**ASX** Release



#### EMvision Medical Devices Ltd ACN 620 388 230 Level 10, 12 Creek Street, Brisbane Qld 4000 02 8667 5337 contact@emvision.com.au

# **CEO HALF-YEAR UPDATE**

**EMVision Medical Devices Limited (ASX:EMV) ("EMVision" or the "Company"),** a medical device company focused on the development and commercialisation of medical imaging technology, today released its Appendix 4D and Interim Report for the half-year ended 31 December 2021 and is pleased to provide the following CEO Update to shareholders.

Dear Shareholders,

EMVision is approaching a major catalyst in expanded studies with our 1st Gen device intended for commercialisation, and together with our strong financial position, our outstanding team and capabilities, we have a remarkable opportunity ahead of us to change the landscape of stroke care, and portable neuroimaging, for the better.

#### Product Development, Pilot Study and Team Update

EMVision continues to advance our product to realisation and commercialisation, underpinned by very encouraging results from our first clinical trial with stroke patients, at the Princess Alexandra Hospital (PAH) in Brisbane. This study with our clinical prototype has provided an important foundation from which we are taking valuable learnings and building our fully-fledged first of its kind commercial product.

We have recently received the bespoke Vector Network Analyser (VNA) system from Keysight Technologies (NYSE:KEYS) for assessment and integration, which is in process. This VNA system, which has been miniaturised and customised to our technical specifications, has allowed us to dramatically shrink the physical footprint of our device in a relatively short period of time, with an eye to the pre-hospital space. The speed of acquisition that the customised VNA allows for has enabled us to develop ultrafast and pulsatility scan protocols that today are largely unavailable on other imaging platforms. In the short term we anticipating to further engage with and develop our relationship with Keysight, which we envisage will give us a further competitive edge.

Developing a new way of imaging the human body and breakthrough products requires a coordinated team effort and we are fortunate to have a team who have exceptional personal track records in developing novel medical devices and taking devices through clinical validation, the regulatory approvals process and on to global commercialisation. Apart from developing products that we believe will be a gamechanger for the diagnosis of stroke, these efforts also lay a foundation that will allow us, in the future, to leverage our core IP and know-how in electromagnetic imaging to develop complimentary portable, affordable and accessible imaging products targeting other large unmet clinical needs. Our IP Portfolio continues to grow with over 11 Patent Families across software, hardware, calibration and imaging techniques, with these patent applications in various stages of international prosecution for our key markets.

# NVIDIA Collaboration (NASDAQ:NVDA)

EMVision has been an NVIDIA Inception Program member since 2019. We are using various NVIDIA tools to accelerate our productization efforts, including the NVIDIA DGX A100 to train imaging models and run simulations, and NVIDIA's Jetson Xavier AGX on board our 1st Gen device to aid in rapid image reconstruction and our AI powered decision support. Many of our shareholders will be aware that accelerated computing and AI are supercharging the next generation of medical devices and that NVIDIA, a

\$600bn+ multinational and inventor of the GPU, is at the forefront of enabling this innovation. Via their Inception Program we will continue to benefit from their deep learning expertise and their support in upcoming co-marketing initiatives.

# Australian Stroke Alliance, International Stroke Conference and Peer Review Publications

The Australian Stroke Alliance has brought together an extraordinary team of clinicians, paramedics, researchers and consumer advocacy groups, that promises to have a huge impact on global stroke medicine. The enthusiastic commitment that we receive from the group for what we are doing, really does energise us. We were pleased to feature at the American Stroke Association's International Stroke Conference 2022 with our partners at the Australian Stroke Alliance, who presented on our very encouraging clinical study. The conference is a world premier meeting for clinicians dedicated to the science of stroke and was held in person in New Orleans and virtually. The feedback we have received from the presentation has been encouraging.

