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ASX Release

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EMVISION REACHES STAGE 2 CLINCIAL TRIAL RECRUITMENT TARGET AND UNVEILS EMU AT RSNA

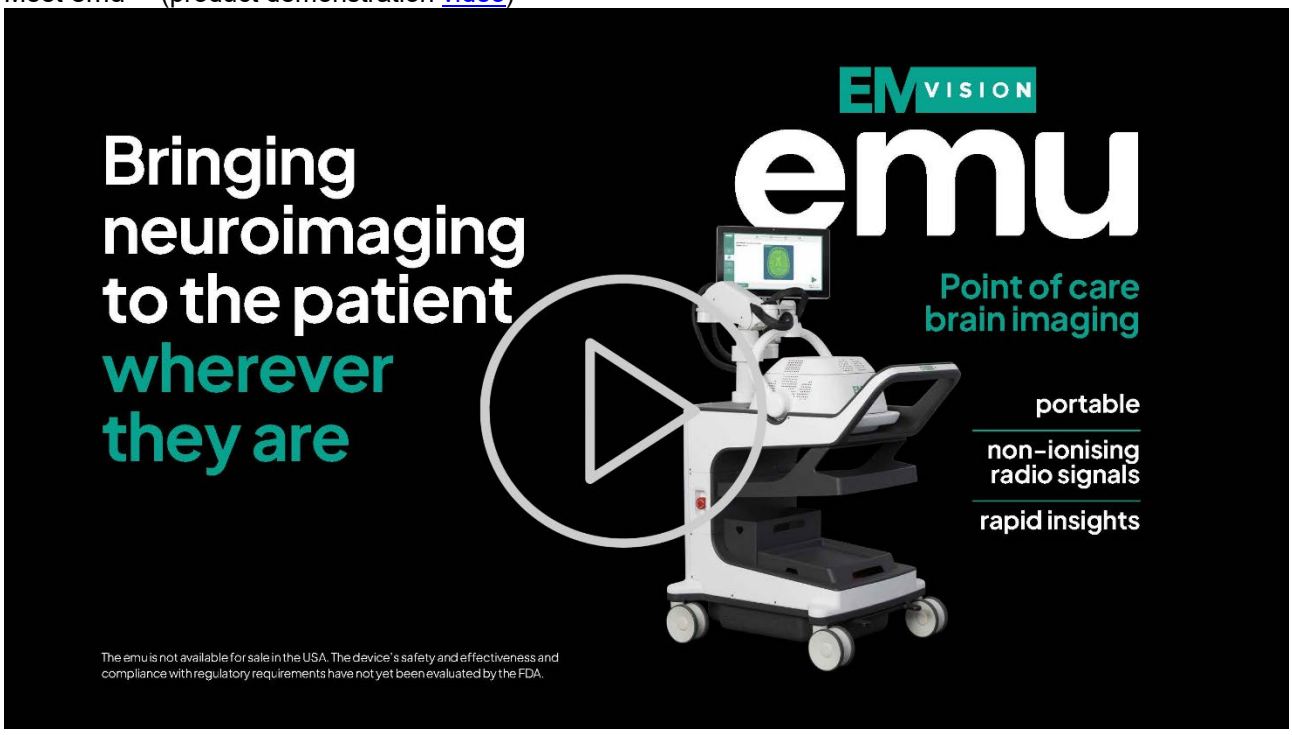
EMVision Medical Devices Limited (ASX:EMV) ("EMVision" or the "Company") is pleased to advise that it has unveiled the naming of its first production unit, emu™, at the Radiological Society of North America ('RSNA') 2023. EMVision is also pleased to announce that it has reached its recruitment target for Stage 2 of its multi-site clinical trials in line with its planned timetable.

Branding of first-generation device

The name emu™ was adopted to represent the excellent vision, speed and agility of EMVision's point-of-care brain scanner device. A uniquely Australian animal, the emu shares these qualities of mobility and precision. It always travels forward, representing constant progress. The EM in emu™ echoes the core technology (electromagnetic) and hence, company name of EMVision.

EMVision is showcasing its world first point-of-care brain scanners at the RSNA conference from November 26-29 2023 alongside innovation partner Keysight Technologies (NYSE:KEYS). RSNA represents a unique opportunity to engage with the international clinical community including key opinion leaders and prospective go-to-market partners and customers.

