

ASX Release

EMVISION ACHIEVES PRODUCT DEVELOPMENT MILESTONES AND FURTHER GRANT FUNDING

Highlights:

- *Device improvements introduced for Stage 2 of multi-site clinical trial, ensuring Gen 1 portable brain scanner is easy to operate and deploy by any trained healthcare professional.*
- *\$600,000 non-dilutive grant payment received following pivotal milestone for Gen 2 device reached under MRFF program in partnership with the Australian Stroke Alliance (ASA).*
- *Collaboration with Titan Neurosciences Research Australia ('Titan'), the Australian Stroke Alliance's national digital telehealth partner, for core imaging lab services and preparation for telehealth integration.*

EMVision Medical Devices Limited (ASX:EMV) ("EMVision" or the "Company"), is pleased to provide a clinical trial and product development update.

Gen 1 – Bedside Device

EMVision is in the late stages of integration, testing and documentation to release its upgraded Gen 1 devices in the coming weeks for Stage 2 (pre-validation) of the Company's multi-site clinical trial. Advancements include an enhanced disposable cap with integrated fiducial marker. This single use per scan consumable provides a combined solution for infection prevention and ease of headset positioning. Other enhancements for ease of deployment include a backup power source and updated graphical user interface. These improvements have been introduced to make EMVision's novel portable brain scanner as easy to use as possible with seamless workflows.

The Company has also commenced a collaboration with Titan Neuroscience Research Australia ('Titan'), the Australian Stroke Alliance's national digital telehealth partner. Titan is a specialist clinical R&D firm supporting Phase I-IV clinical trials and providing brain imaging and analytics expertise to expedite clinical validation for new technologies. Titan will provide Core Imaging Lab services to EMVision, namely clinical stroke imaging expertise and segmentation analyses of "ground truth" CT/MRI during Stage 2 of the multi-site trial. In addition, preparations are commencing for integration with Titan's telehealth platform, Zeus.

Gen 2 – Pre-hospital Device

EMVision has achieved a significant milestone for its Gen 2 device under the Commonwealth of Australia Medical Research Future Fund (MRFF) program in partnership with the Australian Stroke Alliance (ASA), "Technical Adaption of Ambulance Devices", triggering a \$600,000 non-dilutive milestone grant payment. This follows an advanced CAD of the ultra-lightweight Gen 2 helmet system, as well as miniaturised component prototyping and successful bench testing of the 3D Gen 2 antenna array. Development of an advanced prototype suitable for in-human studies is progressing well, with the 'proof of concept' unit anticipated to be fabricated within the next two quarters.

EMVision CEO, Dr Ron Weinberger commented: “We are making strong progress and it’s great to see the learnings from the Gen1 device being incorporated, while more importantly we have another attractive consumable revenue stream in the integrated disposable cap and fiducial marker. Bringing Titan on board will enable state of the art imaging expertise and analysis of the CT and MRI datasets from our trial and we look forward to integrating with Titan’s national telehealth platform. In the background we have also made substantial progress with the design and development of Gen 2 and are excited to display and test the proof of concept device within the next two quarters.”

| OVERVIEW OF PATH TO MARKET | | | | |
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| GEN 1  | Pre-Validation Stage 2 Stage 2 will enroll up to 150 acute stroke/mimic participants to achieve hardware verification, safety and acute stroke data to advance AI algorithm objectives. | Validation Validation phase will confirm sensitivity/specificity and safety. Sample size and end points to be confirmed during pre-validation. | Regulatory Key jurisdictions regulatory submission and approval process including FDA, CE and TGA. | Go-to-market First target markets United States, Europe and Australia. |
| Commencing coming weeks | | | Target FY25 | |
| GEN 2  | Advanced Prototype Fabrication CY Q2/Q3 2023 | Healthy Volunteer Testing CY Q4 2023 | Road/Air Ambulance Trials CY 2024 | Regulatory Targeting expedited FDA 510(k) marketing pathway leveraging Gen 1 as predicate device. |
| KEY DEVELOPMENT MILESTONES | | | | |

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 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 \$1.5 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.