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ASX Release

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EMVISION REPORTS VERY ENCOURAGING PILOT CLINICAL TRIAL DATA

Highlights:

- A total of 30 patient datasets (21 ischaemic and 9 haemorrhagic) were processed for this primary study analysis. The primary end point was met, with significant data collected to inform the value proposition and guide improvements in device hardware and software.
- It was observed that the EMVision device was able to classify stroke type (haemorrhagic or ischaemic) with an overall accuracy of between 93.3% and 96%.[1]
- It was observed that the EMVision device was able to localize targets in the correct quadrant (compared to ground truth CT/MRI) with an overall accuracy of between 86.7% and 96%.[1]
- Fusion methodology, which leverages data from multiple algorithms, produced particularly encouraging results, alongside select individual algorithms, which continue to be advanced.
- Positive feedback was received from both operators and patient participants on all scans.
- This is a data acquisition study and not intended to be an interventional study. Hence appropriate caution should be used in extrapolating these results to those of the general population at this stage of the development.

EMVision Medical Devices Limited (ASX: EMV) ("EMVision" or the "Company"), a medical device company focused on the development and commercialisation of portable medical imaging technology, is pleased to announce very encouraging findings from its pilot clinical trial.

The single-site study, at the Princess Alexandra Hospital (PAH) in Brisbane, of patients with diagnosed ischaemic or haemorrhagic stroke, is the first clinical study for EMVision's novel imaging technology. The primary endpoint was the collection of a dataset of stroke patients which improves the understanding of stroke on electromagnetic scattering effects in the brain. This end point has been met, producing datasets that have enabled EMVision to advance its imaging algorithm development and observe the correlation of EMVision scans with "ground truth" CT and/or MRI scans. Furthermore, clinician and patient feedback on the usability and comfort of EMVision's clinical prototype has been collected. The contract research organisation (CRO) is Mobius Medical Pty Ltd. No intervention or modification to the standard of care of hospital-based treatment of stroke was done as part of this study. The scanner was not used for clinical evaluation or imaging. The Clinical Trial Summary is part of this announcement as Appendix A.

The study was designed to collect data to tune the EMVision algorithms. The de-identified patient ground truth CT/MRI "training sets" made it possible for the algorithm team to refine the imaging and classification algorithms. Additionally, clinical advisors in conjunction with the technical team identified five datasets where pathologies were estimated to fall outside of the anticipated prototype hardware range. Data has been presented below with, and without, the 5 excluded datasets for completeness. Due to the design of the study and smaller sample size (including a small number of haemorrhagic cases), the dataset does not enable statistically significant conclusions to be drawn on diagnostic sensitivity/specificity at this stage.

[1] *The algorithms may be subject to further refinement and investors should note there is no guarantee the algorithms will replicate the same level of accuracy on larger data sets without further refinement, or at all.*

The study enrolled and processed datasets from 30 patients (21 ischaemic and 9 haemorrhagic) representing the diversity of stroke in localisation, size and clinical severity. The mean age was 66.7 years of age with the majority, 70% of patients, aged 60 years and over. There were slightly fewer male patients (43.3%) than female (56.7%). Of the 30 patients, 19, (63.3%) had only a CT performed whereas 11, (36.7%) had CT/MRI performed. As a result of these scans, 30% of patients were diagnosed as having had a haemorrhagic stroke and 70% as having had an ischaemic stroke. National Institutes of Health Stroke Scale (NIHSS) was recorded. The NIHSS score is used to measure stroke severity. The mean NIHSS score was calculated as 5.2 which indicates mild severity. The participating patients' de-identified CT and/or MRI ground truth scans were interpreted and classified independently by EMVision clinical and radiology advisors. The EMVision device scans were acquired close to the timing of the corresponding ground truth scans. After the EMVision datasets were processed by the algorithm team, the algorithm classification and localisation outputs were verified by clinical advisors.

