27/04/23

EMVision Medical Devices Ltd
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ASX Release

APPENDIX 4C – 31 MARCH 2023 QUARTERLY ACTIVITIES & CASHFLOW REPORT

Highlights:

- *Gen 1 device and multi-site clinical trial progressing to plan. Upgraded version to be released in May for activation and enrolment commencement of Stage 2 (pre-validation phase) of the Company's multi-site clinical trial.*
- *Gen 2 device development continues to gain significant momentum. Two further important technical milestones achieved under the Commonwealth of Australia Medical Research Future Fund (MRFF) program in partnership with the Australian Stroke Alliance (ASA).*
- *Professor Alan Coulthard appointed to Clinical Advisory Board.*
- *Collaboration with Titan, the Australian Stroke Alliance's national digital telehealth partner, for core imaging lab services and preparation for telehealth integration.*
- *Cash reserves of $10.4 million as at 31 March 2023, following the receipt of substantial non-dilutive cash funding in the quarter of $3.1 million from the ASA ($0.6 million) and NSW Medical Devices Fund ($2.5 million). A further $0.6 million milestone grant payment was received from the ASA subsequent to quarter end.*

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 9-month period ended 31 March 2023.

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:

Gen 1 Device & Multi-site Clinical Trial Progress

EMVision is in the late stages of integration, testing and documentation to release its upgraded Gen 1 devices in May for activation and enrolment commencement of Stage 2 (pre-validation phase) of the Company's multi-site clinical trial. The Gen 1 device is an in-hospital brain scanner which aims to provide bedside imaging for stroke patients and a range of potential clinical uses.

Stage 2 will enrol up to 150 suspected stroke patients presenting to the emergency department at three leading stroke centres, Liverpool Hospital, Royal Melbourne and Princess Alexandra. The sites will be activated in a staggered manner. Scanning of healthy volunteers for Stage 1 has been successfully completed at Liverpool Hospital and initial training in the operation of the EMVision brain scanner device, at the second trial site, Royal Melbourne Hospital, is scheduled for early May, with training at Princess Alexandra to follow thereafter.

Advancements introduced to the Gen 1 product include an enhanced disposable cap with an integrated fiducial marker. This single use per scan consumable provides a combined solution for infection prevention and ease of headset positioning. Other enhancements for ease of deployment include a backup power source and updated graphical user interface. These improvements have been introduced to make EMVision's novel portable brain scanner as easy to use as possible with seamless workflows for time sensitive medical emergencies, such as acute stroke.

During the quarter, Stage 1 (30 healthy volunteers) of the multi-site clinical trial was successfully completed at Liverpool Hospital. Each healthy baseline volunteer received a scan with the EMVision Gen 1 portable brain scanner alongside an MRI. Stable and consistent high quality signals were obtained from the Gen 1 scanner for these healthy baseline scans. The hardware is performing as designed and the participant data, alongside ground truth segmented MRIs is being used to advance EMVision's Artificial Intelligence algorithms and other imaging techniques.

Gen 2 Device Progress & Australian Stroke Alliance Milestones

During the quarter, EMVision continued to progress development of its Gen 2 pre-hospital "first responder" device which triggered two further $600,000 non-dilutive milestone grant payments under the Commonwealth of Australia Medical Research Future Fund (MRFF) program in partnership with the Australian Stroke Alliance (ASA). The "Technical Validation of Algorithms commenced and in progress" milestone grant was received in February 2023 and the "Technical Adaption of Ambulance Devices" milestone subsequent to quarter end.

Achievement of these important technical milestones generated an advanced CAD of the ultra-lightweight Gen 2 helmet system, as well as miniaturised component prototyping and successful bench testing of the 3D Gen 2 antenna array.

The algorithm validation related 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 Gen 1 system and the Gen 2 road and air ambulance device, currently under development, demonstrated high levels of performance in these environments.

Development of an advanced prototype suitable for in-human studies is progressing well, with the 'proof of concept' unit anticipated to be fabricated within the next two quarters and healthy volunteer testing anticipated in Q4 of this calendar year. With this progress, EMVision expects to participate at a number of leading pre-hospital and aeromedical conferences and exhibitions in the coming months.

