ASX Announcement

BUSINESS UPDATE AND SEPTEMBER 2020 QUARTERLY APPENDIX 4C

- Solid progress in signing new clinical sites during the last quarter, with an acceleration in lab roll outs since the European summer vacation season resulting in eight clinical sites now contracted across Germany, The Netherlands and France.
- A strong and growing pipeline of new sites, with twelve additional sites having the potential to sign agreements by the end of 2020. Imricor expects that at least six of these sites will sign agreements by 31 December, with the remaining executed in early 2021.
- Imricor expects to have at least 14 clinical sites with signed purchasing agreements in place by the end of 2020, assuming no unanticipated COVID related disruptions arise.
- The current COVID-19 spike in Europe is having a varied impact across sites Imricor is engaged with, however solid progress continues to be achieved with five agreements signed in the past six weeks and enthusiasm by physicians to provide iCMR ablations to their patients remaining strong.
- Following the signing of a non-exclusive collaborative sales agreement with Philips enabling Philips to sell Imricor's capital equipment, training of the Philips sales force is scheduled for November. The agreement is already delivering new sites to Imricor's pipeline and is expected to drive a material increase in Imricor's installed base in 2021. Discussion with Siemens are ongoing and progressing towards the establishment of a similar sales distribution agreement.
- Imricor's strategy on FDA approval in the United States and TGA approval in Australia is progressing well with clinical trials to support FDA approval targeted for 2021-2022 and the appointment of a local agent to facilitate TGA approval expected by year-end.
- Market appetite for expanding indications under MRI to treat arrythmias other than atrial flutter continues to increase, driven by early clinical success and ongoing physician engagement. The Company continues to advance the development of products to support these procedures, with clinical trials anticipated to occur during 2021.
- In September, Imricor was awarded a contract by the US National Institutes of Health to develop an MRI compatible myocardial biopsy system. This has the potential to mark Imricor's first product line expansion beyond cardiac ablation in a significant addressable market likely to be similar to the cardiac ablation catheter market.
- Imricor maintained a cash balance of US$7.771 million at 30 September 2020.

29 October 2020 – 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 30 September 2020 and provides a business update.

Progress of iCMR Lab Rollout

Eight clinical sites contracted

Imricor has achieved solid progress in signing new clinical sites during the last quarter, with an acceleration in lab rollouts after the conclusion of the European summer vacation season. Imricor currently has eight 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; and
- Lübeck University Heart Centre, UKSH, Germany.

A strong and growing pipeline of new sites

Imricor's pipeline of new sites continues to grow. Twelve additional sites have the potential to sign agreements by the end of 2020. However, given the current uptick of the COVID pandemic at some locations, Imricor expects that a number of these agreements may not be executed until early 2021. Of the twelve additional sites, the Company expects to sign agreements with at least six by 31 December 2020.

Imricor's Chair and CEO, Steve Wedan said: "We continue to see good progress in the establishment of clinical sites across Europe, particularly in light of the pandemic. The impact of the current European COVID spike is highly variable across the sites we're dealing with, ranging from significant at a couple of locations to non-existent at others, with most sites experiencing some level of distraction. Nonetheless, our processes are continuing to move forward, and given the current status, we expect a total of 14 clinical sites will have agreements to purchase Imricor's products in place by the end of 2020, assuming no unanticipated COVID related disruptions arise.

"The most important thing we can do during the pandemic is to continue growing the installed base of iCMR labs, and that's what we are doing. We've signed five labs in the past six weeks, and we are undaunted by COVID. We will continue to adjust and adapt to the local circumstances, and work with our enthusiastic physicians to provide iCMR ablations to their patients," he said.

Continued focus on growth opportunities

Imricor's growth strategy is focused on two key revenue drivers – the number of established iCMR labs and the number of procedures performed using Imricor's products in each lab. Imricor continues to execute its growth strategy through a number of areas:

1. Growing awareness of Imricor's products through sales and marketing, engagement with Key Opinion Leaders globally and its collaborative agreements with leading MRI vendors, Philips and Siemens;

2. Expanding the geographies in which the Company has approval to sell its products;
3. Expanding the approved use of its products for cardiac ablation procedures other than atrial flutter; and
4. Expanding the portfolio of products outside of cardiac ablation.

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

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.

