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ASX Release

FIRST RESPONDER SUCCESSFULLY TRIALLED WITH MOBILE STROKE UNIT, STROKE ALLIANCE MOU SIGNED

Key Highlights

- **Stage 1 of the Pre-Hospital Mobile Stroke Unit (MSU) Study successfully completed, achieving its primary usability and workflow objectives in the first deployment of EMVision's portable First Responder Brain Scanner in a road vehicle setting.**
- **Building on the aeromedical RFDS study completed earlier in the year, the First Responder advanced prototype has now been successfully operated in both air and road environments.**
- **Device versatility demonstrated across a range of real world environments, with scans performed at the scene, in patients' homes, in the back of the ambulance, at a workplace, on stretchers, beds and on the ground.**
- **Scan procedure completed in under seven minutes on average, with scanner operation consistently rated as easy in operator responses.**
- **Stage 1 MSU findings are being directly incorporated into the next generation, production equivalent commercial First Responder units, which have fewer components, are lower weight and are advancing well for the next stage of studies and market access.**
- **Industry Growth Program (IGP) progress payment of $650,437 received.**
- **MoU signed with the Australian Stroke Alliance to jointly pursue research and translational funding for pre-hospital stroke diagnosis, building on a partnership that has already delivered the MRFF Stage 2 "golden hour" program, and combines ASA's clinical networks, expertise, air and road ambulance partners with EMV's technology platform to target large scale non-dilutive funding bids.**

EMVision Medical Devices Limited (ASX:EMV) ("EMVision" or the "Company") is pleased to announce the successful completion of the first in-field feasibility study of its First Responder brain scanner, conducted with the Melbourne Mobile Stroke Unit, Australia's first mobile stroke unit, operating out of the Royal Melbourne Hospital. Stage 1 of the study was a single-site, usability and workflow evaluation (non-diagnostic) in which patients attended by the MSU for suspected stroke were scanned in the field.

Mobile Stroke Unit (MSU) – Study Results

Ten participants (5 female, 5 male; median age 84, range 22–92) were enrolled across the Melbourne MSU catchment. Scans were performed in residences (n = 6), ambulances (n = 3) and a workplace (n = 1), with participants on a stretcher (n = 6), bed or couch (n = 3) or the ground (n = 1), with a mean scan time of 6.7 minutes, at scenes 3–18 km by road from the Royal Melbourne Hospital. There were no device related adverse events reported.

Operator feedback was strong on the aspects that matter most for clinical use. Scanner operation was rated easy in 100% of responses, and participant preparation, head-size assessment, start-up and tablet connection were rated positively. Securing the device in the MSU as well as packing and preparation were also rated positively in 90% and 80% of cases, respectively. As expected in a feasibility study, operators identified opportunities for improvement in moving and loading the scanner, which has given EMVision's engineering team a prioritised set of design targets for the production equivalent First Responder device. Where obtained, participant feedback (n = 6) was highly positive, all respondents reported feeling calm during the scan, found the instructions clear, and would be comfortable with the scanner being used on a family member. This level of patient acceptance in an emergency setting is a strong endorsement of EMVision's non-invasive, non-ionising technology.

Aiming for scale

Mobile Stroke Units, ambulances fitted with a CT scanner, have shown that treating patients before they reach hospital delivers dramatically better outcomes. Landmark MSU trials in Melbourne, Berlin and the United States, among other locations, have established the clinical case for pre-hospital stroke diagnosis. This includes earlier thrombolysis, and faster and more accurate triage of patients to hospitals capable of performing thrombectomy, the highly effective clot-retrieval procedure for large vessel occlusion strokes. The benefit is not limited to ischaemic stroke. The INTERACT4 trial showed that early intensive blood pressure lowering in the ambulance significantly improves outcomes for patients with intracerebral haemorrhage, but is harmful in ischaemic stroke, making early identification of stroke type the key to unlocking this treatment. Mobile Stroke Units in Melbourne and Berlin already use on-board CT to identify haemorrhage and begin blood pressure lowering and anticoagulation reversal before hospital arrival. However, CT equipped ambulances cost millions of dollars, require specialist crews and as a result are not widely deployed. EMVision's First Responder is designed to change that equation with its helmet sized, ultra-lightweight scanner intended to bring stroke type identification into any road or air ambulance, at a fraction of the cost and complexity.

