

# ASX Release

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# SIGNIFICANT BREAKTHROUGHS IN TECHNOLOGY AND PRODUCT DEVELOPMENT

## Highlights:

- Processing of clinical patient data using the EMVision technology has enabled the development of two additional techniques that have potential to significantly improve stroke care and diagnosis:
  - **Dielectric mapping** has shown potential to provide high fidelity anatomical detail to clinicians to assist in assessing stroke impact, and
  - **Pulsatility** has potential to assist in diagnosis of Large Vessel Occlusion ("LVO") ischaemic strokes. Successful earlier diagnosis and treatment of LVO strokes can have significant impact on patient outcomes
- Both techniques are undergoing further development and require additional clinical validation
- Successful development of this additional functionality has potential to greatly increase the clinical utility of the EMV technology, by providing additional valuable insights to clinicians to enable earlier interventions and better patient outcomes

**EMVision Medical Devices Limited (ASX:EMV)** ("EMVision" or the "Company"), a medical device company focused on the development and commercialisation of portable medical imaging technology, is pleased to provide the following product development update.

In contrast to every other imaging technology EMVision's electromagnetic (EM) imaging uses the interaction of the brain tissue with both the electric field and the magnetic fields that emanate from the EMV device's antennae. These electromagnetic fields are scattered and transmitted through the brain, and are received back by the EMVision device. These interactions provide a wealth of data which can be leveraged using EMVision's various signal processing algorithms.

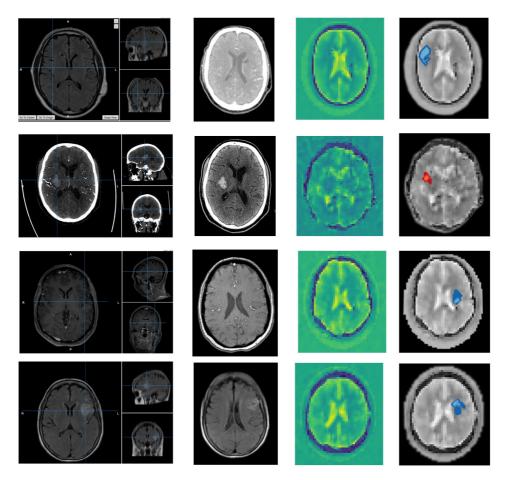
The EMVision Brain Scanner is a portable imaging device intended to provide diagnostic information obtained non-invasively from patients and without using ionizing radiation to rapidly distinguish between ischaemic and haemorrhagic strokes. In addition to this functionality, the EMVision team has recently developed two new potentially important techniques to further enhance diagnostic capability - anatomical dielectric maps and pulsatility. The Company is reviewing development options to advance these techniques.

### **Dielectric Maps**

The EMVision technology has produced world leading, high fidelity images of brain structures, by mapping and analysing tissue permittivity, so opening a breakthrough for mobile imaging for clinician interpretation of the effect of anatomical structural changes, known as "dielectric maps". This will enable clinicians to see an image that uniquely visualises anatomical electrical properties, alongside diagnostic algorithms, yet is familiar in appearance to a CT or an MRI image. Whilst the visualisation may now feel familiar to a CT or MRI image, the intention for the EMVision technology remains the same - to be deployed where CT and MRI

are not accessible or practical, by the bedside and in the future, in the prehospital setting (road and air ambulances).

Dielectric maps produce an image of one of the electrical properties of brain tissue and this reflects the anatomy of the tissue; in almost real time it will allow clinicians to see the structure, better understand the impact of the stroke and watch what they are imaging. It is intended to be used in conjunction with existing diagnostic algorithms that display stroke localisation and classification. The dielectric maps are produced from the data acquired by the prototype brain scanner, take seconds to acquire and do not rely on any other imaging modality for anatomical templates. The EMVision dielectric map images have been indicatively verified against the findings of other modalities such as MRI and CT, with additional validation and verification work ongoing.



