30/10/20

EMVision Medical Devices Ltd
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ASX Release

APPENDIX 4C – 30 SEPTEMBER 2020 QUARTERLY ACTIVITIES & CASHFLOW REPORT

Highlights:

- *Very encouraging pilot clinical trial data reported subsequent to quarter end. The EMVision device was able to classify stroke type (haemorrhagic or ischaemic) with an overall accuracy of between 93.3% and 96% and localize targets in the correct quadrant (compared to ground truth CT/MRI) with an overall accuracy of between 86.7% and 96%.This data has allowed EMVision to build significant improvements into our product development plan, including software, hardware and usability features, as we progress down our commercialisation path.*
- *Keysight's first prototypes of the next generation customized healthcare VNAs, remains on track for delivery to EMVision for testing in Q4 calendar year 2020.*
- *Dr Philip Dubois appointed as a Non-Executive Director, strategic hire of Forough Khandan in the role of Head of Program Management and building of in-house product team underway.*
- *$9.0 million placement (before costs) to institutional and sophisticated investors successfully completed.*
- *$12.75 million of cash reserves as at 30 September 2020.*

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 3-month period ended 30 September 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:

Very encouraging clinical trial outcomes

Subsequent to the end of the quarter, the Company was pleased to report very encouraging data from the pilot clinical trial:

- 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.
- It was observed that the EMVision device was able to classify stroke type (haemorrhagic or ischaemic) with an overall accuracy of between 93.3% and 96%.
- It was observed that the EMVision device was able to localize targets in the correct quadrant (compared to ground truth CT/MRI) with an overall accuracy of between 86.7% and 96%.

- Fusion methodology, which leverages data from multiple algorithms, produced particularly encouraging results, alongside select individual algorithms, which continue to be advanced.
- Positive feedback was received from both operators and patient participants on all scans.
- This is a data acquisition study and not intended to be an interventional study. Hence appropriate caution should be used in extrapolating these results to those of the general population at this stage of the development.

This data has allowed EMVision to build significant improvements into our product development plan, including software, hardware and usability features, as we progress down our commercialisation path. The pilot study data also provides a strong foundation for EMVision to advance its unique value proposition. The intention is not to replace CT or MRI, but to function much like ultrasound does, by providing valuable information to clinicians, wherever the patient is, by the bedside or in the community, to intervene earlier and make critical decisions earlier, when time matters, and where CTs and MRIs may not be accessible or practical. 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. Notwithstanding that, the Company believes it has sufficient information from the study to continue to aggressively advance its product development. The Company is well positioned to plan its next stage of expanded clinical studies and continue discussions with potential commercial partners.

(Please refer to the Company's announcement ASX announcement titled "EMVision Reports Very Encouraging Pilot Clinical Trial Data" released on 28 October 2020 for further details).

Australian Stroke Alliance update

EMVision's clinical trial results have been met with much enthusiasm by the leads at the Australian Stroke Alliance (ASA), who have provided expert feedback. The EMVision team is looking forward to working with the Australian Stroke Alliance on expanded studies of the EMVision technology.

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.

At present, there has been no announcement of the final decision of the successful grant/s for round two of the MRFF Frontier Health and Medical Research initiative. As previously indicated, the Company expects to learn of the outcome of the review process and the ASA Stage 2 competitive bid prior to the end of the 2020 calendar year.

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.

Keysight's first prototypes of the next generation customized healthcare VNAs, are currently progressing positively through testing at Keysight and remain on track for delivery to EMVision for testing in Q4 calendar year 2020. Importantly, these next generation VNAs offer a dramatic size reduction on the VNA unit currently deployed in EMVision's pilot clinical study and greatly support the ongoing miniaturization efforts of EMVision's 1st Gen commercial device currently under development.

Non-Executive Director appointment, strategic hire and building of in-house engineering team underway

During the quarter, the Company was pleased to appoint Dr Philip Dubois as a Non-Executive Director. Dr Philip Dubois, an imaging executive and neuroradiologist has joined the board as an independent Non-executive Director. Dr Dubois is Non-executive Director of Sonic Healthcare (ASX:SHL), former CEO of their imaging division and served as Executive Director from 2001 to 2020. He is also the founder and former CEO and Chairman of Queensland X-Ray. Dr Dubois is currently an Associate Professor of Radiology at the University of Queensland Medical School. He has served on numerous government and radiology group bodies, including the councils of the Royal Australian and New Zealand College of Radiologists and the Australian Medical Association, and as Vice-President of the Australian Diagnostic Imaging Association. Dr Dubois is a Nonexecutive Director of Magnetica Limited.

