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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 TRIAL EXPANSION ADDS ACUTE ISCHAEMIA DETECTION, BROADENING CLINICAL AND COMMERCIAL OPPORTUNITY

Key Highlights

- **Following significant R&D progress in the parallel Continuous Innovation study, EMVision is actively preparing to add an acute ischaemia detection feature to the Pivotal (Validation) Trial, with FDA engagement to follow.**
- **Bringing forward simultaneous validation of the emu™ brain scanner's haemorrhage and ischaemia detection capabilities streamlines the regulatory pathway while maximising clinical utility and commercial opportunity from first FDA release.**
- **Pivotal (Validation) Trial recruitment has surpassed key enrolment milestones (>125 total patients) and continues to build as recruitment acceleration initiatives come into effect. Trial ramp-up, protocol enhancements and active FDA engagement support a path to full enrolment from late CY2026 / early CY2027, with sequential cohort readouts shortly thereafter.**
- **The emu™ Regional Benefit Study is also progressing to plan, with site selection well advanced ahead of ethics approval in H2 CY2026. The third CRC-P Program non-dilutive funding instalment of $0.4 million was received in May 2026.**
- **With this important addition to the Pivotal (Validation) Trial, register to listen to a clinical webinar recording with Dr Reade De Leacy, an interventional neuroradiologist at Mt Sinai NY, who shares his expert perspective on unmet clinical needs in acute stroke care and the opportunities this opens up for EMVision's technology.**

EMVision CEO and Co-Founder, Scott Kirkland, commented “Bringing forward validation of ischaemia detection in the Pivotal Trial is a step-change for our emu™ Brain Scanner, substantially expanding its clinical utility and commercial opportunity from first FDA release, while leveraging the same trial infrastructure for capital and time efficiency. With recruitment past key milestones, growing interest from leading stroke centres, and a clear path through to read-out and FDA submission, our emu™ program is gathering pace while laying critical groundwork for our First Responder device”

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

EMVision's Pivotal (Validation) Trial, which underpins the planned FDA De Novo clearance pathway for the emu™ Brain Scanner, is progressing across several recruiting sites in the United States and Australia. The participating institutions include leading US academic medical centres and Australian tertiary stroke hospitals:

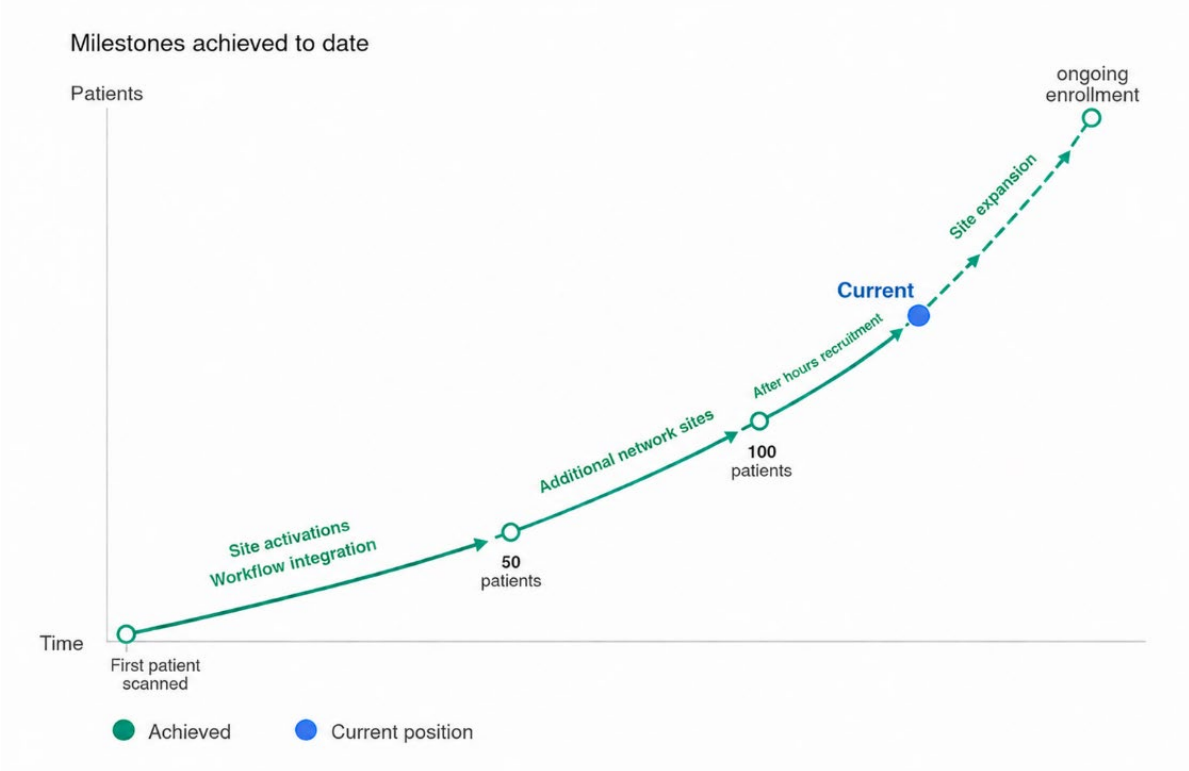
United States

- Mayo Clinic, Florida
- Mt Sinai Hospital, New York
- Mt Sinai West, New York
- Ronald Reagan UCLA Medical Center, Los Angeles
- Memorial Hermann – Texas Medical Centre, Houston
- Memorial Hermann – Memorial City, Houston

