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ASX Release

FIRST RESPONDER PROGRAM ADVANCED & GRANT MILESTONE ACHIEVED

Key Highlights:

- **Ethics approval granted for two important studies that will advance the prototype First Responder Device towards a commercial device:**
  - **Royal Flying Doctor Service (RFDS) aeromedical study**
  - **Mobile Stroke Unit (MSU) study**
- **Studies are designed to demonstrate that the First Responder brain scanner device can fit seamlessly into emergency workflows and collect valuable data in the pre-hospital setting.**
- **$400,000 non-dilutive milestone payment received under Australian Stroke Alliance Project Agreement on achievement of First Responder development milestone**

EMVision Medical Devices Limited (ASX:EMV) ("EMVision" or the "Company") is pleased to provide a progress update on its First Responder portable brain scanner program.

The First Responder device aims to address significant unmet needs in stroke and traumatic brain injury (TBI) care by enabling earlier triage, transfer or treatment decisions at the scene and is being advanced in parallel to the emu™ bedside scanner. With a First Responder advanced protype developed, ethics approval has been granted for two studies that will progress the device towards commercial production equivalence.

First Responder Pre-Hospital Studies

Ethics approval has been granted for a feasibility, usability and workflow implementation aeromedical study (Clinical Investigation Summary outlined below). The study involves a collaboration of the Royal Flying Doctor Service, South Australia Ambulance Service's emergency retrieval service MedStar, South Australia Health's Rural Support Services, the Royal Adelaide Hospital and the Australian Stroke Alliance. The study will evaluate the First Responder device's usability, reliability, functionality, workflow metrics and other tests as necessary to meet user and international regulatory requirements. The study is on track to commence recruitment this quarter, with study results expected to be reported next quarter.

Ethics approval has also been granted for a First Responder study during acute suspected stroke cases attended by the Melbourne Mobile Stroke Unit (MSU). This study provides a unique opportunity to collaborate with the only MSUs in Australia and one of a few MSUs globally who participate in clinical research. The study aims to evaluate the use of the EMVision First Responder device during pre-hospital emergency response to acute suspected stroke patients, while gathering contemporaneous ground-truth MSU CT-scan data. This study, on track to commence later this quarter, will inform commercial device development and ultimately substantial equivalence testing to support the FDA 510(k) regulatory pathway.

