

ASX Release

EMvision Medical Devices Ltd
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EMVISION RELEASES HALF YEARLY REPORT & ACCOUNTS

EMVision Medical Devices Limited (ASX:EMV) (“EMVision” or the “Company”) is pleased to provide its Appendix 4D Half-Yearly Report & Accounts for the period ended 31 December 2024.

Operational milestones during the half-year:

- EMVision announced exceptional results from our ‘EMView’ pre-validation multi-centre trial, which deployed the Company’s world-first neurodiagnostic portable brain scanner device (emu™) for identifying stroke and stroke type (haemorrhage or ischemia). Diagnostic algorithms tested on unseen data demonstrated high performance, with haemorrhage or not (‘blood or not’) Sensitivity of 92% and Specificity of 85%, and ischemia or not (‘clot or not’) sensitivity of 85% and specificity of 78%.
- Positive meeting with FDA provided confidence in EMVision’s pivotal (validation) clinical trial design to support emu™ FDA De Novo clearance.
- Shortly after the half-year end, Central IRB (Institutional Review Board) ethics approval was received for EMVision’s pivotal (validation) multi-centre diagnostic performance trial of the emu™ brain scanner in the US. The study was designated non-significant risk (NSR) by the IRB, which will expedite the trial execution.
- Pilot commercial production line completed, with the capacity for the build, test and release of up to 3 emu™ brain scanners per week, established at EMVision’s head office in Macquarie Park, Sydney.
- EMVision produced its first ultra-light weight First Responder proof-of-concept scanners designed for road and air ambulance deployment, which leverage the principles and mode of operation of the emu™ device. Several healthy volunteers were successfully scanned with this device at EMVision’s head office.
- Balance sheet remains well funded and positioned to execute clinical validation plan. Cash reserves of \$13.6m as at 31 December 2024, further bolstered with the receipt of a \$2.1m R&D tax rebate in January 2025.

Key upcoming milestones:

- emu™ pivotal (validation) trial commencement on track for March 2025, with sites to be activated in a staggered manner.
- First Responder pre-hospital study also on track to commence in March 2025, initially in the aeromedical environment, with EMVision’s portable neurodiagnostic technology taking to the skies.
- Execution of EMVision’s high-impact publication, presentation and exhibition podium strategy to enhance industry visibility and market positioning.

Authorised for release by the Board.

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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 neurodiagnostic 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.