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ASX Release

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PROMISING CLINICAL TRIAL DATA DRIVES CONFIDENCE FOR EXPANDED STUDIES

Highlights:

- A total of 50 patient datasets (37 ischaemic and 13 haemorrhagic) have now been processed, with 20 new patients added, for this primary study analysis. The study was designed to collect data to tune the EMVision algorithms, which have been applied to the full 50 patient dataset.
- Key findings:
  - It was observed that the EMVision device was able to classify stroke type (haemorrhagic or ischaemic) with an overall accuracy of 98% in the full sample (50)[1]
    - Urgent neuroimaging is key to the diagnosis and treatment of acute stroke. Proven and effective time-critical therapies require differentiation between ischaemic and haemorrhagic stroke.
  - It was observed that the EMVision device was able to localise target/s in the same quadrant as on comparator CT or MRI scans with an overall accuracy of 78% in the full sample (50)[1]
    - Localization provides useful guidance to the area of abnormality.
- The primary end point was met, with invaluable data collected throughout the study which has informed the value proposition and guided improvements in headset design, patient positioning and software. There were no device related adverse events. This was an observational 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 additional 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, has been 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 was met, producing datasets that have enabled EMVision to advance its electromagnetic (EM) imaging algorithm development and observe the correlation of EMVision scans with "ground truth" CT and/or MRI scans. 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 Clinical Trial Summary is part of this announcement as Appendix A.

EMVision's CEO, Dr Ron Weinberger, commented "The results indicate that the ability to distinguish stroke types was very high. This is the most critical element as it goes directly to the type of intervention that needs to be made in hospital and importantly whether clot busting drugs could reliably be introduced in the field in

[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 future in road and air ambulance settings. The results in this respect are very encouraging. We are pleased with the progress achieved and the data points towards our ability to achieve positive outcomes in our wider clinical trials planned for next year."

The study was designed to collect data to tune the EMVision algorithms. The deidentified patient ground truth CT/MRI "training sets" made it possible for the algorithm team to refine the imaging and classification algorithms. Due to the design and sample size of the study, the dataset does not enable statistically significant conclusions to be drawn on diagnostic sensitivity/specificity.

As previously advised, analysis performed on an initial 30 patient cohort was reported in October 2020. This analysis included classification observations of between 93% to 96% and localization observations of between 86% to 96% respectively. In addition, a fusion process was employed which involves leveraging data points from multiple algorithms to arrive at a final output. Please see ASX Release "EMVision reports very encouraging pilot clinical trial data" for further information.

In total the study has enrolled and processed data from 50 patients (37 ischaemic and 13 haemorrhagic). The refined classification and localisation algorithms have been applied to the entire 50 patient dataset. The patients enrolled represent a diversity of stroke in localisation, size and clinical severity. The mean age was 67.7 years of age with the majority, 72% of patients, aged 60 years and over. There were equal numbers of male and female patients. Of the 50 patients, 29, (58%) had only a CT performed whereas 21, (42%) had CT/MRI performed. As a result of these scans, 26% of patients were diagnosed as having had a haemorrhagic stroke and 74% as having had an ischaemic stroke. National Institutes of Health Stroke Scale (NIHSS) was recorded for 49 patients. The NIHSS score is used to measure stroke severity. The mean NIHSS score was calculated as 5.9 which indicates mild-moderate 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 classification algorithms and localisation algorithms outputs were verified by clinical advisors.

Continued Testing Drives Further Confidence

The EMVision fusion classification was observed to demonstrate an ability to differentiate between haemorrhagic and ischaemic stroke with an overall accuracy of 98% in the full sample (50).

Stroke causes an enormous health, societal and economic burden throughout the world. Stroke is a leading cause of death and disability. Urgent neuroimaging is key to diagnosis, treatment 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 and interventions. The latest data shows highly encouraging discrimination between ischaemic stroke and haemorrhage in the dataset, with classification algorithms offering potential decision support capabilities not found with traditional CT or MRI.

In clinical practice, determination of the stroke location is most often made by assimilating all the available patient information, which includes the physical neurological symptoms, as well as any findings from neuroimaging scans. In this study, 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 localise target/s in the same quadrant as per patient's CT or MRI scan with an overall accuracy of 78% in the full sample (50).

The Clinical Prototype used during the study acquired data from a single default position on a patient's head. Some sensitivity to patient positioning was noticed to impact consistency of co-localisation in later datasets. The Company's 1st Gen device intended for commercialisation, has been designed such to allow for up to three scan positions and superior patient positioning, enabling multiple acquisition positions, and is anticipated to allow for greater consistency of co-localization between EM neuroimaging and CT or MRI neuroimaging.

This study and the data collected has allowed EMVision to build significant improvements into its product development pathway, including software and hardware advancements that feed into its 1st Gen portable brain scanner and 2nd Gen development plans. The Company is currently preparing for expanded clinical studies with its 1st Gen device intended for commercialization.

Stroke neurologist and EMVision clinical advisor Professor Michael O'Sullivan commented, "These results, in a larger sample of patients with different types of stroke, have been eagerly awaited. 'Ischaemia or heamorrhage?' is the first question asked when a patient with suspected stroke is placed in a scanner. It is critical to determining the type of urgent intervention the patient needs. It is even more important at the point of care, away from hospital scanning facilities, as any delay in answering this question reduces the chance of a good final outcome. These results are highly promising in suggesting that the EMVision device can produce highly accurate discrimination of ischaemia and haemorrhage.".

Authorised for release by the Board of the Company.

[ENDS]

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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 20 researchers is led by co-inventor Professor Amin Abbosh, who is considered a global leader in electromagnetic microwave imaging. EMVision's Chief Scientific Officer is Professor Stuart Crozier, who is a co-inventor and is globally renowned for creating 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 $2 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	50
Number of Centres	1 in Australia
Site	Princess Alexandra Hospital, Brisbane
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 thirty-five (35) participants will be enrolled in each group: haemorrhagic stroke (group A) and ischemic stroke (group B) with up to 50 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).