29/01/21

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ASX Release

APPENDIX 4C – 31 DECEMBER 2020 QUARTERLY ACTIVITIES & CASHFLOW REPORT

Highlights:

- *Product development progressing well following very encouraging clinical trial results.*
- *Prof Stuart Crozier appointed as Chief Scientific Officer and in-house commercial product development team strengthened, includes a number of seasoned medtech innovators formerly from Nanosonics and ResMed.*
- *Subsequent to the end of quarter, FDA Guidance received. The De Novo guidance is in line with our expectations and planning as a truly novel device.*
- *$13.17 million of cash reserves as at 31 December 2020, following receipt of $1.28 million R&D tax incentive rebate during the quarter.*

EMVision Medical Devices Limited (ASX: EMV) ("EMVision" or the "Company") is pleased to lodge the following update and attached Appendix 4C Quarterly Cashflow Report for the 6-month period ended 31 December 2020.

In partnership with The University of Queensland (UQ), EMVision is developing and commercialising medical imaging diagnostics for various disease states and medical emergencies. The Company's primary focus is a portable, cost effective, non-invasive brain scanner to monitor and help with the diagnosis of brain injuries and stroke by creating rapid images of the brain.

Key activities undertaken during the quarter are outlined below:

Product development progressing well following very encouraging clinical trial results

During the quarter, the Company was pleased to report very encouraging data from its pilot clinical trial which were also outlined in the prior quarter's activities report. A total of 30 patient datasets (21 ischaemic and 9 haemorrhagic) were processed for this primary study analysis. The primary end point was met, with significant data collected to inform the value proposition and guide improvements in device hardware and software. For further details please refer to ASX announcement titled "EMVision Reports Very Encouraging Pilot Clinical Trial Data" released on 28 October 2020.

Good progress has been made on product development activities during the quarter with learnings from the clinical trial across usability, algorithms, software and general mechanical design leading to incremental improvements in the Company's 1st Gen commercial device. EMVision has recently made a number of in-house hires across a range of engineering and software disciplines and secured premises in Sydney including workshop facilities to drive these product development activities.

Some of the product development advancements will be included in the collection of data from an additional 20 patients. EMVision's ethics approval and clinical trial contractual arrangements with Princess Alexandra Hospital allow for up to 50 patients to be enrolled. With the successful outcomes obtained from the datasets collected to date and the strong support the Company has obtained from its clinical advisors and

investigators, the Company sees additional benefit in enrolling a further 20 patients, concurrently with its other activities. Further "training datasets" for some of the algorithms, in particular, from haemorrhagic patients, will allow for a larger database to better inform localisation and classification. These additional patient data sets are expected to be obtained in the first half of calendar year 2021.

Notwithstanding that, the Company believes it has sufficient information from the study to continue to aggressively advance its product development and is planning its next stage of expanded clinical studies and continues discussions with potential commercial partners.

Chief Scientific Officer appointed, and in-house commercial development team strengthened

During the quarter, global medical imaging innovator and co-inventor of the EMVision technology, Professor Stuart Crozier, was appointed to the role of Chief Scientific Officer. Prof Crozier is a co-inventor of the EMVision IP and is world renown for his advancements in MRI, with approximately 2/3rds of all MRIs leveraging IP developed by Prof Crozier. Prof Crozier will provide strategic direction, oversight and execution of the research and development efforts that underpin EMVision's novel imaging products.

As noted earlier, the Company's in-house commercial product development team has been strengthened with several experienced appointments across software, mechanical, radiofrequency (RF), production and process engineering. These key hires, which include a number of seasoned medtech innovators formerly from Nanosonics and ResMed, will be focused on delivering our 1st Gen commercial device for our expanded clinical trials for regulatory approval.