Professor Alan Coulthard appointed to Clinical Advisory Board

During the quarter EMVision was pleased to appoint Professor Alan Coulthard to its Clinical Advisory Board. Alan is Professor of Neuroradiology at the University of Queensland and a full-time Senior Staff Specialist in diagnostic and interventional neuroradiology at the Royal Brisbane and Women's Hospital. He is Director of Research for the Department of Medical Imaging with an emphasis on mentoring junior doctors in research. He has over 35 years of experience in medical imaging and 20 years experience in the endovascular treatment of cerebrovascular diseases including ischaemic stroke. Alan has a National leadership profile, having served as President of the Australian and New Zealand Society of Neuroradiology (ANZSNR), inaugural chair of The Conjoint Committee for Recognition of Training in Interventional Neuroradiology (CCINR) and in many roles for the Royal Australian and New Zealand College of Radiologists (RANZCR), stepping down from the Board of Directors at the end of 2022.

Professor Coulthard performs endovascular thrombectomies. EMVision's technology aims to provide more suitable candidates for this breakthrough intervention, earlier, alongside routine bedside post-intervention monitoring. A series of clinical studies around the world have demonstrated that timely endovascular thrombectomy, for eligible stroke patients, more than doubles their odds of returning to an independent life. Globally as of 2019, only 2.79% of potential endovascular thrombectomy patients were receiving the procedure (Rosenfield, Kenneth et al)

Professor Coulthard commented "Effective stroke intervention requires efficient and robust patient selection with minimal delay to treatment. This technology will lead to better outcomes for a larger geographical range of stroke patients in Australia and internationally."

Professor Alan Couthlard's appointment is an unsalaried position.

Titan Neurosciences Collaboration

The Company has commenced a collaboration with Titan Neuroscience Research Australia ('Titan'), the Australian Stroke Alliance's national digital telehealth partner. Titan is a specialist clinical R&D firm supporting Phase I-IV clinical trials and providing brain imaging and analytics expertise to expedite clinical validation for new technologies. Titan will provide Core Imaging Lab services to EMVision, namely clinical stroke imaging expertise and segmentation analyses of "ground truth" CT/MRI during Stage 2 of the multi-site trial. In addition, preparations have commenced for integration with Titan's telehealth platform, Zeus.

Cashflow commentary, cash reserves of $10.4 million as at 31 March 2023, following the receipt of substantial non-dilutive cash funding in the quarter of $3.1 million.

The Company had cash reserves of $10.4 million at the end of the quarter following net operating cash inflows of $0.9 million. It benefited from substantial non-dilutive cash funding in the quarter of $3.1 million. This included grant funding from the Australian Stroke Alliance (ASA) ($0.6 million) and $2.5 million from the NSW Medical Devices Fund. As noted earlier, a further $0.6 million was received from the ASA subsequent to quarter end.

Operating cashflows outflows included expenditure on research and development (R&D) activities totalling $0.523 million (Dec22Q: $0.300 million), staff costs $1.226 million (Dec22Q: $1.298 million) and corporate administration costs of $0.356 million (Dec22Q: $0.415 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 investing cash outflows of $0.119 million resulting from investment in a NVIDIA supercomputer which provides additional capacity for EMVision's in-house machine learning activities.

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 March 2023
Australian Stroke Alliance	$8.0 million	$3.8 million[1]
Modern Manufacturing Initiative	$5.0 million	$3.0 million[2]
NSW Medical Device Fund	$2.5 million	Nil[3]
Total	$15.5 million	$6.8 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 (ASX:EMV) is an innovative Australian medical device company developing a novel approach to looking inside the human body. Our product pipeline includes portable, non-invasive, affordable and safe neuroimaging devices.

Our vision is to help transform and improve the timely diagnosis and treatment of stroke and other time sensitive medical emergencies, at the point-of-care.

EMVision has offices in Sydney and Brisbane www.emvisionmedical.com

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 MARCH 2023

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (9months) $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	(523)	(1,143)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs including research and development staff	(1,226)	(3,705)
	(f) administration and corporate costs	(356)	(1,144)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	24	53
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
	- ASA grant income	600	2,400
	- MMI grant income	-	2,000
	- NSW Medical Device Fund	2,500	2,500
1.8	Other (provide details if material)		
	- Net GST (paid) / received	(100)	274
1.9	**Net cash from / (used in) operating activities**	**919**	**3,736**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9months) $A'000
2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(119)	(138)
	(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**	**(119)**	**(138)**

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	-	(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**	**-**	**(3)**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9months) $A'000
4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	9,572	6,777
4.2	Net cash from / (used in) operating activities (item 1.9 above)	919	3,736
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(119)	(138)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	(3)
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**10,372**	**10,372**

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	5,100	9,295
5.2	Call deposits	5,000	-
5.3	Bank overdrafts	(23)	(18)
5.4	Other (provide details) - term deposits for bank guarantees	295	295
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**10,372**	**9,572**

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)	919
8.2	Cash and cash equivalents at quarter end (item 4.6)	10,372
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	10,372
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: ....27 April 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.