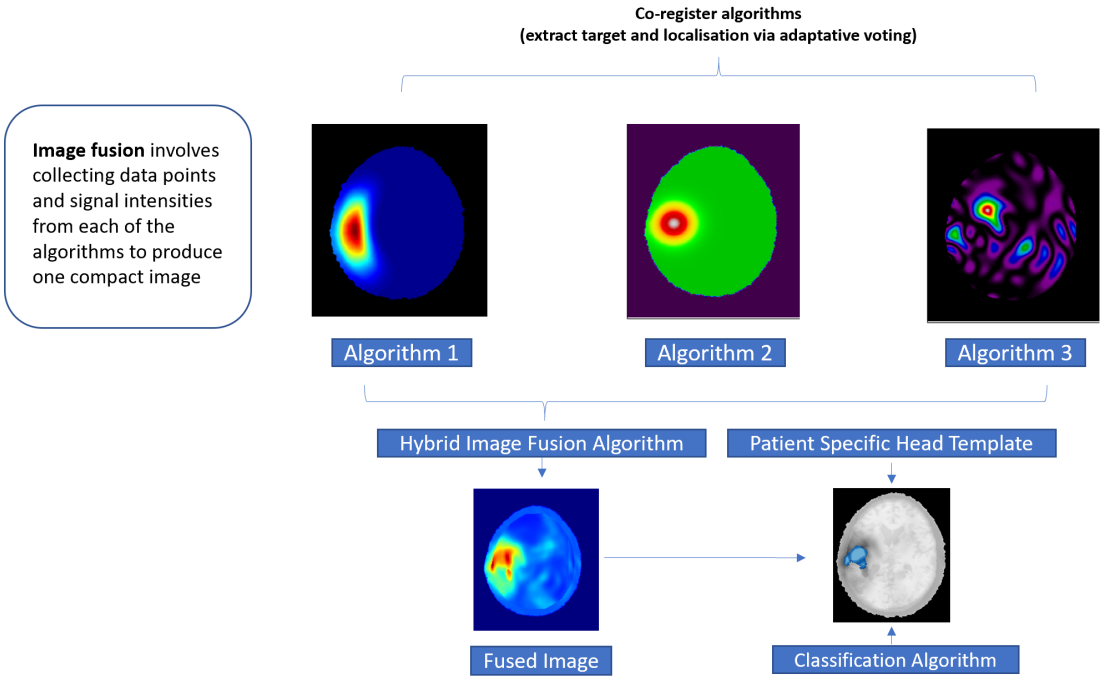
Clinical Trial Results

The EMVision classification was observed to demonstrate an ability to differentiate between haemorrhagic and ischaemic stroke with an overall accuracy of 93.3% [95% CI[2]] in the full sample (30) and 96% (95% CI) in the sample excluding patients with pathologies located outside the estimated prototype hardware range.

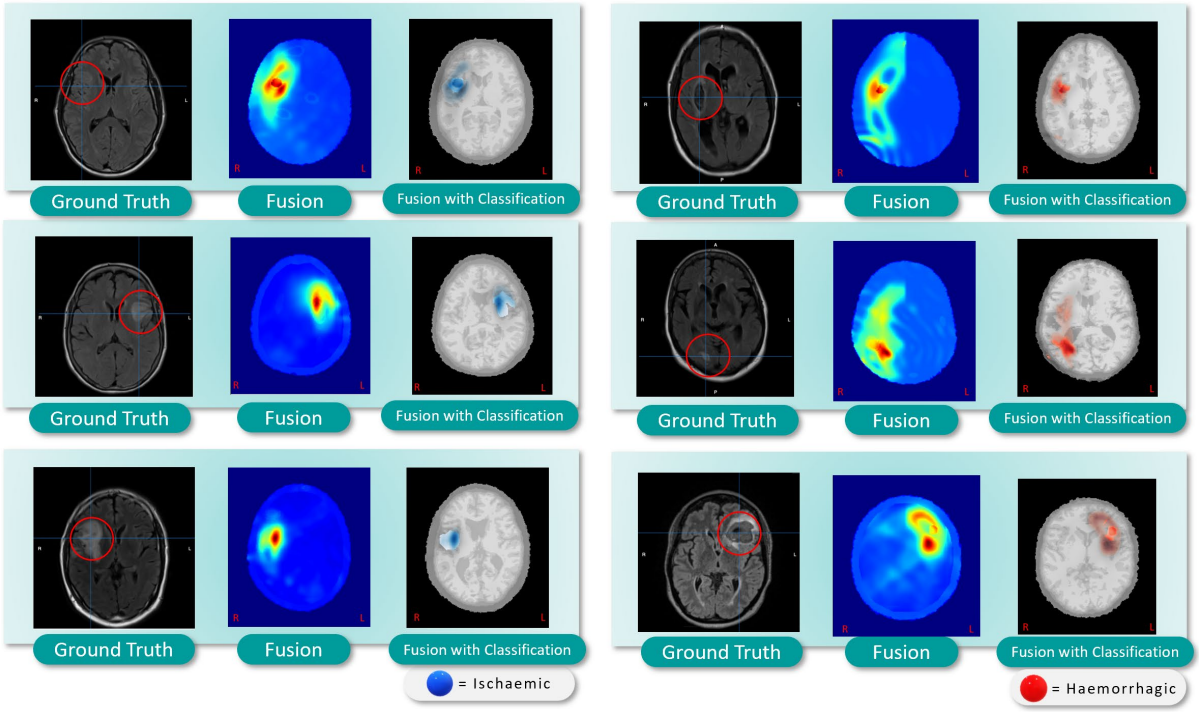
Localisation has been evaluated based on whether the EMVision fusion images resulted in target detection in the same quadrant as the ground truth scans (CT/MRI). For any scenarios where the ground truth image or fusion image had multiple areas of pathology identified, the clinical verifier has taken the most prominent / intense area to be the area of interest.

