24/04/2024

EMVision Medical Devices Ltd
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Level 10, 12 Creek Street,
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ASX Release

APPENDIX 4C – 31 MARCH 2024 QUARTERLY ACTIVITIES & CASHFLOW REPORT

Highlights:

- *Strategic $15.28 million investment secured via a placement to Keysight Technologies Inc (NYSE:KEYS), a long-standing technology collaborator of the Company; provides funding to support the commercialisation phase of the emu™ device with market entry targeted for next year.*
- *Stage 2 clinical trial interim analysis confirms strong AI model performance in determining in suspected acute stroke haemorrhage or not ('blood or not'); emu™ device fits well into acute stroke workflows, in time sensitive situations, with a mean scan time of 5.5 minutes and encouraging usability feedback.*
- *Stage 3 of multi-site clinical trial (pre-validation) recruitment on track.*
- *Design and development activities for the ultra-lightweight Gen 2 first responder unit are culminating in the near-term assembly of the proof-of-concept unit.*
- *Preparations underway for a pre-submission meeting with the FDA on critical elements of EMVision's Validation trial design.*
- *Well-funded with cash reserves of $21.35 million and a further $2.65 million of non-dilutive funding available from current grant programs, subject to delivery of milestones and satisfactory reporting.*

EMVision Medical Devices Limited (ASX:EMV) ("EMVision" or the "Company") is pleased to lodge the following update and attached Appendix 4C Quarterly Cashflow Report for the 9-month period ended 31 March 2024.

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:

Strategic $15.28m Investment From Keysight Technologies (NYSE:KEYS)

During the quarter, EMVision was pleased to secure a $15.28 million investment from Keysight Technologies Inc ("Keysight"), with which it has had a long-standing technology collaboration. The investment was via a placement of 7,454,231 ordinary shares at an issue price of $2.05 per share, representing 8.73% of EMVision's issued share capital.

Keysight (NYSE:KEYS), part of the S&P 500, is a technology company headquartered in California, with a market capitalisation of approximately US$26 billion. This investment represents Keysight's first investment globally in enabling innovation in point-of-care medical imaging, demonstrating its strong belief in the clinical and commercial value of EMVision's innovative neuroimaging technology.

EMVision and Keysight's collaboration began with a new generation of Vector Network Analysers (VNA) for the healthcare market and resulted in the development of a miniaturised and high-performance VNA which is now embedded in every emu™ device. The companies jointly showcased EMVision's world first point-of-care brain scanner emu™ device at the Radiological Society of North America meeting in November 2023.

The investment provides substantial funding to support the commercialisation phase of its emu™ device, which is targeting market entry next year. Key initiatives the investment supports include:

- accelerating recruitment in its current multi-site trials
- attaining comprehensive data sets during the upcoming clinical trial validation phase, which are essential for confirming the product's sensitivity and specificity in support of FDA approval
- increasing the production of emu™ devices for targeted clinical trials at prestigious stroke centres in the US, the world's largest healthcare market

Stage 2 clinical trial insights confirm stroke diagnostic and clinical viability

During the quarter, interim analysis was conducted on data from Stage 2 of the Company's ongoing (pre-validation) multi-site clinical trials. Stage 2 has enrolled a total of 180 patients presenting to the emergency department with stroke like symptoms across the three trial sites: Liverpool Hospital, Royal Melbourne and Princess Alexandra Hospital Brisbane. The data set included 75 ischaemic stroke, 18 haemorrhagic stroke, 20 transient ischaemic attacks and 67 stroke mimics.

Per protocol, data from Stage 2 is being used to enhance AI algorithms in preparation for the upcoming validation (sensitivity/specificity confirmation) trial phase. The AI model is in a continuous development and integration phase and will progress with data obtained in Stage 3 of the pre-validation trial phase, for which EMVision is currently recruiting.

This interim analysis confirmed strong AI model performance in answering the important clinical question in acute stroke of haemorrhage or not ('blood or not'). The interim stroke diagnostic performance aligned with expectations following first deployment of emu™ in this front door study of a wide variety of acute strokes and mimics, providing confidence in achieving desirable validation (sensitivity/specificity) outcomes. An abstract related to the Stage 2 insights has been accepted for the 10th European Stroke Organisation Conference (ESOC 2024) in Basel, Switzerland in May.

