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EMVision Medical Devices Ltd
ACN 620 388 230
Suite 4.01, 65 Epping Rd
Sydney NSW 2113
02 8667 5337
contact@emvision.com.au

ASX Release

emu™ PIVOTAL (VALIDATION) TRIAL RECRUITMENT SURPASSES 200 PATIENTS

Key Highlights

- **Total recruitment for the emu™ Pivotal (Validation) Trial has now surpassed 200 patients across training and primary analysis cohorts, with record recruitment recorded in July.**
- **The emu™ continues to integrate well into "code stroke" pathways at participating hospitals, with no device-related adverse events reported to date.**
- **Mayo Clinic clinicians will present preliminary findings from an "Early Experience" paper on the emu™ Brain Scanner in the Pivotal (Validation) Trial, in electronic presentation format, at the 18th Annual Mayo Clinic Stroke and Cerebrovascular Disease Review, Amelia Island, Florida, in October 2026, where EMVision will also participate in a technology showcase.**
- **Trial ramp up, protocol enhancements, additional site activations and active FDA engagement continue to support the Company working towards full enrolment in early CY2027, with sequential cohort readouts to follow shortly thereafter, underpinning the planned FDA De Novo clearance pathway.**

EMVision Medical Devices Limited (ASX:EMV) ("EMVision" or the "Company") is pleased to provide an emu™ clinical program update. The emu™ is EMVision's 1st generation point-of-care Brain Scanner designed to enable earlier triage, transfer or treatment decisions at the bedside for time sensitive medical emergencies such as stroke. It is the precursor and predicate to EMVision's 2nd generation portable Brain Scanner, the First Responder, designed for pre-hospital environments.

emu™ Pivotal (Validation) Trial

Recruitment momentum has accelerated, supported by trial ramp up initiatives, protocol enhancements and expanded hours of coverage at participating sites. Additional US academic medical centres referred into the study are in the process of being added to the Trial, expanding recruitment capacity and deepening engagement with the US stroke community ahead of planned commercialisation.

EMVision CEO and Co-Founder, Scott Kirkland, commented "Crossing 200 patients is an important milestone that demonstrates our recruitment initiatives are contributing to enrolment acceleration. We are also excited to see the Mayo Clinic clinicians share their early experience with the emu™ at the Stroke and Cerebrovascular Disease Review at Amelia Island this October, where our team will be on site showcasing EMVision technology to the US stroke community."

The emu™ has been incorporated into "code stroke" workflows at participating hospitals, and no device-related adverse events have been reported to date.

The Trial is a multi-centre, prospective, blinded diagnostic study designed to support U.S. Food and Drug Administration (FDA) De Novo clearance of the emu™ point-of-care brain scanner. The primary objective is to demonstrate haemorrhage detection sensitivity and specificity of greater than 80%. The training and verification cohorts support consistent, protocol standard device operation across sites, including operator

proficiency, scan acquisition and integration into hospital workflows, while the primary analysis cohort (300 patients) will provide the dataset for assessment of the Trial's primary endpoint.

Recruiting sites include Mayo Clinic (Jacksonville, Florida), Mount Sinai Hospital and Mount Sinai West (New York), Ronald Reagan UCLA Medical Center (California), Memorial Hermann (Texas Medical Center and Memorial City, Texas), Royal Melbourne Hospital (Victoria) and Liverpool Hospital (New South Wales), with Princess Alexandra Hospital (Queensland) transitioning into the Trial from the Company's Continuous Innovation Study.

FDA Engagement

Preparations to add an acute ischaemia detection endpoint to the Trial, alongside haemorrhage detection, continue to advance. Rather than conducting a separate validation program for ischaemia detection in the future, this approach leverages the same patient cohort, trial infrastructure and regulatory pathway already in place, potentially saving up to two years and multimillion-dollar costs. Critically, simultaneous validation would enable the emu™ to address both major stroke types from its first release, expanding the device's clinical utility and addressable patient population. FDA pre-submission (Q-Sub) engagement on the proposed ischaemia endpoint is planned in the coming months, building on the Company's active and ongoing engagement with the FDA regarding the De Novo clearance pathway.

Growing Clinical Engagement

Mayo Clinic clinicians will present preliminary findings from an “Early Experience” paper on the emu™ Brain Scanner in the Pivotal (Validation) Trial at the 18th Annual Mayo Clinic Stroke and Cerebrovascular Disease Review at Amelia Island, Florida, in October 2026. EMVision is also participating in a technology showcase at the conference, engaging directly with the U.S. stroke community.

