31/01/23

EMVision Medical Devices Ltd
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ASX Release

APPENDIX 4C – 31 DECEMBER 2022 QUARTERLY ACTIVITIES & CASHFLOW REPORT

Highlights:

- *Multi-site clinical trial for 1st Gen portable brain scanner device underway and progressing well. The trial is taking place at leading comprehensive stroke centres including Liverpool Hospital in NSW, Royal Melbourne and the Princess Alexandra Hospital, Brisbane, starting with Liverpool Hospital. This is a pivotal moment for the Company.*

- *EMVision backed by NSW Medical Devices Fund (MDF) with $2.5M non-dilutive grant awarded. The Fund assists bringing local innovation to market and provides connectivity and access to the broader NSW healthcare system.*

- *Three key milestones were achieved during the quarter under EMVision's collaboration with the Australian Stroke Alliance (ASA), resulting in receipt of $1.8 million in non-dilutive grant funding. The ASA collaboration is progressing positively in our mission to deliver pre-hospital stroke care to all Australians, regardless of their location.*

- *Cash reserves of $9.6 million as at 31 December 2022, following the receipt of substantial non-dilutive cash funding in the quarter of $6.3 million. NSW MDF $2.5 million funding agreement executed, and funds expected to be received shortly in addition to a further $600,000 milestone payment under MRFF / ASA program.*

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 2022.

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:

Clinical trial commenced and progressing to schedule, a pivotal moment for EMVision

During the quarter, EMVision was pleased to progress its multi-site clinical trial for its 1st Gen portable brain scanner device which is now underway. This is a pivotal moment for the Company. The clinical trial will take place at leading comprehensive stroke centres including Liverpool Hospital in NSW, Royal Melbourne and the Princess Alexandra Hospital, Brisbane. The trial consists of two phases. The primary aim of the initial pre-validation phase is to verify hardware and safety and to provide acute stroke/stroke mimic data for AI algorithms. The subsequent validation phase aims to confirm sensitivity and specificity (efficacy). Completion of both stages is expected to generate the prerequisite data for EMVision's first regulatory approvals.

Following Human Research Ethics Committee (HREC) approval for the trial, user training at Liverpool Hospital was completed and the administrative "green light" activation letter received to commence enrolment and scanning at the first site, Liverpool Hospital. The trial is progressing well under the leadership of Dr Dennis Cortado of Liverpool Hospital who is the principal investigator.

The initial pre-validation Stage 1 phase of the trial commenced with the scanning of healthy volunteers. To date EMVision has enrolled and scanned well over half of the healthy volunteers (total 30) and has had no device related adverse events. The operation of the devices has been smooth with clinicians and participants noting the ease of operation and speed of scanning. We are looking to complete the scanning of the healthy baseline volunteers in the coming weeks after which we will initiate Stage 2 of the pre-validation phase which will assess up to 150 acute stroke/stroke mimic patients. These patients will be enrolled across the three major stroke centres, Liverpool Hospital, Royal Melbourne and Princess Alexandra, Brisbane, activated in a staggered manner, commencing with Liverpool Hospital. The ASX announcement on 4th October 2022 titled "Ethics Approval Received for Multi-Centre Clinical Trial" includes a "Clinical Investigations Roadmap" diagram which sets out a summary of the clinical trial plan.

A considerable cache of technical documents and testing reports which demonstrate safety and required performance of the product for a clinical environment have been generated by EMVision's product development team in the lead up to the trial. A sub-set of these documents will be used in final regulatory submissions including but not limited to formative usability reports, Biocompatibility reports, Safety Data Sheet of the consumable, real time shelf-life report of consumable and Specific Absorption Rate assessment.

EMVision backed by NSW Medical Devices Fund with $2.5M non-dilutive grant awarded

During the quarter, EMVision was awarded a $2.5 million non-dilutive grant from the NSW Medical Devices Fund (MDF) to support its clinical studies.

The NSW Medical Devices Fund is a competitive program to assist bringing local innovation to market alongside seeking to increase the uptake of NSW medical devices by the health system where they are cost effective and contribute to improved patient outcomes. Beyond grant funding, the support from the NSW Medical Devices Fund includes connectivity and access to the broader NSW healthcare system. The Fund is run by the NSW Office for Health and Medical Research. An independent expert panel, chaired by NSW Chief Scientist and Engineer Professor Hugh Durrant-Whyte, selected the MDF grant recipients.

Subsequent to the end of the quarter, the Funding Agreement between NSW Health, acting through the Health Administration Corporation (HAC) and EMVision has been executed, triggering the $2.5 million upfront payment which is expected to be received shortly. Repayment of the grant is triggered upon a "commercial success" milestone, defined as $500,000 positive EBITDA. The appropriate timing and structure of any repayment of the funds is to be agreed by both parties when approaching this milestone. Interest, which is the lower of CPI or 3.5%, is capitalised starting from 1st July 2023. The HAC or EMVision may terminate the Agreement with three months' notice.

The Company is appreciated of the financial support from the NSW MDF and looks forward to the connectivity that this program provides to the NSW healthcare system.

Australian Stroke Alliance collaboration progressing positively

In September 2021, EMVision entered into a Project Agreement with the Australian Stoke Alliance Limited (ASA) for $8.0 million in staged funding as part of the Stage 2 Medical Research Future Fund ("MRFF") 'Golden Hour' grant program. EMVision is a key commercial and industry collaborator to the program and the funding supports the development and clinical validation of EMVision's first responder model for air and road ambulances (2nd Gen device) commencing with validation of the Company's portable brain scanner's diagnostic capabilities in the hospital environment (1st Gen device).

