



ASX Release

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CLINICAL TRIAL STAGE 1 ENROLMENT COMPLETED WITH ENCOURAGING DATA

EMVision Medical Devices Limited (ASX:EMV) (“EMVision” or the “Company”), is pleased to provide an update on its clinical trial.

The pre-validation phase of the clinical trial is tracking well, with all 30 participants for Stage 1 (healthy volunteers) having now been successfully enrolled and scanned at Liverpool Hospital. Each healthy baseline volunteer received a scan with the EMVision 1st Generation portable brain scanner alongside an MRI.

The full dataset, once received, will be processed and analysed, however early indications from an engineering review of an initial cohort are promising, with high quality signals, that are stable and consistent, having been obtained from the EMVision 1st Gen scanner for the healthy baseline scans. The hardware is performing as designed and the participant data, alongside ground truth segmented MRIs from our core imaging lab, is being used to advance EMVision’s Artificial Intelligence algorithms and other imaging techniques.

Preparations, including product enhancements from Stage 1, are now underway to enable Stage 2 of pre-validation phase to shortly be activated. Stage 2 will enrol up to 150 acute stroke and stroke mimic patients across leading comprehensive stroke centres including Liverpool Hospital, Royal Melbourne Hospital and Princess Alexandra Hospital in Brisbane.

The “Clinical Investigations Roadmap” diagram below provides a summary of the clinical trial.

EMVision CEO, Dr Ron Weinberger commented: “This is an encouraging start to our trials. Having highly reproducible inputs to our algorithms is a critical first step and a key aim of this phase. We are excited to shortly move our potentially game changing technology into the Emergency Department environment to begin generating valuable acute stroke and stroke mimic data.”

Authorised for release by the Board of the Company.

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Clinical Investigations Roadmap

The sites will be activated progressively, commencing with Liverpool Hospital. All sites 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	<p>Site 1 - Liverpool Hospital</p> <p>Site 2 - Royal Melbourne Hospital</p> <p>Site 3 - Princess Alexandra Hospital</p> <p>Additional site to be added and activated as required</p>									
PARTICIPANTS	Presenting to Emergency Department with suspected stroke									
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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	<p>Adults ≥ 18 years of age.</p> <p>Presenting to hospital with acute neurological deficit suspect to be stroke and within 24 hours of symptom onset.</p> <p>The use of the EMV Brain Scanner will not delay the treatment of the participant.</p> <p>CT brain imaging following clinical evaluation in Emergency Department per standard of care.</p> <p>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.</p> <p>Head size deemed suitable for scanning with the EMVision Brain Scanner.</p>									
EXCLUSION CRITERIA	<p>Has received treatment for current (suspected) stroke event prior to initial CT scan AND EMVision Brain Scanner scan.</p> <p>Pregnant or breastfeeding.</p> <p>Contraindication to neuroimaging, such as a contrast allergy or other condition that prohibits CT, MRI and/or angiography.</p> <p>Presence of any implanted electro-stimulating devices in the head and neck.</p> <p>Presence of any large metallic craniofacial implants, such as bone fixation plates, mesh etc. (Note that small metallic objects, such as aneurysm coils etc., are acceptable)</p> <p>Presence of an intracranial pressure monitor or any other similar sensor that may compromise the placement of the investigational device</p> <p>Inability to wear the investigational device (skin lesions on scalp, previous intracranial surgeries etc.).</p> <p>Unable to lie still for the duration of the scan.</p> <p>Any other condition or symptoms preventing the participant from entering the study, according to the investigator's judgment</p>									
SCANNING PROCESS FOR A TYPICAL STROKE PATIENT	<table border="1"> <thead> <tr> <th>Admission</th> <th>+24 Hours</th> <th>3-5 Days later</th> </tr> </thead> <tbody> <tr> <td>Emergency Department</td> <td>Radiology / In-ward</td> <td>Radiology / In-ward</td> </tr> <tr> <td>CT + EMV Scans</td> <td>CT and/or MRI + EMV Scans</td> <td>CT and/or MRI + EMV Scans</td> </tr> </tbody> </table>	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
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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 is 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 \$1.5 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.