26/11/20

ASX Release

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AGM CHAIRMAN'S ADDRESS & CEO 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 2020 Annual General Meeting at 1.00pm AEST today.

Chairman's Address

Good afternoon Ladies and Gentlemen. Thank you for joining us today, I'm delighted to welcome you to EMVision's AGM for 2020.

The past twelve months have been very successful year for the Company. It was around this time last year that we had built our initial clinical prototype in anticipation of the first clinical trial of our groundbreaking technology.

Now a year later, we are delighted to be able to report very encouraging results from our first in hospital stroke patient trial. Whilst there is still a long way to go in our journey, the outcomes from this study exceeded expectations and provide an excellent foundation from which to advance our commercial product development. The widespread enthusiasm and interest we received and continue to receive from medical practitioners, who recognise the need for our novel technology, both in the pre-hospital and in-hospital settings and the positive impact our devices could have, truly keeps us energized.

Our success is due to our teams' ability to focus on executing against our plans, and the excellent commitment from our collaborators, including some brightest minds in the world in electromagnetic imaging at the University of Queensland and dedicated clinicians at the Princess Alexandra Hospital together with the ongoing support of the State and Federal Governments.

Looking ahead, EMVision is now designing and developing our next generation device intended for commercialisation and preparing, with our clinical collaborators, for expanded clinical studies.

I would now like to introduce your Board of Directors and our Company Secretary who are all on line today:
Dr Ron Weinberger, Managing Director
Mr Scott Kirkland, Executive Director
Dr Philip Dubois
Mr Tony Keane
Mr Geoff Pocock
Ms Emma Waldon, our Company Secretary

This year we welcome Dr Philip Dubois to the board. Dr Dubois is a neuroradiologist and the former CEO of Sonic Healthcare's imaging division. He brings an invaluable combination of deep clinical expertise and commercial acumen to EMVision. Welcome Philip.

We also farewelled Ryan Laws who stepped down from the board with Philip joining. We thank Ryan for his valuable contributions to the Company, especially his pivotal role in our successful IPO.

To ensure that we are in a strong position to accelerate our product development and clinical validation activities, EMVision completed an oversubscribed capital raising during the year. On behalf of the board I would like to thank all new and existing shareholders who supported the placement.

I look forward to a great year ahead in 2021, we have a number of exciting milestones ahead and we have an exceptional team in place to execute on our value creation plans to build a device that will truly be a game changer for stroke sufferers worldwide.

Authorised for release by the Board of the Company.

[ENDS]

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About Stroke

Stroke causes an enormous health and economic burden throughout the world. Stroke is the second leading cause of death and the third leading cause of disability. Imaging is the key to diagnosis and monitoring of acute stroke. The treatments offered require differentiation between ischaemic and haemorrhagic stroke. This determination is essential before pursuing proven effective, time-critical therapies.

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 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 $1.65 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.

AGM - 2020
CEO PRESENTATION

Dr Ron Weinberger
November 2020

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The research and modelling in this presentation is based on a number of assumptions, which include but are not limited: to the successful clinical validation of EMVision's first generation device; the performance and availability of the device once operational; the representativeness of the limited sample size; the availability of suitably trained staff at hospitals capable of both using the EMVision device, and interpreting the results produced. These forward-looking statements are not historical facts but rather are based on EMVision's current expectations, estimates and projections about its product and the industry in which it operates, and its beliefs and assumptions. EMVision has not yet obtained definitive clinical validation for its first generation device and, while the Company continues to work towards clinical validation, there are no certainties that validation will be obtained within the 24 months from this Presentation, or at all, or that the device ultimately the subject of clinical validation will be able to perform in the manner assumed in this presentation. The study is not indicative of the proposed unit pricing of EMVision's devices, nor does it assert that there will be demand for EMVision's products at certain prices. Impact Health is a consultant to EMVision and makes no representation regarding, and to the extent permitted by law excludes any responsibility for, any statements in or omissions from any part of this presentation.