The EMVision fusion images were observed to be able to localise in the correct quadrant with an overall accuracy of 86.7% [95%CI] (full sample of 30 datasets) and 96% [95%CI] (sample with the 5 excluded datasets).

The study datasets have enabled the algorithm team to advance the hybrid "fusion" methodology, which is a powerful approach to imaging. The fusion hybrid works by extracting the target lesion and estimated location in each algorithm and applies a pixel-wise voting algorithm. The fused image then leverages the classification algorithm and can be overlaid on a predicted head template. The algorithm team will continue to advance this fusion methodology in consultation with EMVision's clinical advisors. The fusion imaging approach is illustrated below with examples.

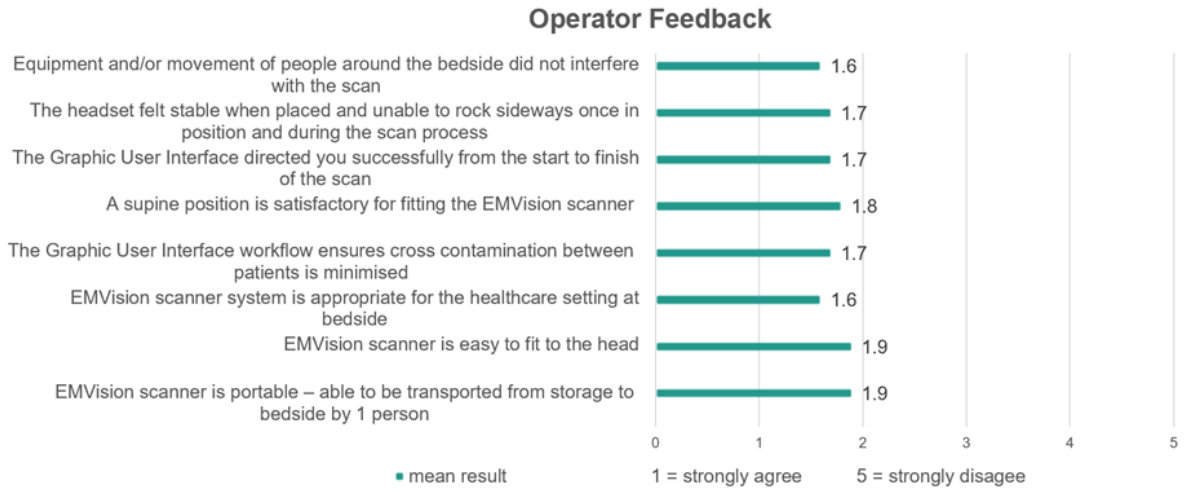


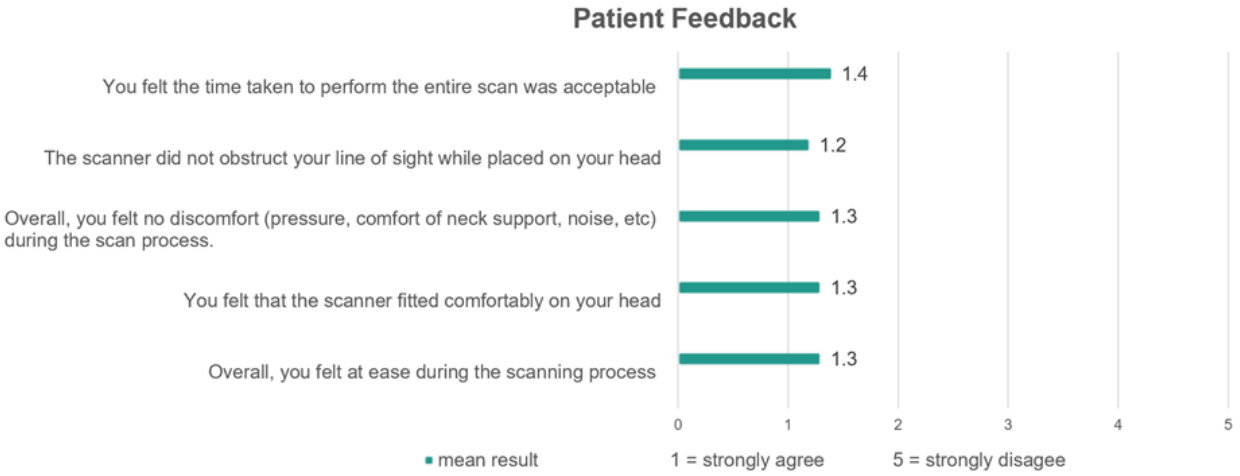
2 CI: Confidence Interval



The above examples have been selected to demonstrate how the fusion methodology can be used to detect, localise, and classify stroke type and should be interpreted in light of the intent and results of this study to date.

Secondary endpoints for operator and patient feedback were reported by a Likert scale (1-5), with a score of 1 representing 'strongly agree' and 5 representing 'strongly disagree'. Despite being a prototype, the device was well tolerated by both operators and patients. The feedback was consistently positive and is provided below. Furthermore, there were no device-related adverse events reported for the patients defined in the primary study analysis.





What is the clinical significance of these findings?

Co-chairs of the Australian Stroke Alliance and past presidents of the World Stroke Organisation, Professors Stephen Davis AM and Geoffrey Donnan AO provided expert feedback. Prof Davis commented “These developments are highly encouraging, clearly showing localisation of ischaemic and haemorrhagic events. An important future step will be testing the fusion approach for specificity and sensitivity to blood.” Prof Donnan commented “We are impressed with the progress and we are looking forward to ongoing collaboration and facilitating further validation across additional centres.” Both Professors Davis and Donnan concurred that “it cannot be underestimated how important this cutting-edge technology could become for future pre-hospital stroke management.”

