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ASX Release

STAGE 2 INSIGHTS CONFIRM STROKE DIAGNOSTIC AND CLINICAL VIABILITY

Highlights:

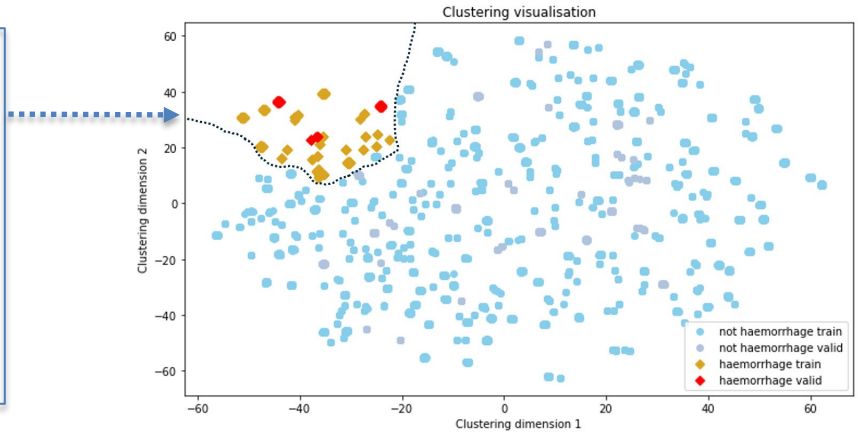
- *Stage 2 interim analysis confirms strong AI model performance in answering the important clinical question in acute stroke of haemorrhage or not ('blood or not').*
- *emu™ device seamlessly fit into acute stroke workflows, in time sensitive situations, with a mean scan time of 5.5 minutes and encouraging usability feedback.*
- *Interim analysis of stroke diagnostic performance aligns with expectations following first deployment of emu™ in this front door study of a wide variety of acute strokes and mimics, providing confidence in achieving desirable validation (sensitivity/specificity) outcomes.*
- *EMVision is preparing for a FDA pre-submission meeting, critical to ensuring the upcoming validation trial phase meets regulatory requirements.*

EMVision Medical Devices Limited (ASX:EMV) ("EMVision" or the "Company") is pleased to provide insights from Stage 2 of its ongoing (pre-validation) multi-site clinical trials. Stage 2 has enrolled a total of 180 patients presenting to the emergency department with stroke like symptoms, across the three trial sites: Liverpool Hospital, Royal Melbourne and Princess Alexandra Hospital Brisbane.

Per protocol, data from Stage 2 is being used to enhance AI algorithms. In preparation for the upcoming validation (sensitivity/specificity confirmation) trial phase, cross-validation interim analysis has been undertaken. Cross-validation is a statistical method of evaluating AI algorithms by dividing data into two segments: one used to train a model and the other used to validate the model. The detection and classification performance of the AI algorithm can then be estimated by observing clustering that occurs in the cross-validation data. The cross-validation evidence for interim analysis of 'blood or not' detection and classification, as presented below, demonstrates this desired clustering and confirms strong AI model performance in answering this important clinical question in suspected acute stroke 'blood or not'.

The ideal clustering being haemorrhage (red and orange) and the non-haemorrhage (blue and grey) are distinctly separate.

This illustrates the ability to detect and classify haemorrhage and non-haemorrhage cases.



The AI model is in a continuous development and integration phase and will continue to progress with data obtained in Stage 3 of the pre-validation trials, for which EMVision is currently recruiting. In addition, AI models deployed to the hardware platform have been tested to generate a detection and classification output in semi-real time following completion of a scan.

Interim analysis for the ischemia cohort is pending data processing, with further insights from the patient data collected anticipated to be shared during Stage 3 and following the completion of the pre-validation trial.

Stage 2 enrolled a total of 180 patients presenting to the emergency department with stroke like symptoms, across the three trial sites: Liverpool Hospital, Royal Melbourne and Princess Alexandra Hospital Brisbane. This included 75 ischaemic stroke, 18 haemorrhagic stroke, 20 transient ischaemic attacks and 67 stroke mimics. The mean age of participants was 67.4±15.02 years (range 24-95 years), with 44.4% being female. The severity of stroke symptoms as measured by the National Institutes of Health Stroke Scale (NIHSS) was as follows:

	Haemorrhagic Stroke	Ischaemic Stroke	Migraine	Seizure	Other	Overall
NIHSS Score[1]						
Mean ± SD	9.5 ± 7.85	7.9 ± 6.36	1.9 ± 2.56	9.2 ± 6.61	2.4 ± 3.72	5.7 ± 6.23
Median (Q1, Q3)	7 (5, 14)	7 (3, 12)	1 (1, 2)	7 (5, 14)	1 (0, 3)	4 (1, 8)
Range	0 to 26	0 to 27	0 to 8	2 to 18	0 to 22	0 to 27

[1] National Institutes of Health Stroke Scale, 42 point scale measuring stroke severity, allowing categorization as follows: no stroke symptoms, 0; minor stroke, 1–4; moderate stroke, 5–15; moderate to severe stroke, 16–20; and severe stroke, 21–42

Time metrics from Stage 2 are important to quantify the *emu*™ device's ability to fit within streamlined stroke care workflows, and to ensure the cohort represents acute stroke early after the onset of stroke symptoms. The mean time from the start of scan data acquisition to removal of the device as measured by the emu device software logs was 5.5 minutes (range of 4.2 to 14.6 minutes). In terms of acute timing, based on interim analysis of a partially verified dataset, the majority of patients (53%) were scanned by the emu™ device within 4.5 hours of symptom onset, as associated with the window for administration of thrombolysis.

The *emu*™ device's demonstrated suitability for deployment within the streamlined code-stroke hospital protocol along with promising interim analysis of stroke diagnostic performance confirm the viability of EMVision's disruptive modality to address key clinical requirements in acute stroke care.

Stroke Neurologist and Principal Investigator Dr Michael Devlin commented "The stroke team at Princess Alexandra Hospital have found the emu scanner easy to operate in a very busy and time-pressured environment when treating people with acute stroke. We have needed to adopt only minor workflow changes to ensure no impact on the other aspects of care in the emergency department. We eagerly await the outcomes of continuing clinical trials as the impact of stroke on individuals and the community is significantly reduced with its earlier diagnosis and treatment."

EMVision CEO and Managing Director Scott Kirkland commented "The performance of our AI models thus far to help answer the big question 'blood or not' in acute stroke care is particularly encouraging. We will be using what we have achieved to help inform our upcoming consultation with the FDA. Additionally, we have been pleased with the *emu*™ device's ease of use and suitability to the clinical environment given the time sensitive nature of acute stroke care. The feedback from the clinical community is clear; the use of non-ionising and portable neuroimaging devices, that can be easily deployed and provide insights in minutes, has game changing implications for prehospital and bedside stroke management. We look forward to sharing additional outcomes as we process further data from Stage 2 and 3."

Authorised for release by the Board of the Company.

[ENDS]

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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** — Emergency Department — CT + EMV Scans **+24 Hours** — Radiology / In-ward — CT and/or MRI + EMV Scans **3-5 Days later** — Radiology / In-ward — CT and/or MRI + EMV Scans

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

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.