31/07/21

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ASX Release

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

Highlights:

- *Design and development of the first generation of EMVision's brain scanner progressed well throughout the quarter. Substantial effort has gone into design for manufacture and reducing our bill of materials in line with our commercial objectives.*
- *EMVision has applied for the FDA Breakthrough Device Designation program and anticipates an outcomes of its application no later than the end of this calendar year.*
- *EMVision and Australian Stroke Alliance (ASA) teams continued to collaborate closely in preparation for expanded multi-site studies.*
- *EMVision and Metro South Health executed a research and innovation partnership to continue to advance and translate EMVision's novel electromagnetic imaging into products that improve patient outcomes.*
- *$9.7 million of cash reserves as at 30 June 2021.*

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 12-month period ended 30 June 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:

Product development update

Design and development of the first generation of EMVision's bedside brain scanner progressed well throughout the quarter. This is the Company's first model intended for commercialisation and is targeted for use in ICUs, stroke and neurology wards, angiogram suites and emergency departments. This device intends to offer a bedside decision support and monitoring capability for stroke patients. Substantial effort has gone into design for manufacture and reducing our bill of materials in line with our commercial objectives.

The assembly of the device is on target, with the first device build to be completed next month. New accessories, and consumables, are also on track for integration. The integrated product and accessories will be assessed against the product's design, customers' needs and business requirements.

Please refer to ASX announcement titled "EMVision 1st Generation Device Progressing Well" released on 20 July 2021 for further details.

In addition, to ensure that the new product, its accessories, and consumables will satisfy the FDA, TGA and other regulatory requirements applicable to EMVision's brain scanner, early pre-compliance and safety tests are being undertaken. Pending satisfactory outcome of early verification of the design, an official supplier qualification process for bulk ordering of the parts for pilot production and site certification will be initiated.

As previously advised, the Company is enrolling an additional 20 stroke patients with the prototype at PAH, to further inform algorithm advancements in parallel with its product development activities and multi-site clinical study preparation. This includes evaluating dielectric mapping and pulsatility techniques that are under development. This enrolment is ongoing and the Company expects to provide updates to the market as it reaches further relevant product development and clinical validation milestones

Our team continues to grow with additional engineering skills in software and data science engaged. These skillsets are particularly focussed on strengthening our in-house knowledge and expertise. Our Head of Regulatory and Quality Affairs, Ruth Cremin is leaving and is replaced by Dr Merricc Edgar-Hughes. Merricc brings extensive regulatory experience having had global roles in Nanosonics and Ellex, as well as senior roles in Bayer and Eli Lilly. Ruth is leaving to concentrate on her young family and has made an outstanding contribution in developing positive relations with the US FDA and other regulatory bodies. We welcome Merricc and wish Ruth the best for the future.

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.

Close collaboration of Keysight and EMVision's technical teams has resulted in identifying opportunities for improvement of the VNA modules under design and development by Keysight. These improvements are anticipated to further enhance the imaging outputs of the EMVision Brain scanner. The VNA modules now sit within the headset resulting in a smaller form factor for the device and has been developed with a look forward to the ambulance version. The majority of the critical hardware is now in the headset, excluding the computer screen.

Australian Stroke Alliance update

As previously advised, the Australian Stroke Alliance (ASA), of which EMVision is a key commercial collaborator, was successful in its competitive medical research future fund (MRFF) bid to transform pre-hospital stroke care.

The ASA has executed its agreements with the MRFF and EMVision's project agreements with the Australian Stroke Alliance are anticipated to be executed shortly. In addition, the EMVision and Australian Stroke Alliance teams continued to collaborate closely, including protocol and ethics planning, in preparation for expanded multi-site studies.

As previously announced, EMVision has been advised by the ASA that it will receive $8 million in non-dilutive cash funding in staged payments weighted to the earlier years of the 5- year program. The funding will support EMVision's development and clinical validation of its first responder model for air and road ambulances as well as confirmation of EMV'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 as well as the Royal Flying Doctor Service.