Time metrics from Stage 2 are also important to quantify the emu™ device's ability to comfortably fit within streamlined stroke care workflows, and to ensure the cohort represents acute stroke early after the onset of stroke symptoms. The mean time from the start of scan data acquisition to removal of the device as measured by the emu device software logs was 5.5 minutes (range of 4.2 to 14.6 minutes), confirming the emu™ device seamlessly fits into acute stroke workflows, in time sensitive situations.

Interim analysis for the ischemia cohort is pending data processing, with further insights from the patient data collected anticipated to be shared this quarter. Refer to ASX Announcement "Stage 2 Insights Confirm Stroke Diagnostic and Clinical Viability" released on 27 March 2024 for further details.

Preparations well advanced for a pre-submission meeting with the FDA

The United States Food and Drug Administration ("FDA") will be engaged via the pre-submission program to clarify and confirm the points remaining to finalise the Validation Trial design. The pre-submission program begins with our delivery of a pre-submission document package, including context about our device and regulatory approach, as well as the points for discussion. The pre-submission package is well advanced for near-term submission. The FDA will then review the pre-submission package and provide written feedback, prior to meeting, to discuss in detail. Following this meeting, EMVision will finalise the Validation Trial design (such as endpoints, minimum performance criteria, sample size and site locations) aligned to FDA expectations, ensuring that the trial will deliver the clinical data critical to the emu™ device's De Novo market clearance application.

First Responder System on Track to Hit the Road and Skies

The design and development activities for the ultra-lightweight Gen 2 first responder device are progressing well and leading to the near-term assembly of the proof-of-concept unit. This unit will be the subject of healthy human volunteer testing, for which ethics approval has already been received. These activities then lead into planned pre-hospital road and air ambulance studies later this year.

Cash reserves of $21.35 million as at 31 March 2024

The Company had cash reserves of $21.35 million at the end of Q3 FY24 including the Keysight investment, net operating cash outflows of $2.00 million and net investing cash outflows of $0.35 million. EMVision also benefited from non-dilutive grant funding in the quarter of $0.6 million from the Australian Stroke Alliance.

Net operating cash outflows included expenditure on research and development (R&D) activities totalling $0.797 million (Q2 FY24: $0.746 million), staff costs $1.410 million (Q2 FY24: $1.330 million) and corporate administration costs of $0.408 million (Q2 FY24: $0.485 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.

Net investing cash outflows of $0.35 million during the quarter included the purchase of perpetual licenses for specialist engineering software.

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 March 2024
Australian Stroke Alliance	$8.0 million	$1.40 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	$2.65 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 $0.165 million was paid to related parties during the quarter (as noted in section 6 of the attached Appendix 4C) and these payments were salaries, Directors fees and superannuation paid to Directors.

Authorised for release by the Board of the Company.

[ENDS]

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

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About EMVision Medical Devices

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

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

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

Forward-looking Statements

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

Inherent risks of Investment in Medical Device development Companies

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

Appendix 4C

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

Name of entity	
EMVISION MEDICAL DEVICES LTD	
ABN	**Quarter ended ("current quarter")**
38 620 388 230	31 MARCH 2024

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (9months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(797)	(2,123)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs including research and development staff	(1,410)	(4,202)
	(f) administration and corporate costs	(406)	(1,453)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	60	156
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	-	-
	- ASA grant income	600	1,800
1.8	Other (provide details if material)		
	- Net GST (paid) / received	(48)	(195)
1.9	**Net cash from / (used in) operating activities**	**(2,002)**	**(3,431)**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9months) $A'000
2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(349)	(397)
	(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**	**(349)**	**(397)**

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

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9months) $A'000
4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	8,451	9,929
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,002)	(3,431)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(349)	(397)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	15,249	15,249
4.5	Effect of movement in exchange rates on cash held	2	2
4.6	**Cash and cash equivalents at end of period**	**21,347**	**21,347**

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	6,566	4,171
5.2	Call deposits	14,500	4,000
5.3	Bank overdrafts	(29)	(30)
5.4	Other (provide details) - term deposits for bank guarantees	310	309
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**21,347**	**8,451**

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	165
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)	(2,002)
8.2	Cash and cash equivalents at quarter end (item 4.6)	21,347
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	21,347
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	10.7

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: ....24 April 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.