28/07/22

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ASX Release

APPENDIX 4C – 30 SEPTEMBER 2022 QUARTERLY ACTIVITIES & CASHFLOW REPORT

Highlights:

- *Ethics approval received for upcoming multi-centre clinical trial; 1st Gen portable brain scanner devices scheduled for delivery to first site in November 2022 to commence clinical trial upon governance "green light".*
- *During device commissioning for the trial, valuable intellectual property relating to factory and in-situ calibration techniques has been generated, alongside internal hardware verification confirming the 1st Gen hardware performance is significantly improved upon our original clinical prototype.*
- *$5m Modern Manufacturing Initiative (MMI) non-dilutive grant Funding Agreement signed, unlocking $2m upfront payment. The Medical Products Manufacturing Translation Stream award will support establishment of commercial production of EMVision's 1st Gen portable brain scanner product.*
- *IDR Medical conducted valuable US market assessment providing insights on current stroke patient workflows, evaluation of the EMVision value proposition, alongside testing willingness to pay, pricing models, likely use profile and scan volumes. These insights have reaffirmed the strength of our product value proposition, the multitude of unmet clinical need opportunities available to us and confidence in our go-to-market strategy.*
- *IP Portfolio strengthened, US Patent allowed relating to one of EMVision's imaging techniques.*
- ***Substantial non-dilutive cash funding of at least $5.7 million expected in the next quarter** from grant programs and the Company's FY22 R&D tax incentive rebate. Cash reserves of $4.9 million as at 30 September 2022.*

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 3-month period ended 30 September 2022.

In partnership with The University of Queensland (UQ), 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-centre clinical trial ethics approval obtained, 1st Gen portable brain scanner devices scheduled to be delivered to first clinical site in November 2022 to commence clinical trial.

During the quarter, EMVision received Human Research Ethics Committee (HREC) approval for its multi-centre clinical study which will take place at leading comprehensive stroke centres including Liverpool Hospital (NSW), Royal Melbourne (VIC) and the Princess Alexandra Hospital (QLD). Activation of the first site, Liverpool Hospital, under the direction of principal investigator, Dr Dennis Cortado, is expected to proceed in November 2022, following receipt of the governance "green light" letter.

1st Gen product advancement

During the process of device commissioning for the upcoming clinical trial, valuable intellectual property relating to factory and in-situ calibration techniques has been generated, alongside internal hardware verification confirming 1st Gen hardware performance is significantly improved upon our original clinical prototype. In addition, documentation relating to the safety of the device has been generated which will support EMVision's technical file for future regulatory submissions.

$5m Modern Manufacturing Initiative (MMI) non-dilutive grant Funding Agreement signed

EMVision was awarded $5 million in non-dilutive funding under the Federal Government's Modern Manufacturing Initiative ("MMI") Medical Products Manufacturing Translation Stream to establish commercial production of EMVision's 1st Gen portable brain scanner product. This includes supporting quality systems, engineering personnel, equipment, tooling, production line fit out for in-house manufacture and other relevant eligible expenditure planned to transition to commercial production. Additional project expenditure will be funded by EMVision's current and future cash reserves. An initial upfront $2 million payment has been triggered with execution of the Funding Agreement.

The MMI grant is consistent with EMVision non-dilutive funding strategy which involves the pursuit of complimentary federal and state grant opportunities to accelerate the commercialisation of EMVision's novel technology portfolio.

IDR Medical commissioned to explore unmet needs in stroke care and assess the US market opportunity; uncovered valuable insights

IDR Medical, a leading international medical market research and consulting firm, conducted a valuable US market assessment providing insights on current stroke patient workflows, evaluation of EMVision's value proposition, alongside testing willingness to pay, pricing models, likely use profile and scan volumes. 20 in-depth interviews with decision makers in hospital stroke centres were conducted. This cohort included neurologists, neuro intensivists, stroke nurses and interventional neuroradiologists. Respondents were from academic teaching & community hospital stroke centres with more than 250 beds and saw a minimum of 20 new stroke patients per month. They were required to be involved in decisions to purchase Point-of-Care imaging technology for the diagnosis and/or monitoring of stroke.

The overall response to EMV's 1st Gen was positive, with 18/20 respondents highly interested in having access to the device in their facility. The device's portability, ease of use and non-ionizing radiation convinced respondents that it could be a "game changer" for routine monitoring of patients' post-treatment / intervention at the Point-of-Care as it would help clinical staff to look for signs of change / deterioration and potentially inform treatment decisions or further scanning. Most believed that using the device at this stage in the workflow would also help to address patient transportation and staff shortage challenges. Significant patient volume, staff shortages, patient location, and transportation challenges/bottlenecks were identified as having an impact on imaging access across every phase of the stroke patient pathway today. An assumed scan volume of 5 scans per day per system at stroke centres was considered too low if being used for routine monitoring, with closer to ~20 scans per day considered reasonable. The responses also indicated a potential benefit in rural / non-hospital settings where CT and/or specialist staff access is more difficult. In this setting the device could be utilized as a tool to inform patient transfer decision making – where there is no access to CT.