TEAM

Significant experience developing and commercialising medical devices

Dr Ron Weinberger
CEO & MD
Former Nanosonics MD

John Keep
Non-Executive Chairman
Former CEO Queensland Diagnostic Imaging

Scott Kirkland
Executive Director
Co-Founder EMVision

Prof Stuart Crozier
Co-inventor
2/3rd MRIs use Prof Crozier developed IP

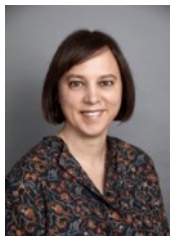
Robert Tiller
Head of Design
Founder Tiller Design

Forough Khandan
Head of Program Management
Former Nanosonics Program Manager

Geoff Pocock
Non-Executive Director
Former Hazer MD

Tony Keane
Non-Executive Director
National Storage NED

Dr Philip Dubois
Non-Executive Director
Former CEO of Sonic Healthcare - Imaging



Emma Waldon
Company Secretary
Capital markets and corporate governance expert

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

Ruth Cremin
Head of Quality & Regulatory Affairs
Former Head of Regulatory at Nanosonics

PARTNERS & COLLABORATORS

Australian Government
Department of Industry, Innovation and Science

The University Of Queensland
AUSTRALIA

GE Healthcare

Princess Alexandra Hospital
BRISBANE • AUSTRALIA

Commonwealth CRC-P Grant Program Collaborators

KEYSIGHT TECHNOLOGIES

Product Collaboration

Australian Stroke Alliance

Clinical Development & Validation

TRANSFORMATIVE POINT-OF-CARE IMAGING

FAST

SAFE

PORTABLE

ACCESSIBLE

Video available on EMVision website (www.emvision.com.au)

ADDRESSING ACCESSABILITY

2/3rds of the world does not have access to diagnostic imaging.

LOW-COST HARDWARE

Energy emitted from a scan is **less than 1%** of energy emitted from a mobile phone. Does not emit harmful radiation.

PLATFORM MODALITY

Applications across the entire body, targeting time sensitive neurological disorders first.

Artistic impression of first-generation commercial device. Device under development and subject to clinical validation. Clinical prototype pictured right. Source: WHO

2020 HIGHLIGHTS

VERY ENCOURAGING CLINICAL TRIAL OUTCOMES

Promising imaging capabilities, and very encouraging accuracy in stroke type differentiation and localization from the 30 patient dataset

INVALUABLE DATASET COLLECTED

Dataset to tune and advance algorithms' ability to detect, localise and classify strokes and explore unique clinically relevant information.

HARDWARE LEARNINGS

Whilst operator and patient feedback was consistently positive on the prototype device during the trial, several improvements are being made to the hardware for the next gen device.

TEAM STRENGTHENED AND MOVING INTO NEW FACILITY

Strengthening our team at the executive level with strong focus on execution and building our core team and facility in Sydney. Appointment of Dr Philip Dubois to the Board who is also a Non-Executive Director of Sonic Healthcare (ASX:SHL)

IP PORTFOLIO BOLSTERED

Growing portfolio of Australian and International patent applications, trade secrets and know-how for imaging the human body using electromagnetic imaging techniques.

STRONG COLLABORATIONS

Strengthened collaborations across clinical (Princess Alexandra Hospital, Australian Stroke Alliance), R&D (UQ) , Keysight (VNA progressing to plan) and industry CRC-P partner GE Healthcare.

WELL CAPITALISED

Cash Balance of $12.7m (30th Sept 2020), following Placement of $9m.

Artistic impression of first-generation commercial device. Device under development and subject to clinical validation.

EMVISION'S PILOT CLINICAL TRIAL

STUDY DESIGN

PILOT CLINICAL TRIAL

- The single-site study, at the Princess Alexandra Hospital (PAH) in Brisbane, of patients with diagnosed ischaemic or haemorrhagic stroke, is the first clinical study for EMVision's novel imaging technology.
- Patients were scanned with EMVision's prototype device at close proximity to their standard of care imaging (CT and/or MRI).
- No intervention or modification to the standard of care of hospital-based treatment of stroke was done as part of this study.

STUDY OBJECTIVE

PRIMARY END POINT ACHIEVED

- The primary endpoint was the collection of a dataset of stroke patients which improves the understanding of stroke on electromagnetic scattering effects in the brain. This end point has been met, producing datasets that have enabled EMVision to advance its imaging algorithm and hardware development.
- The dataset enabled an observation of the correlation of EMVision scans with patients' "ground truth" CT and/or MRI scans.
- This is a data acquisition study and not intended to be an interventional study. Hence appropriate caution should be used in extrapolating these results to those of the general population at this stage of the development.

