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ASX Release

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EMV COMMENCES PRE-HOSPITAL MOBILE STROKE UNIT (MSU) STUDY WITH FIRST RESPONDER DEVICE

Key Highlights:

- **Pre-Hospital Mobile Stroke Unit (MSU) Study launched in Melbourne to evaluate EMVision's First Responder Brain Scanner, with objectives spanning usability, workflow integration and data collection.**
- **Study takes place in one of the world's ~45 MSUs (specially equipped ambulance outfitted with a CT scanner), providing a rare real-world study setting for pre-hospital stroke care.**
- **Study will be conducted in collaboration with the Australian Stroke Alliance, Ambulance Victoria and the Royal Melbourne Hospital.**
- **Successful device training and site initiation visit held. Recruitment to commence next week.**

EMVision Medical Devices Limited (ASX:EMV) ("EMVision" or the "Company") is pleased to announce the commencement of its Pre-Hospital Mobile Stroke Unit Study evaluating the Company's First Responder Brain Scanner.

About the Study

Following on from the successful aeromedical retrieval environment testing with volunteers and the Royal Flying Doctor Service earlier this year, the Pre-Hospital Mobile Stroke Unit Study is a staged workflow assessment and data collection study of EMVision's First Responder Brain Scanner in the Melbourne Mobile Stroke Unit (MSU) — one of only ~45 MSUs globally, and one of only two in Australia.

- Two-Stage Design:
  - Stage 1 – Evaluates the usability and workflow integration of the EMVision First Responder scanner within the MSU environment in the hyperacute stroke phase.
  - Stage 2 – Utilises the production equivalent First Responder device, collecting EMVision scan data matched with ground-truth radiological imaging (Head CT) to support the advancement and evaluation of EMVision's AI-enhanced stroke detection algorithms.

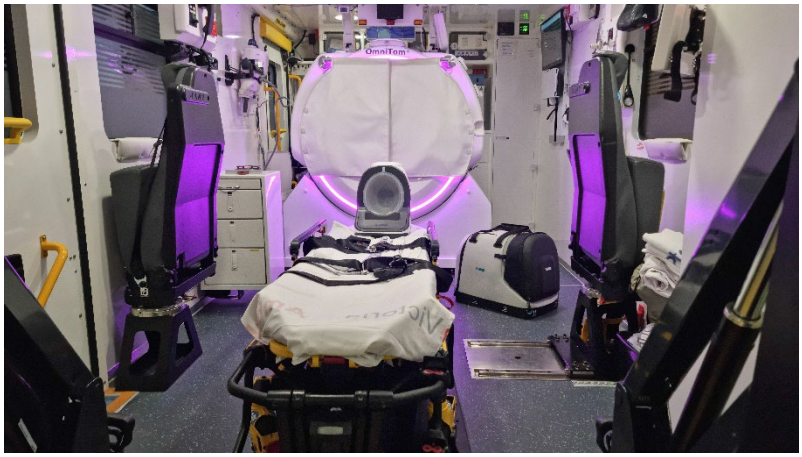
Stage 1 will enrol 10 suspected stroke patients, with reporting anticipating during Q4 CY2025.

Significance

This study provides a globally unique opportunity to evaluate EMVision's First Responder Brain Scanner in one of the world's limited number of Mobile Stroke Units. The study is designed to deliver the highest quality pre-hospital data by conducting both the EMVision First Responder and ground-truth MSU CT scan at the same time. MSUs are excellent for patients, with the clinical benefits well established – faster diagnosis and

treatment leading to better functional outcomes. However, due to size, cost, staffing requirements and complexity, a more scalable solution is required to provide broad access to pre-hospital models of stroke care. EMVision's First Responder seeks to fill this unmet need.