Australia

- Royal Melbourne Hospital, Victoria
- Liverpool Hospital, New South Wales
- Princess Alexandra Hospital, Queensland (transitioning into Pivotal)

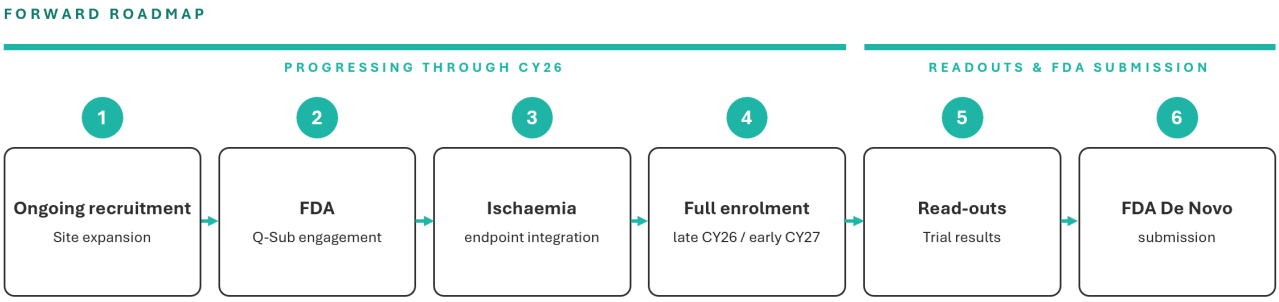
Pivotal (validation) trial total patient recruitment progress



Recruitment in the emu™ Pivotal (Validation) Trial continues to build steadily across all eight active US and Australian hospitals with over 125 patients enrolled in total to date across training and primary analysis cohorts. The device continues to integrate seamlessly into hospital code stroke workflows, with no device related adverse events reported.

Recently introduced initiatives, including broader clinical team engagement and extended after hours coverage, are expected to further accelerate recruitment. In addition, Princess Alexandra Hospital, a participating site in EMVision's Continuous Innovation Study, will transition into the Pivotal (Validation) Trial, leveraging existing site readiness, trained staff, and clinical familiarity with the technology. EMVision is also considering the inclusion of additional leading US stroke centres that have been referred to the Company, reflecting growing clinical interest in the Pivotal (Validation) Trial and our technology.

Following significant progress in the Continuous Innovation Study, EMVision is actively preparing for the addition of an acute ischaemia detection endpoint to the Pivotal (Validation) Trial. As ischaemic stroke patients are already being enrolled in the Pivotal (Validation) Trial, modifications to the trial are expected to be modest and incremental rather than wholesale by leveraging the data already collected and the workflows that have been integrated. This may include minor adjustments to the required sample to ensure the ischaemic sub-cohort meets statistical objectives and pre-specification of the ischaemia endpoint analysis plan via protocol amendment. EMVision intends to engage the FDA through an upcoming pre-submission (Q-Sub) meeting to align on the proposed endpoint expansion, including the clinical claims and performance thresholds. Including the ischaemia detection endpoint in the current Pivotal (Validation) Trial leverages the same patient cohorts, infrastructure, and regulatory pathway to generate expanded indications, potentially saving up to 2 years and multi-million dollar trial costs compared to funding and enrolling a standalone trial later.



The validation of an ischaemia feature is expected to substantially strengthen the device's clinical and commercial value proposition. An ischaemia detection feature extends the device's clinically actionable use case in the dominant majority (~80%) of stroke presentations. Because ischaemic stroke interventions (clot dissolving drugs and clot retrieval) are highly time-dependent, the ability to rapidly identify ischaemia at the bedside has the potential to meaningfully reduce intervention delays and improve patient outcomes, including by enabling identification of true strokes earlier in the pathway. Every minute saved in the door-to-thrombectomy pathway translates to preserved brain tissue and better functional outcomes. Acute ischaemic stroke detection is widely recognised as a more complex clinical and technical problem than haemorrhage detection, particularly in the hyperacute window and in care settings where advanced multimodal neuroimaging is not immediately available. The emu™ Brain Scanner is designed to address these gaps in the acute care pathway. In addition, generating ischaemia performance data on the emu™ also builds the clinical and regulatory foundation for the Company's First Responder device in pre-hospital patient management settings.