The collaboration is progressing positively in our mission to deliver pre-hospital stroke care to all Australians, regardless of their location. The support received from the ASA's clinical team has been excellent.

Three key milestones were achieved during the quarter which resulted in the receipt of a total of $1.8 million in non-dilutive funding under the ASA Project Agreement:

- Algorithm validation studies – Planning commenced and in progress
- Ethics clearance received for algorithm validation / multi-site clinical study
- Device delivery to clinical site

Subsequent to the end of the quarter, the Company was pleased to advise that it has successfully achieved an important technical development milestone "Technical Validation of Algorithms commenced and in progress". This has triggered an additional $0.6 million milestone payment, which the Company expects to receive in February 2023. The milestone activities focused on extensive benchtop (phantom brain and complex simulation) experiments designed to mimic clinical use of the EMVision technology to support stroke subtype diagnosis. Pleasingly, both the existing 1st Gen system and the 2nd Gen road and air ambulance device, currently under development, demonstrated high levels of performance in these experiments. As a result, a full 3D 2nd Gen antenna array has been fabricated for further verification and development. EMVision is targeting road/air ambulance device trials next year.

Modern Manufacturing Initiative - $5M Non-dilutive Funding Agreement executed

As previously advised, during the quarter, EMVision signed the binding $5.0 million non-dilutive Funding Agreement (Agreement) with the Department of Industry, Science and Resources for EMVision's Modern Manufacturing Initiative ("MMI") grant award to establish commercial production of EMVision's 1st Gen portable brain scanner product. An initial upfront $2.0 million payment under the Funding Agreement has been received with the next payment of $1.75 million due in May 2023.

Cashflow commentary, cash reserves of $9.6 million as at 31 December 2022, following the receipt of substantial non-dilutive cash funding in the quarter of $6.3 million.

The Company had cash reserves of $9.6 million at the end of the quarter following net operating cash inflows of $4.7 million. The Company benefited from substantial non-dilutive cash funding in the quarter of $6.3 million. This included grant funding from the Australian Stroke Alliance ($1.8 million), the initial $2.0 million payment due on execution of the Modern Manufacturing Initiative grant Funding Agreement and $2.5 million from the Company's R&D tax incentive claim for the financial year ending 30 June 2022.

Operating cashflows included expenditure on research and development (R&D) activities totalling $0.300 million (Sep22Q: $0.320 million), staff costs $1.298 million (Sep22Q: $1.182 million) and corporate administration costs of $0.415 million (Sep22Q: $0.372 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, components and materials for clinical trial devices as well as ongoing prototyping and product development, and initial set up costs for the clinical trial.

The Company also had minor investing and financing cash outflows during the quarter resulting from plant and equipment purchases and share issues costs from an Employee Share Scheme share award respectively.

EMVision actively pursues non-dilutive funding opportunities and is appreciative of the financial and collaborative support from the following grant programs:

Grant Program	Total Funding	Funding Remaining as at 31 Dec 2022
Australian Stroke Alliance	$8.0 million	$4.4 million[1]
Modern Manufacturing Initiative	$5.0 million	$3.0 million[2]
NSW Medical Device Fund	$2.5 million	$2.5 million[3]
Total	$15.5 million	$9.9 million

[1] Refer to ASX Announcement "Australian Stroke Alliance and EMVision Sign $8m Project Agreement" on 16 September 2021 for further detail on the grant conditions and milestones. Milestone based staged payments over the five-year "Golden Hour" project weighted to the earlier years.

[2] Refer to ASX Announcement "$5M Modern Manufacturing Initiative Funding Agreement Signed" on 25 October 2022 for further detail on the grant conditions and milestones. Anticipated payment schedule $2.0m (Nov 22), $1.75m (May 23) and $1.25m (May 24). The Medical Products Manufacturing Translation Stream award will support establishment of commercial production of EMVision's 1st Gen portable brain scanner product.

[3] Grant from the NSW Medical Devices Fund to support EMVision's clinical studies. Repayment of the grant is triggered upon a "commercial success" milestone, defined as $500,000 positive EBITDA. The appropriate timing and structure of any repayment of the Funds is to be agreed by both parties when approaching this milestone. Interest, which is the lower of CPI or 3.5%, is capitalised starting from 1st July 2023. Either party may terminate the Agreement with three months' notice.

As required by ASX Listing Rule 4.7C3, the Company notes that $0.221 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]

For further information, media or investor enquiries, please contact:

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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	31 DECEMBER 2022

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	-	-
1.2	Payments for		
	(a) research and development	(300)	(620)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs including research and development staff	(1,298)	(2,479)
	(f) administration and corporate costs	(415)	(788)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	17	29
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	2,501	2,501
	- ASA grant income	1,800	1,800
	- MMI grant income	2,000	2,000
1.8	Other (provide details if material)		
	- Net GST (paid) / received	374	374
1.9	**Net cash from / (used in) operating activities**	**4,679**	**2,817**

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	(17)	(19)
	(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**	**(17)**	**(19)**

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	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(2)	(3)
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**	**(2)**	**(3)**

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	4,912	6,777
4.2	Net cash from / (used in) operating activities (item 1.9 above)	4,679	2,817
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(17)	(19)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(2)	(3)
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**9,572**	**9,572**

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	9,295	4,518
5.2	Call deposits	-	120
5.3	Bank overdrafts	(18)	(17)
5.4	Other (provide details) - term deposits for bank guarantees	295	291
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**9,572**	**4,912**

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	223
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)	4,679
8.2	Cash and cash equivalents at quarter end (item 4.6)	9,572
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	9,572
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	N/A

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: ....31 January 2023.....

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.