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## ASX Release

# ADDITIONAL PIVOTAL TRIAL SITE ACTIVATIONS MOUNT SINAI NY & LIVERPOOL HOSPITAL SYDNEY

### Key Highlights:

- **Activation of third US site, Mount Sinai in New York, scheduled for this month. Mount Sinai is recognised as a leader in stroke research and treatment.**
- **Activation of second Australian site, Liverpool Hospital in Sydney, in progress this week. Liverpool Hospital is known as one of the largest stroke referral centres in NSW.**
- **These activations will bring the total of sites activated in the pivotal (validation) trial to five, including UHealth and Memorial Hermann-Texas Medical Centre in Houston, Mayo Clinic in Jacksonville and the Royal Melbourne Hospital. The sixth site for the pivotal (validation) trial will be activated shortly thereafter.**
- **The pivotal (validation) trial is designed to support FDA De Novo clearance of the emu™ point-of-care brain scanner device.**

**EMVision Medical Devices Limited (ASX:EMV)** (“EMVision” or the “Company”) is pleased to provide a pivotal (validation) trial progress update for EMVision’s first commercial device, the emu™ bedside brain scanner.

The site initiation visit and device training at the second Australian site, Liverpool Hospital, is in progress this week. Liverpool Hospital in Sydney offers comprehensive stroke care services, including acute stroke care, endovascular clot retrieval, and ongoing rehabilitation. It is known as one of the largest stroke referral centers in NSW, with a particular focus on acute stroke diagnosis and management. EMVision has a strong relationship with the research team at Liverpool having previously collaborated on studies such as the earlier successful emu™ ‘EMView’ multi-site pre-validation trial.

In addition, the site initiation visit at the third US site, Mount Sinai, New York, is scheduled for this month. Mount Sinai is recognised as a leader in stroke research and treatment. The Mount Sinai Stroke Centers are dedicated to providing world-class care for both the treatment and prevention of stroke and other cardiovascular disorders.

**Associate Professor Reade De Leacy, neurointerventional radiologist, neuroendovascular surgeon and co-director of the Neuroendovascular Surgery Fellowship at Mount Sinai commented** “The pivotal trial represents a critical step in validating the diagnostic performance of EMVision’s emerging modality for point-of-care stroke diagnosis. By enabling rapid differentiation of suspected stroke type at the point-of-care, the technology has the potential to significantly reduce time to treatment and intervention to improve patient outcomes in both pre-hospital and in-hospital settings.”

**EMVision CEO and Managing Director, Scott Kirkland, commented** “It is a pleasure to work with so many highly engaged clinical research teams across our trial sites. We’re proud to collaborate with these luminary sites, with excellent track records in driving innovation in stroke care and look forward to the successful conduct of our study.”

Liverpool and Mount Sinai Hospitals will bring the total of sites activated in the pivotal (validation) trial to five, including UTHealth and Memorial Hermann-Texas Medical Centre in Houston, Mayo Clinic in Jacksonville and the Royal Melbourne Hospital, with a sixth to be activated shortly thereafter. The study is designed to support an FDA De Novo clearance for the emu™ bedside brain scanner.

Authorised for release by the Board of the Company.

