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ASX Release

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LATEST IMAGING AND CLINICAL TRIAL INSIGHTS

Highlights:

- *Completion of initial imaging case studies using an advanced AI-powered probabilistic imaging technique being developed by the Company.*
- *Confirmation of 100% scan success rate through Stage 1 of EMVision's clinical trial for production of processable signals with mean time for completion of full workflow and brain scan of 9.2 minutes.*
- *Device met safety objectives of Stage 1, with no patient adverse events nor any adverse device effects occurring.*
- *Latest imaging case studies will be presented at Stroke Society of Australasia (SSA) conference alongside an abstract on Stage 1 clinical trial insights in press at the International Journal of Stroke.*

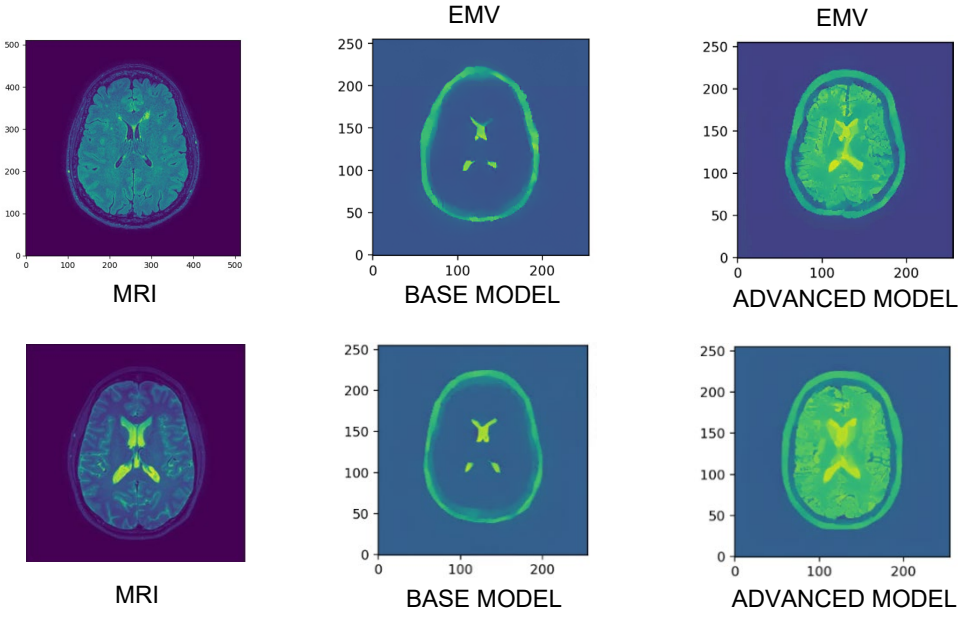
EMVision Medical Devices Limited (ASX:EMV) ("EMVision" or the "Company") is pleased to announce insights from its latest imaging case studies, which use an advanced AI-powered probabilistic imaging technique.

The results from the latest imaging case studies build upon the pre-validation trial progress reported by EMVision on 29 May 2023. In Stage 1 (pre-validation) of EMVision's clinical trial, the Gen 1 portable brain scanner device scanned 30 healthy participants (17 male and 13 female), with a mean age of 64, for baseline healthy brain assessment. This was used for hardware verification and as an input for the further development of AI algorithms.

The mean time for completion of the full workflow and brain scan was 9.2 minutes, indicative of the ease of deployment of the Gen 1 device.

In terms of safety, no adverse events nor any adverse device effects occurred, while the hardware had a 100% scan success rate in terms of production of processable signals, with data and learnings obtained used to further advance AI-based algorithm techniques.

Following the completion of Stage 1 of the clinical trial and after initial algorithm training, EMVision has now completed an initial round of testing of the AI-powered imaging technique on additional healthy volunteer scans. Exemplar case studies are provided below. This technique is a probabilistic anatomical imaging approach and is subject to further development, verification and validation. It is intended for this background anatomical reconstruction to be combined with a separate series of algorithms to aid in the classification and localisation of stroke type.



The base model is designed to reconstruct inner-outer boundaries and ventricles. The advanced model is designed to reconstruct inner-outer boundaries, grey matter, white matter and ventricles. The ground truth 'MRI' slice is an approximate reference point to the EMV scan acquisition, and not the identical plane.

EMVision is pleased to advise that the latest imaging case studies will be presented at 'Stroke 2023', the joint annual scientific meeting of the Stroke Society of Australasia (SSA) and Smart Strokes. The presentation is to be given by the Australian Stroke Alliance co-chair Prof Stephen Davis, alongside an abstract titled 'EMVision Gen 1 Brain Scanner Study Stage 1 Insights' in press at the International Journal of Stroke.

Principal investigator at Liverpool Hospital Dr Dennis Cortado commented "This is an exciting development in stroke and neurological care. We have found the EMVision scanner to be a very user-friendly portable imaging modality. The EMVision scanner has the potential for wide application in both the prehospital and acute hospital settings."

EMVision CEO & MD, Scott Kirkland said, "Our team is achieving significant breakthroughs with our Gen 1 product over the last 12 months, made possible with our talented engineers, proprietary simulation data pipeline alongside latest advancements in high performance computing and AI. As we progress through our studies, we are excited to learn about the full potential and capabilities of our world first technology and look forward to sharing further insights with the market."

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.