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ASX Release

NEURODIAGNOSTIC ALGORITHMS DELIVER EXCELLENT RESULTS IN EMVIEW STUDY

Highlights:

- EMVision today announces excellent results from its world first neurodiagnostic technology aimed at early identification of strokes and stroke type.
- The 'EMView' multi-site study involved 307 participants, including 277 acute suspected stroke patients.
- Diagnostic algorithms tested on unseen data demonstrated high performance:
  - Haemorrhage or not ('blood or not')
    - Sensitivity: 92% Specificity: 85%
  - Ischemia or not ('clot or not')
    - Sensitivity: 85% Specificity: 78%
- Case studies highlight exceptional sensing capabilities, including successful detection and classification of very small haemorrhages such as a thalamic haemorrhage of 0.7mL and a subarachnoid haemorrhage of 1.7mL.
- The AI based diagnostic models demonstrated steadily improved performance as additional clinical training data was provided.
- The promising results allow EMVision to confidently proceed with the validation trial as planned to support an FDA De Novo clearance and product commercialisation. Total direct costs of the validation trial are anticipated to be approximately $4m, to be funded from cash reserves, with an estimated duration of 6 - 12 months.

EMVision Medical Devices Limited (ASX:EMV) ("EMVision" or the "Company") is pleased to announce exceptional results for its world first neurodiagnostic technology to identify stroke and stroke type.

In total 307 participants were enrolled in the EMView trial and successfully scanned with the EMVision emu™ brain scanner across Liverpool Hospital, Royal Melbourne Hospital and the Princess Alexandra Hospital. This included 277 suspected stroke patients with 48 haemorrhages and 140 ischemic confirmed strokes. The study's primary objective of collecting matched EMVision emu™ and CT/MRI ground-truth brain scans, for the advancement of the device's AI-based diagnostic 'blood or not' and 'clot or not' algorithms, was achieved. The results of the 'EMView' multi-site study with the point-of-care emu™ brain scanner will be submitted for publication following peer review.

To train the AI algorithms, over 240 participants' scan data was used (including confirmed haemorrhagic and ischaemic strokes, a variety of common stroke mimics along with healthy volunteer scans). This enabled the algorithm to learn patterns and features associated with a normal versus abnormal brain, including hyperacute, acute, subacute and chronic ischaemic and haemorrhagic stroke. The training set was diverse, with varied cases (across demographics, stroke sizes and locations, and time from onset) to enhance the model's generalisability. The neurodiagnostic AI algorithms were then applied to a test dataset that was

isolated and not used in the training. This prevented the model from "learning" any patterns from the test data, ensuring the assessment provided a real-world evaluation with truly unseen cases, albeit on a smaller sample size, prior to definitive sensitivity/specificity confirmation in the upcoming validation (pivotal) trial.

Table 1: *'Blood or not' detection and classification results*

	Haemorrhage	**Not Haemorrhage** (including 20 ischaemic, 15 mimics, 20 healthy)
Total Test Cases	13	55
Correctly Identified Cases	12	47
Performance	92% Sensitivity	85% Specificity

Table 2: *'Clot or not' detection and classification results*

	Ischaemic	**Not Ischaemic** (including 10 haemorrhagic, 20 mimics, 2 Transient Ischaemic Attacks)
Total Test Cases	20	32
Correctly Identified Cases	17	25
Performance	85% Sensitivity	78% Specificity

