30/10/2024

EMVision Medical Devices Ltd
ACN 620 388 230
Level 10, 12 Creek Street,
Brisbane Qld 4000

ASX Release

APPENDIX 4C – 30 SEPTEMBER 2024 QUARTERLY ACTIVITIES & CASHFLOW REPORT

Highlights:

- *'EMView' multi-centre pre-validation trial recruitment complete, enrolling over 300 participants. Stage 3 trial results anticipated in November.*
- *EMVision continues validation trial preparations after positive FDA engagement.*
- *Transformative ultra-light weight First Responder Proof-of-Concept brain scanner device unveiled. Preparations for road and air study well advanced.*
- *Well-funded with cash reserves of $16.85 million. Activities over the next few months will be supported by further non-dilutive funding from the Company's FY24 R&D Tax Incentive claim, currently being finalised, and the Australian Stroke Alliance grant 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 3-month period ended 30 September 2024.

EMVision is an Australian company focused on the development and commercialisation of innovative neurodiagnostic technology. The Company's primary focus is portable, cost effective and non-invasive brain scanners, including a bedside device (emu™) and an ultra-light weight pre-hospital device (First Responder). EMVision's first indication is in stroke care.

Key activities undertaken during the quarter are outlined below:

'EMView' multi-centre pre-validation trial recruitment complete, enrolling over 300 participants. Stage 3 trial results anticipated in November

During the quarter, recruitment for EMVision's 'EMView' pre-validation multi-site clinical trial was completed with the Stage 3 enrolment target of 30 haemorrhagic patients being achieved.[1] In total, 307 participants were enrolled in the EMView trial and successfully scanned with the EMVision emu™ brain scanner, including 277 suspected stroke patients, providing valuable data to power EMVision's neurodiagnostic 'blood or not' and 'ischemia or not' AI algorithms. This dataset builds on the positive interim analysis previously reported from Stage 2 of the trial. Stage 3 trial results are anticipated to be reported in November. A clinical podium strategy will be employed to maximise impact and visibility of the 'EMView' trial.

Validation trial preparations continuing to progress after positive FDA engagement

EMVision received valuable insights and guidance from the FDA on its planned validation trial to support the emu™ De Novo regulatory clearance pathway. A consultative meeting with the FDA was held in late September as part of EMVision's planned validation trial preparation via the FDA's Q-submission program, a

[1] See ASX Announcement dated 8 July 2024 'Stage 3 Recruitment Target achieved and Validation Trial FDA Engagement underway'

mechanism whereby industry may gain alignment with FDA prior to final regulatory submission. The meeting answered critical questions relating to EMVision's validation program, including key parameters of the validation study, sites outside the US and statistical powering.

The study design was confirmed as a multi-centre, prospective, consecutive, paired diagnosis, diagnostic performance study that is anticipated to enrol up to 300 suspected stroke patients at a minimum 5 stroke centres including a minimum 3 based in the United States. For further information on indicative trial design see ASX Announcement 'EMV prepares for validation trial following positive FDA engagement' dated 29 October 2024. EMVision will continue to engage with the FDA to ensure alignment up to regulatory submission.

Ethics approval submissions as well as contracts and other administrative elements are being prepared with validation trial activation anticipated in the coming months. EMVision's leadership is visiting US investigational sites for advanced site engagement, including preliminary device training in November, prior to participating at the Society of Vascular and Interventional Neurology (SVIN) annual meeting.

Transformative ultra-light weight First Responder Proof-of-Concept brain scanner device unveiled. Preparations for road and air study well advanced.

During the quarter, EMVision unveiled the Proof-of-Concept (PoC) unit of its breakthrough First Responder device. It is an ultra-light weight (<12kgs), non-ionising, non-invasive device that can be easily operated by trained healthcare professionals and is designed for cost-effectiveness, to enable rapid stroke and stroke sub-type diagnosis at the point-of-care. It represents an opportunity to fundamentally transform stroke and thereafter traumatic brain injury (TBI) outcomes, for all patients, regardless of their location. It is intended to enable much earlier diagnosis and therefore much earlier triage, transfer or treatment decisions, which in acute stroke and TBI is proven to lead to improved patient outcomes.

The PoC device leverages the principles and mode of operation of EMVision's bedside emu™ brain scanner device. It is a lighter and miniaturised physical embodiment with expanded antennas (28), designed to provide entire cranial vault coverage in a single scan.

The delivery of the First Responder PoC device satisfied the "Ambulance Device Fabrication" milestone under the Company's Project Agreement with the Australian Stroke Alliance (ASA), which is funded by the Commonwealth of Australia's Medical Research Future Fund (MRFF), resulting in a $600,000 non-dilutive milestone payment during the quarter.

