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ASX Release

EMvision Medical Devices Ltd
ACN 620 388 230
Level 10, 12 Creek Street,
Brisbane Qld 4000
02 8667 5337
contact@emvision.com.au

ENTRY INTO CLINIC ACHIEVED

EMVision Medical Devices Limited (ASX: EMV) ("EMVision" or the "Company"), a medical device company focused on the development and commercialisation of medical imaging technology, is pleased to advise that the Princess Alexandra's biomedical engineering department has successfully completed functional and electrical safety testing of the EMV brain scanner unit and key checks (ethics approval, notification to TGA, Electromagnetic compatibility results) essential to commence the Company's clinical trials. The Company has worked with the lead clinical investigator to complete the necessary training with the device prior to the commencement of clinical trials

In parallel to this work in the clinic, the Company has continued to test the newly fabricated clinical units on several healthy volunteers, and demonstrated encouraging progress on the imaging algorithms, establishing a solid imaging "baseline'' to support the clinical trial. The Company anticipates receiving administrative "green light" for activation and to commence patient scanning shortly. This marks an important phase of the clinical development program for EMVision's portable brain scanner for stroke and traumatic brain injury diagnosis and monitoring.

During the trial, the Company's primary objective will be to collect imaging data from stroke patients that allows refinement and selection of the optimal imaging algorithms as well as early data on correlation with CT and/or MRI. The single centre study, up to 6 months, will enrol 30 diagnosed stroke patients with confirmatory CT and/or MRI. No intervention or modification to the usual hospital-based treatment of stroke is proposed as part of this trial.

The Company expects to provide updates to the market as it reaches relevant milestones throughout the clinical testing.

EMVision CEO, Dr Ron Weinberger, commentated "To enter the clinic, on schedule, with a breakthrough technology like ours, is an exciting milestone. The clinical trial will provide us with valuable learnings and enablement to explore the potential of our technology for diagnosing and monitoring time sensitive neurological disorders at the point of care in a manner otherwise not possible today.

EMV was recently invited to the Radiological Society of North America's 105th Scientific Assembly and Annual Meeting in Chicago, the world's biggest radiology conference with more than 50,000 attendees from around the world as well as the largest exhibition of imaging products and companies. It is clear from the meetings that we had with executives of world leading imaging manufacturers and distributors, that point of care diagnosis and monitoring of stroke is a significant unmet need for which there is no imaging solution in use. This strongly validates our approach of having a small footprint, safe and easy to use device that can be quickly deployed for diagnosis and continuous monitoring."

Lead Investigator Dr David Cook commented "the rapid progress made by EMV in deploying the brain scanner in the hospital for us to initiate our trial with stroke patients is great. Our vision is that timely and widespread access to a portable, point-of-care scanning will improve patient survival, reducing personal disability and the community burden of stroke. While stroke is the first clinical target, Electromagnetic (EM) scanning has a broad potential for diagnosing and monitoring a range of other brain disorders."

The Clinical Trial summary is part of this ASX Announcement as Appendix A.

Authorised for release by the Board of the Company.

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For further information, media or investor enquiries, please contact:

Michael Wills
Investor & Media Relations
+61 468 385 208
michael@spring-communications.com.au

Scott Kirkland
Executive Director
+61 2 8667 5337
skirkland@emvision.com.au

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 '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	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).