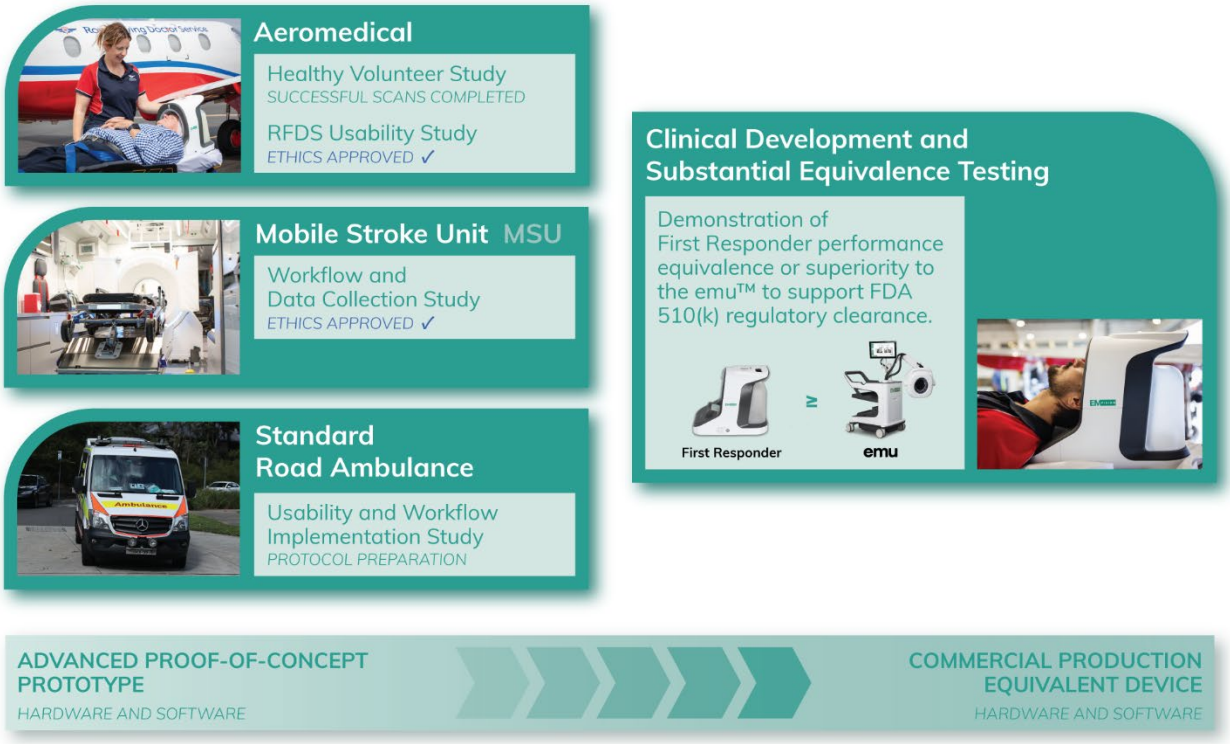
Milestone Payment

As per EMVision's Project Agreement with the Australian Stroke Alliance (ASA), which is funded by the Commonwealth of Australia's Medical Research Future Fund (MRFF), the "Telemedicine and Road/Air Integration" milestone has been completed. EMVision has received the $400,000 non-dilutive milestone payment pertaining to this achievement.

EMVision's CEO Scott Kirkland commented: "We are delighted to report the successful achievement of this important milestone, which brings together the power of our point-of-care neurodiagnostic capabilities with the reach of telehealth. This combination has the potential to transform patient workflows and outcomes, particularly in the pre-hospital setting.

In the coming months, EMVision will be conducting several studies to progress the development of our First Responder device, which will be integral to expediating its commercialisation via the FDA 510(k) regulatory pathway. We look forward to communicating the results of these studies to the market in due course."

First Responder pathway to market entry



Authorised for release by the Board of the Company.

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Clinical Investigation Summary (Aeromedical)

Study Title	Usability and Workflow Implementation of the EMVision First Responder Brain Scanner in Aeromedical Retrievals.
Investigational Site	Royal Flying Doctor Service, Adelaide Base.
Design of the Clinical Investigation	Single-arm, non-randomised, workflow implementation of the EMVision First Responder device.
Objectives	To determine the workflow impacts and usability of in-field (i.e., not at a hospital) brain scan procedures conducted during aeromedical retrievals.
Endpoints	• Usability of the device as assessed by users • Workflow metrics • Safety
Inclusion Criteria	1. Adults ≥ 18 years of age 2. Patients receiving an aeromedical transport 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
Exclusion Criteria	1. Patients who cannot freely provide consent. 2. Contraindicated to the EMVision First Responder scan. 3. Patients suffering from or suspected of suffering from an acute head injury (e.g., concussion, scalp laceration, skull fracture). 4. Patients suffering from or suspected of suffering from an acute neurological condition (e.g., stroke, seizure, migraine). 5. Unable to lie still for the duration of the scan. 6. Any other medical or logistical contraindication at the discretion of the aeromedical retrieval team or attending physician. ***Note:*** *Exclusion criteria 3 and 4 are due to potential for confusion of the patient resulting from a brain scan unrelated to their condition.*
Sample Size	The research team will actively recruit participants for a total period of 8 weeks. It is anticipated that during this time approximately 30 participants will be enrolled.
Duration of Clinical Investigation	The total study duration including site training, site activation, closure is anticipated to be ≤6 months.

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 (MSU)
Investigational Site	Melbourne MSU, Ambulances Victoria Royal Melbourne Hospital
Design of the Clinical Investigation	Staged, single-arm, non-randomised study of workflow implementation (Stage 1) then data collection (Stage 2) of the EMVision First Responder device onboard the MSU.
Objectives	Stage 1: To refine the workflow and assess usability of in-field brain scan procedures on MSU 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 • 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. Stage 2 only: Patients with acute neurological deficit suspected to be stroke and within 12 hours of symptom onset and receiving an MSU CT scan*
Exclusion Criteria	1. Contraindicated to the EMVision First Responder scan. 2. Unable to lie still for the duration of the scan. 3. Any other medical or logistical contraindication at the discretion of the aeromedical retrieval team or attending physician. *4. Stage 2 only: Has received treatment for current (suspected) stroke event prior to MSU CT scan OR EMVision First Responder Brain Scanner scan (such as thrombolysis)*
Sample Size	Stage 1: 10 participants Stage 2: TBD following analysis of Stage 1 data and estimation of required datasets for diagnostic algorithms
Duration of Clinical Investigation	The total study duration including site training, site activation, closure of both stages is anticipated to be ≤18 months.

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.