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ASX Release

ENCOURAGING INTERIM CLINICAL TRIAL RESULTS

Highlights:

- *First interim analysis of haemorrhagic stroke detection algorithm ('blood or not') with patient data from Stage 2 of the Company's clinical trial delivers encouraging performance with correct identification.*
- *Simulations successfully leveraged to accelerate AI algorithm development and achieve promising performance in real patient data.*
- *Abstract on this first interim algorithm analysis is in press at the International Journal of Stroke as part of the 15th World Stroke Congress, Toronto in October 2023.*
- *Clinical Trial Stage 2 recruitment on track to complete this quarter, with 100 patients recruited to date.*

EMVision Medical Devices Limited (ASX:EMV) ("EMVision" or the "Company") is pleased to announce encouraging interim analysis from Stage 2 of its clinical trial and enrolment progress.

Interim analysis

A haemorrhagic stroke detection algorithm ('blood or not') has been developed based on simulated scan data and augmented real scan data. The objective of this algorithm is analogous to the primary role of Non-Contrast CT imaging in Acute stroke care which is used to rule out bleeding (a contraindication to the administration of intravenous tPA which is used to restore blood flow in the brain in eligible acute ischemic stroke patients).

A first interim analysis utilising patient data obtained during Stage 2 of the Company's clinical trial that is currently enrolling, has been completed to indicate the accuracy of the haemorrhagic stroke detection algorithm prior to any fine-tuning with real haemorrhagic patient datasets. The preliminary test dataset included 15 patients (5 haemorrhagic, 2 ischaemic and 8 without stroke) that were external to and not included in prior algorithm training. The algorithm correctly identified all 5 haemorrhagic stroke patients as well as the other patients as being without haemorrhage.

The interim analysis serves as an encouraging indicator of the robustness of the model and ability of simulation data to accurately represent real-world clinical scenarios, notwithstanding that the sample size is too small to draw definitive conclusions regarding the algorithm's performance. Following this interim analysis, complete clinical data from Stage 2 of the clinical trial will be used to train/test the full suite of AI algorithms.

Simulation has proven to be a powerful tool in the development and refinement of EMVision's algorithms, particularly in the absence of large sets of historical data and with simulation measurements closely matching real world measurements. The simulation data pipeline allows for large numbers of simulated patient cases (both healthy and unhealthy) to be used in algorithm training and testing, with this particular 'blood or not' model having been trained on 1,560 simulated scans prior to testing. A simulation data pipeline can speed up development as it is quicker and more cost effective to generate synthetic simulation data

compared to obtaining patient data from clinical trials alone, and it can be augmented with real patient datasets.

Professor Geoffrey Donnan, Co-Chair of the Australian Stroke Alliance, said “The identification of blood is an important prerequisite for therapeutic decision making in acute stroke management. These early results are encouraging and the lightweight nature of the EMV device makes it ideally suited to the prehospital stroke environment.”

Professor Stephen Davis, Co-Chair of the Australian Stroke Alliance, added: “Following these promising results, the next steps will be to validate the sensitivity and specificity for detection of blood in hyperacute stroke patients using the EMV device, against CT scanning, the current gold standard in stroke management.”

EMVision is pleased to advise that this first interim algorithm analysis will be published as an abstract in the International Journal of Stroke as part of the 15th World Stroke Congress, Toronto October 2023.

Recruitment progress

Recruitment into Stage 2 of EMVision’s clinical trial continues to progress well across all three sites (Liverpool Hospital, Royal Melbourne Hospital and Princess Alexandra Hospital). 100 patients have now been recruited, including 10 haemorrhagic, 43 ischaemic and 47 mimics/other (including migraines and seizures). The Company expects to complete Stage 2 recruitment of 150 suspected stroke patients this quarter.

EMVision CEO & MD, Scott Kirkland said: “We are very encouraged by this early analysis, albeit from a small sample set. Using simulation data is an effective way to accelerate our AI algorithm development alongside the patient data we are capturing from Stage 2 of our clinical trial which will support algorithm training and testing, dialogue with prospective partners and our planned engagement with the FDA. The recruitment process for Stage 2 is progressing well, which we are on track to complete this quarter.”

Authorised for release by the Board of the Company.

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Clinical Investigations Roadmap

The sites have been activated progressively, commencing with Liverpool Hospital. All sites that have been selected are major stroke centres that treat significant volumes of stroke patients each year.

TITLE	'EMVIEW' EMVision Gen 1 Brain Scanner Study on Acute Stroke Participants
DEVICE DESCRIPTION	The EMVision Brain Scanner is a device system which obtains images of human brain using electromagnetic (microwave) techniques.
STUDY SITES	**Site 1** - Liverpool Hospital **Site 2** - Royal Melbourne Hospital **Site 3** - Princess Alexandra Hospital Additional site to be added and activated as required
PARTICIPANTS	Presenting to Emergency Department with suspected stroke
PATIENT COHORT	***Pre-validation Phase*** **Stage 1:** 30 Healthy participants **Stage 2:** Up to 150 Acute stroke/stroke mimic participants **Stage 3:** To be advised as required **Regulatory Body Engagement** ***Validation Phase*** Endpoint and sample size will be confirmed during the pre-validation phase
ENDPOINTS	• Hardware verification • Safety • Stroke mimic and acute stroke data to enhance AI algorithms • Efficacy (sensitivity/specificity) • Safety
DURATION & REPORTING	**Anticipated to be 12+ months. The Company expects to provide updates to the market as it reaches relevant milestones throughout the clinical testing**
INCLUSION CRITERIA	Adults ≥ 18 years of age. Presenting to hospital with acute neurological deficit suspect to be stroke and within 24 hours of symptom onset. The use of the EMV Brain Scanner will not delay the treatment of the participant. CT brain imaging following clinical evaluation in Emergency Department per standard of care. Ability to provide informed consent. Participants will provide written informed consent. Where this is not possible, consent from a legal authorized representative will be obtained. Head size deemed suitable for scanning with the EMVision Brain Scanner.
EXCLUSION CRITERIA	Has received treatment for current (suspected) stroke event prior to initial CT scan AND EMVision Brain Scanner scan. Pregnant or breastfeeding. Contraindication to neuroimaging, such as a contrast allergy or other condition that prohibits CT, MRI and/or angiography. Presence of any implanted electro-stimulating devices in the head and neck. Presence of any large metallic craniofacial implants, such as bone fixation plates, mesh etc. (Note that small metallic objects, such an aneurysm coils etc., are acceptable) Presence of an intracranial pressure monitor or any other similar sensor that may compromise the placement of the investigational device Inability to wear the investigational device (skin lesions on scalp, previous intracranial surgeries etc.). Unable to lie still for the duration of the scan. Any other condition or symptoms preventing the participant from entering the study, according to the investigator´s judgment
SCANNING PROCESS FOR A TYPICAL STROKE PATIENT	**Admission** → **+24 Hours** → **3-5 Days later** Emergency Department → Radiology / In-ward → Radiology / In-ward CT + EMV Scans → CT and/or MRI + EMV Scans → CT and/or MRI + EMV Scans

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.