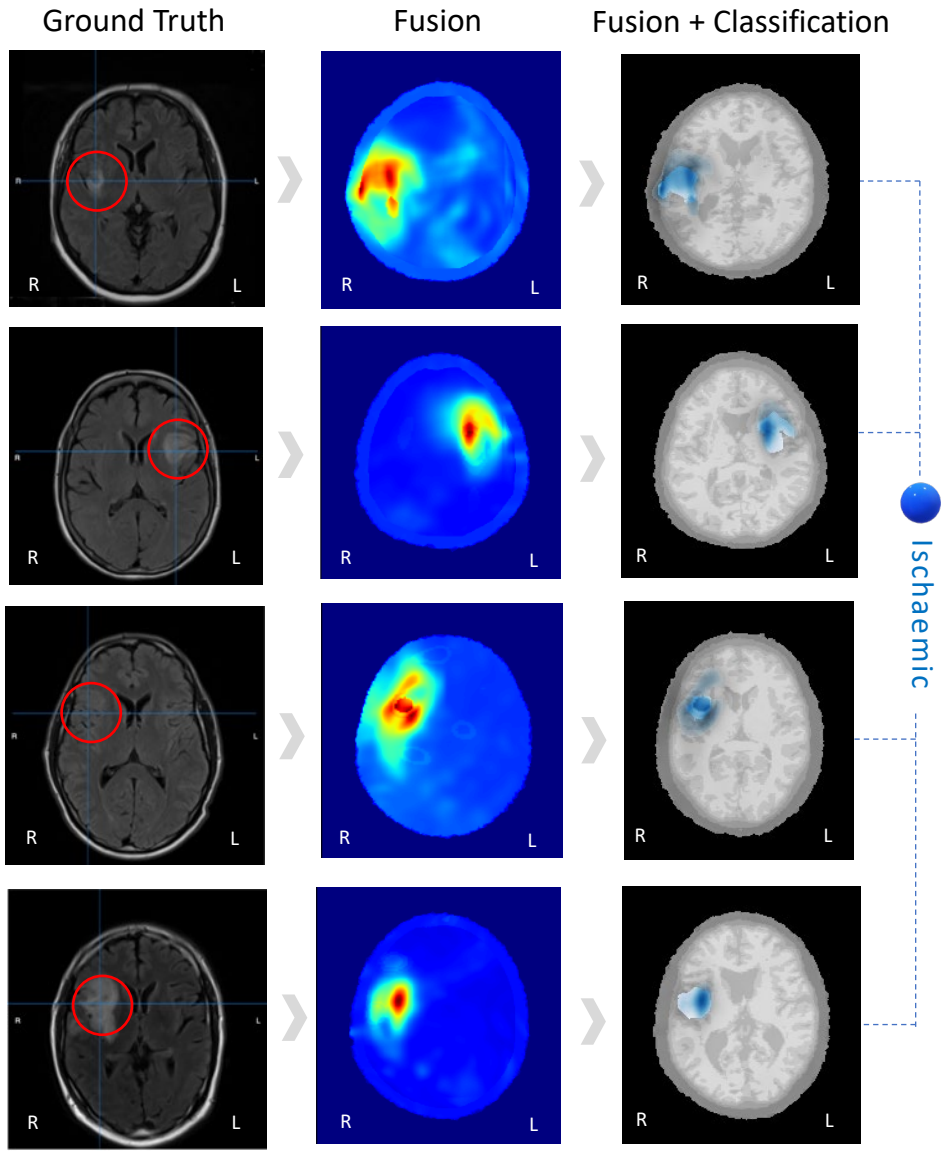
PATIENT COHORT

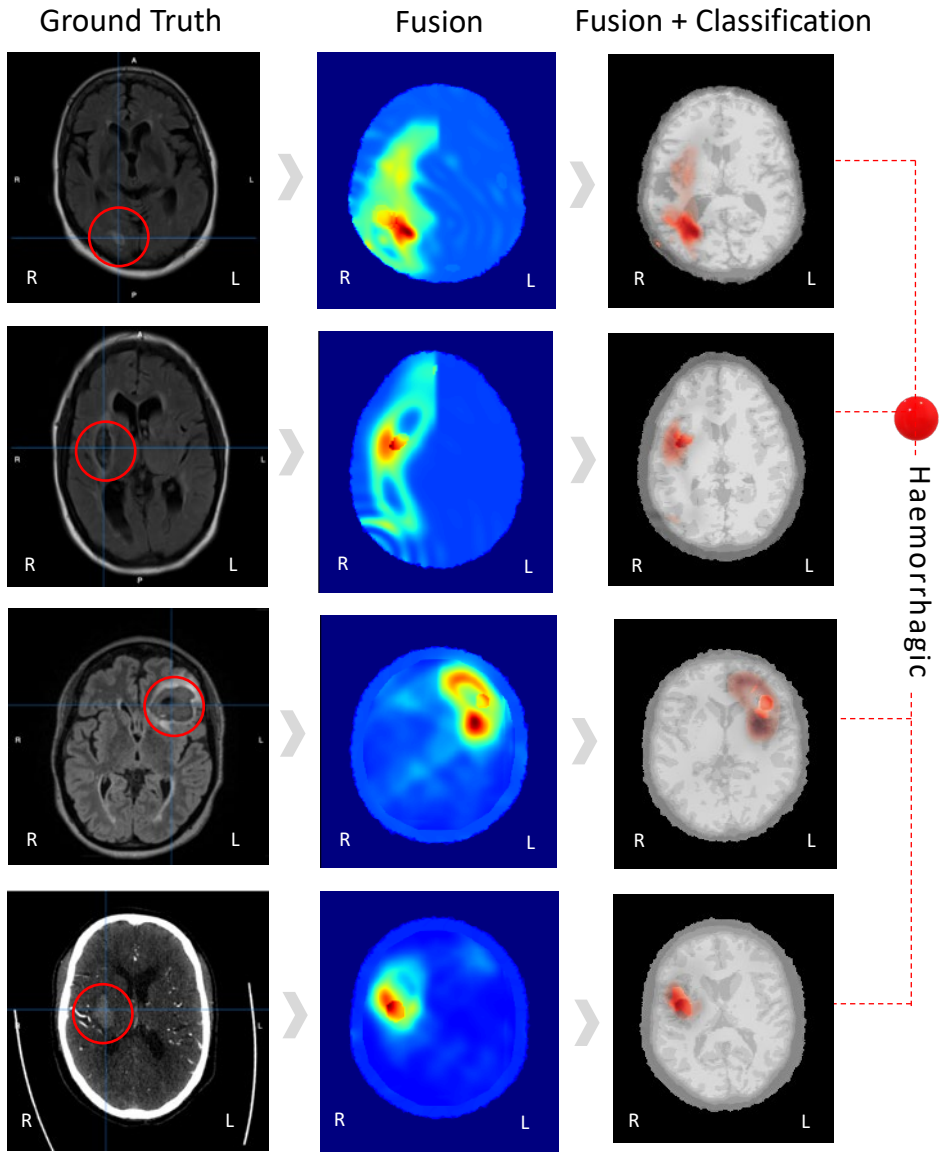
30 STROKE PATIENTS ENROLLED

- The study enrolled and processed datasets from **30 patients (21 ischaemic and 9 haemorrhagic)** representing the diversity of stroke in localisation, size and clinical severity.
- The mean age was 66.7
- Of the 30 patients, 19, (63.3%) had only a CT performed whereas 11, (36.7%) had CT/MRI performed.
- The mean NIHSS score was calculated as 5.2 which indicates mild severity.

Please refer to the Company's ASX announcement titled "EMVision Reports Very Encouraging Pilot Clinical Trial Data" released on 28 October 2020 for further details

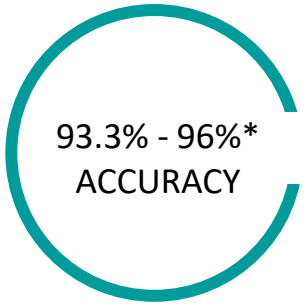
FUSION WITH CLASSIFIER - EXAMPLES





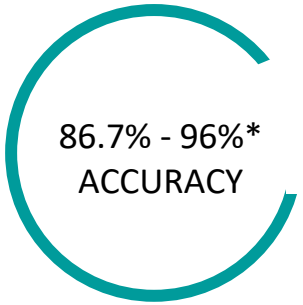
The above examples have been selected to demonstrate how the fusion methodology can be used to detect, localise, and classify stroke type and should be interpreted in light of the intent and results of this study to date.

STUDY OUTCOMES & UPCOMING MILESTONES



STROKE SUBTYPE CLASSIFICATION

Collect data from stroke patients, both ischaemic and haemorrhagic



LOCALISATION IN CORRECT QUADRANT

Compare EMVision scans with ground truth CT and MRI images

OPERATOR AND PATIENT FEEDBACK

Despite being a prototype, positive feedback on non-invasive nature of device

UPCOMING MILESTONES

CY Q4 2020

- FDA Feedback
- Outcome of Australian Stroke Alliance competitive MRFF Frontiers bid
- Further Strategic Hires

CY H1 2021

- Expanded clinical study preparation (Protocol, Site selection, Ethics)
- Next-Gen Product Development Updates
- Additional 20 patient dataset
- Commercial and Collaboration Updates
- