ASX Announcement

BUSINESS UPDATE AND DECEMBER 2020 QUARTERLY APPENDIX 4C

- Three new clinical sites contracted during the last quarter with signed purchasing agreements in place across a total of nine sites at 31 December 2020.
- Discussions well advanced across a further twelve sites, with many of these agreements at the stage of final review and execution.
- In recent months Imricor has experienced delays in the final execution of these agreements due to hospital closures associated with strict COVID-19 containment measures implemented across key target geographies of Germany and The Netherlands; however the Company remains focused on progressing these sites as expediently as possible.
- The Company is working closely with contracted sites to schedule installation, training and the commencement of cases in the coming weeks as COVID-19 restrictions ease.
- With a strong and growing pipeline further supported by Philips and Siemens, Imricor is well positioned as COVID-19 restrictions ease to progress quickly to deliver an acceleration in lab adoption in 2021.
- Imricor continues to make solid progress on other key growth strategies including FDA approval in the United States, TGA approval in Australia, the development of products to enable expanded indications and the development of an MRI compatible myocardial biopsy system with the potential to mark Imricor's first product line expansion beyond cardiac ablation.
- During the quarter, Imricor successfully completed an A$28.45 million institutional placement and A$1.55 million SPP with strong support shown by new and existing investors.
- At 31 December 2020, Imricor maintained a cash balance of US$25.140 million.

27 January 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 ended 31 December 2020 and provides a business update.

Progress of iCMR Lab Rollout

Imricor currently has nine clinical sites contracted at the following locations:

- Dresden Heart Centre, Germany, a training Centre of Excellence;
- Haga Hospital, The Netherlands;
- Amsterdam University Medical Centre, The Netherlands;
- Leipzig Heart Centre, Germany;
- Rhön Clinic Bad Neustadt Campus, Germany;

- Maastricht University Medical Centre, The Netherlands;
- South Paris Cardiovascular Institute, France;
- Lübeck University Heart Centre, Germany; and
- Münster University Hospital, Germany.

As previously advised, Imricor is in well advanced discussions across a further 12 sites with many of these agreements currently at the stage of final review and execution. The Company maintains a strong focus on progressing these agreements as expediently as possible.

Across the key target geographies of Germany and The Netherlands, strict COVID-19 containment measures remain in place, with extensions of these measures recently announced. Notwithstanding these restrictions, Imricor is working closely with contracted sites in certain regions to schedule installation, training, and the commencement of cases in the coming weeks.

Imricor's Chair and CEO, Steve Wedan said: "We continue to be closely engaged with targeted sites while remaining respectful of the pressures faced by hospitals in particular geographic areas as they navigate challenges associated with current COVID-19 containment measures. Interest in Imricor's products remains very strong across the medical community and while this community navigates the ongoing challenges of the COVID-19 pandemic, we are not seeing a withdrawal of potential Imricor customers from our sales pipeline. In fact, our pipeline of future iCMR labs continues to grow, supported by our sales agreement with Philips and ongoing collaborative agreement with Siemens.

"COVID-19 vaccination programs are currently being rolled out across Europe with clinical staff a priority. As these programs extend further into the population and the benefits of COVID-19 measures are realised, we expect to see significant easing of restrictions that have delayed our lab roll out program over recent months. We are well positioned to progress quickly once restrictions begin to ease across hospitals and clinics in Europe, and I remain confident that Imricor will deliver an acceleration in lab adoption as we move through 2021."

Maintaining Progress on Growth Opportunities

While delays have been experienced in the roll out of new clinical sites due to the impact of the COVID-19 second wave in Europe, Imricor has continued to achieve solid progress in the execution of its growth strategy across a number of other areas.

Mr Wedan said: "While the pandemic situation across Europe has delayed the signing of contracts with new sites, we have been actively moving forward on our future growth initiatives and making excellent progress in these areas. Expanding our future indications and our geographic reach will drive accelerated growth for Imricor in the future and I am very excited about the opportunities for the Company over the coming year and beyond."

1. Sales distribution agreement with Philips and ongoing discussions with Siemens

Imricor continues to work closely with Philips[1] to target future iCMR labs as well as in training and installation at contracted labs to support the commencement of procedures at these sites. In November, Imricor commenced training the Philips European sales force on the Company's technology and products. This sales force will become active in the field as soon as COVID-19 restrictions allow and is expected to drive a material increase in Imricor's installed base in 2021.

Imricor continues to work closely with Siemens and is currently working towards the establishment of a similar sales distribution agreement.

2. Expanding geographies

Imricor's strategy on FDA approval in the United States continues to progress well. The Company has held two pre-submission meetings with the FDA, and in subsequent meetings, the Company expects to establish alignment on Imricor's future clinical trial design.

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

Imricor is close to finalising the appointment of a local agent to facilitate both TGA approval and the eventual distribution of Imricor's products in the Australian market. Both parties expect to finalise the required agreements in March. It is not expected that a clinical trial will be required to support TGA approval.

3. Expanding indications

Imricor's research and development pipeline, focussed 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.

4. 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. 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 set[2] required for completion of atrial flutter ablation procedures.

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[1] In July 2020, Imricor signed a non-exclusive collaborative sales distribution agreement with Philips, enabling Philips to sell Imricor's capital product, the Advantage-MR EP Recorder/Stimulator System, as part of its comprehensive iCMR lab installation package in Europe.

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

5. Opportunities beyond cardiac ablation

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.

Imricor believes that the addressable market for an MRI compatible biopsy system is significant, and likely similar to that for Imricor's MRI compatible cardiac ablation catheter. In-depth market research to determine the size of the opportunity is currently progressing and is expected to be complete in the second quarter of 2021.

Appendix 4C Cashflow for Q4 2020

During the quarter ended 31 December 2020 (Q4 2020) net cash outflows from operating activities were US$2.906 million. Receipts from customers during the period were US$0.358 million comprising the sale of an Advantage-MR EP Recorder/Stimulator System, service agreements, consumable product sales and proceeds from the contract with the US National Institutes of Health. Revenue and associated cash receipts in Q4 2020 continued to be impacted by the COVID-19 pandemic, however, an additional three clinical sites were established during the quarter.

Payments made in relation to operating costs of US$3.264 million were down slightly on the prior quarter due primarily to timing of insurance payments and lower recruiting fees.

Net cash outflows from investing activities were US$0.098 million during Q4 2020. Net cash inflows from financing activities were US$20.339 million in the period. This included proceeds from Imricor's A$28.45 million institutional placement completed in November 2020 and A$1.55 million SPP completed in December 2020 both of which were well over-subscribed.

At 31 December 2020, Imricor maintained a cash balance of US$25.140 million.

Investor Conference Call

Investors are invited to join a conference call on Thursday 28 January 2021 at 9:00am AEDT (Wednesday 27 January 2021 at 4:00pm CDT) with Steve Wedan, Chair and CEO and Lori Milbrandt, CFO.

Please register for the call using the link below:
https://catoandclive.zoom.us/meeting/register/tJwkc-CqqzwjG9AG3v5E-VM-Chg-P3J_HsGN

After registering, you will receive a confirmation email containing information about joining the meeting. It is recommended that participants wishing to ask questions on the call, join via computer rather than telephone.

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

ENDS

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 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 31 December 2020 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$m)	Actual Expenditure since admission on 30 August 2019 to 31 December 2020 (US$m)
Sales and marketing	1.475	1.564
Clinical and regulatory	5.418	5.551
Costs of the Offer	1.198	1.325
Other working capital[(a)]	1.536	5.035
All other[(a)]	-	4.402
Total	**9.627**	**17.877**

(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	31 December 2020

Consolidated statement of cash flows		**Current quarter $USD'000**	**Year to date (12 months) $USD'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	358	847
1.2	Payments for		
	(a) research and development	(275)	(1,088)
	(b) product manufacturing and operating costs	(334)	(1,881)
	(c) advertising and marketing	(103)	(352)
	(d) leased assets	-	-
	(e) staff costs	(1,792)	(6,479)
	(f) administration and corporate costs	(697)	(2,772)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	8	29
1.5	Interest and other costs of finance paid	(71)	(301)
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**	**(2,906)**	**(11,997)**
2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(51)	(664)
	(d) investments	-	-
	(e) intellectual property	(47)	(135)
	(f) other non-current assets	-	(29)

Consolidated statement of cash flows		Current quarter $USD'000	Year to date (12 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**	**(98)**	**(828)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	21,394	34,801
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	73	478
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(1,025)	(1,778)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	(103)	(382)
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**	**20,339**	**33,119**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	7,771	5,049
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,906)	(11,997)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(98)	(828)

Consolidated statement of cash flows		Current quarter $USD'000	Year to date (12 months) $USD'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	20,339	33,119
4.5	Effect of movement in exchange rates on cash held	34	(203)
4.6	**Cash and cash equivalents at end of period**	**25,140**	**25,140**

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	25,140	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)**	**25,140**	**25,140**

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*	117
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** *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)	(2,906)
8.2	Cash and cash equivalents at quarter end (item 4.6)	25,140
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	25,140
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	8.7

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 January 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.