27/01/2026

ASX Release

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

STRONG emu™ CLINICAL TRIAL AND PROGRAM PROGRESS

Key Highlights

- **Seven world-class stroke hospitals actively recruiting under the Pivotal (Validation) Trial, with activation of an additional U.S. high-volume Mt Sinai (New York) network hospital complete.**
- **Extensive and disciplined approach to training verification has led to new software features which are undergoing in-house testing ahead of integration.**
- **Activation of a second recruiting Memorial Hermann (Houston) network hospital in final stages, and with recruitment accelerating week to week, gives confidence that recruitment objective remains on target for completion in first half of CY2026.**
- **The Continuous Innovation Study, running in parallel to the Pivotal Trial, is progressing well since going live in 3Q CY2025, providing additional training data for algorithm enhancement, feature development, and indication expansion.**
- **Grant-funded Regional Benefits Study progressing through preparations ahead of launch in 2HCY2026. Study is expected to demonstrate the real-world benefits of the emu™ brain scanner device in regional areas.**

EMVision Medical Devices Limited (ASX:EMV) ("EMVision" or the "Company") is pleased to provide an update on progress in the clinical programs of the Company's first commercial product, the emu™ point-of-care Brain Scanner to support regulatory clearance, device enhancement and future clinical adoption.

emu™ Pivotal (Validation) Trial

Following an extensive onboarding, training and activation process at each participating hospital, all six Pivotal (Validation) Trial (the "Trial") locations (4 US and 2 Australian), with a total of 7 hospitals, are actively enrolling patients. The world class sites include Mayo Clinic, FL, Mt Sinai, NY, Memorial Hermann TX, UCLA CA, The Royal Melbourne Hospital VIC and Liverpool Hospital NSW.

As communicated in previous announcements, the initial phase of the Trial involved local institutional review board clearance and contracting, emu™ device delivery, site initiation, activation and training, ahead of sites going live for patient recruitment, training verification and primary analysis.

By completing rigorous preparatory processes early, the Company aims to minimise operational variability, support efficient patient screening, and generate high-quality clinical data through:

- Verification of emu™ scan quality and consistency.
- Validation of clinical workflow integration.
- Confirmation of adherence to protocol and data capture requirements.

Several patients were recruited and scanned at each site as part of training verification. These scans are excluded from the primary analysis and are designed to set the study site up for success. Operational learnings obtained during the training verification phase have been systematically incorporated into the Trial's execution. In addition, feedback from users and evaluation of training verification data has enabled the development of a new software feature that will provide users with real-time feedback on scan quality at the point of acquisition. This software enhancement is currently undergoing in-house testing ahead of integration into emu™ devices.

At the request of two participating Trial sites, additional emu™ devices have been shipped to support the activation of additional hospital network sites within Mt Sinai (New York) and Memorial Hermann (Houston) healthcare systems.

- Mt Sinai West, located in the West Midtown area of Manhattan, was activated for enrolment in late December.
- Memorial Hermann Memorial City in Houston's west is due to commence enrolling next month.

These additional network sites are expected to further enhance trial momentum by providing increased access to large and diverse stroke populations. In acute stroke trials of medical devices like the emu™ brain scanner, and from EMVision's experience with the 'EMView' clinical trial, recruitment generally follows a "exponential" pattern rather than a linear one. This is driven by early operational ramp up, followed by accelerated recruitment as sites mature and workflows optimise.

Scott Kirkland, CEO and Managing Director of EMVision, said: "We have taken a deliberate and disciplined approach to preparing the emu™ Pivotal (Validation) Trial, with a strong focus on site readiness, training verification, and data quality. With all flagship locations now actively recruiting, additional network sites coming online, and enrolment acceleration taking place, we expect the pace of enrolling to continue to increase as the Trial continues. We are pleased with the progress to date, the engagement of our clinical collaborators and look forward to achieving our recruitment and trial objectives."

