

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

AGM CHAIRMAN'S ADDRESS & PRESENTATION

EMVision Medical Devices Limited (ASX: EMV) ("EMVision" or the "Company"), is pleased to provide the following Chairman's address and CEO Presentation to be made at the Company's 2021 Annual General Meeting at 12.30pm AEST today.

Chairman's Address

I am pleased to report that the EMVision team have delivered an important series of milestones this year including in the field of technology and commercial product development, the build of our 1st Generation portable brain scanner intended for commercialization and the significantly enhanced market awareness and recognition of our device through our strengthened collaboration with the Australian Stroke Alliance, which also delivered significant non-dilutive funding to accelerate our activities.

The successes over the last year, despite Covid-19, has been due to the quality of our teams, especially our product development team, research collaborators and The University of Queensland and the quality of our technology together with the enthusiasm and engagement we receive from clinicians, together helping us towards solving the huge unmet need in the area of stroke diagnosis and care.

Our technology is well on the way to revolutionizing the diagnosis, monitoring and treatment of stroke and other neurological conditions with the potential to save countless lives and greatly improve outcomes for patients.

Our vision is to meet this challenge and help overcome health inequity through our innovative neuroimaging technology that can provide point-of-care stroke diagnosis and monitoring, wherever the patient is, starting in the hospital, and in the future, in the back of the ambulance, enabling "golden hour" care.

Turning to EMV's balance sheet, we were pleased to secure \$8m of non-dilutive staged grant funding via the Australian Stroke Alliance and Medical Research Future Fund during the year, further strengthening our financial position. \$1.2 million of this grant funding has been received in the current quarter. We also anticipate the receipt of our FY21 R&D tax refund shortly and the balance of funds due under the CRC-P grant.

I would like to acknowledge the directors of EMVision who's extensive range of experience and expertise contributes significantly to the company's success and our hard working and very talented management team who are driving our Company forward.

Our business is in a strong position to capitalize on the enormous opportunity ahead and the board is confident in our management team's ability to execute against strategic priority and maximize shareholder value. I would like to thank all our shareholders for their ongoing support.

Shortly our CEO and Managing Director Dr Ron Weinberger, and his management team, will review the operational highlights for the year and the road ahead.

Authorised for release by the Board of the Company.

[ENDS]

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

Andrew Keys Investor Relations +61 400 400 800 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 quarantees 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.



TEAM

Significant experience developing and commercialising medical devices



Dr Ron Weinberger CEO & MD Former Nanosonics MD (ASX:NAN)



John Keep Non-Executive Chairman Former CEO Queensland Diagnostic *Imaging*



Scott Kirkland **Executive Director** Co-Founder EMVision



Prof Stuart Crozier Chief Scientific Officer 2/3rd MRIs use Prof Crozier developed IP



Robert Tiller Head of Design Founder Tiller Design



Forough Khandan Head of Product Development Former Nanosonics Program Manager



Geoff Pocock Non-Executive Director Former Hazer MD (ASX:HZR)



Tony Keane Non-Executive Director National Storage NED (ASX:NSR)



Dr Philip Dubois Non-Executive Director Neuroradiologist, Former CEO, imaging division, Sonic Healthcare Ltd (ASX:SHL)



Emma Waldon Company Secretary Capital markets and corporate governance expert



Dr. Konstanty Bialkowski Head of Tech Development EM Imaging expert and Co-Inventor



Dr Merricc Edgar-Hughes Head of Quality & Regulatory **Affairs** Former Manager of Global Regulatory Affairs Nanosonics. Multiple successful FDA, CE, TGA registrations.

PARTNERS & COLLABORATORS







Princess Alexandra Hospital BRISBANE • AUSTRALIA









2021 HIGHLIGHTS

1ST GEN SUCCESSFULLY MANUFACTURED

First units built and undergoing verification and validation. Designed for portability, accessibility, speed, safety and to be as cost effective as possible.

CLINICAL DATA & TECHNOLOGY ADVANCEMENTS DRIVES FURTHER CONFIDENCE

New techniques, such as dielectric mapping, under development to enhance functionality. Reporting on full 50 patient processed dataset is anticipated to be released next week.

SUCCESSFUL MRFF BID

Australian Stroke Alliance (ASA), with EMVision as a key commercial and technology partner, successful in \$40M Medical Research Future Fund bid to transform pre-hospital stroke care.

METRO SOUTH HEALTH CLINICAL PARTNERSHIP

Gives EMVision access to neurology, radiology and critical care expertise and provides a unique relationship with a major health network that runs five hospitals.

IP PORTFOLIO BOLSTERED

IP Portfolio has grown to 11 Patent Families across software, hardware, calibration and imaging techniques, with patent applications in various stages of prosecution.

\$8M NON-DILUTIVE STAGED FUNDING

Non-dilutive funding via ASA and MRFF to support development and clinical validation of EMVision's portable brain scanner technology

WORLD LEADING PRODUCT TEAM ASSEMBLED

We have brought together a talented team from a diverse range of disciplines, united by razor sharp focus to deliver transformative portable imaging products to international standards.



