



EMVision Medical Devices Ltd
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ASX Release

APPENDIX 4C – 31 DECEMBER 2021 QUARTERLY ACTIVITIES & CASHFLOW REPORT

Highlights:

- *Expanded clinical studies preparation progressing well. Prospective clinical sites have been identified and site surveys have been completed.*
- *Encouraging findings from additional pilot clinical trial data. The study was designed to collect data to tune the EMVision algorithms, which were applied to the full 50 patient dataset. It was observed that the EMVision device was able to classify stroke type (haemorrhagic or ischaemic) with an overall accuracy of 98% and to localize targets in the correct quadrant (compared to ground truth CT/MRI) with an overall accuracy of 78% in the full sample (50).*
- *A presentation on the EMVision technology titled “Electromagnetic (EM) Portable Imaging For Stroke”, was accepted for presentation at the prestigious International Stroke Conference, New Orleans February 2022.*
- *The Company finished the quarter well-funded, benefiting from substantial non-dilutive cash funding during the quarter totalling \$3.4 million. This non-dilutive funding resulted in an increase in cash reserves to \$10.495 million as at 31 December 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 6-month period ended 31 December 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:

Expanded Clinical Studies Preparation Progressing Well

Prospective clinical sites for EMVision’s next stage of clinical studies have been identified and site surveys have been completed addressing factors such as patient population availability and resources at site to successfully conduct the study. The Company has been pleased with the enthusiasm and support from clinical collaborators to participate in our next stage of studies. In parallel, the study protocol design has advanced, with input from clinical experts and leaders in stroke via the Australia Stroke Alliance. The Company anticipates preparing its ethics application shortly, after finalisation of the study protocol.

As the Company looks to its expanded clinical studies, it intends to be able to enrol patients with cardiovascular implantable electronic devices such as pacemakers as these patients make up a meaningful portion of the stroke population, with studies having shown that atrial fibrillation is associated with approximately one in four strokes. During the quarter, EMVision engaged an external consultant to perform a review and test of electromagnetic immunity levels required by a variety of standards for medical products

typically worn or implanted near the head (e.g. Pacemakers, Cochlear implants/ External sound processor, Neurostimulators), to ensure that such medical products would not be adversely affected by the use of EMVision's portable brain scanner product. Initial testing has identified no safety risks. Further tests will be performed in external labs as part of the product validation exercise to collect data for future regulatory submissions in different jurisdictions.

In addition, in preparation for taking the 1st Gen device into the first hospital sites in the clinical study, a medical device usability consultancy was engaged to review the usability engineering planning, risks, protocols, documents and design of graphical user interface among other elements. These elements will form part of future regulatory submissions. The feedback received from the consultancy is under review for implementation ahead of the next round of internal formative usability studies in a simulated environment.

Upcoming activities, alongside clinical trial preparation (protocol, ethics, clinical trial site contracts) and internal usability, include the fabrication of multiple 1st Gen devices for various testing (including verification & validation, software/hardware integration and electrical/EMC testing among others), in readiness for entry into the clinic.

Clinical Trial Data Drives Further Confidence

During the quarter, EMVision was pleased to announce additional encouraging findings from its pilot clinical trial. A total of 50 patient datasets (36 ischaemic and 14 haemorrhagic with a mean NIHSS score of 5.9) were processed for the primary study analysis. The study was designed to collect data to tune the EMVision algorithms, which were applied to the full 50 patient dataset. It was observed that the EMVision device was able to classify stroke type (haemorrhagic or ischaemic) with an overall accuracy of 98% and to localize targets in the correct quadrant (compared to ground truth CT/MRI) with an overall accuracy of 78% in the full sample (50).

Stroke neurologist and EMVision clinical advisor Professor Michael O'Sullivan commented, "These results, in a larger sample of patients with different types of stroke, have been eagerly awaited. 'Ischaemia or haemorrhage?' is the first question asked when a patient with suspected stroke is placed in a scanner. It is critical to determining the type of urgent intervention the patient needs. It is even more important at the point of care, away from hospital scanning facilities, as any delay in answering this question reduces the chance of a good final outcome. These results are highly promising in suggesting that the EMVision device can produce highly accurate discrimination of ischaemia and haemorrhage."

Please refer to ASX announcement titled "Clinical Trial Data Drives Confidence for Expanded Clinical Studies" released on 30 November 2021 for further details on the study.

EMVision Technology Accepted to be Presented at Prestigious International Stroke Conference

During the quarter, the Company was pleased to advise that a presentation on the EMVision technology titled "Electromagnetic (EM) Portable Imaging For Stroke", was accepted for the prestigious International Stroke Conference, New Orleans. Stroke neurologist and Australian Stroke Alliance clinical expert Dr Angela Dos Santos will be giving the presentation in early February.

