

## ASX Release

# APPENDIX 4C – 31 DECEMBER 2024 QUARTERLY ACTIVITIES & CASHFLOW REPORT

### Highlights:

- *Excellent results from pre-validation 'EMView' clinical trial allowed EMVision to confidently proceed with validation (pivotal) trial preparations to support an FDA De Novo clearance and product commercialisation for the emu™ Bedside Scanner.*
- *Commencement of the validation (pivotal) trial for the emu™ Bedside Scanner is fast approaching, pending ethics approval and local investigational site clearance.*
- *Transformative ultra-light weight First Responder Proof-of-Concept brain scanner device fabricated, healthy human volunteer study underway and commencement of road and air feasibility study imminent.*
- *Well-funded with proforma cash reserves of \$15.78 million (including the \$2.12 million FY24 R&D tax rebate received after quarter end). 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 6-month period ended 31 December 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:

### **emu™ Bedside Scanner advanced towards commercialisation**

During the quarter, EMVision advanced a number of initiatives towards the regulatory clearance and commercialisation of our first device, the emu™ Bedside Scanner.

#### *1. Neurodiagnostic algorithms deliver excellent results in EMView study:*

Results of the pre-validation 'EMView' clinical trial were released during the quarter, which showed very encouraging diagnostic performance test data and case studies, including the detection of small haemorrhages. The results demonstrated 92% sensitivity (scans of patients that do have the condition as a positive) and 85% specificity (scans of patients that do not have the condition as a negative) on haemorrhages (bleeds) vs non-haemorrhages, and 85% sensitivity and 78% specificity on ischemic strokes (clots) vs non-ischemia.

In addition, a clear trend was observed where diagnostic performance continued to increase on test data as further clinical training data was provided to the AI algorithms. This early test data positions the emu™ device favourably in the point-of-care neurodiagnostic environment.

2. *Validation (pivotal) trial preparations well progressed after positive FDA engagement, commencement of the validation (pivotal) trial fast approaching:*

Following positive engagement with the FDA during the quarter, EMVision is preparing for its validation (pivotal) trial to support FDA De Novo clearance (pathway to market for novel devices with a low-to-medium risk profile). A trial size of up to 300 suspected stroke patients is expected, with a primary endpoint of 'blood or not' sensitivity and specificity. Approximately 6 leading clinical sites (4 in the US, 2 in Australia) will be utilised, with an anticipated enrolment duration of 6 – 12 months. Assuming successful trial and regulatory outcomes, market entry is projected to be during CY26.

In November 2024, EMVision held engaging and productive site visits with US investigational sites. These site visits focused on study flow procedures, site suitability to execute the study in a timely manner, preliminary device training, and socialising the device with broader hospital leadership. The reception was overwhelmingly positive, with sites demonstrating their excellence in acute stroke research, enthusiasm for the EMVision project and the opportunity to positively transform clinical practice. The tour of US investigational sites culminated with an exhibition at the annual Society of Vascular and Interventional Neurologists (SVIN) conference, which provided a forum for EMVision to strengthen relationships with existing collaborators, generate leads for new collaborations and industry partnerships, and familiarised the US stroke community with the progress of our technology.

The commencement of the above validation (pivotal) trial for the emu™ device is fast approaching, pending ethics approval and local investigational site clearance. In the US, EMVision is seeking Non-Significant Risk ("NSR") medical device study designation to expedite the start-up process. A central Institutional Review Board (IRB) is engaged to assess the study for NSR and ethics approval. In Australia, EMVision is pursuing the same ethics approval process as established by the preceding 'EMView' pre-validation multi-site trial. In parallel with the ethics applications in US and Australia, local investigational site contracts and administrative elements are progressing well to ensure prompt study start-up targeted for this quarter.

EMVision has contracted Vastrax, a leading full-service clinical research organisation ("CRO") specialising in clinical neurovascular studies. Vastrax's team of experts have been directly responsible for similar acute stroke studies and will help ensure smooth progress from protocol development and ethics approval through participant enrolment and report publication. Several emu™ devices have already been built and commissioned to support the validation trial.