The Company was also pleased to appoint Forough Khandan, in the role of Head of Program Management during the quarter. Forough was previously Program Manager at Nanosonics (ASX:NAN), reporting directly to the CTO, where she led a large multi-disciplined team of engineers and scientists across the business. During her 9-year tenure at Nanosonics, Forough successfully planned and executed highly complex new product development programs and was key in leading activities required to define, develop and deliver Nanosonics' second generation of trophon device from prototype through to after-market release. Forough was also responsible for specific strategic partnerships and engagement programs.

Following Forough's appointment, EMVision has been building out its core product team, focused on designing and developing products that meet international medical device standards. A number of hires have been made across software engineering and radio-frequency (RF) engineering. The product development team will shortly be moving into a new facility in Sydney, which will include a lab, production (assembly) and product test area. The EMVision team will continue to work very closely with the University of Queensland scientists and engineers as well as clinical advisors and investigators at the Princess Alexandra Hospital in Brisbane.

FDA 513(g) Request for Information submitted

During the quarter, the Company submitted a 513(g) Request for Information to the United States Food and Drug Administration (FDA). The purpose of this submission is to seek guidance from the FDA on what product classification would be most appropriate for EMVision's planned next generation portable brain scanner device and what the appropriate regulatory pathway will be. The submission is under review with a response expected by the end of calendar year 2020.

Cashflow commentary, cash reserves of $12.75 million as at 30 September 2020 following completion of a $9.0 million placement (before costs) during the quarter

The Company had net cash operating outflows for the quarter of $1.197 million and cash reserves of $12.746 million as at 30 September 2020.

Net operating cashflows included expenditure for research and development activities ($0.794 million), staff costs (including research and development employees) ($0.365 million) and corporate administration ($0.198 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.

Operating expenditure was partly offset by the receipt of $0.191 million in Cooperative Research Centre project (CRC-P) grant funding and $0.038 million in COVID related government support.

EMVision was awarded a $2.6 million CRC-P grant from the Government of the Commonwealth of Australia in late 2017 and to date has received $2.3 million from the government. The CRC-P was extended for 12 months during the quarter to the end of calendar year 2021 and the final $0.300 million of the grant is now scheduled to be received during the second half of calendar year 2021.

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 30 September 2020, the Company has received $0.413 million from grant participant partners with the remaining contributions expected to be received by end of calendar year 2021.

The Company had net financing cash inflows for the quarter of $8.537 million including placement and option exercise proceeds, net of share issue costs. The Company was pleased to successfully raise $9.0 million (before costs) from a placement to institutional and sophisticated investors at $1.42 per share. The Company was delighted with the strong support for the placement from existing and new shareholders and now has a fortified balance sheet to execute our product development and commercialisation strategy

As required by ASX Listing Rule 4.7C3, the Company notes that $0.175 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 30 September 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 30 September 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	-	$163
CRC Project Grant Funding	-	$1,820
R&D Tax Incentive Rebates	-	$937
ATO Covid Cash Bonus	-	$88
Interest received	-	$45
Total funds available	**$6,837**	**$23,388**

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 30 September 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	$900	$788
General working capital	$240	-
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	$3,449
Clinical studies and trials	$150	$75
Quality Management systems and regulatory consultancy costs	$100	$141
Fees associated with patent and intellectual property protection	$75	$137
Directors' fees	$100	$92
Corporate administration costs	$600	$921
General working capital	$240	-
Share issue costs	-	$843
Net GST	-	$27
Total Expenditure – Year 2	**$2,665**	**$5,686**
TOTAL FUNDS ALLOCATED / SPENT	**$6,837**	**$10,642**
CLOSING CASH BALANCE	**-**	**$12,746**

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 30 researchers is led by co-inventors Professor Amin Abbosh, who is considered a global leader in electromagnetic microwave imaging, along with Professor Stuart Crozier, who created 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 $1.6 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	30 SEPTEMBER 2020

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (3 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers		
	- CRC-P participant contributions	-	-
1.2	Payments for		
	(a) research and development	(794)	(794)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs including research and development staff	(365)	(365)
	(f) administration and corporate costs	(198)	(198)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	8	8
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	-	-
	- CRC-P grant income	191	191
	- Covid-19 cash boost payment	38	38
1.8	Other (provide details if material)		
	- Net GST received / (paid)	(77)	(77)
1.9	**Net cash from / (used in) operating activities**	**(1,197)**	**(1,197)**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 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	9,000
3.2	Proceeds from issue of convertible debt securities		
3.3	Proceeds from exercise of options	128	128
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(591)	(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**	**8,537**	**8,537**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 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	**5,406**	**5,406**
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,197)	(1,197)
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)	8,537	8,539
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**12,746**	**12,746**

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	1,725	2,386
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other – term deposit	11,021	3,021
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	12,746	5,407

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	175
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 ($175k)

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)	(1,197)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	12,746
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	12,746
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	10.6

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: 30 October 2020.....

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.