EMVision has recorded a clinical webinar featuring Dr Reade De Leacy, a leading interventional neuroradiologist and key opinion leader at Mount Sinai (New York), one of the world's premier stroke centres. Dr De Leacy will discuss the unmet needs in acute stroke care and the role EMVision's technology can play in addressing them, including the additional clinical utility acute ischemia detection offers, providing investors with valuable clinical context on the opportunity ahead. Details to view the webinar are available below:

https://us02web.zoom.us/webinar/register/WN_gQ2z6XQgRbWiAZbam57UnA

emu™ Pivotal (Validation) Trial Details

The emu™ Pivotal (Validation) Trial is designed to support FDA De Novo clearance for EMVision's first commercial product, the emu™ point-of-care Brain Scanner. The trial enrolment period is followed by data analysis and reporting (read out).

The primary objective of the Trial is to demonstrate haemorrhage detection sensitivity and specificity of greater than 80% to support regulatory submission. A small number of suspected stroke participants are enrolled at each site as part of training verification and a total of three hundred (300) suspected stroke participants are to be enrolled across multiple locations in the United States and Australia as part of the primary analysis cohort. All participating Trial sites are leading, high volume Comprehensive Stroke Centres.

Data is being collected in a manner that allows sequential validation and read-outs of additional diagnostic features, including haemorrhage and ischemia detection, without the need to undertake a supplementary full validation trial.

EMVision remains blinded to certain study data, with results to be analysed at the conclusion of enrolment. This trial design enables ongoing algorithm and feature development throughout the patient enrolment period, leveraging data obtained in EMVision's Continuous Innovation Study, while preserving the integrity of the final Trial analysis. EMVision will continue to update the market as the Trial progresses through major milestones.

EMVision is well-funded with cash reserves of $18.4m as at 31 March 2026 and further non-dilutive funding is available under current grant programs ($6.2m net of $400k received in May 2026) providing a strong runway to execute on commercialisation milestones.

emu™ Continuous Innovation Study Progress

The emu™ Continuous Innovation Study (the "Study") is a strategic complement to the Pivotal (Validation) Trial, running concurrently across multiple leading Australian clinical sites. The Study generates paired scan data from suspected stroke and traumatic brain injury patients, providing a proprietary dataset that supports continued algorithm refinement, new feature development and future indication expansion.

Data acquired to date has enabled the ischaemia detection feature to move from R&D into the validation pipeline, with ongoing enrolment continuing to support algorithm refinement and future development. Enrolment in the study now exceeds one hundred patients. John Hunter Hospital continues in the study while Box Hill Hospital joins in place of Princess Alexandra Hospital who are transitioning into the Pivotal (Validation) Trial. Additional site activations are underway. This growing clinical footprint is expected to scale data generation efficiently as the Study progresses.

emu™ Regional Benefits Study Update

In August 2025, EMVision was awarded $3 million in non-dilutive funding from the Australian Government under the Cooperative Research Centres Projects (CRC-P) Round 17 grant program, supporting an emu™ Regional Benefit Study. EMVision has partnered with the Australian Stroke Alliance, Titan Pre-Hospital Innovation and South Australia's Rural Support Service to demonstrate real-world benefits of a telehealth supported EMVision emu™ Brain Scanner to patients in regional South Australia. During May 2026, EMVision received a $0.4 million payment representing the third instalment of CRC-P Program funding for this study.

The project team, including experts in stroke and regional systems of care, have modelled and critically analysed multiple deployment models based on South Australian telestroke data and expert clinical input. The analysis identified the regional healthcare settings and clinical workflow where patient benefit and study impact are maximised.

Workstreams with objectives in protocol development, hospital deployment and telehealth integration are progressing towards delivery of the identified clinical workflow. The extensive clinical and research experience of the partners, together with the South Australian Rural Support Services data infrastructure, ensure effective execution of the workstreams and study progression.

The clinical implementation selected for this study focuses on locations and stroke patients underserved by current stroke diagnostic practices reliant on advanced neuroimaging at larger healthcare hubs. In these scenarios, patients may require hours of travel before their stroke is diagnosed and treatment initiated (if still within treatment windows). With an emu™ Brain Scanner deployed to these locations, and expert stroke neurologists engaged via telemedicine through the integrated Zeus™ platform, there is a major opportunity to expedite patient management and improve outcomes for regional Australians suffering stroke. Critically, the model of care being validated in this Regional Benefit Study is not unique to Australia. Regional and remote populations face the same diagnostic bottleneck in health systems worldwide, positioning this study as a blueprint for global deployment of the emu™ Brain Scanner.

Authorised for release by the Board of the Company.

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

Melanie Singh
NWR Communications
+61 (0) 439 748 819
smelanie@nwrcommunications.com.au

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*

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 (ischemic 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.