FDA Provides De Novo Guidance

Subsequent to the end of the quarter, EMVision was pleased to advise that the United States Food and Drug Administration (FDA) has recommended that the appropriate regulatory pathway for the EMVision portable brain scanner is the De Novo process. The De Novo pathway is designed for low to moderate-risk, first-of-a-kind products and employs a risk-based strategy for evaluating applications. It is used for new, novel devices without previous classification that are likely classified, based on their intended use and risk profile, as class II (same as MRI, ultrasound and CT) and for which there is no immediate comparable device.

The Company will engage with the FDA to confirm the required evidence including the planned clinical performance data necessary to support a De Novo submission as well as an application for the FDA's "breakthrough device program". The breakthrough program aims to speed development and assessment of devices that promise a more effective treatment or diagnosis for a life-threatening or irreversibly debilitating conditions. The Company intends to submit an application for breakthrough device designation, acceptance into this program is not guaranteed.

The De Novo guidance is in line with our expectations and planning as a truly novel device, and offers typically less complexity and shorter approval times compared to a Premarket Approval (PMA) pathway which is a more burdensome pathway for higher risk devices. As we continue to grow our commercial product development team, we have focused on bringing on experienced individuals who have a successful track record in developing and validating medical devices to meet international regulatory standards, including the FDA De Novo pathway and success in the breakthrough device program.

Australian Stroke Alliance update

As previously advised, the Company has collaborated with the ASA to submit a Stage 2 bid for the Medical Research Future Fund (MRFF) program. The Company is a commercial partner in the ASA, which is administered by the Australian Stroke Alliance Limited, and incorporates a group of over 30 organisations across patient advocacy, healthcare, academia and industry.

The Stage 2 research and development program is a competitive grant program that aims to deliver modern prehospital stroke care to indigenous, remote and metropolitan Australians by developing a suite of portable imaging technologies, for the air and road ambulance market, that will radically transform access to early pre-hospital treatments, and dramatically improve stroke outcomes.

The Company notes that the competitive funding process remains on foot and an announcement of successful bids is expected in early 2021.

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Keysight Technologies (NYSE:KEYS) collaboration update

To accelerate EMVision's product development, in April 2019 the Company signed a Memorandum of Understanding with US-based technology company Keysight Technologies (NYSE:KEYS) to collaborate on a new generation of vector network analysis (VNA) units for the healthcare market, a key measurement component in EMVision's portable brain scanner.

Following successful receipt of prototype units of the customised healthcare vector network analysers (VNA) with a smaller footprint, lower power consumption and lower component count, preliminary testing is being conducted alongside initial software integration. The Keysight and EMVision product teams continue to collaborate very closely. The first production equivalent VNA units, for use in EMVision's expanded clinical studies intended for first regulatory submissions, are expected to be delivered to EMVision in the first half of calendar year 2021.

Cashflow commentary, cash reserves of $13.172 million as at 31 December 2020 following receipt of $1.28 million R&D tax incentive rebate during the quarter

The Company had net cash operating inflows for the quarter of $0.235 million and cash reserves of $13.217 million as at 31 December 2020 following the receipt of a $1.281 million R&D tax incentive rebate for the financial year ended 30 June 2020, $0.122 million in Cooperative Research Centre project (CRC-P) grant funding and $0.012 million in Covid related support from the federal government.

Operating payments in the quarter totalled $1.254 million and included expenditure on research and development activities ($0.519 million), staff costs (including research and development employees) ($0.498 million) and corporate administration ($0.237 million). Research and development expenditure included payments to third party research and engineering contractors as well as components and materials for the Company's prototype devices and ongoing product development.

EMVision was awarded a $2.6 million CRC-P grant from the Government of the Commonwealth of Australia in late 2017. The CRC-P also includes grant participant partners GE Healthcare, a US$19 billion healthcare business of GE (NYSE:GE), The University of Queensland and The Queensland Government Metro South Hospital & Health Service operating at the Princess Alexandra Hospital. These partners committed to provide a further $0.910 million in grant funds to EMVision. To 31 December 2020, the Company has received $2.330 million from the government and $0.504 million from grant participant partners, remaining funding under the CRC-P totalling $0.676 million is expected to be received by end of calendar year 2021.

