

# ASX Release

## STAGE 2 OF CLINICAL TRIAL ACTIVATED

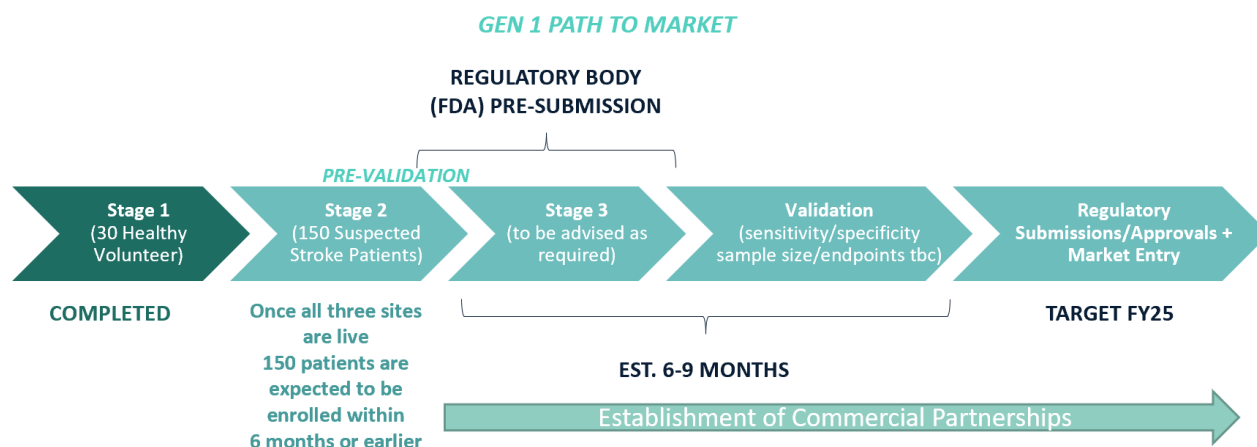
**EMVision Medical Devices Limited (ASX:EMV)** (“EMVision” or the “Company”) is pleased to announce that Stage 2 of its multi-site clinical trial for its First Generation portable brain scanner has been activated.

Following the successful completion of Stage 1 (30 healthy volunteers), Stage 2 will enrol up to 150 acute stroke and stroke mimic patients presenting to the Emergency Department. The trial is taking place across major comprehensive stroke centres in Australia, including Liverpool Hospital, Royal Melbourne and Princess Alexandra. Each site has the stroke patient population and dedicated research team to support an expediated enrolment process.

Insights from Stage 1 healthy volunteers have resulted in important usability, workflow and technical improvements to the device. As a result, operators will be able to perform EMVision scans in even shorter windows, important when dealing with time sensitive medical emergencies such as acute stroke. Liverpool Hospital is the first site activated for Stage 2, with Royal Melbourne scheduled to be activated in June and Princess Alexandra within a couple of weeks of Royal Melbourne activation.

**EMVision CEO, Dr Ron Weinberger commented:** “We have now achieved the critical and noteworthy phase of acquiring data from suspected stroke patients in the acute setting. Significant preparation and positive collaboration between the EMVision team and hospital staff has been underway to ensure the next phase of our multi-site clinical trials is set up for success. A key part of this preparation has been a keen focus on strategies and support to enable brisk patient recruitment. We are grateful to our clinical collaborators for their enthusiasm and commitment. We have taken the technical and usability information from Stage 1 and refined our device for Stage 2 and although the modifications are not major, they will result in significant improvements in performance.”

An overview of path to market and anticipated timeline below



THE COMPANY EXPECTS TO PROVIDE UPDATES TO THE MARKET AS IT REACHES RELEVANT MILESTONES THROUGHOUT THE CLINICAL TRIALS

GEN 2 (AMBULANCE DEVICE) INTENDS TO USE GEN 1 (BEDSIDE DEVICE) AS A PREDICATE DEVICE FOR AN EXPEDIATED PATH TO MARKET

Authorised for release by the Board of the Company.

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## Clinical Investigations Roadmap

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	<div><div>Pre-validation Phase</div><div>Validation Phase</div></div> <div><div>Stage 1: 30 Healthy participants Stage 2: Up to 150 Acute stroke/stroke mimic participants Stage 3: To be advised as required</div><div>Regulatory Body Engagement</div><div>Endpoint and sample size will be confirmed during the pre-validation phase</div></div>		
ENDPOINTS	<div><div><ul style="list-style-type: none"><li>• Hardware verification</li><li>• Safety</li><li>• Stroke mimic and acute stroke data to enhance AI algorithms</li></ul></div><div><ul style="list-style-type: none"><li>• Efficacy (sensitivity/specificity)</li><li>• Safety</li></ul></div></div>		
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>		
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	<div><div>Admission</div><div>+24 Hours</div><div>3-5 Days later</div></div> <div><div>Emergency Department</div><div>Radiology / In-ward</div><div>Radiology / In-ward</div></div> <div><div>CT + EMV Scans</div><div>CT and/or MRI + EMV Scans</div><div>CT and/or MRI + EMV Scans</div></div>		

## 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](http://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.