The above clinical examples have been selected to demonstrate how the dielectric mapping technique can be used alongside fusion and classification techniques - Ground truth (Left and Middle-Left), Anatomic Dielectric Maps (Middle-Right) and Anatomic Dielectric Maps with Fusion and Classification (Right). In the classification, blue indicates an ischaemic stroke and red a haemorrhagic stroke. The halo surrounding the head is the coupling media.

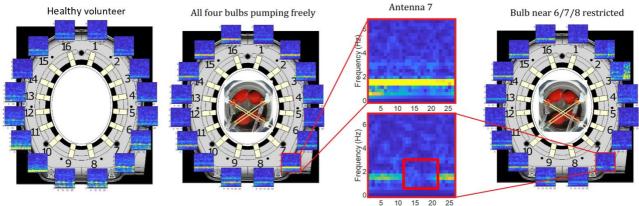
#### Pulsatility

Large Vessel Occlusion (LVO) is a blockage in one of the major arteries in the brain. Patients with ischaemic stroke due to large vessel occlusion (approximately 1/3<sup>rd</sup> of ischaemic strokes) will typically have severe neurological deficits and poor outcomes if not treated quickly.

The EMVision team has identified a novel method of processing signal data known as "pulsatility", to potentially enable the earlier identification and triage of LVO patients. The technique may be used to measure blood flow through the brain, and therefore identify the degree of occlusion (blockage) at the earliest stages as well as potentially localizing the extent of salvageable tissue and effect of reperfusion therapy (treatment to restore blood flow). This may avoid devastating treatment delays, unnecessary disability and help minimize the associated downstream healthcare, insurer, and societal costs.

This technique could be delivered at the point-of-care without the need of contrast agents or ionising radiation. For individuals who have an acute ischemic stroke, the key to effective treatment is early reperfusion of ischaemic brain without causing adverse effects.

The front-line therapy to achieve reperfusion is often intravenous thrombolytic therapy (breaking up the clot) – which is recommended in stroke treatment guidelines. Mechanical thrombectomy (physically retrieving the clot) is a newer and highly effective additional treatment option for a sub-group of ischaemic stroke patients. Clinical trials around the world have demonstrated that earlier identification of and taking patients with Large Vessel Occlusions directly to the angiography suite for intervention (mechanical thrombectomy) significantly improves their 90-day functional outcomes. Thrombectomy (clot retrieval) is profoundly time sensitive and only available at these comprehensive stroke centres. The pulsatility technique may enable rapid triage of these patients directly to the angiography suite at comprehensive stroke centres for earlier intervention.



Time (s)

Healthy human volunteer and Phantom based test has successfully demonstrated the effectiveness of being able to detect changes in pulse. The initial goal was to replicate the results seen in the healthy humans (example - left). Following this, the next step was to restrict blood flow in one quadrant of the head (right). The initial results show that the loss of pulse could be detected to a position around 1/8 of the head.

Australian Stroke Alliance Co-Chair and past president of the World Stroke Organization, Professor Stephen Davis said: "The progress made by EMVision is likely to advance the Australian Stroke Alliance's mission to diagnose and treat acute patients out in the field. This could occur in the back of road ambulances or in helicopter or fixed-wing aircraft. We hope that further advances in this technology will allow treatment of patients in rural and remote locations in Australia who would otherwise remain untreated. Based on the very promising data from EMVision, we are engaged in preparing for multi-site clinical trials and it is hoped this will lead to future widespread application of this technology".

EMVision CEO Dr Ron Weinberger commentated "The dielectric maps will have a dramatic impact on the interpretation of data from our algorithms. For the first time using EM imaging, clinicians will be able to make good approximations to the anatomical region at which stroke occurs and will enable a visualisation of the EM image for clinicians that is familiar to them and what they have been looking at for decades, CT and MRI. Extensive clinical trials around the world have demonstrated the robust patient outcomes that can be achieved for stroke patients with earlier thrombolysis (tPA) and thrombectomy (clot retrieval) for those eligible. Pulsatility is a complimentary technique that alongside our existing diagnostic algorithms, has the potential to improve diagnosis and treatment and save more lives."

Authorised for release by the Board of the Company.

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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 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 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 \$1.9 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.

#### 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.