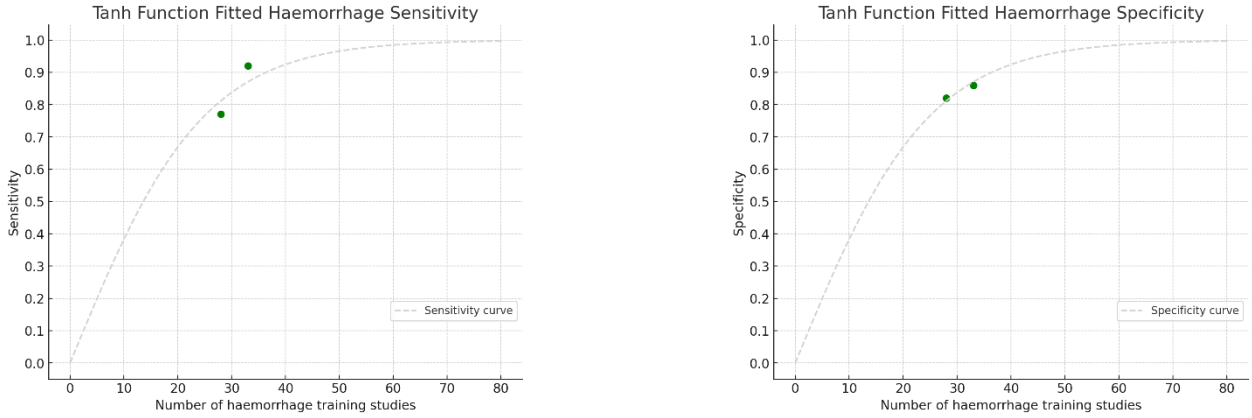

Figure 1: *Learning curves for the sensitivity (left) and specificity (right) of the haemorrhage or not ('blood or not') neurodiagnostic algorithm as derived from actual test datasets (green dots), illustrating the relationship of device performance and number of training datasets*

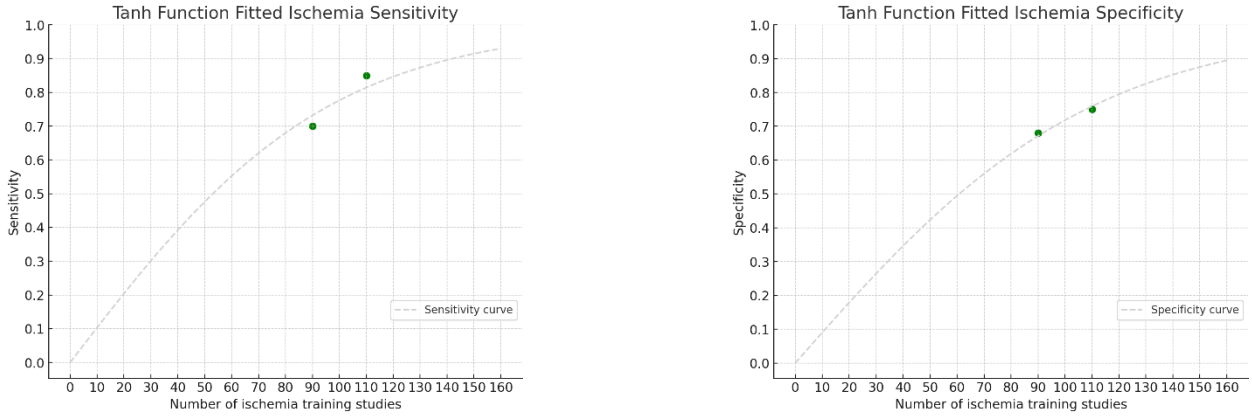

Figure 2: *Learning curves for the sensitivity (left) and specificity (right) of the ischemia or not ('clot or not') neurodiagnostic algorithm as derived from actual test datasets (green dots), illustrating the relationship of device performance and number of training datasets*

The learning curves presented above illustrate the AI model's improving recognition of a wide range of dielectric patterns and anomalies with additional clinical training data, resulting in steady sensitivity (true positive rate) and specificity (true negative rate) improvements. Meaningful performance gains are observed as more data is added, indicating the AI model's scalability to continue improvement with expanded data. Following this exercise, the isolated test data is then added into the complete training dataset.

Key terms:

Sensitivity (true positive rate):	The ability of a tool to correctly identify those *with* the condition. E.g. sensitivity of 92% means for every 100 people with the condition, the tool correctly diagnosed 92 with the condition.
Specificity (true negative rate):	The ability of a tool to correctly identify those without the condition. E.g. specificity of 85% means for every 100 people without the condition, the tool correctly diagnosed 85 without the condition.
Haemorrhage:	Bleeding in or around the brain, resulting from a rupture of a blood vessel. There are two main types of haemorrhage resulting in stroke presentation: intracerebral haemorrhage and subarachnoid haemorrhage.
Ischemic:	Occurs when blood flow to a part of the brain is blocked, commonly caused by a blood clot.
Large Vessel Occlusion (LVO):	A type of ischemic stroke that occurs when a major artery, such as the middle cerebral artery that supplies blood to a significant portion of the brain, becomes blocked by a blood clot.
Transient Ischemic Attack (TIA):	Similar to but is not considered an acute ischemic stroke. In a TIA, blood flow to a part of the brain is temporarily blocked, causing stroke-like symptoms that typically last only a few minutes to a few hours and resolve within 24 hours.
Mimic:	Refers to a medical condition that causes symptoms similar to those of a stroke, such as weakness, numbness, difficulty speaking, or confusion, but is not actually a stroke. Common conditions that can mimic stroke include seizures, migraines, hypoglycaemia and brain tumours.
Acute:	Refers to the immediate onset and early stage of the stroke, typically within the first few hours. This phase is critical because it is when intervention is most effective in preventing further damage and improving outcomes.