EMVision will continue to update the market as the Trial progresses.

emu™ Pivotal (Validation) Trial Details

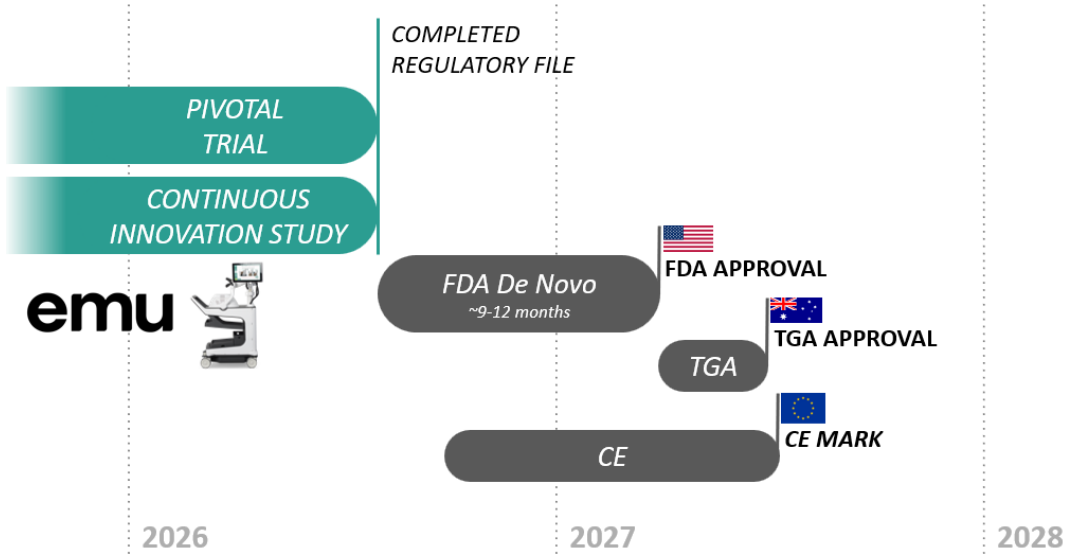
The emu™ Pivotal (Validation) Trial is designed to support FDA De Novo clearance for EMVision's first commercial product, the emu™ point-of-care Brain Scanner. The trial enrolment period is followed by data analysis and reporting (read out).

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

Data is being collected in a manner that allows sequential validation of additional diagnostic features, such as ischaemia 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.

Figure 1: *Indicative emu™ regulatory and market access roadmap*



emu™ Continuous Innovation Study Update

The emu™ Continuous Innovation Study (the "Study") is running in parallel with the Pivotal (Validation) Trial at two separate clinical sites in Australia. The purpose of the Study is to collect additional training data that can be utilised for ongoing algorithm and feature development, device innovation and indication expansion. The Study will enrol up to three hundred (300) suspected stroke and traumatic brain injury patients at Comprehensive Stroke Centres and level 1 Trauma Centres, including Princess Alexandra Hospital and John Hunter Hospital, with the addition of Box Hill Hospital at advanced stages.

Ongoing incorporation of high-quality real-world data enables EMVision to refine its algorithms over time, improving accuracy and reliability across diverse patient populations and clinical environments, supporting clinical performance and differentiation.

emu™ Regional Benefits Study Update

EMVision was awarded a $3 million, non-dilutive grant under the Australian Government's Cooperative Research Centres Projects (CRC-P) Round 17 program to support a regional clinical benefits study of the Company's emu™ point-of-care brain scanner, alongside project partners including the Australian Stroke Alliance, Titan Pre-hospital Innovation and South Australia's Rural Support Service.

This study is focused on evaluating the real-world benefits of using the emu™ Brain Scanner integrated with a telehealth network in regional hospitals across South Australia, with the aim of improving the timeliness and effectiveness of stroke diagnosis and care in environments where access to advanced neuroimaging and specialist clinicians is limited.

With CRC-P funding and project partner collaboration agreements now executed, the project team is establishing clinical workflows and protocols for the study, as well as progressing site selection in advance of ethics submission and study activation.

This is the first study to demonstrate the benefit of the emu™ point-of-care brain scanner in clinical use, which will form part of a comprehensive clinical and economic evidence dossier to assist in driving real-world adoption of the emu™.

Authorised for release by the Board of the Company.

[ENDS]

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

Simon Hinsley
NWR Communications
+61 (0) 401 809 653
simon@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*
Duration of Clinical Investigation	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

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.