Mr Wedan said: "Achieving this agreement in the last quarter has been a major milestone for Imricor, enabling us to focus on supporting utilisation, growing our portfolio of consumable devices and expanding our indications for use. In November we will commence training the Philips European sales force on Imricor's technology and products. Even at this early stage, the agreement has already resulted in two new sites entering our pipeline. We expect Philips to drive a material increase of our installed base in 2021."

Imricor continues to work closely with Siemens and is currently working towards the establishment of a similar sales distribution agreement. Imricor will continue to be the exclusive provider of its consumable devices including the Vision-MR Ablation Catheter and at this time continues to supply the Advantage-MR EP Recorder/Stimulator System to Siemens sites.

2. Expanding geographies

Imricor's strategy on FDA approval in the United States is progressing well. The Company 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. 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, ie. for the treatment of arrythmias other than atrial flutter. In particular, focus is 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 Imricor's diagnostic catheter is also well progressed with the Company aiming for commercial release in mid-2021, pending CE mark approval. As a scaled down version of Imricor's ablation catheter, the diagnostic catheter will provide material improvements in gross

margin through its inclusion in the two-catheter set[1] required for completion of atrial flutter ablation procedures.

4. Opportunities beyond cardiac ablation

In September, Imricor was awarded a contract by the US National Institutes of Health (NIH) to develop an MRI compatible myocardial biopsy system. Under this agreement, Imricor will receive US$399,539 over a 12-month period to develop a prototype system of devices that can biopsy the inner walls of the heart while using MRI imaging to guide the procedure. 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 progressing currently.

Governance

During the last quarter, the Board resolved to appoint Non-Executive Director and Lead Independent Director, Mark Tibbles as Deputy Chair.

Appendix 4C Cashflow for Q3 2020

During the quarter ended 30 September 2020 (Q3 2020) net cash outflows from operating activities were US$3.404 million. Receipts from customers during the period were US$0.118 million comprising the sale of consumable products (US$0.079) and contract receipts (US$.039). Revenue and associated cash receipts in Q3 2020 continued to be impacted by the COVID-19 pandemic, however as noted above, an additional three clinical sites were established in September and two additional sites have signed in October. A total of 14 clinical sites are expected to have purchasing agreements in place by the end of 2020, assuming no unanticipated COVID related disruptions arise.

Payments made in relation to operating costs of US$3.522 million were up from the prior quarter due primarily to an increase in and the timing of insurance payments and differences in the timing of payment of board fees. Research and development costs were up on the prior quarter as well as staffing and other administrative costs as Imricor continued to expand its workforce across a number of functional areas.

Net cash outflows from investing activities were US$0.221 million during Q3 2020. Net cash outflows from financing activities were US$0.056 million in the period, consisting of US$0.066 in proceeds from the exercise of options less additional payment of transaction costs related to the institutional placement completed in February 2020 and payments on lease obligations.

At 30 September 2020, Imricor maintained a cash balance of US$7.771 million.

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

ENDS

[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 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 September 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$m)	Actual Expenditure since admission on 30 August 2019 to 30 September 2020 (US$m)
Sales and marketing	1.475	1.122
Clinical and regulatory	5.418	4.352
Costs of the Offer	1.198	1.325
Other working capital[(a)]	1.536	4.093
All other[(a)]	-	3.912
Total	**9.627**	**14.804**

(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.

Payment 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 September 2020

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	118	489
1.2	Payments for		
	(a) research and development	(337)	(813)
	(b) product manufacturing and operating costs	(438)	(1,547)
	(c) advertising and marketing	(82)	(249)
	(d) leased assets	-	-
	(e) staff costs	(1,709)	(4,687)
	(f) administration and corporate costs	(898)	(2,075)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	19	21
1.5	Interest and other costs of finance paid	(77)	(230)
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**	**(3,404)**	**(9,091)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(203)	(613)
	(d) investments	-	-
	(e) intellectual property	(18)	(88)
	(f) other non-current assets	-	(29)

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**	**(221)**	**(730)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	13,407
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	66	405
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(24)	(753)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	(98)	(279)
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**	**(56)**	**12,780**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	11,425	5,049
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,404)	(9,091)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(221)	(730)

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)	(56)	12,780
4.5	Effect of movement in exchange rates on cash held	27	(237)
4.6	**Cash and cash equivalents at end of period**	**7,771**	**7,771**

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	7,771	11,425
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)**	**7,771**	**11,425**

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*	59
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)	(3,404)
8.2	Cash and cash equivalents at quarter end (item 4.6)	7,771
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	7,771
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	2.3

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: 30 October 2020

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.