30/07/2024

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

ASX Release

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

Highlights:

- *Interim Stage 2 pre-validation clinical trial analysis confirms hyperacute and acute ischaemic stroke detection capabilities.*
- *Recruitment target for Stage 3 of the pre-validation clinical trial achieved (30 haemorrhagic stroke patients). These additional data sets support the advancement of EMVision's neurodiagnostic AI algorithms to aid in the diagnosis of suspected haemorrhagic or ischaemic stroke.*
- *FDA pre-submission package under FDA review prior to a consultation meeting in the coming months. The FDA pre-submission is a critical confirmation of the requirements for EMVision's upcoming validation clinical trial to support market entry.*
- *Pilot commercial production line established for point-of-care emu™ brain scanner. Achievement of this milestone enabled receipt of the final $1,250,000 non-dilutive cash payment under the Company's $5 million Modern Manufacturing Initiative (MMI) grant award.*
- *Fabrication of the First Responder (Gen 2) Proof of Concept device completed. Healthy human volunteer study to commence shortly, followed by road and air environment clinical studies targeted later this calendar year.*
- *Well-funded with cash reserves of $18.66 million. Activities for the remainder of calendar year 2024 will be supported by further non-dilutive funding from the Company's FY24 R&D Tax Incentive claim, currently being prepared, 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 12-month period ended 30 June 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:

Interim Stage 2 clinical trial analysis confirms hyperacute and acute ischaemic stroke detection capabilities

During the quarter, EMVision was pleased to share further positive interim analysis from the latest phase of its clinical trials. These multi-site clinical trials are focused on advancing EMVision's neurodiagnostic AI algorithms to aid in the diagnosis of suspected haemorrhagic or ischaemic stroke.

In Stage 2 of the pre-validation trial, a total of 180 patients were enrolled, being patients who presented to the emergency department with stroke-like symptoms, across the three trial sites: Liverpool Hospital, Royal Melbourne and Princess Alexandra Hospital Brisbane.

EMVision reported hyper acute and acute ischaemic detection and classification capabilities from interim cross validation analysis of the Stage 2 multisite trial data. This included several cases of early ischaemia that were positively detected and classified by the emu™ AI algorithms that were not detected on Non-Contrast CT (plain CT). In these clinical cases, the suspected ischaemic cases required confirmation via CT Angiogram (CTA), CT Perfusion (CTP) or MRI.

Advanced imaging is used to help identify patients with suspected ischaemia and large vessel occlusion that may benefit from thrombectomy (clot retrieval). This enables the correct triage, transfer or intervention decisions to be made, to reduce reperfusion (blood flow restoration) times and improve patient outcomes. Today, many patients are initially transferred to a hospital that does not have thrombectomy capabilities which can result in substantial treatment delays and worse patient outcomes. The average acute ischaemic stroke patient loses 1.9 million neurons per minute, and every 30-minute delay in reperfusion decreases the chance of a good functional outcome by approximately 10%. CTP and MRI are advanced imaging capabilities that are not widely available in many resource constrained settings and are not typically available on Mobile Stroke Units.

See ASX release 'Interim Stage 2 analysis confirms hyperacute and acute ischaemic stroke detection capabilities' 27th May 2024 for further information.

Stage 3 clinical trial recruitment target achieved and FDA engagement underway for validation trial

In early July, EMVision advised that its recruitment target for Stage 3 of its multi-site pre-validation clinical trial had been achieved (30 haemorrhagic stroke patients), and the Company's FDA pre-submission package for its upcoming validation trial had been delivered.

Rapid achievement of the Stage 3 recruitment target is attributed to continued positive engagement at the investigational sites and introduction of several recruitment accelerating initiatives.

In addition to haemorrhagic stroke patients, the Stage 3 cohort includes a large number of ischaemic stroke participants, providing valuable data to enhance EMVision's AI algorithm's "blood or not" and "ischaemia or not" neurodiagnostic capabilities. Following final participant recruitment, investigational sites are collating all relevant data, which then undergoes verification by the study's Contract Research Organisation (CRO), Avania, before final delivery to EMVision. Once all the data is received and verified, it will be analysed with Stage 3 results reporting anticipated during H2 CY2024.

