30/04/2025

EMVision Medical Devices Ltd
ACN 620 388 230
Level 10, 12 Creek Street,
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ASX Release

APPENDIX 4C – 31 MARCH 2025 QUARTERLY ACTIVITIES & CASHFLOW REPORT

Highlights:

- *Commenced the Pivotal (Validation) clinical trial for EMVision's first commercial device, the emu™ bedside brain scanner. The trial is designed to support FDA De Novo clearance for the device.*
- *First Responder Proof-of-Concept device in successful aeromedical testing, with ethics approval applications submitted for further usability and workflow implementation studies.*
- *Implementation of a cost-effective strategy for continued device innovation and enhancement during the Pivotal (Validation) trial via a parallel Continuous Innovation Study. Ethics approval received and recruitment is anticipated to commence this quarter.*
- *Attendance planned at a number of leading industry events to showcase the Company's technology and products.*
- *Well-funded with cash reserves of $12.58 million as at 31 March 2025. Activities over the remainder of FY25 will be supported by $0.8 million of non-dilutive milestone payments under 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 9-month period ended 31 March 2025.

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:

Pivotal (Validation) clinical trial commences on target

During the quarter, EMVision was pleased to commence the Pivotal (Validation) clinical trial for its first commercial device, the emu™ bedside brain scanner. The trial is designed to support FDA De Novo clearance for the emu™ device. This important milestone marks the culmination of many years of hard work and dedication from our team and our clinical collaborators, in pursuit of the development and validation of world-first neurodiagnostic technology that has the potential to significantly reduce the global burden of stroke.

The first of the six sites to be activated was the Royal Melbourne Hospital, which is a world-class comprehensive stroke centre and home to the Melbourne Brain Centre – the largest brain research collaboration in the southern hemisphere.

In addition, an emu™ device has been shipped to the first US site, University of Texas Health Science Center at Houston (UTHealth) Medical School and Memorial Hermann-Texas Medical Center (TMC).

UTHealth Houston has a long tradition of stroke care innovation, having pioneered the use of tissue-type plasminogen activator (tPA), a life saving treatment for acute ischaemic stroke, and mobile stroke units to expedite its delivery. The site initiation visit and device training at UTHealth and TMC commences this week.

Subsequent to quarter end, EMVision shipped an emu™ Brain Scanner to the Mayo Clinic in Jacksonville, Florida. The Mayo Clinic site initiation visit and training is scheduled to commence early May.

Additional sites will be announced and activated shortly.

See ASX release 'emu™ Pivotal Validation Trial commences' on 27th March for further details on the Pivotal (Validation) trial design and objectives.

Continuous Innovation Study ethics approval received

As previously advised, EMVision is implementing a cost-effective strategy for continued device innovation and enhancement during the Pivotal (Validation) trial via a parallel Continuous Innovation Study. Additional patients will be scanned at multiple sites in Australia outside of the Pivotal (Validation) trial, including the Princess Alexandra Hospital, Brisbane and John Hunter Hospital.

This study data will be used to progress the development of additional device features, scale the training library for EMVision's diagnostic AI algorithms and potentially extend indications by the enrolment of patients with traumatic brain injury. EMVision observed meaningful performance increases in the sensitivity/specificity of its diagnostic AI algorithms during the previous 'EMView' pre-validation study when additional training data was utilised. This study is separate to, and isolated from, the Pivotal (Validation) trial dataset.

During the quarter, ethics approval was received for the Continuous Innovation Study, and recruitment is anticipated to commence this quarter.

First Responder Proof-of-Concept (PoC) device in successful aeromedical testing, with ethics approval applications submitted for further usability and workflow implementation studies

During the quarter, EMVision was pleased to announce an important milestone in the development of the Company's second device, targeting the pre-hospital market.

EMVision's First Responder PoC scanner was successfully deployed via a Royal Flying Doctor Service (RFDS) aeromedical retrieval service with a series of volunteer scans with the device carried out in remote settings, in collaboration with the RFDS and the Australian Stroke Alliance. RFDS staff received preliminary training in the operation of the device and the scans were successfully completed under an existing ethics approval. Pleasingly, the First Responder device demonstrated an ability to withstand the physical stress, environmental conditions and operational constraints unique to aeromedical retrieval.

An ethics application has been submitted and is under review, under which RFDS staff will shortly enrol and scan patients in a usability and workflow implementation study.

In addition, a further ethics application has been submitted and is under review to undertake EMVision First Responder scans during acute suspected stroke cases attended by the Melbourne Mobile Stroke Unit (MSU). This additional study provides a unique opportunity to collaborate with the only MSUs in Australia and one of a few MSUs globally who participate in clinical research. The study aims to evaluate the use of the EMVision First Responder PoC device during pre-hospital emergency response to acute suspected stroke patients, while gathering contemporaneous ground-truth MSU CT-scan data.