The Company had net financing cash inflows for the quarter of $0.192 million from option exercise proceeds.

As required by ASX Listing Rule 4.7C3, the Company notes that $0.210 million was paid to related parties during the quarter (as noted in section 6 of the attached Appendix 4C) and these payments were salaries, fees and superannuation paid to Directors.

IPO Prospectus use of funds compared to actual expenditure

In accordance with ASX listing rule 4.7C.2, the Company provides below a use of funds comparison table showing actual spend for the period 11 October 2018 to 31 December 2020 compared to the expected use of funds table provided in the Company's initial listing prospectus lodged with ASIC on 11 October 2018.

The following table shows the sources of funds outlined in the Company's initial listing prospectus compared to actual sources of funds from 11 October 2018 to 31 December 2020:

Source of funds	Prospectus $'000	Actual $'000
Approximate cash as at the date of this Prospectus / Opening cash balance	$837	$837

Proceeds from the Public Offer	$6,000	$6,000
Proceeds from Placement – November 2019	-	$4,500
Proceeds from Placement – July 2020		$9,000
Proceeds from Exercise of Options	-	$355
CRC Project Grant Funding	-	$1,820
R&D Tax Incentive Rebates	-	$1,941
ATO Covid Cash Bonus	-	$100
Interest received	-	$64
Total funds available	**$6,837**	**$25,014**

The following table shows the intended use of funds in the two-year period following Admission to the ASX (as outlined in the Company's initial listing prospectus) compared to actual expenditure to 31 December 2020:

Proposed use of funds – Year 1	**Prospectus $'000**	**Actual $'000**
Product design, research and development	$1,800	$3,193
Clinical studies and trials	$350	$38
Quality Management systems and regulatory consultancy costs	$100	$83
Fees associated with patent and intellectual property protection	$100	$94
Directors' fees	$150	$139
Corporate administration costs & General working capital	$1,140	$788
Estimated expenses of the Offer	$532	$532
Net GST	-	$91
Total Expenditure – Year 1	**$4,172**	**$4,958**
Proposed use of funds – Year 2	**Prospectus $**	**Actual $**
Product design, research and development	$1,400	$4,182
Clinical studies and trials	$150	$106
Quality Management systems and regulatory consultancy costs	$100	$176

Fees associated with patent and intellectual property protection	$75	$181
Directors' fees	$100	$125
Corporate administration costs & General working capital	$840	$1,300
Share issue costs	-	$843
Net GST	-	($28)
Total Expenditure – Year 2	**$2,665**	**$6,886**
TOTAL FUNDS ALLOCATED / SPENT	**$6,837**	**$11,842**
CLOSING CASH BALANCE	**-**	**$13,172**

The Company was admitted to the Official List of the ASX on 11 December 2018.

The proposed use of funds outlined in the Company's initial listing prospectus did not include anticipated access to additional sources of cash funding from the CRC Project Funding Agreement and the CRC Project Participants Agreement, and proceeds from a placement to sophisticated and institutional investors in November 2019 that raised $4.5 million (before costs) and a placement to sophisticated and institutional investors in July 2020 that raised $9.0 million (before costs).

As indicated in the initial listing prospectus, additional funds received from CRC Project grant funding were applied to further progress the Company's research and development activities.

As indicated in the initial listing prospectus, the Company was able to access research and development tax incentive funding from the Australian Commonwealth Government to assist funding research and development. As this funding was uncertain it was not included in the use of funds in the initial listing prospects.

With the receipt of these additional sources of funds, the Company was able to increase expenditure on product design, research and development above that which was outlined in the use of funds in the initial listing prospects. Clinical trial expenditure is less than the amount outlined in the use of funds in the initial listing prospects due to timing differences, this expenditure is expected to be paid in future periods.

