



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

FDA BREAKTHROUGH DEVICE APPLICATION UPDATE

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, provides an update on its application for Breakthrough Device Designation (BDD) from the U.S. Food and Drug Administration (FDA). The FDA BDD is a discretionary program that offers priority review and interactive communication across the device development and validation path.

Feedback received on the application is that the preliminary evidence supports the potential of the technology to differentiate and localize haemorrhagic and ischemic stroke, however additional clinical study data is required by the FDA, which EMVision will generate through further clinical development. EMVision advises that it has not been granted BDD at this time. The Company anticipates to further pursue BDD once the required clinical data is available.

EMVision’s pursuit of the FDA De Novo regulatory marketing authorisation pathway for its 1st Gen portable brain scanner product, as previously advised, remains unaffected.

The Company is also pleased to advise that it expects to complete enrolment of the additional 20 patient datasets (50 in total), of its pilot trial this month, with processing and reporting of these additional datasets anticipated this quarter.

EMVision CEO Dr Ron Weinberger commented “We’re grateful for the quality feedback received from the FDA. Our pathway to FDA marketing authorisation remains unchanged, as does our preparation for expanded clinical studies and future commercialisation. We look forward to updating the market with the outcomes of our pilot study in the near term.”

Authorised for release by the Board of the Company.

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

Andrew Keys
Investor Relations
+61 400 400 800
andrew.keys@keysthomas.com

Sling & Stone
Media and Communications
emvision@slingstone.com
02 8073 5390

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 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.