2021, Imricor maintained a cash balance of US$15.607 million.

**Half Year Results for 1H 2021**

Imricor Medical Systems, Inc. will release its results for the half year ended 30 June 2021 on Thursday, 26 August 2021 (AEST). Due to restrictions on travel and public gatherings associated with COVID-19 this will be held as a virtual meeting. Details on the briefing will be provided in the upcoming weeks.

**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 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 CHESS Depositary 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 30 June 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$m) | Actual Expenditure since admission on 30 August 2019 to 30 June 2021 (US$m) |
|---|---|---|
| Sales and marketing | 1.475 | 3.044 |
| Clinical and regulatory | 5.418 | 9.448 |
| Costs of the Offer | 1.198 | 1.325 |
| Other working capital[(a)] | 1.536 | 7.343 |
| All other[(a)] | - | 6.247 |
| **Total** | **9.627** | **27.407** |

(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.

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

# 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 | 30 June 2021 |

| **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 | 138 | 372 |
| 1.2 | Payments for | | |
| | (a) research and development | (962) | (1,437) |
| | (b) product manufacturing and operating costs | (418) | (986) |
| | (c) advertising and marketing | (328) | (472) |
| | (d) leased assets | - | - |
| | (e) staff costs | (2,381) | (4,836) |
| | (f) administration and corporate costs | (794) | (1,396) |
| 1.3 | Dividends received (see note 3) | - | - |
| 1.4 | Interest received | - | 4 |
| 1.5 | Interest and other costs of finance paid | (60) | (123) |
| 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** | **(4,805)** | **(8,874)** |

| | | | |
|---|---|---|---|
| **2.** | **Cash flows from investing activities** | | |
| 2.1 | Payments to acquire or for: | | |
| | (a) entities | - | - |
| | (b) businesses | - | - |
| | (c) property, plant and equipment | (188) | (380) |
| | (d) investments | - | - |
| | (e) intellectual property | (22) | (41) |
| | (f) other non-current assets | - | - |

| 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** | **(210)** | **(421)** |

| | | | |
|---|---|---|---|
| **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 | 50 | 75 |
| 3.4 | Transaction costs related to issues of equity securities or convertible debt securities | - | (77) |
| 3.5 | Proceeds from borrowings | - | - |
| 3.6 | Repayment of borrowings | (115) | (224) |
| 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** | **(65)** | **(226)** |

| | | | |
|---|---|---|---|
| **4.** | **Net increase / (decrease) in cash and cash equivalents for the period** | | |
| 4.1 | Cash and cash equivalents at beginning of period | 20,682 | 25,140 |
| 4.2 | Net cash from / (used in) operating activities (item 1.9 above) | (4,805) | (8,874) |
| 4.3 | Net cash from / (used in) investing activities (item 2.6 above) | (210) | (421) |

| 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) | (65) | (226) |
| 4.5 | Effect of movement in exchange rates on cash held | 5 | (12) |
| **4.6** | **Cash and cash equivalents at end of period** | **15,607** | **15,607** |

| 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 | 15,607 | 20,682 |
| 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)** | **15,607** | **20,682** |

| 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 * | 98 |
| 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 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) | (4,805) |
| 8.2 | Cash and cash equivalents at quarter end (item 4.6) | 15,607 |
| 8.3 | Unused finance facilities available at quarter end (item 7.5) | - |
| 8.4 | Total available funding (item 8.2 + item 8.3) | 15,607 |
| 8.5 | **Estimated quarters of funding available (item 8.4 divided by item 8.1)** | 3.2 |

*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 July 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.