Development of the production equivalent First Responder units is well advanced. These units are lighter than the prototypes used in our field studies and are designed to surpass the emu™ in diagnostic performance, drawing on learnings from both the emu™ and First Responder programs. We expect them to be ready H1 CY27, with the clinical and operational groundwork, including collaborations with leading international centres, already underway. This means data collection, including Stage 2 of the MSU study, and subsequent validation to demonstrate performance equal or surpassing the emu™ scanner ('substantial equivalence') can commence as soon as the production equivalent units are available.

Industry Growth Program progress payment

EMVision has also received a progress payment of $650,437 under its Industry Growth Program (IGP) non-dilutive grant. The IGP is an Australian Government program that supports Australian businesses to commercialise innovative products. EMVision was awarded a $5.0 million IGP grant in June 2025 to support and accelerate the development and commercialisation of its First Responder scanner with $2.2 million in funding remaining to be received over the life of the program.

Australian Stroke Alliance - Memorandum of Understanding (MoU)

EMVision has signed a non-binding MoU with Australian Stroke Alliance Ltd (ASA) to work together on securing non-dilutive research and translational funding for pre-hospital stroke diagnosis. The MoU builds on the parties' existing collaboration under the Medical Research Future Fund (MRFF) $40m Stage 2 "golden hour" program, with a focus on securing comparable continuation funding via the MRFF and other competitive grant schemes. The "golden hour" program is a five-year MRFF Frontiers initiative, led by ASA, to develop and validate lightweight brain scanners for road and air ambulances so that stroke can be diagnosed and treated within the first critical hour. EMVision has received $8m in non-dilutive funding under that program.

The MoU is a two-year, non-exclusive framework that either party can end on 30 days' notice, and it does not commit either party to any particular application. As with any competitive funding process, there is no certainty of success.

EMVision CEO and Managing Director Scott Kirkland commented, “This study shows the First Responder scanner can be easily deployed where strokes occur, at the scene, and via the road. Operators found it easy to use and patients found it unobtrusive. What we learned has already shaped the next-generation production equivalent First Responder which is even lighter, simple to operate and engineered to better the diagnostic performance of the emu™, and we're excited to move them into the studies that take us toward market. Our MoU with the Australian Stroke Alliance builds on a partnership that has already delivered the golden hour program. Together we bring clinical networks, ambulance partners and technology to pursue non-dilutive funding that will help make pre-hospital stroke diagnosis routine care. I'd like to thank the MSU team at the Royal Melbourne Hospital, Ambulance Victoria and the participants and families who took part.”

Authorised for release by the Board of the Company.

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Clinical Investigation Summary (Mobile Stroke Unit)

Study Title	Staged Workflow Assessment and Data Collection Study of the EMVision First Responder Brain Scanner in the Melbourne Mobile Stroke Unit
Investigational Site	Melbourne Mobile Stroke Unit, Royal Melbourne Hospital
Design of the Clinical Investigation	Staged, single-arm, non-randomised, workflow implementation and data collection study of the EMVision First Responder brain scanner
Objectives	*Stage 1:* To refine the workflow and assess usability of in-field (i.e., not at a hospital) brain scan procedures on Mobile Stroke Unit calls. *Stage 2:* To collect paired EMVision First Responder and standard of care diagnostic data from patients suspected of suffering from an acute stroke for algorithm advancement purposes.
Endpoints	• Usability of the device as assessed by users • Workflow metrics • Paired EMVision First Responder and MSU CT scan data • Safety
Inclusion Criteria	1. Adults ≥ 18 years of age 2. Patients attended to by a Mobile Stroke Unit 3. Head size deemed suitable to fit the device 4. The use of the EMVision First Responder Brain Scanner will not delay the treatment of the patient 5. Suspected of suffering from an acute stroke (within 12 hours of symptom onset) and are receiving a CT brain scan from the MSU *(Stage 2 only)*
Exclusion Criteria	1. Contraindicated to the EMVision First Responder scan. 2. Unable to lie still for the duration of the scan. 3. Has received treatment for current (suspected) stroke prior to MSU CT scan or EMVision First Responder Brain Scan *(Stage 2 only)* 4. Any other medical or logistical contraindication at the discretion of the MSU team.
Sample Size	*Stage 1:* 10 participants *Stage 2:* To be determined

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 (haemorrhagic 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.