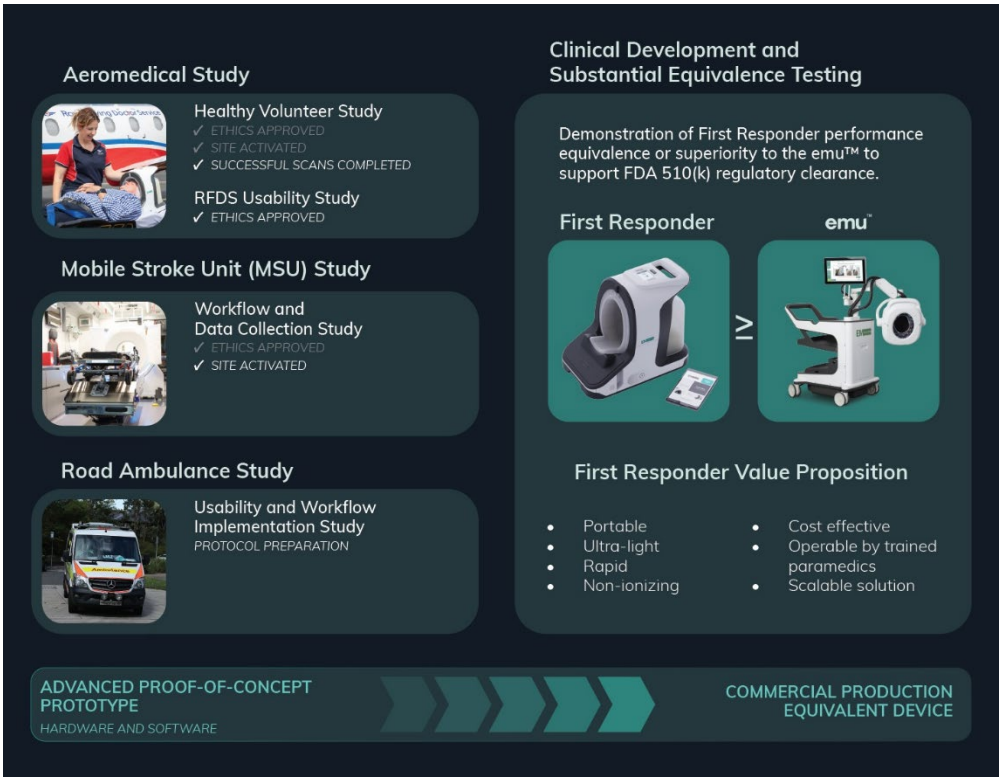
Stage 1 of the study aims to prove the workflow of the First Responder device in the critically ill patient population serviced by the MSU, before broader rollout in a larger sample under Stage 2. By focusing on real-world usability, workflow integration, and paired radiological validation, the trial represents an important step toward enabling rapid, portable neurodiagnostic capabilities for stroke in pre-hospital settings.



Left – Current Mobile Stroke Unit with CT. (EMVision's First Responder device and carry case pictured alongside)
Right - EMVision's First Responder device

First Responder Market Access Roadmap

The Pre-Hospital Mobile Stroke Unit Study is one of several studies (below) being conducted to progress the development and validation of our First Responder device. Collectively, these initiatives will be integral to expediating commercialisation of the First Responder via the FDA 510(k) regulatory pathway.



Prof Stephen Davis AO, neurologist and Co-chair of the Australian Stroke Alliance: “This is a really important study to validate EMVision’s First Responder device in prehospital stroke care on our mobile stroke unit. MSUs have been proven to improve clinical outcomes by treating patients before they reach hospitals leading to significant health economic benefit.”

Prof Geoffrey Donnan AO, neurologist and Co-chair of the Australian Stroke Alliance: “This will provide an important proof of principle as we set up conventional ambulances to deliver mobile brain imaging in the years ahead.”

EMVision’s CEO Scott Kirkland commented: “We are delighted to have commenced this important study on the Melbourne Mobile Stroke Unit. With limited MSUs in operation globally, this is a rare opportunity to evaluate the usability of our First Responder Brain Scanner and collect data in a world-class environment. The outcomes will generate critical workflow and patient data that will help refine our device and accelerate its substantial equivalence testing, clinical and commercial pathways.”

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 aeromedical retrieval team or attending physician.
Sample Size	*Stage 1:* 10 participants *Stage 2:* To be determined based on results of Stage 1
Duration of Clinical Investigation	*Stage 1:* 3 months *Stage 2:* To be determined following sample size determination

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

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.