29/02/2024

EMVision Medical Devices Ltd
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ASX Release

CEO HALF YEARLY UPDATE

EMVision Medical Devices Limited (ASX:EMV) ("EMVision" or the "Company") today released its Appendix 4D and Interim Report for the half-year ended 31 December 2023 and is pleased to provide the following CEO Update to shareholders.

Dear Fellow Shareholders,

We are pleased with the achievements the Company has made during the half-year which are highlighted as follows:

Multi-site clinical trials
Strong progress continues with EMVision's multi-site clinical trials, reaching our Stage 2 recruitment objective on target in the fourth quarter CY23, and now underway in Stage 3. The investment we have made in our pre-validation trial phase has allowed us to collect incredibly valuable patient data across a broad spectrum of suspected stroke patients. This enables us to advance our AI algorithms, as well as verify device hardware, usability and safety, as we prepare for the upcoming product Validation trial phase (demonstrating device sensitivity/specificity).

Upcoming FDA engagement and Validation
The Validation phase of our trials is a critical component to regulatory market clearance as it demonstrates device efficacy, in terms of sensitivity and specificity. Planning has progressed well, through continued consultation with clinical, industry and regulatory experts. Alignment with the FDA is critical to ensuring the Validation trial meets regulatory requirements. Preparations for an FDA pre-submission meeting are in progress under guidance from MCRA, a global regulatory consultancy with industry-leading expertise and experience with the FDA. The FDA pre-submission meeting is focused on gaining alignment on key trial design considerations, such as sample composition, data collection methodology and objectives. The final Validation trial design will be set following FDA confirmation of these key considerations, which in turn allows finalisation of site engagement activities that are being progressed in parallel.

emu™ international showcase
The showcase of our emu brain scanner at RSNA 2023, the world's premier medical imaging conference, with Keysight Technologies, generated significant in-bound interest in our product pipeline of portable brain scanners, reinforcing our view that we are uniquely positioned to satisfy the clinical community's demand for rapid point-of-care insights in stroke care. In addition, the interest from industry and potential future distributors of the product was also particularly strong, with a clear desire to add innovative offerings to their portfolios. We will continue to build upon these relationships as we advance through the commercialisation pathway.

First responder
Our first responder unit (Gen 2) presents a paradigm shift in pre-hospital stroke and neurological care. With a weight of under 12kg and non-ionising energy profile, our system requires no special infrastructure investments to deploy. We believe that an ultra-lightweight and cost-effective device operated by trained paramedics at the point-of-care, with images transmitted through Telestroke to guide urgent decision making, presents an unparalleled value proposition. Pleasingly, ethics approval has now been received which enables us to commence healthy human volunteer testing in the coming months. The major targeted milestones for this device for 2024 are; proof-of-concept unit fabrication, healthy human volunteer testing, road and air ambulance studies.

Keysight strategic investment and funding
Today we were pleased to announce a strategic A$15.28m investment via a placement to long standing technology collaborator and supplier, Keysight Technologies Inc (NYSE:KEYS). Keysight, part of the S&P 500, is a technology company headquartered in California, with a market capitalisation of approximately US$26 billion.

Following the placement, EMVision's proforma cash balance as at 31 December 2023 is A$23.73 million, providing substantial funding to support the Company through its commercialisation phase and taking our emu™ device to market entry next year. The investment will support accelerating recruitment in our current multi-site trials, the acquisition of comprehensive data sets during the upcoming clinical trial validation phase, which is essential for confirming the product's sensitivity and specificity in support of FDA approval and increasing the production of emu™ devices for targeted clinical trials at prestigious stroke centres in the United States, smoothing the pathway to commercialisation and adoption in the world's largest healthcare market.

In addition, during the half-year we have been fortunate to benefit from $3.79m in non-dilutive cash funding, including $1.2m from the Australia Stroke Alliance MRFF grant program and a $2.59m R&D tax rebate. We continue to actively pursue Federal, State and International non-dilutive grant schemes to accelerate our commercialisation and product pipeline.

Scott Kirkland
Chief Executive Officer and Managing Director

Authorised for release by the Board of the Company.

[ENDS]

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

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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.