

# ASX Release

## APPENDIX 4C – 30 JUNE 2025 QUARTERLY ACTIVITIES & CASHFLOW REPORT

### Highlights:

- *Pivotal trial, to support FDA De Novo clearance for the emu™ point-of-care bedside brain scanner, progressing well with 5 luminary high-volume sites recruiting.*
- *Continuous Innovation Study initiated to advance additional features for stroke evaluation and support future indication expansion into traumatic brain injury assessment.*
- *First Responder took to the skies in a world-first, with successful aeromedical testing. Ethics approvals granted to undertake pre-hospital studies with the First Responder device in air with the Royal Flying Doctors Service, and road with Melbourne's Mobile Stroke Unit.*
- *Awarded \$5 million Industry Growth Program non-dilutive grant to accelerate commercialisation of the First Responder device.*
- *On-going non-dilutive grant funding strategy continues to be pursued across international, federal and state channels.*
- *Multiple podium presentations secured at high-profile forums, including pivotal study presentation at World Stroke Congress in Spain in October 2025, as well as presentation and technology demonstration at the Military Health System Research Symposium in the United States in August 2025.*
- *Head office premises increased to expand production capabilities, including the establishment of a pilot commercial production line for the First Responder device*
- *Well-funded with cash reserves of \$10.5 million as at 30 June 2025. In addition, a \$0.4 million non-dilutive ASA milestone grant payment was received subsequent to quarter end and a further \$4.4 million in non-dilutive funding is available from current grant programs. The Company's FY25 R&D tax incentive rebate is also anticipated to be received in CY Q4 2025.*

**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 12-month period ended 30 June 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 targets acute stroke care, with a second planned indication in traumatic brain injury. Both indications represent substantial societal and health economic burdens. There are critical unmet needs for portable brain scanners to enable more timely triage, transfer or treatment decisions to improve patient outcomes.

FY25 was a year of substantial progress for EMVision, across clinical, regulatory, and commercialisation activities for the both the emu™ and First Responder devices. EMVision is advancing its products towards market entry through the following key activities:

- emu™: Pivotal (Validation) trial to support FDA De Novo clearance of the emu™ point-of-care bedside brain scanner, which is underway at sites in the US and Australia;
- First Responder: three studies planned with the advanced proof-of-concept device to transition it to a commercial production equivalent device. This includes an aeromedical usability study with the RFDS in Adelaide, a workflow and data collection study with the Melbourne Mobile Stroke Unit (MSU) and a Road Ambulance feasibility and usability study in NSW; and
- Continuous Innovation Study: in parallel with the emu™ Pivotal Trial, EMVision is scanning additional patients with suspected stroke or traumatic brain injury (“TBI”) at Princess Alexandra Hospital (Brisbane) and John Hunter Hospital (Newcastle). This initiative provides a cost-effective strategy for continued device innovation, algorithm enhancement and data collection to support product enhancements and indication expansion (TBI).

Key activities undertaken during the quarter are outlined below:

### **Pivotal Trial progressing well with 5 luminary sites recruiting and Continuous Innovation Study initiated**

EMVision commenced the Pivotal (Validation) Trial (the “Trial”) to support FDA De Novo clearance of the emu™ point-of-care bedside brain scanner. Up to 300 suspected stroke patients are to be enrolled across four sites in the United States and two sites in Australia. All participating Trial sites are luminary, high volume comprehensive stroke centres.

Five of the six Trial sites have been activated and are actively enrolling patients, with the final West Coast US site to be announced and activated shortly. The first sites to be activated under the Trial were The Royal Melbourne Hospital in Australia and the University of Texas Health Science Center at Houston (UTHealth) Memorial Hermann-Texas Medical Center (TMC) in the United States. This was followed by the Mayo Clinic in Florida, Mount Sinai in New York, and Liverpool Hospital in Sydney.

A Trial Steering Committee, made up of Key Opinion Leaders (KOLs) in stroke care and research, has been established to provide independent clinical oversight, guide conduct based on deep expertise, and signal to regulators and clinical peers that our emu™ device is being evaluated to the highest standards by leaders in the field.

The Trial for our emu™ device has an estimated enrolment period of 6-12 months, followed by analysis and reporting of the clinical data. The emu™ device is then anticipated to become the predicate device for EMVision’s second commercial product, the First Responder device, allowing an expedited 510(k) FDA pathway for the pre-hospital market (i.e. ambulance and aeromedical services).

EMVision is excited by the enthusiasm and engagement of our new US based Trial sites as well as our experienced Australian sites previously involved in the pre-validation EMView study. All current study sites have commenced and are actively enrolling participants. The US sites are gaining momentum as they familiarise with the study workflow, following the same pattern as new sites in the prior EMView study. The Australian sites have benefitted from their prior experience and quickly resumed study activities. We anticipate recruitment rates will continue to steadily increase following the initial implementation period. EMVision will report on recruitment rates as the Trial progresses.