Comparative initial bench tests have been conducted with the First Responder PoC device and emu™ bedside scanners. Pleasingly, the First Responder PoC device is demonstrating at a minimum equivalent sensing performance in these initial tests. Performance benchmarking, which is ongoing, is necessary to demonstrate the comparative performance between First Responder device and the emu™ device to ultimately leverage 'substantial equivalence' regulatory pathways including for FDA 510(k) and TGA, minimising the scope of clinical evaluation and expediting the road to market for the First Responder product.

Preparations are underway for healthy volunteer testing which leads into a road and air study that is on track to commence early in the new year. Study protocol, ethics, CRO engagement and contracts are well progressed for this pre-hospital study. The First Responder brain scanner's pre-hospital workflow will be evaluated in real emergency scenarios onboard road and air ambulances to evaluate device usability and reliability. The study will be carried out with key collaborators, the ASA, the Royal Flying Doctor Service and state ambulance network providers.

Showcase at the Asia Pacific Stroke Conference

In September, EMVision participated at the Asia Pacific Stroke Conference. The co-chairs of the ASA, Profs Stephen Davis and Geoffrey Donnan, gave a keynote on 'The Stroke Golden Hour' program, in which EMVision's transformative technology featured prominently.

During the conference, EMVision's CEO Scott Kirkland was fortunate to have the opportunity to showcase EMVision's emu™ and first responder brain scanners for Federal Health Minister Mark Butler. Minister Butler's feedback on the opportunity for EMVision's technology, in collaboration with the ASA, to positively

impact many patients' lives, was incredibly encouraging. The ASA's forward planning is looking towards national wide implementation of world-first prehospital stroke care.

Cash reserves of $16.85 million as at 30 September 2024

The Company had cash reserves of $16.85 million at the end of Q1 FY25 including net operating cash outflows of $1.72 million. In the quarter, EMVision benefited from interest income of $0.17 million and non-dilutive grant funding of $0.60 million from the ASA 'The Stroke Golden Hour' grant program.

Net operating cash outflows included expenditure on research and development (R&D) activities totalling $0.402 million (Q4 FY24: $1.896 million), staff costs $1.673 million (Q4 FY24: $1.496 million) and corporate administration costs of $0.502 million (Q4 FY24: $0.613 million). Staff costs include 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.

Net investing cash outflows for the quarter were $0.02 million, being minor equipment capex to support R&D activities.

EMVision's activities over the next few months will be supported by further non-dilutive funding from its FY24 R&D Tax Incentive claim, currently being finalised, and the ASA grant program. The final ASA milestone payments are due on achievement of telemedicine and road/air integration activities ($400,000) and commencement of pilot studies of the first responder device targeted for first quarter CY 2025 ($400,000).

With grant programs that have supported development and commercialisation of the emu™ bedside scanners reaching their conclusion, EMVision continues to actively pursue non-dilutive funding opportunities to advance and accelerate other activities including the First Responder device. EMVIsion is appreciative of the significant financial and collaborative support it has received from the following grant programs:

Grant Program	Total Funding	Funding Remaining as at 30 September 2024
Australian Stroke Alliance	$8.0 million	$0.80 million[1]
Modern Manufacturing Initiative	$5.0 million	Nil[2]
NSW Medical Device Fund	$2.5 million	Nil[3]
Total	$15.5 million	$0.80 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). Payments are subject to satisfactory progress on the project, reporting and compliance with EMVision's obligations under the Agreement. 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 $0.192 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:

Dejan Toracki	Sling & Stone	Scott Kirkland
Head of Investor Relations	Media and Communications	CEO and Managing Director
+61 409 340 641	02 8073 5390	+61 2 8667 5337
dtoracki@emvision.com.au	emvision@slingstone.com	skirkland@emvision.com.au

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 2024

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	-	-
1.2	Payments for		
	(a) research and development	(402)	(402)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs including research and development staff	(1,673)	(1,673)
	(f) administration and corporate costs	(502)	(502)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	172	172
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	-	-
	- ASA grant income	600	600
1.8	Other (provide details if material)		
	- Net GST (paid) / received	82	82
1.9	**Net cash from / (used in) operating activities**	**(1,723)**	**(1,723)**

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	(20)	(20)
	(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**	**(20)**	**(20)**

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)	(2)
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)**	**(2)**

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	18,657	18,657
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,723)	(1,723)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(20)	(20)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(2)	(2)
4.5	Effect of movement in exchange rates on cash held	(57)	(57)
4.6	**Cash and cash equivalents at end of period**	**16,855**	**16,855**

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	5,586	5,368
5.2	Call deposits	11,000	13,000
5.3	Bank overdrafts	(42)	(22)
5.4	Other (provide details) - term deposits for bank guarantees	311	311
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**16,855**	**18,657**

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	192
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)	(1,723)
8.2	Cash and cash equivalents at quarter end (item 4.6)	16,855
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	16,855
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	9.78

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: ....30 October 2024.....

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 – e.g. 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.