31/01/2024

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ASX Release

APPENDIX 4C – 31 DECEMBER 2023 QUARTERLY ACTIVITIES & CASHFLOW REPORT

Highlights:

- *Stage 2 patient recruitment target achieved for the clinical trial pre-validation phase. Activating Stage 3 of the trial (pre-validation) as planned with additional haemorrhagic stroke samples expected to enable fine tuning of AI algorithms and further increase confidence going into validation.*
- *Preparations underway for a pre-submission meeting with the FDA in the coming months. This meeting aims to establish a consensus with the FDA on critical elements of EMVision's validation trial design.*
- *First interim 'blood or not' algorithm analysis with encouraging initial test results published as an abstract in the International Journal of Stroke as part of the 15th World Stroke Congress, Toronto October 2023.*
- emu™ *showcased at Radiological Society of North America Annual Meeting 2023, in collaboration with Keysight Technologies (NYSE:KEYS), generating significant clinical and industry interest.*
- *An advanced 28-antenna prototype of the ultra-light weight Gen 2 first responder unit, designed for road and air ambulance deployment, was assembled and successfully bench-tested.*
- *Well-funded with cash reserves of $8.45 million and a further $3.25 million of non-dilutive funding available from current grant programs, subject to delivery of milestones.*

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 2023.

EMVision is developing and commercialising medical imaging diagnostics for various disease states and medical emergencies. The Company's primary focus is a portable, cost effective, non-invasive brain scanner to monitor and help with the diagnosis of brain injuries and stroke by creating rapid images of the brain at the point-of-care.

Key activities undertaken during the quarter are outlined below:

Multi-Site Clinical Trials Progressing Well

EMVision reached its Stage 2 patient recruitment target for its pre-validation clinical trial across the three sites: Liverpool Hospital, Royal Melbourne Hospital and Princess Alexandra Hospital, Brisbane.

The study has successfully enrolled a diverse cohort of participants, including patients presenting with acute haemorrhagic and ischemic strokes (notably, this includes a significant subset of large vessel occlusions (LVO)) and a considerable variety of prevalent stroke mimics, such as migraines and seizures, among others.

Feedback from both operators and patients has been highly positive. The company is focused on the finalisation of the Stage 2 dataset, which involves detailed analysis of imaging lab ground truth (a critical step in ensuring the validity and reliability of medical imaging data) and verification of data quality. Stage 2 results are anticipated to be reported in Q1 CY2024.

EMVision is now activating Stage 3 of the trial (pre-validation) as planned. Study stage transition administration is currently underway with recruitment expected to recommence within weeks. Stage 3 allows for continued recruitment of any suspected stroke patient until up to a further 30 haemorrhagic stroke cases are recruited. The clinical research teams are well-resourced and highly engaged and committed to accelerating patient recruitment and trial execution through this last phase before validation.

Interim Algorithm Analysis Completed

An interim algorithm analysis was completed that provided an encouraging indicator of the robustness of the 'blood or not' classification model. This supports the ability of simulation data to accurately represent real-world clinical scenarios, notwithstanding that the sample size was too small to draw definitive conclusions on algorithm performance. This interim analysis was subsequently published in the International Journal of Stroke as part of the 15th World Stroke Congress, Toronto October 2023.

It is anticipated that once completed, the pre-validation trial datasets (including the broad range of cases from Stages 2 and 3) will provide important training and fine-tuning data for the emu™ AI algorithms. This is intended to help mitigate risks and further increase confidence going into the validation trial phase, primarily to confirm device sensitivity and specificity, in support of an FDA submission.

