28/10/21

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ASX Release

APPENDIX 4C – 30 SEPTEMBER 2021 QUARTERLY ACTIVITIES & CASHFLOW REPORT

Highlights:

- *An important milestone for the Company was reached with the fabrication and assembly of the Company's alpha unit of its 1st Gen portable brain scanner intended for commercialisation. Testing of the 1st Gen units has been initiated.*
- *EMVision and The Australian Stroke Alliance Limited ("ASA") signed a binding Project Agreement enabling EMVision to begin accessing $8m in non-dilutive staged cash funding.*
- *After a rigorous peer-review process, EMVision was pleased to have patient case study images and an introduction to EMVision's novel portable brain scanner technology published in the medical journal Frontiers of Neurology.*
- *$8.054 million of cash reserves as at 30 September 2021, first $600k milestone grant due under ASA Project Agreement received subsequent to quarter end. R&D Tax Incentive claim for FY21 to be lodged shortly.*

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 2021.

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 at the point-of-care.

Key activities undertaken during the quarter are outlined below:

1st Gen successfully manufactured, enrolment of 20 additional patients in pilot trial completed

During the quarter, EMVision was pleased to reach an important milestone for the Company with the fabrication and assembly of the Company's alpha unit of its 1st Gen portable brain scanner intended for commercialisation.

Testing of the 1st Gen units has been initiated and will include functional, reliability, integration (software and hardware), preliminary safety, performance, compliance and other tests intended to meet international regulatory standards. Product suitability for manufacturability, assembly, shipment (environmental impact), use, service and repair will also be assessed. Tests initiated include internal formative usability studies (including consumables and accessories), headset thermal tests, electrical tests (integration of the customized VNA (pre-production version) in the headset), calibration procedure checks and performance evaluation of control mechanisms. Furthermore, qualification of the manufacturing methods and materials for critical parts and processes has also been initiated. The progress of testing has been pleasing in preparation for the Company's planned expanded clinical studies.

The 1st Gen device build milestone has also been the subject of national TV, Digital and Print media coverage. Additional media initiatives are underway to further increase international exposure.

Subsequent to the end of the quarter, the Company is pleased to advise it has completed enrolment of the additional 20 patient enrolment (50 in total), of its pilot trial. Processing of the data is underway. The final results of the clinical study will undergo a detailed review and are anticipated to be released via the ASX during November 2021.

EMVision and ASA sign $8M Non-dilutive Funding Project Agreement

During the quarter, EMVision and The Australian Stroke Alliance Limited ("ASA") signed a binding Project Agreement enabling EMVision to begin accessing $8m in non-dilutive staged cash funding. The staged funding will support the development and clinical validation of EMVision's planned first responder model for air and road ambulances. The development program commences with the ongoing validation of EMVision's portable brain scanner's diagnostic capabilities in the hospital environment.

The ASA provides EMVision with invaluable global clinical connectivity, expertise, and advocacy, including support from the leading minds in stroke care, paramedic services across Australia and the Royal Flying Doctor Service.

The funding is contingent on the project progressing in a manner that warrants continued funding and the ongoing achievement of project milestones. EMVision retains sole intellectual property ("IP") rights over the course of the project. In recognition of the funding and the clinical expertise provided EMVision has agreed to pay the ASA a royalty of 2% of Net Sales in specific, limited scenarios: Royalties are payable only on commercial sales in Australia of devices specifically designed and adapted for road or air ambulance, for a period of five years following from the date on which the full amount of funding under the Project Agreement has been received. Please refer to ASX announcement titled "ASA & EMVision Sign $8m Project Agreement" released on 16 September 2021 for further details on the terms of the Project Agreement.

Subsequent to the end of the quarter, EMVision is pleased to advise that it has received its first $600,000 milestone payment under the Project Agreement. EMVision is working closely with the ASA in preparation for the upcoming expanded clinical studies with the 1st Gen device. These clinical studies are anticipated to validate sensitivity / specificity of the device and also support the 2nd Gen device's path to market.

Technology published in peer-reviewed medical journal, Frontiers in Neurology

Subsequent to the end of the quarter, after a rigorous peer-review process, EMVision was pleased to have patient case study images and an introduction to EMVision's novel portable brain scanner technology published in the medical journal Frontiers of Neurology.

Such publications serve to increase EMVision's visibility in the scientific and medical community, where there continues to be strong enthusiasm and interest in EMVision's unique approach to portable neuroimaging and the future implications for stroke care. EMVision is anticipating further peer-review papers published in the near and medium term.

FDA Engagement

Subsequent to the end of the quarter, EMVision provided an update on its application for Breakthrough Device Designation (BDD) from the U.S. Food and Drug Administration (FDA). The FDA BDD is a discretionary program that offers priority review and interactive communication across the device development and validation path.

Feedback received on the application is that the preliminary evidence supports the potential of the technology to differentiate and localise haemorrhagic and ischemic stroke, however additional clinical study data is required by the FDA, which EMVision will generate through further clinical development.

The Company anticipates to further pursue BDD once the required clinical data is available and notes that its pursuit of the FDA De Novo regulatory marketing authorisation pathway for its 1st Gen portable brain scanner product, as previously advised, remains unaffected.