Finally, a standard road ambulance workflow and usability assessment study protocol is in development.

Upcoming podium and product showcases

As part of EMVision's market engagement and education strategy, EMVision has planned attendance at a number of leading industry events to showcase the Company's technology and products, including with long term collaborators at the Australian Stroke Alliance and Keysight Technologies (NYSE:KEYS).

The co-chairs of the Australian Stroke Alliance are giving a plenary presentation on the 'Golden Hour' program in the 'Stroke Imaging 2025: cutting-edge concepts and practices' session at the 11th European Stroke Organisation Conference (ESOC 2025), hosted in Helsinki, Finland in May. The presentation will feature EMVision's unique neurodiagnostic technology and 'EMView' study data which is also included in an Abstract that was accepted for the conference (see ASX announcement 'Neurodiagnostic algorithms deliver excellent results in EMView study' on 12 November 2024).

EMVision has been invited to present at the inaugural Novel Treatments for Acute Brain Injury (NABI) conference held in Houston in early May. This invite-only meeting of leaders in neurocritical care research is aimed at accelerating the transformation of the field.

EMVision is scheduled to showcase its First Responder PoC device at the Emergency Medical Service (EMS) World Expo 2025 in Indianapolis, United States in October. EMS World Expo is the largest and most respected EMS–dedicated education event globally. This annual event attracts thousands of EMS professionals, including paramedics, EMTs, military medics, physicians, medical directors, first responders, educators and emergency managers from around the world for hands-on education, training, networking and exhibits.

EMVision, in collaboration with Keysight Technologies (NYSE:KEYS), is also scheduled to co-exhibit at MEDICA, in Dusseldorf, Germany, in November. MEDICA is the world's largest B2B trade fair for medical technology and healthcare, attracting approximately 80,000 visitors each year, making it a central hub for international networking and collaboration in the medical sector.

Participation is also planned at a series of domestic stroke, pre-hospital and industry focused events, including the Council of Ambulance Authorities (CAA) Congress, Australia and New Zealand Stroke Organisation (ANZSO) and the NSW Commercialisation Showcase, among others.

Proforma cash reserves of $12.58 million as at 31 March 2025, $2.12 million FY24 R&D tax rebate received during the quarter.

The Company had cash reserves of $12.58 million at the end of Q3 FY25 following net operating cash outflows of $1.06 million during the quarter. The Company received non-dilutive funding during the quarter of $2.12m from its R&D tax rebate relating to activities in FY24, as well as interest income of $0.15m.

Net operating cash outflows included expenditure on research and development (R&D) activities totalling $1.1221 million (Q2 FY25: $1.179 million), staff costs $1.638 million (Q1 FY25: $1.750 million) and corporate administration costs of $0.557 million (Q1 FY25: $0.459 million). Staff costs include EMVision's in-house product development and research team. External R&D expenditure includes payments to third party regulatory, research and engineering contractors, components and materials for clinical trial devices as well as ongoing prototyping and product development, and costs for clinical trial activities.

EMVision's activities over the remainder of FY25 will be supported by further non-dilutive funding from 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 ($400,000).

With grant programs that have supported development and commercialisation of the emu™ Bedside Scanner reaching their conclusion, EMVision continues to actively pursue non-dilutive Federal and State 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 31 March 2025
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 $0.199 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 2025

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 / other income	78	164
1.2	Payments for		
	(a) research and development	(1,221)	(2,802)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs including research and development staff	(1,638)	(5,062)
	(f) administration and corporate costs	(557)	(1,518)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	152	471
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	2,121	2,121
	- ASA grant income	-	600
1.8	Other (provide details if material)		
	- Net GST (paid) / received	7	(25)
1.9	**Net cash from / (used in) operating activities**	**(1,060)**	**(6,051)**

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	(9)	(39)
	(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**	**(9)**	**(39)**

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)
3.5	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)**

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	13,661	18,657
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,060)	(6,051)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(9)	(39)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	(2)
4.5	Effect of movement in exchange rates on cash held	(8)	19
4.6	**Cash and cash equivalents at end of period**	**12,585**	**12,585**

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	4,324	2,373
5.2	Call deposits	8,000	11,000
5.3	Bank overdrafts	(51)	(24)
5.4	Other (provide details) - term deposits for bank guarantees	312	312
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**12,585**	**13,661**

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	199
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)	(1,060)
8.2	Cash and cash equivalents at quarter end (item 4.6)	12,585
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	12,585
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	11.87

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 April 2025.....

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.