



# ASX Release

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## EMVISION COMPLETES 30 PATIENT ENROLMENT

**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 the following update to the market.

The Company advises that it has completed enrolment of its target 30 stroke patients in its pilot clinical study. The patient datasets are now being processed and will undergo clinical review. Top-line results from the study are expected to be released in the 4th quarter of CY 2020.

The single-site study of participants with diagnosed ischaemic or haemorrhagic stroke is the first clinical study for EMVision’s breakthrough imaging technology. The primary endpoint is the collection of a dataset of stroke patients which improves the understanding of stroke on electromagnetic scattering effects in the brain. The Clinical Trial Summary is part of this announcement as Appendix A. These datasets enable EMVision to advance its imaging algorithm development and observe the correlation of EMVision scans with CT and/or MRI scans. Further, clinician and patient feedback on the operation of EMVision’s clinical prototype will be reported on. The outputs from this study feeds into the product development, clinical validation and regulatory strategy for EMVision’s 1st generation device for commercialisation.

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 \$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 ‘Tropon’ 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 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	<ol style="list-style-type: none"> <li>1. Adults <math>\geq 18</math> years of age.</li> <li>2. Admitted to hospital with new neurological signs and confirmed diagnosis of stroke supported by conventional brain imaging.</li> <li>3. Ability to provide informed consent. Participants will provide written informed consent. Where this is not possible, surrogate consent will be obtained.</li> <li>4. Ability to adhere to study visit schedule and other protocol requirements.</li> <li>5. Confirmed diagnosis of stroke within 72h of admission.</li> <li>6. Head size deemed suitable for scanning with the EMVision brain scanner.</li> </ol>
Exclusion Criteria	<ol style="list-style-type: none"> <li>1. Experiences seizures from onset of stroke, or known history of seizure episodes.</li> <li>2. Has injury or known medical condition on the head that would not allow the placement of EMVision brain scanner.</li> <li>3. Is unable to lie still for the duration of the scan.</li> <li>4. Is not a suitable candidate according to the assessing investigator.</li> <li>5. Has any metal implants in the head or neck for example stents, aneurysm clips, surgical clips, pressure monitors and drains.</li> <li>6. Is known to be pregnant or lactating.</li> </ol>
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).