For comparison, the statistical performance of common stroke care tools, including gold standard CT, are provided below:

- Stroke scales for detection of Large Vessel Occlusion in suspected stroke patients
  - NIHSS (at a cut off of 8): 73% sensitivity, 79% specificity[1]
  - NIHSS (at a cut off of 10): 64% sensitivity, 84% specificity[1]
  - LAMS (at a cut off of 4): 69% sensitivity, 81% specificity[2]
- Non-contrast CT for the detection of acute ischemic stroke
  - Reported sensitivity ranges: 39-70%[3,4]
  - Generally lower sensitivity in the early hours after symptom onset
- CT Perfusion for the detection of acute ischemic stroke
  - Reported sensitivity ranges: 80-90%[5]
- Non-contrast CT for the detection of intracranial haemorrhage
  - Reported sensitivity ranges: 90-100%[6,7,8]

[1] Smith et al. Accuracy of Prediction Instruments for Diagnosing Large Vessel Occlusion in Individuals With Suspected Stroke: A Systematic Review for the 2018 Guidelines for the Early Management of Patients With Acute Ischemic Stroke. Stroke. 2018 Mar;49(3):e111-e122.

[2] Ali, M. et al. Sex Differences in Prehospital Identification of Large Vessel Occlusion in Patients With Suspected Stroke. Stroke. 2024 Mar;55(3):548-554.

[3] Brazzelli et al. Magnetic resonance imaging versus computed tomography for detection of acute vascular lesions in patients presenting with stroke symptoms. The Cochrane database of systematic reviews 2009;(4):CD007424.

[4] Mainali et al. Detection of Early Ischemic Changes in Noncontrast CT Head Improved with “Stroke Windows”. ISRN Neurosci. 2014 Mar 9;2014:654980.

[5] Shen, J et al. Comparative accuracy of CT perfusion in diagnosing acute ischemic stroke: a system review of 27 trials. PLOS ONE 12(5): e0176622. 2017

[6] Kidwell, C. S. et al. Comparison of MRI & CT for Detection of Acute Intracerebral Hemorrhage. JAMA. 2004 Oct 20;292(15):1823-30.

[7] Fiebach et al. Stroke Magnetic Resonance Imaging Is Accurate in Hyperacute Intracerebral Hemorrhage: A Multicenter Study on the Validity of Stroke Imaging. Stroke 35, 502–506 (2004).

[8] Kuo W. et al. Expert-level detection of acute intracranial hemorrhage on head computed tomography using deep learning, Proc. Natl. Acad. Sci. U.S.A. 116 (45) 22737-22745 (2019).

Exemplar case studies from unseen test data

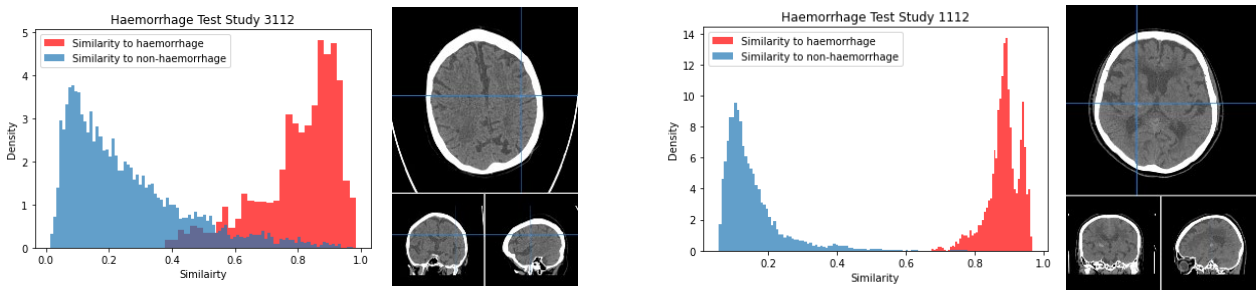

Figure 3: *Right convexity subarachnoid haemorrhage (1.7 mL) successfully detected and classified as haemorrhage (left) and left thalamic intracerebral haemorrhage (0.7 mL) successfully detected and classified as haemorrhage (right).*

The following case studies have been selected due to the small volume of blood present, which can be challenging to detect even with gold standard tools. It is very encouraging that bleeds of this size have been successfully detected and classified by EMVision's portable brain scanner. The sensing limitations of the system, which are influenced by both lesion volume and position, will be confirmed with larger datasets.

