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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 2022 and is pleased to provide the following CEO Update to shareholders.

Dear Shareholders,

Multi-centre clinical trials & regulatory body engagement

Our clinical trials have been progressing well with the timely completion of Stage 1 (30 healthy human volunteers) at Liverpool Hospital. The device was well tolerated by participants and works easily in the hands of the operators. The early engineering outcomes tell us that the hardware is performing as designed, having acquired signals with high fidelity, reproducibility and stability. This is fundamental to feeding the artificial intelligence algorithms accurately and showing that the device works consistently across a range of demographics with multiple users, including nursing staff. This is a promising start and identifies that the improvements from the earlier proof of concept clinical prototype have been well implemented. We still have further relatively minor inputs to improve the device but are pleased with the feedback obtained to date.

As expected, no device related adverse events were reported given the non-invasive and safe nature of our device. We are now gearing up for Stage 2 of the trials which will include stroke patients and patients with stroke mimics. Our regulatory engagement will be reinitiated in the coming months and we will prepare a pre-submission to the FDA. Among our regulatory discussions we expect to clearly define the endpoints, indications for use and statistical requirements for the subsequent validation phase of the multi-centre clinical trials.

Manufacturing Strategy

Recognising the value in the development and commercialisation of EMVision's medical imaging technology, EMVision has received a $5m non-dilutive funding award from the Federal Government via the Modern Manufacturing Initiative to fund our manufacturing establishment and capabilities. The Company has factored manufacturability and serviceability of each Gen 1 device from an early stage. Our current 960 sqm facility in Macquarie Park has ample space for an initial Gen 1 production line and was secured to allow for low to medium volume capabilities. Scaling our manufacturing is not capital nor time intensive and our capacity can be easily increased with the addition of sites or relocation as we move to much larger Gen 1 volumes and when Gen 2 comes online in a commercial capacity. Our aim is to establish an ISO 14385 accredited manufacturing facility locally in order to keep the product development, sustaining engineering and manufacturing capabilities together. This is a well-recognised model for emerging and established medical device products and companies.

As we grow we may choose to outsource manufacturing of our potentially high margin consumable liquid and single use disposable cap in the local geographies where sales are primarily focused. The manufacturing labour force will be a variable head count that can be rapidly scaled up or down depending on conditions and demand. Manufacturing and operational leadership will be brought on to build systems, processes, test jigs and designs for the manufacturing floor. International regulatory and quality compliance will be essential for submissions and sales as well as post market evaluation of safety and efficacy of our device. We have already been speaking to multiple suppliers of our subassemblies and components about volume pricing and feel that we are in a good space for the COGS, continuity of supply and risk management. We are continuously looking at cost and efficiency improvements.

Gen 2 Pre-Hospital and Australian Stroke Alliance (ASA)

Concurrently with out Gen 1 development, we have successfully achieved several important technical and clinical development milestones for our Gen 2 portable imaging device under the Commonwealth of Australia Medical Research Future Fund (MRFF) program in partnership with the Australian Stroke Alliance (ASA). The most recent milestone activities have focused on extensive benchtop (phantom brain and complex simulation) experiments designed to mimic clinical use of the EMVision technology to support stroke subtype diagnosis. Both the existing Gen 1 system and the Gen 2 road and air ambulance device, currently under development, demonstrated high levels of performance in these environments

A full 3D Gen 2 antenna array with 28 ultra-lightweight antennas has been fabricated. This design promises entire brain coverage in a single scan with a targeted weight for the Helmet of under 10kg. A unique coupling and disposable cap solution is under development. With our Gen 1 device now under clinical investigation, product development and engineering resources in Sydney, alongside our Brisbane colleagues at the Translation Research Institute, have been freed up to expediate the development of our Gen 2 product. In-human testing with the prototype system is slated for later this year with road/air ambulance trials targeted for next year. We are designing and developing this product to be to be truly scalable with ease of use and deployability. It has the potential to revolutionise pre-hospital stroke and traumatic brain injury care worldwide.

A key ambition of the ASA program is to provide equitable healthcare for all Australians, regardless of their location. The tyranny of distance makes timely access to traditional imaging technologies particularly challenging. Pleasingly, under our ASA collaboration, early integration assessment of EMVision's technology in aeromedical environments is also underway and on track.

Non-dilutive funding strategy

As at today, the Company has cash reserves of $11.4m following receipt of $2.5m from the NSW Medical Devices Fund and a further $0.6m milestone payment from the ASA grant program subsequent to 31 December 2022. With current cash reserves and remaining milestone payments from existing grant programs, the Company remains well funded as we progress through our product development and multi-centre clinical trial milestones.

Non-dilutive funding is a particularly attractive option to fuel our development and growth as a business. We have been fortunate to attract $7.5m in incremental non-dilutive funding between the MMI and the NSW Medical Devices Fund grants over the last year. We are grateful for the support of Federal and State governments and are pleased that with these awards they recognise the important opportunity to reduce the societal and economic burden of stroke on individuals, families and our healthcare system, particularly the long-term costs of care. The innovative nature of our technology and our ability to generate highly skilled engineering and product roles, also put us in a favourable position to access these Federal and State schemes. We will continue to pursue both domestic and international non-dilutive funding pathways, including US federal agencies and private foundations, that may be available to us.

Commercial and Strategic partnerships

We continue to investigate opportunities in this area and retain good regular contact with key players. One of the learnings we have had is identifying the right strategic partner for our stage of development while keeping doors open for the full spectrum of commercialisation opportunities. We continue to have discussions regarding direct investment as well as distributor/partnering alliances and have recently fielded a number of inbound targets with promise. Developing these strategic investments and relationships remains a key strategic focus for the Company.

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