The International Stroke Conference is the world's premier meeting dedicated to the science and treatment of cerebrovascular disease and brain health. The International Stroke Conference brings together thousands of healthcare professionals including neurologists, neurosurgeons, neuroradiologists and interventional radiologists, emergency medicine specialists, nurses and primary care physicians among others. The ISC 2022 provides a valuable opportunity to engage with key opinion leaders in the field of stroke, to demonstrate EMVision's commitment, alongside its collaborators at the Australian Stroke Alliance, to delivering advances in stroke care and showcase its innovative technology on a global stage.

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. The VNA is a key measurement component of the EMVision's portable brain scanner, with the customised modules designed to sit within the headset of the scanner.

The prototype of the intended miniaturised commercial VNA system was received from Keysight during the quarter for assessment and integration. Integration activities have been initiated and a focused expert team from Keysight and EMVision are undertaking testing as part of the ongoing device verification and validation process ahead of the planned expanded clinical studies.

Cashflow commentary, finished the quarter well-funded benefiting from substantial non-dilutive cash funding during the quarter totalling \$3.4 million

The Company benefited from substantial non-dilutive cash funding during the quarter totalling \$3.4 million. This included grant funding from the Cooperative Research Centre project (CRC-P) (\$0.210 million) and the Australian Stroke Alliance Limited (“ASA”) (\$1.2 million) and \$1.990 million from the company’s R&D tax incentive claim for the financial year ending 30 June 2021. This non-dilutive funding resulted in net cash operating inflows for the quarter of \$1.662 million and an increase in cash reserves to \$10.495 million as at 31 December 2021.

Operating cashflows included expenditure on research and development (R&D) activities totalling \$0.585 million (Sep21Q: \$0.383 million), staff costs \$1.024 million (Sep21Q: \$0.999 million) and corporate administration costs of \$0.277 million (Sep 21Q: \$0.468 million). Staff costs includes EMVision’s in-house product development and research team. 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.

During the quarter, EMVision had net investing cash outflows of \$0.100 million following investment in computing equipment to enable the company to undertake simulation and machine learning activities in-house.

The Company also benefited from net financing cash inflows for the quarter of \$0.919 million from the exercise of options, net of transaction costs (Sep 21Q: \$0.169 million). These options were issued to Directors and key management prior to the Company’s listing on the ASX, as well as the lead manager of the IPO. During the first half of FY22, Directors and management have invested a total of \$0.827 million on the exercise of these options demonstrating strong support for the business.

EMVision was awarded a \$2.6 million CRC-P grant from the Government of the Commonwealth of Australia in late 2017. The CRC-P 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. EMVision anticipates receiving the final outstanding contributions under this CRC-P grant totalling \$330,000 during the next few months, being \$150,000 from the Commonwealth Government and \$180,000 from GE Healthcare.

During the quarter, EMVision was pleased to receive the first milestone payments totalling \$1.2 million under a Project Agreement with the ASA. Under the agreement, EMVision will receive a total of \$8 million of non-dilutive cash funding in staged payments over the five-year project, weighted to the earlier years. The funding will support EMVision’s development and clinical validation of its planned first responder model for air and road ambulances, commencing with ongoing validation of EMVision’s portable brain scanner’s diagnostic capabilities in the hospital environment. The funding is contingent on the project progressing in a manner that warrants continued funding at each stage and the ongoing achievement of project milestones.

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 'Tropon' 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

38 620 388 230

Quarter ended ("current quarter")

31 DECEMBER 2021

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (6months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers		
- CRC-P participant contributions	180	180
1.2 Payments for		
(a) research and development	(585)	(968)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs including research and development staff	(1,024)	(2,023)
(f) administration and corporate costs	(277)	(745)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	4	9
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	1,990	1,990
- CRC-P grant income	30	60
- ASA grant income	1,200	1,200
1.8 Other (provide details if material)		
- Net GST (paid) / received	104	139
1.9 Net cash from / (used in) operating activities	1,622	(158)

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (6months) \$A'000
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(100)	(100)
(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	(100)	(100)

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	929	1,107
3.4 Transaction costs related to issues of equity securities or convertible debt securities	(10)	(19)
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	919	1,088

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6months) \$A'000
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	8,054	9,665
4.2	Net cash from / (used in) operating activities (item 1.9 above)	1,622	(158)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(100)	(100)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	919	1,088
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	10,495	10,495

5. Reconciliation of cash and cash equivalents	Current quarter \$A'000	Previous quarter \$A'000
at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts		
5.1 Bank balances	4,341	1,898
5.2 Call deposits	6,002	6,000
5.3 Bank overdrafts	(23)	(19)
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)	10,495	8,054

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	-
<i>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.</i>	

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

7. Financing facilities	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
<i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i>		
<i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>		
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)	1,622
8.2 Cash and cash equivalents at quarter end (item 4.6)	10,495
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	10,495
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	N/A
<i>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.</i>	
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	
<i>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.</i>	

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:27 January 2022.....

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.