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ASX Release

APPENDIX 4C – 30 SEPTEMBER 2023 QUARTERLY ACTIVITIES & CASHFLOW REPORT

Highlights:

- *Gen 1 bedside device multi-site clinical trial progressing well with 120 patients recruited and successfully scanned in Stage 2 of the trial. On track to complete Stage 2 recruitment of 150 suspected stroke patients this quarter.*
- *Initial round of testing with a new AI-powered probabilistic anatomical imaging technique on volunteers was completed with improved fidelity over earlier anatomical imaging techniques. These imaging case studies were presented at 'Stroke 2023', the joint annual scientific meeting of the Stroke Society of Australasia (SSA) and Smart Strokes.*
- *First interim 'blood or not' algorithm analysis with encouraging initial test results published as an abstract in the International Journal of Stroke as part of the 15th World Stroke Congress, Toronto October 2023.*
- *Gen 2 first responder ultra-light weight advanced prototype assembled for bench testing with, subsequent healthy human volunteer testing to commence in coming months. Road & air ambulance 'proof of concept' unit on track for H1 CY2024.*
- *The Company is well-funded with cash reserves of $7.8 million. In addition, the FY23 R&D tax incentive rebate expected to be received by 31 December 2023 and $3.85 million in non-dilutive grant funding remaining as at 30 September 2023.*

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 3-month period ended 30 September 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:

Clinical trial propelling EMVision forward

During the quarter recruitment into Stage 2 of EMVision's clinical trial progressed well across all three sites (Liverpool Hospital, Royal Melbourne Hospital and Princess Alexandra Hospital), with Princess Alexandra commencing recruitment in July. To date over 120 patients have been recruited and successfully scanned in Stage 2 of the trial. The Company remains on track to complete Stage 2 recruitment of 150 suspected stroke patients this quarter.

The usability feedback on the 1st generation device has been encouraging. A mean time for completion of the full workflow and brain scan of 9.2 minutes was achieved during Stage 1 of the trial. The quality of signals obtained has been high and in terms of safety no device related adverse events have been reported.

During the quarter, an initial round of testing with a new AI-powered probabilistic anatomical imaging technique on healthy volunteers was completed. This technique, with both base (boundaries, ventricles) and advanced models (boundaries, ventricles, grey matter, white matter), represents a promising development with improved fidelity over earlier anatomical imaging techniques. It is intended for the background anatomical imaging technique to be fused with EMVision's classification and localisation algorithms to form the final output displayed to the clinician. These imaging case studies were presented at 'Stroke 2023', the joint annual scientific meeting of the Stroke Society of Australasia (SSA) and Smart Strokes. The presentation was given by Australian Stroke Alliance (ASA) co-chair Prof Stephen Davis, alongside an abstract titled 'EMVision Gen 1 Brain Scanner Study Stage 1 insights' published in the International Journal of Stroke.

Principal investigator at Liverpool Hospital, Dr Dennis Cortado, commented on this progress: "This is an exciting development in stroke and neurological care. We have found the EMVision scanner to be a very user-friendly portable imaging modality. The EMVision scanner has the potential for wide application in both the prehospital and acute hospital settings."

Subsequent to the end of the quarter, first interim 'blood or not' algorithm analysis was published as an abstract in the International Journal of Stroke as part of the 15th World Stroke Congress, Toronto October 2023. This interim analysis utilised patient data obtained during Stage 2 of the Company's clinical trial to indicate the accuracy of the haemorrhagic stroke detection algorithm prior to any fine-tuning with real haemorrhagic patient datasets. The preliminary test dataset included 15 patients (5 haemorrhagic, 2 ischaemic and 8 without stroke) that were external to and not included in prior algorithm training. The algorithm correctly identified all 5 haemorrhagic stroke patients as well as the other patients as being without haemorrhage. Following this interim analysis, complete clinical data from Stage 2 of the clinical trial will be used to train/test the full suite of classification, localisation and imaging algorithms.

The Company is preparing for upcoming engagement with the FDA via Q-Submission to achieve alignment with the FDA regarding planned device validation activities to ensure suitability for market clearance. CMS and Local Medicare Administrative Contractors (MACs) will also be invited to this Q-Submission meeting via the Early Payor Feedback Program. This enables consultation to help inform activities related to future reimbursement applications (including the New Technology Add-on Payment Program (NTAP)).

EMVision wins AFR innovation award for Gen 1 point-of-care brain scanner

During the quarter EMVision was named the top innovator in the healthcare category in the 2023 Australian Financial Review BOSS Most Innovative Companies list.

