

## ASX Release

# APPENDIX 4C – 30 JUNE 2022 QUARTERLY ACTIVITIES & CASHFLOW REPORT

### Highlights:

- *Ethics approval submitted, CRO appointed, in-principle agreements with clinical centres of excellence and encouraging preliminary usability testing completed. Targeting study commencement this quarter with devices in advance stage of commissioning.*
- *End user requirements assessed and system architecture advanced for EMVision's 2<sup>nd</sup> gen (first responder) device, triggering further Milestone Payment under ASA staged funding agreement.*
- *Executed Original Equipment Manufacturer (OEM) Strategic Agreement with Keysight Technologies Australia Pty Ltd (Australian subsidiary of NYSE:KEYS) ("Keysight"). The agreement is for an initial one year term with potential to extend to longer-term relationship.*
- *Successful \$5 million grant application under the Modern Manufacturing Initiative ("MMI") grant program to assist EMVision in establishing manufacturing capabilities at a commercial scale. The non-dilutive grant is a matched funding program and is subject to ministerial review, agreeing final documentation and terms.*
- *The Company finished the quarter well-funded, with cash reserves of \$6.8 million as at 30 June 2022. The Company benefited from substantial non-dilutive cash funding during the FY22 financial year totalling \$4.36 million (including grants and an R&D tax rebate). EMVision has access to a further \$6.2 million remaining under the non-dilutive ASA staged funding agreement.*

**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 2022.

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:

### **Multi-centre clinical trial milestone around the corner**

Pleasing progress has been made with our imminent clinical trials. EMVision has progressed in-principle agreements, which detail the how the studies will be conducted at the first two clinical sites being Royal Melbourne in VIC and Liverpool Hospital in NSW. The sites will be activated progressively starting with Liverpool Hospital. Both sites are centres of excellence in stroke care and management. We have had strong demand from sites in other states and these will be agreed and announced as we roll out the trial. EMVision has also appointed Avania Clinical a global leading medical technology Clinical Research Organisation (CRO) to support EMVision's upcoming multi-centre study.

EMVision is targeting study commencement this quarter, multi-centre ethics has been submitted to the Human Research Ethics Committee (HREC) and devices are in advance stage of commissioning. The Company will provide further information on the clinical trial plan shortly. Next steps include execution of clinical site contracts, completion of device commissioning alongside ethics and governance approval to commence patient enrolment.

### **Product commissioning progressing positively**

During the quarter EMVision's product development team have been commissioning devices for the multi-centre clinical trials, alongside preparing documentation which will ultimately go into technical files for regulatory submissions. Pre-compliance testing, including electromagnetic compatibility (EMC) testing, has been initiated in external certified labs. The initial tests have been very promising, i.e., the product has passed radiated and conducted emission tests which means the device is suitable to be used safely in common areas of health care facilities without any need for additional shielding.

Preliminary usability testing has also been conducted which is an essential process to ensure that the device can be used safely and effectively. This testing was undertaken with two user cohorts; the first received minimal training, the second, more extensive training. Importantly, the first group who received the minimal training did not experience challenges in operating the device. This indicates the operation of the device is intuitive, and that future users will be unlikely to require extensive training courses to master use of the device.

On software development, a simulation pipeline leveraging thousands of CT/MRI datasets has been setup to provide more synthetic scattering data for the algorithm engineers to continue to advance our artificial intelligence powered classification, localisation, and imaging techniques.

### **First responder milestone achieved**

Important progress with EMVision's 2nd Gen (first responder) device was made during the quarter. The Milestone activities have focused on extensive end user requirements gathering, with workshops held with VIC Ambulance, NSW Ambulance and the Royal Flying Doctor Service, among others, to ensure that the device being developed is fit for purpose, easy to operate and can integrate seamlessly into clinical workflows. Alongside these activities, an advanced concept for the 2nd Gen device has progressed positively.

Leveraging the core technology from EMVision's 1st Gen in-hospital bedside scanner, the 2nd Gen first responder scanners' proposed design includes a new hybrid antenna array, proprietary coupling cap and integrated neck, head and shoulder support. An initial prototype of the array is targeted for later this year. The regulatory strategy for EMVision's 2nd Gen pre-hospital device intends to employ an expedited path to FDA clearance by leveraging the 1st Gen in-hospital device as a predicate device.

Achievement of this milestone resulted in EMVision receiving a \$600,000 milestone payment from the Australian Stroke Alliance Limited ("ASA") under the Commonwealth of Australia Medical Research Future Fund (MRFF) program in partnership with the ASA, "Ambulance Device Planning". Please refer to ASX announcement titled "ASA & EMVision Sign \$8m Project Agreement" released on 16th September 2021 for further details of the Australian Stroke Alliance collaboration.