Cashflow commentary

The Company had net cash operating outflows for the quarter of $1.780 million and cash reserves of $8.054 million at 30 June 2021 after the receipt of $0.030 million in Cooperative Research Centre project (CRC-P) grant funding.

Net operating cash outflows of $1.780 million (Jun21Q: $1.754 million) were consistent with the prior quarter. Net operating cash outflows included expenditure on research and development (R&D) activities totalling $0.383 million (Jun21Q: $0.616 million), staff costs (including research and development employees) totalling $0.999 million (Jun21Q: $0.835 million) and corporate administration costs of $0.468 million (Jun21Q: $0.370 million).

Over the last 6 months EMVision has established our in-house product development team and whilst doing so have been able to reduce our reliance on more expensive external contract services, ensuring we continue to manage our cash prudently. This is reflected in the increase in staff costs and lower contracted external R&D expenditure compared to the prior quarter. External R&D expenditure includes 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. As at 30 September 2021, the Company has $0.180 million of government contributions and $0.360 million of participant partner contributions outstanding under the CRC-P. These contributions are expected to be received by end of Q1 calendar year 2022.

The Company had net financing cash inflows for the quarter of $0.169 million from option exercise proceeds received, net of transaction costs.

As noted, EMVision is pleased to advise that it has received its first $600,000 milestone payment under the $8 million Project Agreement with the ASA. In addition, the Company will shortly lodge its R&D Tax Incentive claim for FY21. The Australian Federal Government's R&D Tax Incentive Program provides a cash refund on eligible research and development activities performed by small to medium Australian companies and is an important program that strongly supports Australian innovation.

As required by ASX Listing Rule 4.7C3, the Company notes that $0.214 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.

Authorised for release by the Board of the Company.

[ENDS]

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About EMVision Medical Devices

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 and globally renowned for creating 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 $1.9 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.

Forward-looking Statements

This release may contain certain forward-looking statements with respect to matters including but not limited to the financial condition, results of operations and business of EMVision and certain of the plans and objectives of EMVision with respect to these items. These forward-looking statements are not historical facts but rather are based on EMVision's current expectations, estimates and projections about the industry in which EMvision operates, and its beliefs and assumptions. Words such as "anticipates," "expects," "intends," "plans," "believes," "seeks," "estimates", "guidance" and similar expressions are intended to identify forward looking statements and should be considered an at-risk statement. Such statements are subject to certain risks and uncertainties, particularly those risks or uncertainties inherent in the process of developing technology and in the endeavour of building a business around such products and services. These statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties and other factors, some of which are beyond the control of EMVision, are difficult to predict and could cause actual results to differ materially from those expressed or forecasted in the forward looking statements. EMVision cautions shareholders and prospective shareholders not to place undue reliance on these forward-looking statements, which reflect the view of EMVision only as of the date of this release. The forward-looking statements made in this announcement relate only to events as of the date on which the statements are made. EMVision will not undertake any obligation to release publicly any revisions or updates to these forward-looking statements to reflect events, circumstances or unanticipated events occurring after the date of this announcement except as required by law or by any appropriate regulatory authority.

Inherent risks of Investment in Medical Device development Companies

There are a number of inherent risks associated with the development of new medical device products to a marketable stage. The clinical trial process, which is often lengthy, is designed to assess the safety and efficacy of a device prior to commercialisation and there is no guarantee of achieving the outcomes necessary to generate a viable commercial product. Other risks include uncertainty of patent protection and proprietary rights, the obtaining of necessary regulatory authority approvals and the evolving competitive landscape. Companies such as EMVision are dependent on the success of their research and development projects, product development and on the ability to attract funding to support these activities. Investment in research and development and novel product development cannot be assessed on the same fundamentals as trading and manufacturing enterprises. Therefore investment in Companies specialising in such development must be regarded as speculative. EMVision recommends that professional investment advice be sought prior to such investments and cautions investors that the risks of an investment in an entity such as EMVision is not limited to the risks disclosed in this announcement.

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 2021

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (3months) $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	(383)	(383)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs including research and development staff	(999)	(999)
	(f) administration and corporate costs	(468)	(468)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	5	5
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	30	30
1.8	Other (provide details if material)		
	- Net GST (paid) / received	35	35
1.9	**Net cash from / (used in) operating activities**	**(1,780)**	**(1,780)**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3months) $A'000
2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(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**	**0**	**0**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	178	178
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(9)	(9)
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**	**169**	**169**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3months) $A'000
4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	9,665	9,665
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,780)	(1,780)
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)	169	169
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**8,054**	**8,054**

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	1,898	1,482
5.2	Call deposits	6,000	8,032
5.3	Bank overdrafts	(19)	(24)
5.4	Other (provide details) - term deposits for bank guarantees	175	175
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**8,054**	**9,665**

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	214
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

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 $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)	(1,780)
8.2	Cash and cash equivalents at quarter end (item 4.6)	8,054
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	8,054
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	4.5

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 available 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: N/A

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: N/A

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: N/A

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above 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 October 2021.....

Authorised by: ....By the Board of the Company.....
(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.