3. *Strategy for continuous innovation:*

EMVision's strategy for continuous innovation during the pivotal trials involves parallel and cost-effective clinical data collection initiatives across multiple sites. This data will provide a diverse set of clinical cases to support future algorithm advancements and software upgrades. This includes potential additional features, clinical indication expansion, and expanded training datasets for increased sensitivity and specificity.

**EMVision's second product, a transformative ultra-light weight First Responder Proof-of-Concept brain scanner device fabricated, healthy human volunteer study underway and road and air feasibility study imminent.**

Since unveiling the First Responder Proof-of-Concept device, two additional First Responder devices have been fabricated, alongside a series of ancillary accessories including purpose-built carry cases, battery packs and charging docks. An intuitive and easy-to-use graphical interface and workflow has been generated to enable scans to be captured in under 5 minutes.

A healthy human volunteer study is underway, and these additional devices are targeted for deployment in a pre-hospital feasibility study scheduled to commence this quarter. The aim of the study is to demonstrate the First Responder device's integration into pre-hospital patient care pathways, both under the challenging environmental conditions in aeromedical deployment to remote Australia and urban road ambulance use. The study's ethics application is well underway, with collaborating research sites preparing for study activation. Up to 30 participants are expected to be enrolled across aeromedical (Royal Flying Doctor Service) and road ambulance study arms.

**Proforma cash reserves of \$15.78 million as at 31 December 2024 including the \$2.12 million FY24 R&D tax rebate received after quarter end.**

The Company had cash reserves of \$13.66 million at the end of Q2 FY25 following net operating cash outflows of \$3.27 million during the quarter. The Company's funding position increased after quarter-end, with the receipt of a \$2.12m R&D tax rebate relating to activities in FY24.

Net operating cash outflows included expenditure on research and development (R&D) activities totalling \$1.179 million (Q1 FY25: \$0.402 million), staff costs \$1.750 million (Q1 FY25: \$1.673 million) and corporate administration costs of \$0.459 million (Q1 FY25: \$0.502 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. R&D costs increased in the current quarter due to the purchase of components for devices to be used in the upcoming validation trial.

Net investing cash outflows for the quarter were \$0.01 million, being minor equipment capex to support R&D 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 targeted for first quarter CY 2025 (\$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 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:

<b>Grant Program</b>	<b>Total Funding</b>	<b>Funding Remaining as at 30 September 2024</b>
Australian Stroke Alliance	\$8.0 million	\$0.80 million <sup>1</sup>
Modern Manufacturing Initiative	\$5.0 million	Nil <sup>2</sup>
NSW Medical Device Fund	\$2.5 million	Nil <sup>3</sup>
<b>Total</b>	<b>\$15.5 million</b>	<b>\$0.80 million</b>

<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 "\$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.

<sup>3</sup> 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](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")**

31 DECEMBER 2024

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (6months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers / other income	86	86
1.2 Payments for		
(a) research and development	(1,179)	(1,581)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs including research and development staff	(1,750)	(3,423)
(f) administration and corporate costs	(459)	(961)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	147	319
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
1.8 Other (provide details if material)		
- Net GST (paid) / received	(114)	(32)
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(3,268)</b>	<b>(4,991)</b>

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (6months) \$A'000
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(11)	(30)
(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 Net cash from / (used in) investing activities</b>	<b>(11)</b>	<b>(30)</b>

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

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (6months) \$A'000</b>
<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	16,855	18,657
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,268)	(4,991)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(11)	(30)
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	85	28
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>13,661</b>	<b>13,661</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	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
5.1	Bank balances	2,373	5,586
5.2	Call deposits	11,000	11,000
5.3	Bank overdrafts	(24)	(42)
5.4	Other (provide details) - term deposits for bank guarantees	312	311
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>13,661</b>	<b>16,855</b>

<b>6.</b>	<b>Payments to related parties of the entity and their associates</b>	<b>Current quarter \$A'000</b>
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	-
<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>		

## Quarterly cash flow report for entities subject to Listing Rule 4.7B

<b>7. Financing facilities</b>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
<i>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.</i>		
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
<b>7.4 Total financing facilities</b>	-	-
<b>7.5 Unused financing facilities available at quarter end</b>	[ ]	
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. Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (item 1.9)	(3,268)
8.2 Cash and cash equivalents at quarter end (item 4.6)	13,661
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	13,661
<b>8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	4.18
<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: .....28 January 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.