Stroke neurologist and EMVision clinical advisor Professor Michael O’Sullivan commented, “The latest results are exciting in showing excellent discrimination between ischaemic stroke and haemorrhage in the data collected to date. Interesting future questions include the sensitivity of the technique for early detection of bleeding, both in the pre-hospital setting and in stroke units, where monitoring is currently limited to detection of clinical deterioration. The value of combining multiple algorithms in a fusion approach is also an emerging theme, which could help to tailor the approach to the setting and clinical question”.

EMVision’s CEO, Dr Ron Weinberger, commented “These promising results, the first in stroke patients for our technology, provide a strong foundation with which to progress our development program. We are delighted by these results which indicate that we are able to discriminate and localize haemorrhagic and ischaemic strokes with an encouraging degree of accuracy under these conditions. We have exceeded our original objectives for this study. While we still have a way to go, we are well placed to develop our value proposition into a fully-fledged commercial product.”

This data has allowed EMVision to build significant improvements into our product development plan, including software, hardware and usability features, as we progress down our commercialisation path. EMVision’s ethics approval and clinical trial contractual arrangements with Princess Alexandra Hospital allow for up to 50 patients to be enrolled. With the successful outcomes obtained from the datasets collected to date and the strong support the Company has obtained from its clinical advisors and investigators, the Company sees additional benefit in enrolling a further 20 patients, concurrently with its other activities. Further “training datasets” for some of the algorithms, in particular, from haemorrhagic patients, will allow for a larger database to better inform localisation and classification. Notwithstanding that, the Company believes it has sufficient information from the study to continue to aggressively advance its product development. The Company is well positioned to plan its next stage of expanded clinical studies and continue discussions with potential commercial partners.

