**ASX** Release



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# PROMISING FIRST STROKE PATIENT IMAGES FROM CLINICAL TRIAL

**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 provide preliminary images from its clinical trial.

The imaging algorithm team, who received blinded data, has processed, with clinical assessment of ground truths, our first set of two similar ischemic patient datasets, with very encouraging progress. These initial datasets have been reviewed extensively by EMV clinical advisors, including neurology and radiology experts. The EMV functional imaging scans demonstrate a strong correlation with the ground truth scans for these patients (MRI and CT). This correlation includes the detection and localization of abnormal brain tissue. This is the first set of fully analysed data with complete clinical assessment. They are provided below:



The above EMV images are reconstructed by creating a map of the electromagnetic wave scattering that arises from the contrast in the electrical parameters between ischemic brain tissue and healthy brain tissue. The EMV scans were taken after the patients' initial treatment and "ground truth" MRI FLAIR and CT perfusion scans (displayed here with universal orientation). The higher intensity regions in the EMV scans, displayed in red, represent higher contrast in electrical properties, as is typical of anomalies. Both patient cases involve a reasonably small infarct (visible on the MRI FLAIR images) and a larger area of abnormal perfusion (penumbra). For both cases, the EMV ision technique produces accurate localisation of abnormal brain tissue which is clearly distinguished from the surrounding brain tissue. This is typically more difficult on plain CT scans.

EMVision clinical advisor and Neurologist specializing in Stroke, Professor Michael O'Sullivan, commented "Although obviously preliminary, these early results are highly promising. In both cases, the EMVision scans were clearly positive and provided a good guide to the extent of brain tissue damaged or under threat." Co-chairs of the Australian Stroke Alliance and past presidents of the World Stroke Organization, Professors Stephen Davis AM and Geoffrey Donnan AO also provided expert feedback. Professor Davis commented "These early images are clinically promising, clearly showing the effects of ischemic stroke in the same region as the gold standard imaging methods". Prof Donnan commented "the lightweight portability of the device makes it a potential candidate for emergency stroke imaging in the pre-hospital setting."

EMVision CEO, Dr Ron Weinberger, commented "Our first set of images, while preliminary, is certainly encouraging, demonstrating a strong correlation with mainstay medical imaging outputs, with the potential to add unique functional information. We are confident that as we continue to process further stroke patient data, we will demonstrate our unique value proposition to meet a major unmet clinical need in rapid and portable stroke diagnosis and monitoring."

The primary endpoint of EMVision's pilot clinical trial, which commenced in late January 2020, is to generate a dataset of stroke patient scans which improves the understanding of stroke on electromagnetic scattering effects in the brain. The Company will use this data to refine and select the optimal imaging algorithms as well as generating early data on correlation with CT and/or MRI images. The Clinical Trial summary is part of this ASX Announcement as Appendix A.

These results reflect an initial two datasets of the patients enrolled to date. The final results of the clinical study, when completed, will undergo a detailed review by the Company's clinical advisors. In the interim, the algorithm team are now processing further patient datasets including different stroke sizes, subtypes and locations. The algorithm team will also refine and validate different "fusion" combinations of algorithms to deliver the ideal clinical output. The Company expects to provide updates to the market as it reaches further relevant milestones throughout the clinical testing.

Authorised for release by the Board of the Company.

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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 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 \$1.9 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.

## 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
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	used to refine the algorithm of the software component of the EMVision
	brain scanner. Up to twenty (20) participants will be enrolled in each
	aroup: haemorrhagic stroke (aroup A) and ischemic stroke (aroup 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 of neck for example stents,
	A le known to be progrant or legiteting
Study	Detential participants with a confirmed diagnosis of stroke would be
Brocedure/Follow, up	reviewed to participate in the study. The participant would be assessed
Frocedure/r onow-up	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).
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