The Company's FDA pre-submission package is under FDA review prior to a consultation meeting in the coming months. The FDA pre-submission is a critical confirmation of requirements for EMVision's upcoming Validation clinical trial to support market entry. In parallel, activities to initiate the Validation clinical trial are well under way, including protocol finalisation, CRO appointment and engagement of investigational sites including luminary US stroke centres.

Pilot production line for emu™ brain scanner established

During the quarter, EMVision established a pilot commercial production line for its point-of-care emu™ brain scanner. The production line, at EMVision's Macquarie Park premises, has an initial capacity for the build, test and release of approximately one emu™ brain scanner per week. With modest personnel additions, under its current configuration, the production line is anticipated to have capacity for the build, test and release of up to 3 emu™ brain scanner devices per week.

Achievement of this milestone enabled receipt of the final $1,250,000 non-dilutive cash payment under the Company's $5 million Modern Manufacturing Initiative (MMI) Medical Products Translation stream grant award.

First Responder Proof-of-Concept device fabricated with studies to commence shortly

Subsequent to quarter end, EMVision was pleased to advise of the fabrication of the Company's First Responder (Gen 2) Proof of Concept device. The First Responder Proof-of-Concept 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 full brain coverage in a single scan. It represents an opportunity to fundamentally transform stroke and traumatic brain injury outcomes for all patients, regardless of their location, by delivering sophisticated neurodiagnostic technology directly to the point of care.

The device will now be the subject of a series of studies and developments including usability, reliability, software development, functionality and other tests intended to meet international regulatory requirements. This will commence shortly with a healthy human volunteer study, followed by road and air environment clinical studies targeted to commence later this calendar year.

Cash reserves of $18.66 million as at 30 June 2024

The Company had cash reserves of $18.66 million at the end of Q4 FY24 including net operating cash outflows of $2.58 million. In the quarter, EMVision benefited from interest income of $0.18 million and non-dilutive grant funding of $1.25 million from the Modern Manufacturing Initiative grant program.

Net operating cash outflows included expenditure on research and development (R&D) activities totalling $1.896 million (Q3 FY24: $0.797 million), staff costs $1.496 million (Q3 FY24: $1.410 million) and corporate administration costs of $0.613 million (Q3 FY24: $0.408 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. Expenditure on R&D activities increased during the quarter due to component purchases for emu™ devices required for the upcoming validation trial.

Net investing cash outflows for the quarter were $0.06 million, being minor equipment capex to support R&D activities.

EMVision's activities for the remainder of calendar year 2024 will be supported by further non-dilutive funding from its FY24 R&D Tax Incentive claim, currently being prepared, and the Australian Stroke Alliance (ASA) grant program. EMVision has submitted the required documentation to the ASA to trigger a further $600,000 non-dilutive milestone payment on completion of the "Ambulance Device Fabrication" milestone. 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 later this year ($400,000).

EMVision actively pursues non-dilutive funding opportunities and 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 June 2024
Australian Stroke Alliance	$8.0 million	$1.40 million[1]
Modern Manufacturing Initiative	$5.0 million	Nil[2]
NSW Medical Device Fund	$2.5 million	Nil[3]
Total	$15.5 million	$1.40 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 $0.175 million was paid to related parties during the quarter (as noted in section 6 of the attached Appendix 4C) and these payments were salaries, Directors fees and superannuation paid to Directors.

Authorised for release by the Board of the Company.

[ENDS]

For further information, media or investor enquiries, please contact:

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About EMVision Medical Devices

EMVision Medical Devices Limited (ASX:EMV) is an innovative Australian medical device company developing a novel approach to looking inside the human body. Our product pipeline includes portable, non-invasive, affordable and safe neuroimaging devices.