Authorised for release by the Board of the Company.

[ENDS]

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Forward Looking Statements

This announcement may contain certain “forward looking statements” which may not have been based solely on historical facts, but rather are based on the Company’s current expectations about future events and results.

Where the Company expresses or implies an expectation or belief as to future events or results, such expectation or belief is expressed in good faith and believed to have a reasonable basis. However, forward looking statements are subject to risks, uncertainties, assumptions and other factors, which could cause actual results to differ materially to futures results expressed, projected or implied by such forward looking statements.

The Company does not undertake any obligation to release publicly any revisions to any “forward looking statements” to reflect events or circumstances after the date of this announcement, or to reflect the occurrence of unanticipated events, except as may be required under the applicable securities laws.

ABOUT EMVISION

EMVision Medical Devices Limited is focused on the development and commercialisation of medical imaging technology. The Company is developing and seeking to commercialise a potentially cost effective, portable, medical imaging device using electromagnetic microwave imaging for diagnosis and monitoring of stroke and other medical applications. The technology is the result of over 10 years of development by researchers at the University of Queensland. The team of approximately 20 researchers is led by co-inventor Professor Amin Abbosh, who is considered a global leader in electromagnetic microwave imaging. EMVision’s Chief Scientific Officer is Professor Stuart Crozier, who is a co-inventor of the EMVison technology and globally renowned for developing technology central to most MRI machines manufactured since 1997. EMVision’s CEO, Dr Ron Weinberger, is the Former Executive Director and CEO of Nanosonics' (ASX:NAN), a $2 billion market cap healthcare company. Dr Weinberger has over 25-years’ experience developing and commercialising medical devices. During his time at Nanosonics, Dr Weinberger co-developed the company’s platform technology and launched their breakthrough product ‘Trophon’ globally, which would go on to become the gold standard for infection prevention. Dr Weinberger was instrumental in transforming Nanosonics from a research and development company to one of Australia’s leading medical device commercialisation success stories.

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity

EMVISION MEDICAL DEVICES LTD

ABN	**Quarter ended ("current quarter")**
38 620 388 230	31 DECEMBER 2020

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (6 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers		
	- CRC-P participant contributions	92	92
1.2	Payments for		
	(a) research and development	(519)	(1,313)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs including research and development staff	(498)	(863)
	(f) administration and corporate costs	(237)	(436)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	19	27
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives		
	- R&D Tax Incentive rebate	1,281	1,281
	- CRC-P grant income	30	221
	- Covid-19 cash boost payment	12	50
1.8	Other (provide details if material)		
	- Net GST received / (paid)	55	(22)
1.9	**Net cash from / (used in) operating activities**	**235**	**(963)**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
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**	**-**	**-**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of shares	-	9,000
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	192	320
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	(591)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
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**	**192**	**8,729**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	**12,744**	**5,406**
4.2	Net cash from / (used in) operating activities (item 1.9 above)	235	(963)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-
4.4	Net cash from / (used in) financing activities (item 3.10 above)	192	8,729
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**13,172**	**13,172**

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 $A'000	Previous quarter $A'000
5.1	Bank balances	5,034	4,756
5.2	Call deposits	8,016	8,000
5.3	Bank overdrafts	(8)	(10)
5.4	Other - term deposit for bank guarantee	130	-
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	13,172	12,746

6.	**Payments to related parties of the entity and their associates**	Current quarter $A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	210
6.2	Aggregate amount of payments to related parties and their associates included in item 2	0

- Salary, Director fees and superannuation paid to Directors ($210k)

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 $A'000**	**Amount drawn at quarter end $A'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**	**$A'000**
8.1	Net cash from / (used in) operating activities (Item 1.9)	233
8.2	Cash and cash equivalents at quarter end (Item 4.6)	13,172
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	13,172
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	N/A

8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

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: N/A

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: N/A

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: N/A

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 January 2021.....

Authorised by: ..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.