Preparations for FDA Pre-Submission Meeting Underway

In parallel, preparations are underway for a pre-submission meeting with the FDA in the coming months. This meeting aims to establish a consensus with the FDA on critical elements of EMVision's validation trial design. Achieving agreement on critical trial design aspects such as sample composition, data collection methodology and objectives, we anticipate a streamlined FDA data review process as part of a future market access submission.

emu™ Unveiled at RSNA 2023

EMVision and Keysight jointly showcased the emu™ device at Radiological Society of North America (RSNA) Annual Meeting 2023 in November, the world's premier medical imaging conference with over 34,000 clinicians and industry professionals in attendance. This was the first time EMVision has exhibited on the international stage, receiving significant clinical and industry interest in both EMVision's emu™ brain scanner and the use of ultra-high frequency radio signals as an emerging point-of-care medical imaging modality.

The EMVision leadership team was on hand during the event to provide product demonstrations and share clinical case studies and field questions. On average, a new enquiry/lead was generated every 10 minutes during the exhibition. This surge in interest came from prominent clinical centres in the United States and Europe, among others, and was accompanied by positive interactions and engagement with global medical imaging Original Equipment Manufacturers (OEMs) and independent distributors.

First Responder System on Track to Hit the Road and Skies

An advanced 28-antenna prototype of EMVision's ultra-light weight Gen 2 first responder unit, designed for road and air ambulance deployment, was assembled and subject to bench-testing. This testing evaluated a range of technical parameters against simulations and progressed to target detection in a three-dimensional environment.

The system successfully passed these initial tests and electromechanical and industrial design work is ongoing to evolve the advanced 28-antenna prototype system into a "fit for purpose" unit ready for road and air testing with our collaborators, the Australian Stroke Alliance, this year. Additionally, an ethics submission was made during the quarter to facilitate usability and ergonomic testing with healthy volunteers in the coming months.

Cashflow commentary, cash reserves of $8.45 million as at 31 December 2023.

The Company had cash reserves of $8.45 million at the end of Q2 FY24 following net operating cash inflows of $0.65 million. EMVision benefited from substantial non-dilutive cash funding in the quarter of $3.2 million. This included grant funding from the Australian Stroke Alliance ($0.6 million) and $2.6 million from the Company's R&D tax incentive claim for the financial year ending 30 June 2023.

Operating cash outflows included expenditure on research and development (R&D) activities totalling $0.746 million (Q1 FY24: $0.580 million), staff costs $1.330 million (Q1 FY24: $1.461 million) and corporate administration costs of $0.485 million (Q1 FY24: $0.562 million). Staff costs includes 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.

EMVision actively pursues non-dilutive funding opportunities and is appreciative of the financial and collaborative support from the following grant programs:

Grant Program	Total Funding	Funding Remaining as at 31 December 2023
Australian Stroke Alliance	$8.0 million	$2.0 million[1]
Modern Manufacturing Initiative	$5.0 million	$1.25 million[2]
NSW Medical Device Fund	$2.5 million	Nil[3]
Total	$15.5 million	$3.25 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). 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 $0.170 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]

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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 DECEMBER 2023

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (6months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers		
	- CRC-P participant contributions	-	-
1.2	Payments for		
	(a) research and development	(746)	(1,326)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs including research and development staff	(1,330)	(2,791)
	(f) administration and corporate costs	(485)	(1,047)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	26	95
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	2,586
	- MMI grant income	-	-
	- ASA grant income	600	1,200
1.8	Other (provide details if material)		
	- Net GST (paid) / received	(1)	(147)
1.9	**Net cash from / (used in) operating activities**	**651**	**(1,429)**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6months) $A'000
2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(15)	(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)	-	-
2.6	**Net cash from / (used in) investing activities**	**(15)**	**(49)**

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	-	-
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**	**-**	**-**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6months) $A'000
4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	7,814	9,929
4.2	Net cash from / (used in) operating activities (item 1.9 above)	651	(1,429)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(15)	(49)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	-
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**8,451**	**8,451**

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	4,171	2,411
5.2	Call deposits	4,000	5,102
5.3	Bank overdrafts	(30)	(8)
5.4	Other (provide details) - term deposits for bank guarantees	309	309
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**8,451**	**7,814**

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	170
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)	651
8.2	Cash and cash equivalents at quarter end (item 4.6)	8,451
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	8,451

8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	N/A

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: ....31 January 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.