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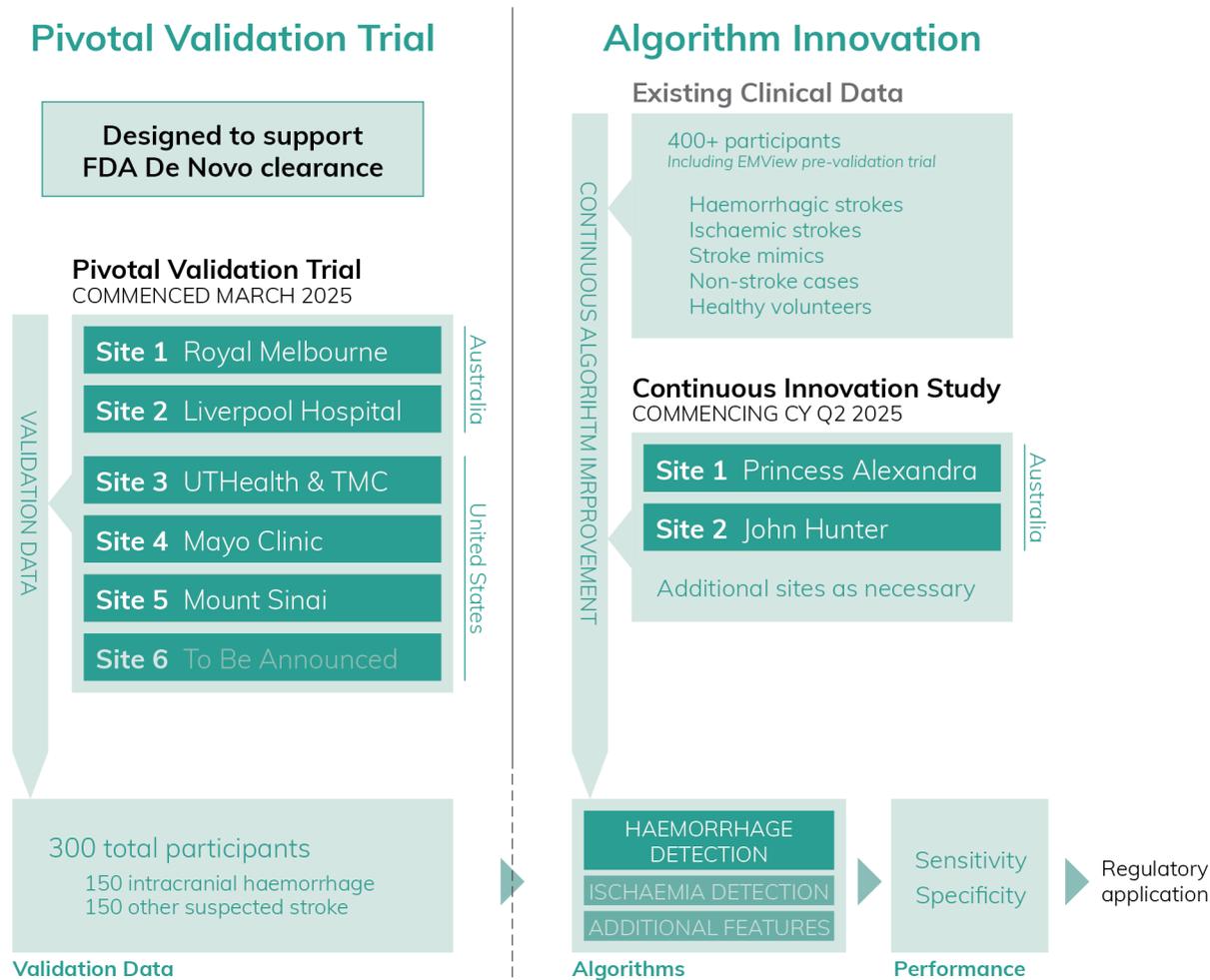
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### emu™ Point-of-Care Brain Scanner - Clinical Program Overview



## Clinical Investigation Summary

Trial sites are activated in a staggered manner.

<b>Study Title</b>	The EMU Study
<b>Investigational Site</b>	Leading Research Institutions and Comprehensive Stroke Centres in the United States and Australia
<b>Design of the Clinical Investigation</b>	Multi-Centre, Prospective, Consecutive, Paired Diagnosis, Diagnostic Performance Study of the EMVision emu™ Brain Scanner
<b>Primary Objective</b>	Demonstrate haemorrhage detection sensitivity and specificity >80%
<b>Inclusion Criteria</b>	<ol style="list-style-type: none"><li>1. Adults ≥22 years of age</li><li>2. Presenting to hospital with acute neurological deficit suspected to be stroke and within 12 hours of symptom onset</li><li>3. The use of the EMVision emu™ Brain Scanner will not delay the treatment of the patient</li><li>4. CT or MRI brain imaging following clinical evaluation in Emergency Department per standard of care</li><li>5. Head size deemed suitable for scanning with the EMVision emu™ Brain Scanner</li></ol>
<b>Exclusion Criteria</b>	<ul style="list-style-type: none"><li>• Has received treatment for current (suspected) stroke event prior to initial CT/MRI scan OR EMVision emu™ Brain Scanner scan (such as thrombolysis)</li><li>• Contraindication to neuroimaging, such as a contrast allergy or other condition that prohibits CT, MRI and/or angiography</li><li>• Contraindications to emu Brain Scanner scan, such as conditions precluding placement of the scanner, metallic implants in the head, or an inability to lie still during the scan</li><li>• Pregnant or breastfeeding</li><li>• Any other condition or symptoms preventing the participant from entering the study, according to the investigator's judgment</li></ul>
<b>Sample Size</b>	300 suspected stroke participants total across 2 study arms: A. Intracranial Haemorrhage – 150 participants B. Other – 150 participants <i>Note: Training verification on a small number of initial participants is performed at each site prior to enrolment of the above sample</i>
<b>Duration of Clinical Investigation</b>	Estimated as 6-12 months enrolment period followed by analysis and reporting

## **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 neurodiagnostic 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.