Authorised for release by the Board of the Company.

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About Stroke

Stroke causes an enormous health and economic burden throughout the world. Stroke is the second leading cause of death and the third leading cause of disability. Imaging is the key to diagnosis and monitoring of acute stroke. The treatments offered require differentiation between ischaemic and haemorrhagic stroke. This determination is essential before pursuing proven effective, time-critical therapies.

About EMVision Medical Devices

EMVision Medical Devices Limited is focused on the development and commercialisation of medical imaging technology. The Company is developing and seeking to commercialise a potentially cost effective, portable, medical imaging device using electromagnetic microwave imaging for diagnosis and monitoring of stroke and other medical applications. The technology is the result of over 10 years of development by researchers at the University of Queensland. The team of approximately 30 researchers is led by co-inventors Professor Amin Abbosh, who is considered a global leader in electromagnetic microwave imaging, along with Professor Stuart Crozier, who created technology central to most MRI machines manufactured since 1997. EMVision's CEO, Dr Ron Weinberger, is the Former Executive Director and CEO of Nanosonics' (ASX:NAN), a $1.65 billion market cap healthcare company. Dr Weinberger has over 25-years' experience developing and commercialising medical devices. During his time at Nanosonics, Dr Weinberger co-developed the company's platform technology and launched their breakthrough product 'Trophon' globally, which would go on to become the gold standard for infection prevention. Dr Weinberger was instrumental in transforming Nanosonics from a research and development company to one of Australia's leading medical device commercialisation success stories.

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.

Appendix A – Clinical Trial Summary

Study Title	Feasibility Study to Obtain Imaging Data from Participants with a Diagnosed Stroke to Refine the Algorithms for the EMVision Brain Scanner
Development Phase	Feasibility
Indication	Stroke
Study Device	EMVision Brain Scanner
Number of Participants	30
Number of Centres	1 in Australia
Site	Princess Alexandra Hospital, Brisbane
Study Duration	Approximately 6 months
Primary Objective (s)	To obtain a set of data from stroke participants to refine the algorithm of the software component of the EMVision brain scanner
Primary Endpoint	A dataset of stroke patient scans which improves the understanding of stroke on electromagnetic scattering effects in the brain.
Study Design	This study is a single-centre, two (2) groups, observational study of participants with a diagnosed stroke. Imaging data acquired would be used to refine the algorithm of the software component of the EMVision brain scanner. Up to twenty (20) participants will be enrolled in each group: haemorrhagic stroke (group A) and ischemic stroke (group B) with up to 30 patients. No intervention or modification to the usual hospital based treatment of stroke is proposed as part of this trial. An initial set of 3 patients will be used to define standard operating procedures around clinical scanning.
Inclusion Criteria	1. Adults >=18 years of age. 2. Admitted to hospital with new neurological signs and confirmed diagnosis of stroke supported by conventional brain imaging. 3. Ability to provide informed consent. Participants will provide written informed consent. Where this is not possible, surrogate consent will be obtained. 4. Ability to adhere to study visit schedule and other protocol requirements. 5. Confirmed diagnosis of stroke within 72h of admission. 6. Head size deemed suitable for scanning with the EMVision brain scanner.
Exclusion Criteria	1. Experiences seizures from onset of stroke, or known history of seizure episodes. 2. Has injury or known medical condition on the head that would not allow the placement of EMVision brain scanner. 3. Is unable to lie still for the duration of the scan. 4. Is not a suitable candidate according to the assessing investigator. 5. Has any metal implants in the head or neck for example stents, aneurysm clips, surgical clips, pressure monitors and drains. 6. Is known to be pregnant or lactating.
Study Procedure/Follow-up	Potential participants with a confirmed diagnosis of stroke would be reviewed to participate in the study. The participant would be assessed and, if eligible, the participant or participant's legal representative would be approached for consent to participating in the study. After consent, the first scan using the EMVision brain scanner would be conducted and follow-up scans would be conducted as deemed appropriate by the investigator. Each scan will be repeated to obtain paired image acquisitions for comparison. Patients will be followed for up to 28 days following admission as inpatients, or until discharge (whichever is sooner).