EMVision technology also featured prominently this month at the Australia and New Zealand Stroke Organisation Conference 2026 in Brisbane, including presentations by Dr Angela Dos Santos on the pivotal validation of the emu™ device in suspected stroke, and Dr Michael Devlin on interpretable AI algorithms for stroke assessment using the bedside scanner. Clinician led presentations at leading scientific forums continue to build awareness and advocacy for our technology ahead of commercialisation.

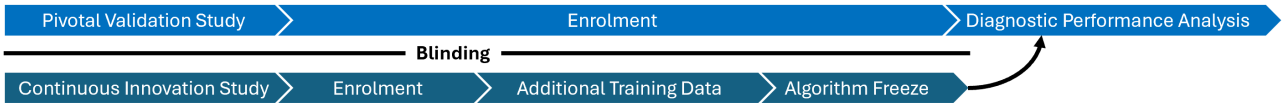
Upcoming emu™ Program Milestones

- Continued site activations and enrolment milestones
- FDA pre-submission (Q-Sub) engagement
- Full Trial enrolment targeted for early CY2027
- Sequential cohort readouts to follow shortly thereafter
- FDA De Novo submission for the first-generation emu™ device

emu™ Continuous Innovation Study

Alongside the emu™ Pivotal (Validation) Trial, EMVision is running a parallel Continuous Innovation Study, which has recruited >150 patients across multiple Australian sites including John Hunter Hospital, Box Hill Hospital and Princess Alexandra Hospital. This study provides cost-effective training data to support the ongoing development of the AI diagnostic models for the emu™.

Under the Pivotal Trial protocol, EMVision is only required to provide the AI diagnostic model at the conclusion of patient enrolment. This means our team can continue to refine the models, including incorporating additional patient training data as enrolment progresses, until the algorithm freeze ahead of the Trial's blinded performance analysis.



Authorised for release by the Board of the Company.

[ENDS]

For further information, media or investor enquiries, please contact:

Scott Kirkland
CEO and Managing Director
+61 2 8667 5337
skirkland@emvision.com.au

Clinical Investigation Summary

Trial sites are activated in a staggered manner.

Study Title	The EMU Study
Investigational Site	Leading Research Institutions and Comprehensive Stroke Centres in the United States and Australia
Design of the Clinical Investigation	Multi-Centre, Prospective, Consecutive, Paired Diagnosis, Diagnostic Performance Study of the EMVision emu™ Brain Scanner
Primary Objective	Demonstrate haemorrhage detection sensitivity and specificity >80%
Inclusion Criteria	1. Adults ≥22 years of age 2. Presenting to hospital with acute neurological deficit suspected to be stroke and within 12 hours of symptom onset 3. The use of the EMVision emu™ Brain Scanner will not delay the treatment of the patient 4. CT or MRI brain imaging following clinical evaluation in Emergency Department per standard of care 5. Head size deemed suitable for scanning with the EMVision emu™ Brain Scanner
Exclusion Criteria	• Has received treatment for current (suspected) stroke event prior to initial CT/MRI scan OR EMVision emu™ Brain Scanner scan (such as thrombolysis) • Contraindication to neuroimaging, such as a contrast allergy or other condition that prohibits CT, MRI and/or angiography • 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 • Pregnant or breastfeeding • Any other condition or symptoms preventing the participant from entering the study, according to the investigator´s judgment
Sample Size	300 suspected stroke participants total across 2 study arms: A. Intracranial Haemorrhage – 150 participants B. Other – 150 participants ***Note: Training verification on a small number of initial participants is performed at each site prior to enrolment of the above sample. In addition, preparations are underway to add an acute ischaemia detection endpoint to the Trial. This may require a modest adjustment to the above sample size, with the final design subject to planned FDA pre-submission (Q-Sub) engagement.***

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

About Stroke

Stroke is a medical emergency that occurs when blood flow to part of the brain is interrupted, either by a blocked vessel (ischaemic stroke) or bleeding into the brain (hemorrhagic stroke). The resulting lack of oxygen and nutrients can rapidly damage brain tissue, leading to disability or death if not treated promptly. Different stroke types require different types of care. Early recognition and fast access to diagnosis and appropriate care are critical, as timely intervention can significantly improve outcomes.

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.