### **\$5M non-dilutive Modern Manufacturing Initiative grant**

During the quarter the Company was advised by the Department of Industry, Science, Energy and Resources that the Company's application under the Modern Manufacturing Initiative ("MMI") grant program was successful. In January 2022, EMVision submitted an application for \$5 million of non-dilutive cash funding under the MMI Manufacturing Translation Stream Medical Products Round 2. The Modern Manufacturing Initiative – Medical Products scheme is intended to support a globally recognised Australian medical products industry with the capability, capacity and expertise to locally manufacture advanced and high-value medical products using sophisticated processes. The non-dilutive grant is a matched funding program and is subject to agreeing final documentation and terms. The Company has been advised the new Minister is undertaking a review of manufacturing grant funding approved by the previous government and we are awaiting confirmation of the next steps from the Department. In preparation the Company has prepared draft documentation as required by the Department.

## **Strategic OEM agreement secured with Keysight Technologies (NYSE: KEYS)**

During the quarter EMVision announced it had entered into a strategic Original Equipment Manufacturer (OEM) Agreement with Keysight Technologies Australia Pty Ltd (with its parent company being NYSE:KEYS) ("Keysight"). The agreement is for an initial one year term with the potential for the agreement to be extended to a long term relationship. EMVision will receive exclusivity in the field of neuroimaging for the supply of the "fast sweep" feature in the VNA, which are core to the sensors that are being used inside EMVision's portable brain scanner. The "fast sweep" feature in the VNA enables high fidelity imaging, and due to the speed of data capture, the measurement of cerebral blood flow via EMVision's proprietary "pulsatility" technique under development.

The VNA is a custom solution developed by Keysight in collaboration with EMVision. The VNA is a high performance, lower component count, miniaturised module responsible for accurate signal measurement and represents a strategic investment by Keysight into the electromagnetic imaging sector. The custom VNA has enabled the EMVision device to be further miniaturised, making it ideal for environments where space is at a premium such as like ICUs and, in the future, ambulances. . The integrated VNA also eliminates the need for expensive cabling, lowers the component count which further optimizes product margins whilst improving performance and ease of use.

## **Cashflow commentary, cash reserves of \$6.8 million as at 30 June 2022**

The Company had cash reserves of \$6.8 million at the end of the quarter following net operating cash outflows of \$1.9 million, including the receipt of the final CRC-P grant payment (\$0.150 million) and a further \$0.6 million milestone payment from the Australian Stroke Alliance Limited ("ASA") and net financing inflows of \$0.2 million from the exercise of options.

Operating cashflows included expenditure on research and development (R&D) activities totalling \$0.911 million (Mar22Q: \$0.493 million), staff costs \$1.257 million (Mar22Q: \$1.288 million) and corporate administration costs of \$0.483 million (Mar22Q: \$0.293 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.

The Company has benefited from substantial non-dilutive cash funding during the FY22 financial year totalling \$4.36 million. This includes grant funding from the Cooperative Research Centre project (CRC-P) (\$0.57 million) and the ASA (\$1.80 million), and \$1.99 million from the company's R&D tax incentive claim for the financial year ending 30 June 2021.

Under a Project Agreement with the ASA, EMVision will receive a total of \$8 million of non-dilutive cash funding (\$6.2 million remaining) 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. The Company anticipates receiving further funding under the ASA Project Agreement in the current quarter.

EMVision is preparing to lodge its R&D tax incentive claim for the financial year ending 30 June 2022 in the near term.

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, Directors 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")**

30 JUNE 2022

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (12months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers		
- CRC-P participant contributions	-	360
1.2 Payments for		
(a) research and development	(911)	(2,372)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs including research and development staff	(1,257)	(4,568)
(f) administration and corporate costs	(483)	(1,521)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	3	12
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
- CRC-P grant income	150	210
- ASA grant income	600	1,800
1.8 Other (provide details if material)		
- Net GST (paid) / received	15	39
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(1,882)</b>	<b>(4,046)</b>

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (12months) \$A'000
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	(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)	-	-
<b>2.6 Net cash from / (used in) investing activities</b>	<b>-</b>	<b>(100)</b>

<b>3. Cash flows from financing activities</b>		
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	171	1,278
3.4 Transaction costs related to issues of equity securities or convertible debt securities	(1)	(20)
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)	-	-
<b>3.10 Net cash from / (used in) financing activities</b>	<b>170</b>	<b>1,258</b>

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (12months) \$A'000</b>
<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of period	8,489	9,665
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,882)	(4,046)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	(100)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	170	1,258
4.5	Effect of movement in exchange rates on cash held	-	-
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>6,777</b>	<b>6,777</b>

<b>5.</b>	<b>Reconciliation of cash and cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
5.1	Bank balances	1,617	2,343
5.2	Call deposits	5,007	6,004
5.3	Bank overdrafts	(22)	(33)
5.4	Other (provide details) - term deposits for bank guarantees	175	175
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>6,777</b>	<b>8,489</b>

<b>6.</b>	<b>Payments to related parties of the entity and their associates</b>	<b>Current quarter \$A'000</b>
6.1	Aggregate amount of payments to related parties and their associates included in item 1	222
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

<b>7. Financing facilities</b>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
<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)	-	-
<b>7.4 Total financing facilities</b>	-	-
<b>7.5 Unused financing facilities available at quarter end</b>	[ ]	
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.	[ ]	

<b>8. Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (item 1.9)	(1,882)
8.2 Cash and cash equivalents at quarter end (item 4.6)	6,777
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	6,777
<b>8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	3.6
<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: ....28 July 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.