

# ASX Release

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## BRAIN SCANNER DEVELOPMENT UPDATE

### *Highlights;*

- *Successful hospital site evaluation in preparation for the pilot clinical trial*
- *Advancement of clinical unit headset architecture for near-term fabrication*
- *Significant advancements in the algorithms used to reconstruct images of the brain*
- *Novel calibration techniques achieved to maintain device consistency in clinical settings*

**EMvision Medical Devices Limited (ASX: EMV) (“EMvision” or the “Company”)** is pleased to provide a product development update on the Company’s portable, cost effective and non-invasive brain scanner, which will be used in the pilot clinical trial at the Princess Alexandra Hospital in Brisbane. In this trial, data will be collected from patients with diagnosed ischaemic and haemorrhagic stroke, with confirmatory CT and/or MRI images.

### **Clinical Input and Successful Site Evaluation:**

As part of the progress towards clinical device installation in Princess Alexandra Hospital, a site evaluation was performed as a prerequisite for the upcoming pilot clinical trial. The data collection tools that will be implemented were assessed and it was established that the population and frequency of patients is sufficient for the clinical trial. It was determined that the logistical device pathway was suitable for the clinical environment. This included identifying the locations in which EMvision’s clinical device is intended to operate and be stored, as well as planning clinical workflow, general bed access and portability throughout the hospital.

This site evaluation allowed further interaction with senior neurology, nursing, critical care staff and interventional radiologists. Feedback from these groups reinforced the need for a small, portable imaging device that provides patients essential access within narrow spaces typically found in-between hospital beds, as well as being unobtrusive while stationary in the wards.

A number of new niche applications in neurology were also identified that could increase the utility of the brain scanner device. Information from interventional radiology identified one such example where there is a small but significant cohort of patients that develop bleeds after thrombolysis and/or clot retrieval. It is intended that the Company’s device will allow frequent monitoring of these patients in neurology, ICU and stroke wards, by the bedside, in a manner not currently possible today.

### **Device Hardware Improvements:**

There has been continual improvement and refinement of the headset design (Figure 1) that will be used in the pilot clinical trial. Procurement and finalisation of key custom-made materials and parts are well underway. Key hardware improvements include the use of specific absorbing material that enhances antenna performance by preventing cross antenna interference (Figure 2 and 3).

Improvements have also been made to the dielectric properties of the antenna assembly and decoupling material that holds the antennas, this continues to increase the quality of imaging. The headset and overall product has undergone a process of improvement in order to ensure reproducible manufacture of the device.

The Company is aiming to meet the below development milestones over the coming quarters

# PROJECT ROADMAP

## BRAIN SCANNER

Identify and monitor stroke and traumatic brain injury



### Q1-Q2 CY 2019:

- ISO 13485 Certification
- Successful Healthy Human Trials
- Clinical trial protocol designed, clinical advisors appointed and ethics clearance obtained
- Successful hospital site evaluation

### Q3 CY 2019:

- Clinical unit bill of materials (BOM) review, release and procurement
- Commence fabrication and assembly of clinical units (x2)
- Verification and testing of clinical trial units prior to hospital delivery

### Q4 CY 2019:

- Delivery of clinical trial units to hospital
- Clinical site initiation visit and training of site staff for trial commencement



Figure 1 – Actual headset and antenna array



Figure 2 – Concept Image of headset in outer skin

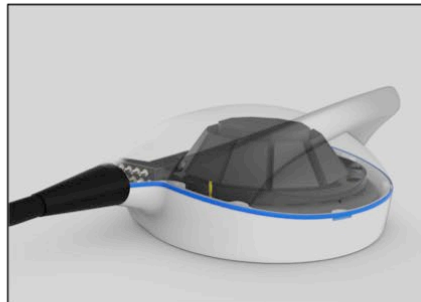


Figure 3 – Concept image of headset with absorbing material

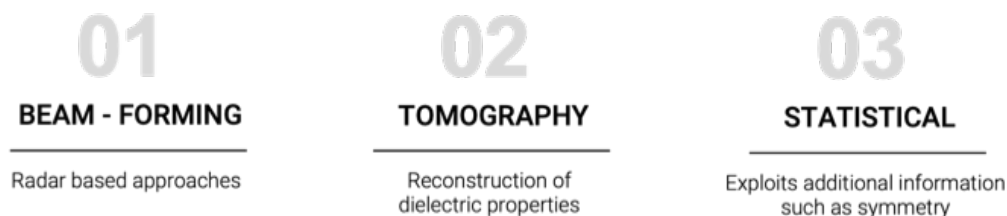


Concept image of clinical trial unit

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

### **Software Development and Testing:**

There has been significant progress in the algorithms that are used to reconstruct images. There are several variations of algorithms that have been developed and tested. The three main types of algorithms are:



Algorithms based on statistical methods are a newer significant adjunct development that offer extremely fast processing and the ability to not just potentially locate anomalies in the head but also possibly verify the size/shape of the anomaly. The full suite of algorithms has been tested in both simulations and on 5 enhanced tissue realistic phantoms. The purpose of these tests was to refine the algorithms but to also identify the best combinations of algorithms, based on their imaging performance and speed. It is anticipated that the planned commercial product will use a fusion of multiple algorithms to arrive at its clinical output.

A number of these algorithms produced encouraging results, using a multi-frequency sweep, consistently identifying and verifying targets. This is a significant advancement towards delivering the best combination of algorithms. This combination provides a very powerful approach to imaging that distinguishes the Company from its competitors and has the potential to be applied to a wide range of additional neurological diagnostic applications.

### **Calibration Techniques:**

Calibration is a universal issue that influences the reliability of microwave imaging devices. The team have developed several specialised calibration techniques, including a factory calibration, maintenance calibration (annual) and operational calibration (between idle use and patient scans). These novel calibration techniques will enhance device fidelity in clinical settings. Operational calibration is the most challenging. Resolving this element is an example of the positive impact of working with Keysight Technologies which assisted in the headset calibration hardware to customise it for our purposes. Additionally, software has been developed to provide a stabilized format for imaging. The Keysight relationship continues positively with regular exchanges of information leading to continuous product improvement (refer to the Company's ASX announcement dated 30 April 2019 for further details regarding the Keysight collaboration).

Dr Ron Weinberger, EMvision CEO, said "We are pleased with our product development progress as we near the major milestone of our pilot clinical trial at the Princess Alexandra Hospital in Brisbane. A huge amount of effort has been expended and the working rhythm with the University of Queensland team is very positive and clinical support is first class. We are excited to place the device on stroke patients shortly as we work to develop a product that has the potential to change lives."

**[ENDS]**

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## 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 over 30 researchers is led by co-inventors Professor Amin Abbosh, who is considered a global leader in electromagnetic microwave imaging, along with Professor Stuart Crozier, who created 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 \$1.7 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.