In addition, the Continuous Innovation Study has been initiated at Princess Alexandra Hospital, Brisbane and John Hunter Hospital in Newcastle. Princess Alexandra Hospital is already recruiting, and John Hunter Hospital is anticipated to commence recruiting this week. This study aims to advance additional features and potential future indications for the emu™ device, such as point-of-care traumatic brain injury assessment.

### **First Responder – Scanners in the skies and on the road**

During the half, EMVision’s First Responder proof-of-concept device took to the skies and successfully completed aeromedical environment testing. A series of volunteer scans were taken in remote Australian settings, in collaboration with the Royal Flying Doctor Service (RFDS) and the Australian Stroke Alliance.

Pleasingly, the First Responder device demonstrated the ability to withstand the physical stress, environmental conditions and operational constraints unique to aeromedical retrieval.

Following the achievement of this milestone and subsequent to quarter end, ethics approval has been granted to enable the RFDS to undertake scans of aeromedical retrieval patients with the First Responder device. In addition, ethics approval has also been granted for a Mobile Stroke Unit study. The clinical research collaboration with the Melbourne Mobile Stroke Unit will provide the opportunity to evaluate the use of the First Responder device during pre-hospital emergency responses to acute suspected stroke patients, while gathering contemporaneous ground-truth MSU CT-scan data. These studies will advance efforts to evaluate the device's usability, reliability, functionality, and workflow metrics, as well as conduct other tests as necessary to meet user and international regulatory requirements.

In parallel with these studies, product development activities will continue to transition from advanced proof-of-concept First Responder devices to production-equivalent commercial devices.

### **Awarded \$5 million non-dilutive government grant to support First Responder commercialisation and adjacent facility leased to expand manufacturing capabilities**

During the quarter, EMVision was pleased to be awarded an Australian Government Industry Growth Program (IGP) Commercialisation and Growth Grant of \$5 million in non-dilutive funding to accelerate the global commercialisation of EMVision's First Responder portable brain scanner.

In addition, to support the First Responder development, EMVision has updated its leased premises to include an adjacent premises to expand EMVision's product development and manufacturing space, ensuring there is sufficient room to accommodate future growth. The expanded facility will enable EMVision to establish a pilot production line for our First Responder device.

### **Multiple podium presentations secured at key events**

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

Our pivotal trial has been accepted for oral presentation at the 17th World Stroke Congress, by one of our ASA clinical collaborators and principal investigators on the study. The Congress is held on October 22-24, 2025, in Barcelona, Spain. The World Stroke Congress is one of the leading, internationally recognised events for stroke research, neurology, and health innovation. A presentation at the congress places EMVision and our world-first technology in front of a global audience of physicians, researchers, healthcare leaders, and potential future customers.

EMVision's technology will also be presented at podium and demonstrated during break-out sessions at the upcoming 2025 Military Health System Research Symposium (MHSRS). The Symposium takes place August 4-7 in Kissimmee, Florida, and is the Department of Defense's premier scientific meeting intended to showcase cutting-edge research and innovation supporting the medical readiness needs of warfighters, to an audience of approximately 4,000 military, clinical and research attendees. The MHSRS presents an important opportunity to introduce EMVision's technology for potential point-of-care traumatic brain injury (TBI) diagnosis.

TBI is considered a 'signature injury' for US warfighters due to the high exposure to blasts, impacts, and battlefield trauma, leading to both immediate and long-term neurological consequences. More than 492,000 U.S. service members worldwide sustained a TBI resulting from military training, deployment, or day-to-day activities from November 2000–2023, according to data compiled by the Defense Health Agency Traumatic Brain Injury Center of Excellence. As a result, the Department of Defense (DOD) has been actively seeking portable TBI detection tools to enable rapid, objective assessment in the field to improve triage, treatment decisions, and long-term outcomes for affected service members.

## Carmel Monaghan appointed Non-Executive Director

In June 2025, EMVision announced the appointment of Carmel Monaghan as a Non-Executive Director who is an accomplished healthcare leader and brings a wealth of experience to EMVision. Ms Monaghan has worked across hospital, corporate and global positions at Ramsay Health Care for almost three decades. Prior to her appointment as CEO of Ramsay Australia in 2020, Ms Monaghan was the Group Chief of Staff of Ramsay's global operations, gaining extensive experience and a comprehensive understanding of healthcare operations and strategy in Australia and overseas. Ms Monaghan also served as the Group Head of Marketing and Public Affairs, driving marketing, brand and communications strategy, during which the group grew to become one of the leading private healthcare operators globally.

The appointment of Ms Monaghan comes at an important inflection point in EMVision's corporate journey, and we look forward to her contributions to the Company.