Metro South Health – Clinical Research and Innovation Partnership

During the quarter, EMVision entered into a clinical research and innovation partnership with Metro South Health to continue to advance and translate EMVision's novel electromagnetic imaging into products that improve patient outcomes. Metro South Health is the major provider of public health care in southern Brisbane, Logan, Redlands and Scenic Rim regions. It runs five hospitals, including the Princess Alexandra

Hospital, Brisbane, Logan Hospital, Queen Elizabeth II Jubilee Hospital, Beaudesert Hospital and a network of community health centres.

Key elements of the partnership are collaborative research and innovation activities focused on areas that combine EMVision's novel brain scanner technology and Metro South Health's clinical expertise, including preparation for EMVision's planned expanded clinical studies.

Under the agreement Metro South Health will provide EMVision with access to neurology, radiology and critical care expertise, assistance with expanded clinical study design and development, access to simulation rooms and hospital infrastructure, advancement of bedside processes as well as input into technology development. This partnership places EMVision in a unique relationship with a major health network that provides specialist health care to a population of more than 1 million people.

Please refer to ASX announcement titled "EMVision and Metro South Health Sign Clinical Research and Innovation Partnership" released on 21 June 2021.

USA Food and Drug (FDA) – Breakthrough Device Designation Application

EMVision has applied for the FDA Breakthrough Device Designation program. The FDA breakthrough device designation is intended to help patients receive more timely access to breakthrough technologies that have the potential to provide more effective diagnosis or treatment for life-threatening diseases, such as stroke. If accepted to the program the FDA would provide EMVision with priority review and interactive communication across the device development and validation path through to commercialization. In addition, there are government policies and programs under consideration for devices that have Breakthrough Designation, that, if eventually adopted, may facilitate reimbursement opportunities in the United States following FDA marketing authorization. The Company anticipates an outcome of its application no later than the end of this calendar year.

Cashflow commentary

The Company had net cash operating outflows for the quarter of $1.754 million and cash reserves of $9.665 million at 30 June 2021 after the receipt of $0.030 million in Cooperative Research Centre project (CRC-P) grant funding.

Operating payments to suppliers and employees excluding GST in the quarter totalled $1.754 million (Mar 21 quarter: $2.052 million) a decrease of $0.298 million compared to the prior quarter. These payments included expenditure on research and development (R&D) activities totalling $0.616 million (Mar 21 quarter: $1.013 million), staff costs (including research and development employees) totalling $0.835 million (Mar 21 quarter: $0.675 million) and corporate administration costs of $0.370 million (Mar 21 quarter: $0.364 million).

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. The decrease in R&D expenditure compared to the prior quarter is due to the payment of six months services for a key R&D contractor in the prior quarter. In addition, with the establishment of our in-house product development team we have been able to reduce our reliance on more expensive external contract services from the end of April 2021, ensuring we continue to manage our cash prudently. The increase in staff costs compared to the prior quarter is due to additional employees hired in key product development specialties.

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 March 2021, the Company has received $2.39 million from the government and $0.550 million from grant participant partners, remaining funding under the CRC-P totalling $0.570 million is expected to be received by end of calendar year 2021.

The Company had net financing cash inflows for the quarter of $0.288 million being option exercise proceeds received, net of transaction costs.

As required by ASX Listing Rule 4.7C3, the Company notes that $0.215 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 JUNE 2021

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (12months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers		
	- CRC-P participant contributions	-	138
1.2	Payments for		
	(a) research and development	(616)	(2,925)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs including research and development staff	(835)	(2,390)
	(f) administration and corporate costs	(370)	(1,170)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	7	46
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
	- CRC-P grant income	30	281
	- Covid-19 cash boost payment	-	50
1.8	Other (provide details if material)		
	- Net GST (paid) / received	30	(52)
1.9	**Net cash from / (used in) operating activities**	**(1,754)**	**(4,741)**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12months) $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)	-	9,000
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	298	618
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(10)	(618)
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**	**288**	**9,000**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12months) $A'000
4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	11,131	5,406
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,754)	(4,741)
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)	288	9,000
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**9,665**	**9,665**

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	1,482	2,955
5.2	Call deposits	8,032	8,026
5.3	Bank overdrafts	(24)	(30)
5.4	Other (provide details) - term deposits for bank guarantees	175	180
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**9,665**	**11,131**

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	215
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)	(1,754)
8.2	Cash and cash equivalents at quarter end (item 4.6)	9,665
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	9,665
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	5.5

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: ....30 July 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.