DEPTH AND TALENT

WE HAVE BUILT A TEAM WITH A SUCCESSFUL TRACK RECORD IN DELIVERING INNOVATIVE MEDICAL DEVICES FOR GLOBAL MARKETS

Multi-disciplinary diverse team with a focus on specialist expertise:

- Radiofrequency Engineering
- **Physics Based Algorithms**
- Artificial Intelligence/Data Science
- Software (Medical imaging, UI and Embedded)
- **Mechanical Engineering**
- **Industrial Design**
- Electrical Engineering
- **Chemical Engineering**
- **Manufacturing and Process**
- **Systems Engineering**
- Regulatory Affairs and Quality Assurance

The team is made up of engineers from several leading medical instrument companies:

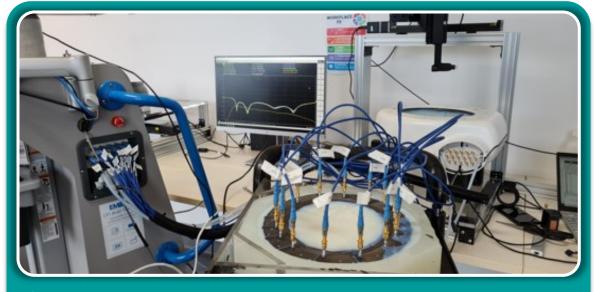










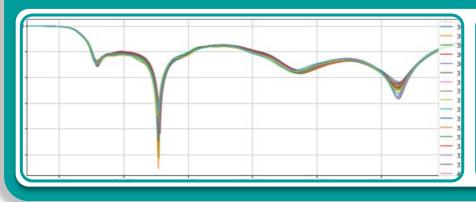


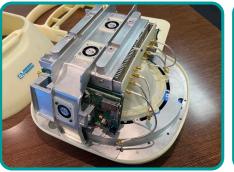
- ✓ 850 SQM facility in Macquarie Park, Sydney
- ✓ Setup lab and low-volume manufacturing capabilities
- Radiofrequency, electrical, mechanical, chemistry, software lab
- ✓ In-house GPU-enabled supercomputer to develop, train and simulate AI-based models
- Hospital ward simulation room for usability testing and clinical workflow development

1ST GEN

USER CENTERED, COMPLIANT AND RELIABLE

- 1st generation pursuing FDA De Novo pathway expected to become 510k predicate for future models
- Distributed electrical and software architecture to provide agility, modular design,
 rapid verification and easy change management
- Designed with manufacturability and reliability at the forefront
- Leveraging expertise of global supply network and partnerships
- Ensuring we have compliant design that meets global medical device standards while maintaining business efficiencies
- Innovation in design integration







2ND GEN

SETTING OUT TO TRANSFORM PRE-HOSPITAL STROKE CARE



Bringing urgent neuro imaging to the patient, wherever they are.

Reduce time to diagnosis, and open the door to earlier treatment



Outputs link to telehealth, delivering images for fast review and clinical decision making wherever they are needed.

More equitable access to "golden hour" treatment.



Deployed and operated by trained paramedics from standard road or air ambulances, without customization.

A truly scalable model of deployment



Leveraging our 1st gen clinical data, knowhow and regulatory process.

1st Gen paving the way for expediated path to market



Clinical guidance from the leading minds and pioneers in pre-hospital stroke care.

\$8M Non-dilutive project funding.



CLINICAL INVESTIGATIONS ROADMAP & MILESTONES

CY 22 H1 H2

CLINICAL INVESTIGATIONS ROADMAP

1ST GEN DEVICES UNDERGOING VERIFICATION AND VALIDATION

PRE-VALIDATION – SITE 1-2

- Preliminary usability on 1st Gen in the clinic (ED & In-ward)
 - User rated hardware, software, accessories
 - Placement/alignment/repositioning

UPCOMING MILESTONES (CY Q4 21 – H1 2022)

- 50 Patient Clinical Dataset
- International Podium Opportunities
 - Product Development Updates
- Keysight (NYSE:KEYS) OEM Supply Agreement
- Protocols, Ethics, Site Selection, Clinical Trial Contracts
 - FDA Engagement
 - Additional Collaborations / Partnerships
 - Patient Enrollment

CENTRES: MULTI CENTRE LOCATION: EMERGENCY DEPARTMENT (ED) & WARDS

Patient total # to be enrolled TBC: Anticipated ~ 100-300

SENSITIVITY/SPECIFICITY
SMALLER SCALE VALIDATION
- FIRST SITES 1-2

- 1. Sensitivity and specificity
- 2. Safety
- 3. Usability

SENSITIVITY/SPECIFICITY
LARGER SCALE VALIDATION
- 1-2 ADDITIONAL SITES

- 1. Sensitivity and specificity
- 2. Safety
- 3. Usability

Preparation for regulatory submissions

ED validation data is anticipated to also support Gen 2 path to authorization

STUDIES DESIGNED FOR MARKETING AUTHORISATION SUBMISSIONS

The indicative timetable is a guide of EMVision's intentions at the date of this presentation only. EMVision reserves the right to vary this timetable at its discretion, and further notes the above timings are subject to change due to circumstances outside of its control.