## Cash reserves of \$10.5 million as at 30 June 2025, bolstered by a \$0.4 million non-dilutive milestone payment received in July 2025, further non-dilutive funding available from secured grant programs (\$4.4m) and the FY25 R&D tax incentive rebate (FY24 \$2.1m).

The Company had cash reserves of \$10.5 million at the end of FY25. Subsequent to quarter end, the Company received a \$0.4 million milestone payment under the Australian Stroke Alliance grant program. Additional non-dilutive funding is available to EMVision from existing grant programs (\$4.4m) and the R&D tax incentive rebate for the year ended 30 June 2025, which is anticipated to be received before calendar year end.

Net operating cash outflows for the quarter were \$2.06 million. The Company benefited from non-dilutive grant funding of \$0.98 million, being the upfront payment from the recently awarded \$5.0 million Industry Growth Program Grant, as well as interest income of \$0.11m.

Net operating cash outflows included expenditure on research and development (R&D) activities totalling \$0.806 million (Q3 FY25: \$1.221 million), staff costs \$1.785 million (Q3 FY25: \$1.638 million) and corporate administration costs of \$0.682 million (Q3 FY25: \$0.557 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.

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. As noted earlier, the Company was delighted to be awarded an Australian Government Industry Growth Program (IGP) Commercialisation and Growth Grant of \$5 million during the quarter to accelerate the commercialisation of EMVision's First Responder portable brain scanner.

EMVision is appreciative of the significant financial and collaborative support it has received from the following grant programs that have greatly assisted the development and commercialisation of the emu™ Bedside Scanner and now the First Responder device:

Grant Program	Total Funding	Funding Remaining as at 30 June 2025
Australian Stroke Alliance	\$8.0 million	\$0.8 million <sup>1</sup>
Modern Manufacturing Initiative	\$5.0 million	Nil
NSW Medical Device Fund	\$2.5 million	Nil
Industry Growth Program	\$5.0 million	\$4.0 million <sup>2</sup>
Total	\$20.5 million	\$4.8 million

<sup>1</sup> 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.

<sup>2</sup> Refer to ASX Announcement "EMVision Awarded \$5m Non-Dilutive Government Grant" on 16 June 2025 for further details. Grant payments will be paid quarterly in advance, based on forecast eligible expenditure, adjusted for unspent amounts from previous payments. Payments are subject to satisfactory progress on the project against agreed activities.

As required by ASX Listing Rule 4.7C3, the Company notes that \$0.19 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, non-ionising, affordable and safe neurodiagnostic devices.

Our vision is to help transform and improve the timely diagnosis and treatment of stroke and traumatic brain injury, at the point-of-care.

EMVision has offices in Sydney and Brisbane [www.emvisionmedical.com](http://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**

38 620 388 230

**Quarter ended ("current quarter")**

30 JUNE 2025

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (12months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers / other income	-	164
1.2 Payments for		
(a) research and development	(806)	(3,608)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs including research and development staff	(1,785)	(6,847)
(f) administration and corporate costs	(682)	(2,200)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	106	577
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
- ASA grant income	-	600
- Industry Growth Fund (IGP) income	978	978
1.8 Other (provide details if material)		
- Net GST (paid) / received	129	104
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(2,061)</b>	<b>(8,111)</b>

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12months) \$A'000
<b>2.</b>	<b>Cash flows from investing activities</b>		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(10)	(49)
	(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)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>(10)</b>	<b>(49)</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
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)	-	-
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>-</b>	<b>(2)</b>

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12months) \$A'000
<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of period	12,585	18,657
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,061)	(8,111)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(10)	(49)
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)	11
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>10,505</b>	<b>10,505</b>

<b>5.</b>	<b>Reconciliation of cash and cash equivalents</b> 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	4,723	4,324
5.2	Call deposits	5,500	8,000
5.3	Bank overdrafts	(31)	(51)
5.4	Other (provide details) - term deposits for bank guarantees	313	312
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>10,505</b>	<b>12,585</b>

<b>6.</b>	<b>Payments to related parties of the entity and their associates</b>	Current quarter \$A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	190
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<i>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.</i>		



<b>7.</b>	<b>Financing facilities</b> <i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i> <i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	<b>Total financing facilities</b>	-	-
7.5	<b>Unused financing facilities available at quarter end</b> <div style="border: 1px solid black; height: 20px; width: 100%;"></div>		
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.		

<b>8.</b>	<b>Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1	Net cash from / (used in) operating activities (item 1.9)	(2,061)
8.2	Cash and cash equivalents at quarter end (item 4.6)	10,505
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	10,505
8.5	<b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	<div style="border: 1px solid black; padding: 5px;">5.10</div>
<i>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.</i>		
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		
<i>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.</i>		

## 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 July 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.