In addition, an abstract on our technology and our clinical study (from our first 30 patients) was published in Stroke. Stroke is considered one of the most important peer-reviewed journals and ranks 13 among 185 journals in the Clinical Neurology category with an impact factor of 8. Our technology has also been published in Frontiers of Neurology, a leading journal in its field, publishing rigorously peer-reviewed articles across a wide spectrum of basic, translational, and clinical research that help improve patient care. Both papers noted that due to speed of imaging, size and mobility of our technology, it is a promising solution for prehospital and bedside neuroimaging.

We anticipate further publications and participation in global conferences in the near future building the credibility of our unique value proposition with both the healthcare community and industry alike. The clinical enthusiasm and strong support we continue to receive from neurologists, radiologists, emergency physicians, paramedics and nurses, among many others, is unlike anything I have seen in my career previously.

# **Upcoming Clinical Trials to Support Regulatory Approvals**

We are entering an exciting period with our upcoming multi-site studies, for which we are currently preparing and planning, anticipated to commence next quarter. Our next stage of multi-site studies is anticipated to have two stages – the first focused on "Usability" and acquiring scans of suspected stroke patients presenting at the Emergency Department (pre-validation) at the initial sites, and the second stage, at up to four sites, is focused on generating sensitivity/specificity validation data.

This early presentation of strokes and suspected strokes will allow the analysis of very early bleeds and blockages for the first time and allows us to get closer to the conditions in an ambulance environment. This is valuable data on which we will report.

The data generated across our multiple clinical sites is intended to support planned major market approvals, including FDA, TGA and CE. In addition, our pathway is anticipated to pave the way for our pre-hospital device solution (2nd Gen). From an FDA perspective, we anticipate our 1st Gen device will, upon receiving marketing authorisation, become a "predicate device" for future models, allowing those models to pursue an expediated 510(k) pathway to market.

As we prepare for these studies, it is important to also appreciate the relative cost-effectiveness of clinical trials for non-invasive Class 2 (low-to-moderate risk) devices. For reference, our first clinical study with 50 patients across one site had a financial cost of approximately \$300,000 for that site. This cost effectiveness, coupled with Australia having some of the globe's top research facilities and clinical sites and an EMVision team with deep regulatory body experience, places us in an excellent position as we enter this exciting new phase.

We look forward to keeping the market updated as we progress towards commencement of our clinical trials.

#### **Non-Dilutive Funding**

We have a strong record in securing non-dilutive funding to accelerate our R&D, product development and clinical studies and achieving our milestones whilst prudently managing the cash burn rate. The \$1.2 million non-dilutive funds we have received to date from the Australian Stroke Alliance via their successful \$40M Medical Research Future Fund (MRFF) Frontiers bid have played an important role in supporting our team growth and product development. We had strong cash reserves of \$10.5 million as at 31 December 2021 which with the \$6.8 million in remaining staged funds under the Australian Stroke Alliance grant will continue to significantly support our 1st/2nd Gen product advancement, and importantly, our upcoming clinical studies. In addition, as part of its ongoing strategy, the Company continues to pursue additional non-dilutive grant opportunities, including federal/state manufacturing support initiatives.

#### **Commercial and Industry Discussions**

We continue to engage with large imaging and accessories companies around the globe including in the EU, USA, China and Japan, with intention to develop long term commercial relationships. Interest is growing and we are finding that these companies are all very supportive of the unmet need we are aiming to solve and the fact that we have a potential first in class product. This supports the clinical validation we are receiving and when combined with the commercial support, identifies that we are heading on the path to a product success.

Ron Weinberger Managing Director and Chief Executive Officer

Authorised for release by the Board of the Company.

#### [ENDS]

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

Andrew Keys Investor Relations +61 400 400 380 andrew.keys@keysthomas.com Sling & Stone Media and Communications emvision@slingstone.com 02 8073 5390 Scott Kirkland Executive Director +61 2 8667 5337 skirkland@emvision.com.au

# **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 \$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 'Trophon' 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.