



ASX Release

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FDA PROVIDES DE NOVO GUIDANCE

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 communicate the guidance received from the FDA regarding the regulatory requirements applicable to EMVision’s portable brain scanner.

The FDA has recommended that the appropriate regulatory pathway for the EMVision portable brain scanner is the De Novo process. The De Novo pathway is designed for low to moderate-risk, first-of-a-kind products and employs a risk-based strategy for evaluating applications. It is used for new, novel devices without previous classification that are likely classified, based on their intended use and risk profile, as class II (same as MRI, ultrasound and CT) and for which there is no immediate comparable device.

The Company will engage with the FDA to confirm the required evidence including the planned clinical performance data necessary to support a De Novo submission as well as an application for the FDA’s “breakthrough device program”. The breakthrough program aims to speed development and assessment of devices that promise a more effective treatment or diagnosis for a life-threatening or irreversibly debilitating conditions. The Company intends to submit an application for breakthrough device designation, acceptance into this program is not guaranteed.

EMVision CEO, Dr Ron Weinberger, commented “The De Novo guidance is in line with our expectations and planning as a truly novel device, and offers typically less complexity and shorter approval times compared to a Premarket Approval (PMA) pathway which is a more burdensome pathway for higher risk devices. As we continue to grow our commercial product development team, we have focused on bringing on experienced individuals who have a successful track record in developing and validating medical devices to meet international regulatory standards, including the FDA De Novo pathway and success in the breakthrough device program.”

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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-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.