Whilst the response to the proposed subscription model was largely positive, capital expenditure was the preferred purchase model overall, with most implying that this is typically how their facility acquires imaging equipment. 60% of the sample considered the target price of $150,000 USD to be reasonable and the highest presented price ($200,000 USD) was considered reasonable by 50%.

These insights have reaffirmed the strength of our product value proposition, the multitude of unmet clinical need opportunities available and confidence in EMVision's go-to-market strategy.

IP position strengthened with US patent

The United States ('US') Patent and Trademark Office ("USPTO") has issued a notice of allowance for the patent Application No16/620430. The allowed patent application is related to one of EMVision's imaging techniques; "A tomographic imaging process and system". The notice of allowance confirms that, following examination of the Patent Application, the USPTO considers EMVision is entitled to a patent under US patent law. The priority date for the accepted patent was established by the original Australian application filed on 8th June 2017.

EMVision's IP protection strategy includes a number of patent applications across novel software, hardware and integration elements.

Cashflow commentary, cash reserves of $4.9 million as at 30 September 2022, substantial non-dilutive cash funding of at least $5.7 million expected in the next quarter.

The Company had cash reserves of $4.9 million at the end of the quarter following net operating cash outflows of $1.9 million.

Operating cashflows included expenditure on research and development (R&D) activities totalling $0.320 million (Jun22Q: $0.911 million), staff costs $1.182 million (Jun22Q: $1.257 million) and corporate administration costs of $0.372 million (Jun22Q: $0.483 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 initial set up costs for the upcoming clinical trial.

The Company also had minor investing and financing cash outflows during the quarter resulting from plant and equipment purchases and share issues costs from an Employee Share Scheme share award respectively.

The Company **expects to receive substantial non-dilutive cash funding in the next quarter of at least $5.7 million.** This includes grant funding from the Australian Stroke Alliance for completed milestones ($1.2 million), the initial $2.0 million payment due on execution of the Modern Manufacturing Initiative grant Funding Agreement and an estimated $2.5 million from the Company's R&D tax incentive claim for the financial year ending 30 June 2022. The R&D claim will be lodged imminently and is subject to review and payment by the ATO.

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 30 Sept 2022
Australian Stroke Alliance	$8.0 million	$6.2 million[1]
Modern Manufacturing Initiative	$5.0 million	$5.0 million[2]
Total	$13.0 million	$11.2 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.

As required by ASX Listing Rule 4.7C3, the Company notes that $0.221 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 is focused on the development and commercialisation of medical imaging technology. The Company is developing and seeking to commercialise a potentially cost effective, portable, medical imaging device using electromagnetic microwave imaging for diagnosis and monitoring of stroke and other medical applications. The technology is the result of over 10 years of development by researchers at the University of Queensland. The team of approximately 20 researchers is led by co-inventor Professor Amin Abbosh, who is considered a global leader in electromagnetic microwave imaging. EMVision's Chief Scientific Officer is Professor Stuart Crozier, who is a co-inventor and globally renowned for creating technology central to most MRI machines manufactured since 1997. EMVision's CEO, Dr Ron Weinberger, is the Former Executive Director and CEO of Nanosonics' (ASX:NAN), a $1.9 billion market cap healthcare company. Dr Weinberger has over 25-years' experience developing and commercialising medical devices. During his time at Nanosonics, Dr Weinberger co-developed the company's platform technology and launched their breakthrough product 'Trophon' globally, which would go on to become the gold standard for infection prevention. Dr Weinberger was instrumental in transforming Nanosonics from a research and development company to one of Australia's leading medical device commercialisation success stories.

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 SEPTEMBER 2022

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (3months) $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	(320)	(320)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs including research and development staff	(1,182)	(1,182)
	(f) administration and corporate costs	(372)	(372)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	12	12
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	-	-
	- CRC-P grant income	-	-
	- ASA grant income	-	-
1.8	Other (provide details if material)		
	- Net GST (paid) / received	-	-
1.9	**Net cash from / (used in) operating activities**	**(1,862)**	**(1,862)**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3months) $A'000
2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(2)	(2)
	(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**	**(2)**	**(2)**

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	(1)	(1)
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**	**(1)**	**(1)**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3months) $A'000
4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	6,777	6,777
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,862)	(1,862)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(2)	(2)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(1)	(1)
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**4,912**	**4,912**

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	4,518	1,617
5.2	Call deposits	120	5,007
5.3	Bank overdrafts	(17)	(22)
5.4	Other (provide details) - term deposits for bank guarantees	291	175
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**4,912**	**6,777**

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	221
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)	(1,862)
8.2	Cash and cash equivalents at quarter end (item 4.6)	4,912
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	4,912
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	2.6

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: Whilst > 2 quarters funding available, the Company notes that at least $5.7 million of funding is expected to be received in the next quarter from grant programs and the Company's FY22 R&D tax incentive claim.

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 October 2022.....

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.