

ASX Release

GEN 2 ADVANCED PROTOTYPE ASSEMBLED

EMVision Medical Devices Limited (ASX:EMV) (“EMVision” or the “Company”) is pleased to advise that an advanced 28-antenna prototype of its 2nd Gen ultra-light weight helmet scanner, designed for road and air ambulance deployment, has been assembled for bench testing. EMVision’s complementary product suite will address a huge unmet clinical need in both bedside (1st Gen, which is currently undergoing multi-site clinical trials), and first responder (2nd Gen) brain imaging.

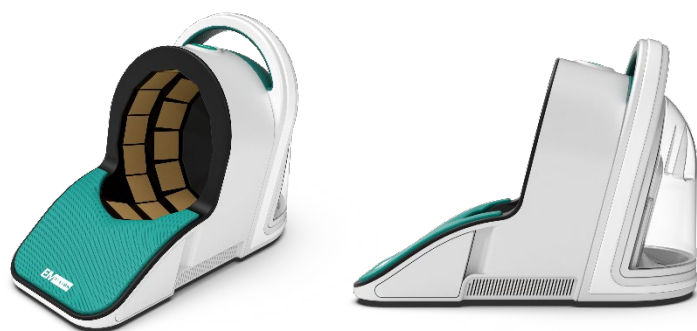
The Gen 2 headset weighs under 10kgs and is intended to be transported to the point-of-care via a backpack. It contains a 28-antenna 3D array which is designed to provide entire brain coverage in a single scan, with high performance ultra-light weight antennas. A silicone membrane with coupling media provides coupling of the antennas to the head. This membrane has been designed as a reusable but replaceable component and the coupling media will be a per scan consumable item. Core algorithms being developed for Gen 1 are planned to be adapted and updated for the Gen 2 device.

The bench testing will evaluate a range of technical parameters compared to simulations, leading to target detection investigations. An ethics submission for healthy human volunteer testing has been submitted and is expected to commence in the coming months. This testing intends to evaluate usability, ergonomics and signal benchmarking.

The regulatory strategy for Gen 2 is to leverage Gen 1 as a predicate device to pursue the FDA 510(k) pathway. Under 510(k) the device seeking clearance is required to prove ‘substantial equivalence’ to a predicate device that has already been deemed safe and effective.

Proof of concept road/air trial system

This advanced prototype is a precursor to the ‘proof of concept’ system (concept pictured below), suitable for pre-hospital deployment, which is on track to be assembled in the first half of calendar year 2024, in line with the company’s development timetable. It will then be used for planned road/air ambulance trials under EMVision’s collaboration with the Australian Stroke Alliance.



Authorised for release by the Board of the Company.

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About EMVision Medical Devices

EMVision Medical Devices Limited (ASX:EMV) is an innovative Australian medical device company developing a novel approach to looking inside the human body. Our product pipeline includes portable, non-invasive, affordable and safe neuroimaging devices.

Our vision is to help transform and improve the timely diagnosis and treatment of stroke and other time sensitive medical emergencies, at the point-of-care.

EMVision has offices in Sydney and Brisbane www.emvisionmedical.com

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.

Inherent risks of Investment in Medical Device development Companies

There are a number of inherent risks associated with the development of new medical device products to a marketable stage. The clinical trial process, which is often lengthy, is designed to assess the safety and efficacy of a device prior to commercialisation and there is no guarantee of achieving the outcomes necessary to generate a viable commercial product. Other risks include uncertainty of patent protection and proprietary rights, the obtaining of necessary regulatory authority approvals and the evolving competitive landscape. Companies such as EMVision are dependent on the success of their research and development projects, product development and on the ability to attract funding to support these activities. Investment in research and development and novel product development cannot be assessed on the same fundamentals as trading and manufacturing enterprises. Therefore investment in Companies specialising in such development must be regarded as speculative. EMVision recommends that professional investment advice be sought prior to such investments and cautions investors that the risks of an investment in an entity such as EMVision is not limited to the risks disclosed in this announcement.

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