Our vision is to help transform and improve the timely diagnosis and treatment of stroke and other time sensitive medical emergencies, at the point-of-care.

EMVision has offices in Sydney and Brisbane www.emvisionmedical.com

Forward-looking Statements

This release may contain certain forward-looking statements with respect to matters including but not limited to the financial condition, results of operations and business of EMVision and certain of the plans and objectives of EMVision with respect to these items. These forward-looking statements are not historical facts but rather are based on EMVision's current expectations, estimates and projections about the industry in which EMVision operates, and its beliefs and assumptions. Words such as "anticipates," "expects," "intends," "plans," "believes," "seeks," "estimates", "guidance" and similar expressions are intended to identify forward looking statements and should be considered an at-risk statement. Such statements are subject to certain risks and uncertainties, particularly those risks or uncertainties inherent in the process of developing technology and in the endeavour of building a business around such products and services. These statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties and other factors, some of which are beyond the control of EMVision, are difficult to predict and could cause actual results to differ materially from those expressed or forecasted in the forward looking statements. EMVision cautions shareholders and prospective shareholders not to place undue reliance on these forward-looking statements, which reflect the view of EMVision only as of the date of this release. The forward-looking statements made in this announcement relate only to events as of the date on which the statements are made. EMVision will not undertake any obligation to release publicly any revisions or updates to these forward-looking statements to reflect events, circumstances or unanticipated events occurring after the date of this announcement except as required by law or by any appropriate regulatory authority.

Inherent risks of Investment in Medical Device development Companies

There are a number of inherent risks associated with the development of new medical device products to a marketable stage. The clinical trial process, which is often lengthy, is designed to assess the safety and efficacy of a device prior to commercialisation and there is no guarantee of achieving the outcomes necessary to generate a viable commercial product. Other risks include uncertainty of patent protection and proprietary rights, the obtaining of necessary regulatory authority approvals and the evolving competitive landscape. Companies such as EMVision are dependent on the success of their research and development projects, product development and on the ability to attract funding to support these activities. Investment in research and development and novel product development cannot be assessed on the same fundamentals as trading and manufacturing enterprises. Therefore investment in Companies specialising in such development must be regarded as speculative. EMVision recommends that professional investment advice be sought prior to such investments and cautions investors that the risks of an investment in an entity such as EMVision is not limited to the risks disclosed in this announcement.

Appendix 4C

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

Name of entity	
EMVISION MEDICAL DEVICES LTD	
ABN	**Quarter ended ("current quarter")**
38 620 388 230	30 JUNE 2024

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (12months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(1,896)	(4,019)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs including research and development staff	(1,496)	(5,698)
	(f) administration and corporate costs	(613)	(2,070)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	185	341
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	-	2,586
	- MMI grant income	1,250	1,250
	- ASA grant income	-	1,800
1.8	Other (provide details if material)		
	- Net GST (paid) / received	(13)	(208)
1.9	**Net cash from / (used in) operating activities**	**(2,583)**	**(6,018)**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12months) $A'000
2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(58)	(455)
	(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**	**(58)**	**(455)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	15,281
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	-	(32)
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**	**-**	**15,249**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12months) $A'000
4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	21,347	9,929
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,583)	(6,018)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(58)	(455)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	15,249
4.5	Effect of movement in exchange rates on cash held	(49)	(48)
4.6	**Cash and cash equivalents at end of period**	**18,657**	**18,657**

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	5,368	6,566
5.2	Call deposits	13,000	14,500
5.3	Bank overdrafts	(22)	(29)
5.4	Other (provide details) - term deposits for bank guarantees	311	310
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**18,657**	**21,347**

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	175
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.

7.	**Financing facilities** *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the sources of finance available to the entity.*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	-	-

7.5	**Unused financing facilities available at quarter end**	
7.6	Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.	

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(2,583)
8.2	Cash and cash equivalents at quarter end (item 4.6)	18,657
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	18,657
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	7.22

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 July 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 – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.