Nominee's scores were based on three components: an innovation they have implemented in the past 24 months; how the company has embedded innovation into their organisation; and Inventium's Innovation Benchmarking survey which assesses performance on a range of innovation drivers. The 2023 list attracted more than 700 nominations.

EMVision to showcase at RSNA 2023

EMVision will be showcasing EMVision's world first point-of-care brain scanners, including unveiling the naming and branding of its 1st Gen point-of-care brain scanner, at the Radiological Society of North America (RSNA) conference, November 26-30, 2023, with innovation partner Keysight Technologies (NYSE:KEYS). RSNA, which is the largest medical imaging conference in the world, represents a unique opportunity to engage with the international clinical community and future prospective customers, including key opinion leaders, alongside potential go-to-market partners.

Gen 2 advanced prototype assembled

Subsequent to the end of the quarter, an advanced 28-antenna prototype of EMVision's 2nd Gen ultra-light weight helmet scanner, designed for road and air ambulance deployment, was assembled for bench testing.

The Gen 2 headset weighs under 10kgs and is intended to be transported to the point-of-care via a backpack. It contains a 28-antenna 3D array which is designed to provide entire brain coverage in a single scan, with high performance ultra-light weight antennas. A silicone membrane with coupling media provides coupling of the antennas to the head. This membrane has been designed as a reusable but replaceable component and the coupling media will be a per scan consumable item. Core algorithms being developed for Gen 1 are planned to be adapted and updated for the Gen 2 device.

The bench testing will evaluate a range of technical parameters compared to simulations, leading to target detection investigations. An ethics submission for healthy human volunteer testing has been submitted and is expected to commence in the coming months. This testing intends to evaluate usability, ergonomics and signal benchmarking.

The regulatory strategy for Gen 2 is to leverage Gen 1 as a predicate device to pursue the FDA 510(k) pathway. Under 510(k) the device seeking clearance is required to prove 'substantial equivalence' to a predicate device that has already been deemed safe and effective.

This advanced prototype is a precursor to the 'proof of concept' system, suitable for pre-hospital deployment, which is on track to be assembled in the first half of CY2024, in line with the Company's development timetable. It will then be used for planned road/air ambulance trials under EMVision's collaboration with the ASA.

Cashflow commentary, cash reserves of $7.8 million as at 30 September 2023.

The Company had cash reserves of $7.8 million at the end of the quarter following net operating cash outflows of $2.0 million. EMVision benefited from non-dilutive grant funding in the quarter of $0.6 million from the ASA.

In the current quarter, EMVision expects to benefit from further non-dilutive funding from the ASA and its R&D tax rebate for FY23 which will shortly be finalised and lodged with the ATO.

Operating cash outflows included expenditure on research and development (R&D) activities totalling $0.580 million (Jun qtr. 23: $0.777 million), staff costs $1.461 million (Jun qtr. 23: $1.323 million) and corporate administration costs of $0.562 million (Jun qtr. 23: $0.597 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 costs for the clinical trial.

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 30 September 2023
Australian Stroke Alliance	$8.0 million	$2.60 million[1]
Modern Manufacturing Initiative	$5.0 million	$1.25 million[2]
NSW Medical Device Fund	$2.5 million	Nil[3]
Total	$15.5 million	$3.85 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 $0.223 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	30 SEPTEMBER 2023

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (3months) $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	(580)	(580)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs including research and development staff	(1,461)	(1,461)
	(f) administration and corporate costs	(562)	(562)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	69	69
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	-	-
	- MMI grant income	-	-
	- ASA grant income	600	600
1.8	Other (provide details if material)		
	- Net GST (paid) / received	(146)	(146)
1.9	**Net cash from / (used in) operating activities**	**(2,080)**	**(2,080)**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3months) $A'000
2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(34)	(34)
	(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**	**(34)**	**(34)**

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	-	-
3.5	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**	**-**	**-**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3months) $A'000
4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	9,929	9,929
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,080)	(2,080)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(34)	(34)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	-
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**7,814**	**7,814**

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	2,411	4,613
5.2	Call deposits	5,102	5,048
5.3	Bank overdrafts	(8)	(40)
5.4	Other (provide details) - term deposits for bank guarantees	309	308
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**7,814**	**9,929**

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	160
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)	(2,080)
8.2	Cash and cash equivalents at quarter end (item 4.6)	7,814
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	7,814
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	3.76

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: The Company notes that at least $4.5 million of funding is expected to be received in the next quarter from grant programs and the Company's FY22 R&D tax incentive claim.

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 October 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.