Meet emu™ (product demonstration video)



Stage 2 clinical trial recruitment objective achieved

EMVision is pleased to announce that it has reached its recruitment objective of 150 suspected stroke patients for Stage 2 of its pre-validation trial being conducted at three leading stroke centres in Australia, namely Liverpool Hospital, Royal Melbourne Hospital and Princess Alexandra Hospital. Once all the data is received from the sites and core imaging lab, it will be processed with the Stage 2 results anticipated to be reported in Q1 CY2024.

In parallel, EMVision is preparing for its engagement with the FDA in early 2024 to achieve alignment for EMVision's validation (sensitivity/specificity confirmation) clinical trial phase. Completion of this phase is anticipated to support the FDA submission for the emu™ product. Concurrently, EMVision will activate Stage 3 of the trial (pre-validation) as planned, allowing recruitment to continue in the interim at the three sites. This will include up to 30 haemorrhagic patients over the coming months with samples expected to further de-risk and set the validation trial phase up for success.

EMVision CEO & MD, Scott Kirkland, commented: "We are delighted to unveil 'emu™' as the brand name for our first-generation product at RSNA. This represents a significant milestone for EMVision and reflects the unique qualities of our product. Additionally, reaching our target patient recruitment for Stage 2 of the trial is an important step towards our pathway to commercialisation and we are encouraged by the clinical response and data to date. We are on track to commence FDA engagement in early 2024 and will continue to collect data in support of the validation phase, further enhanced by Stage 3 of our multi-site trials as planned."

Authorised for release by the Board of the Company.

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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 neuroimaging 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

Clinical Investigations Roadmap

The sites have been activated progressively, commencing with Liverpool Hospital. All sites that have been selected are major stroke centres that treat significant volumes of stroke patients each year.

TITLE	'EMVIEW' EMVision Gen 1 Brain Scanner Study on Acute Stroke Participants
DEVICE DESCRIPTION	The EMVision Brain Scanner is a device system which obtains images of human brain using electromagnetic (microwave) techniques.
STUDY SITES	**Site 1** - Liverpool Hospital **Site 2** - Royal Melbourne Hospital **Site 3** - Princess Alexandra Hospital Additional site to be added and activated as required
PARTICIPANTS	Presenting to Emergency Department with suspected stroke
PATIENT COHORT	***Pre-validation Phase*** **Stage 1:** 30 Healthy participants **Stage 2:** Up to 150 Acute stroke/stroke mimic participants **Stage 3:** Up to 30 bleeds Regulatory Body Engagement ***Validation Phase*** Endpoint and sample size will be confirmed during the pre-validation phase
ENDPOINTS	• Hardware verification • Safety • Stroke mimic and acute stroke data to enhance AI algorithms • Efficacy (sensitivity/specificity) • Safety
DURATION & REPORTING	**Anticipated to be 12+ months. The Company expects to provide updates to the market as it reaches relevant milestones throughout the clinical testing**
INCLUSION CRITERIA	Adults ≥ 18 years of age. Presenting to hospital with acute neurological deficit suspect to be stroke and within 24 hours of symptom onset. The use of the EMV Brain Scanner will not delay the treatment of the participant. CT brain imaging following clinical evaluation in Emergency Department per standard of care. Ability to provide informed consent. Participants will provide written informed consent. Where this is not possible, consent from a legal authorized representative will be obtained. Head size deemed suitable for scanning with the EMVision Brain Scanner.
EXCLUSION CRITERIA	Has received treatment for current (suspected) stroke event prior to initial CT scan AND EMVision Brain Scanner scan. Pregnant or breastfeeding. Contraindication to neuroimaging, such as a contrast allergy or other condition that prohibits CT, MRI and/or angiography. Presence of any implanted electro-stimulating devices in the head and neck. Presence of any large metallic craniofacial implants, such as bone fixation plates, mesh etc. (Note that small metallic objects, such an aneurysm coils etc., are acceptable) Presence of an intracranial pressure monitor or any other similar sensor that may compromise the placement of the investigational device Inability to wear the investigational device (skin lesions on scalp, previous intracranial surgeries etc.). Unable to lie still for the duration of the scan. Any other condition or symptoms preventing the participant from entering the study, according to the investigator´s judgment
SCANNING PROCESS FOR A TYPICAL STROKE PATIENT	**Admission** → **+24 Hours** → **3-5 Days later** Emergency Department → Radiology / In-ward → Radiology / In-ward CT + EMV Scans → CT and/or MRI + EMV Scans → CT and/or MRI + EMV Scans

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.