Case studies from probabilistic imaging model

In addition to EMVision's core diagnostic detection and classification features, the EMView study data is used to advance additional features. This includes probabilistic anatomical imaging in the form of a base model (boundaries and ventricles) and an advanced model (additionally including white and grey matter).

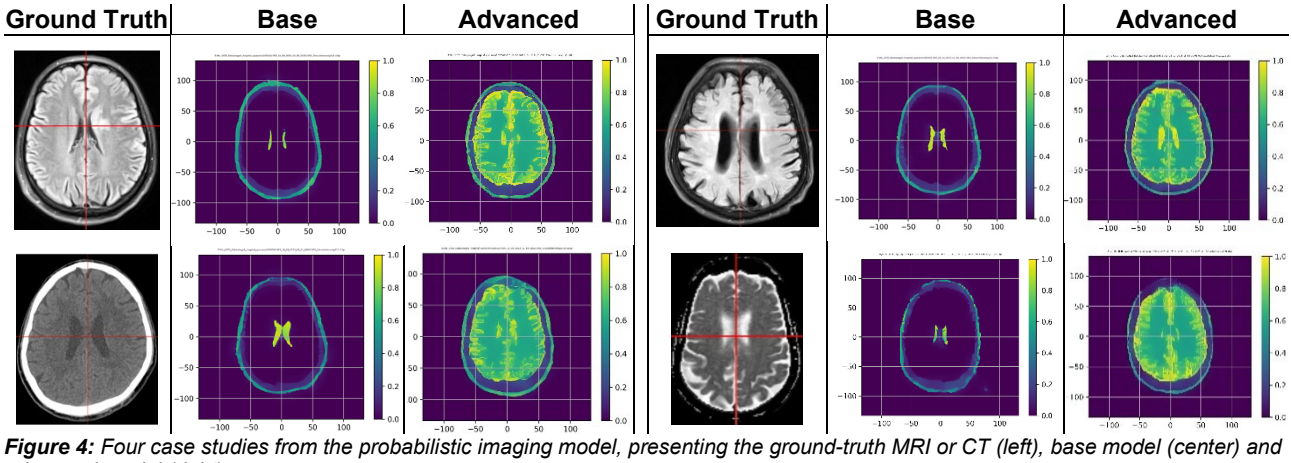

Figure 4: *Four case studies from the probabilistic imaging model, presenting the ground-truth MRI or CT (left), base model (center) and advanced model (right)*

The probabilistic imaging feature, which remains under development, is designed to provide non-diagnostic patient specific fiducial orientation information (i.e. the indicative position of major anatomical landmarks, such as boundaries and ventricles, in front of the device's antennas).

Next steps

The promising results of the EMView study allow EMVision to confidently proceed with the validation trial, as planned, where diagnostic performance of the portable brain scanner will be definitively demonstrated to support an FDA De Novo clearance.

EMVision has site visits scheduled this month with its prospective US investigational sites. The total direct costs of the validation trial, to be funded from cash reserves, are anticipated to be in the region of A$4 million, subject to finalising contracts. The validation trial duration is estimated between 6 and 12 months.

Co-chairs of the Australian Stroke Alliance Professors Geoffrey Donnan and Stephen Davis commented "The results are very encouraging, particularly as related to detection capabilities and sensitivity to small haemorrhages. We look forward to confirmation of this impressive neurodiagnostic capability in the validation trial."

EMVision CEO, Scott Kirkland, commented “There is a huge unmet need for stroke and stroke type diagnosis at the point-of-care. We can fill that need. We are very proud of these results which highlight our technology’s unique neurodiagnostic capabilities. We remain focused on progressing and executing our clinical validation and commercialisation strategy as we look to revolutionise stroke diagnosis and make a substantial positive impact on one of the major causes of global disability.”

Authorised for release by the Board of the Company.

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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	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 Stroke

Stroke is a leading cause of death and disability worldwide. Globally, 1 in 4 adults over the age of 25 will have a stroke in their lifetime. Over 12 million people worldwide will have their first stroke this year and 6.5 million will die as a result.

Rates of stroke are growing fastest in low- and middle-income countries, often where healthcare providers find it more challenging to provide the care that is needed for effective prevention, diagnosis, treatment and rehabilitation of stroke.

According to the World Stroke Organization, the global economic impact of stroke currently represents 0.66% of Global GDP and the total cost of stroke is estimated to tip US$1 trillion by 2030.

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.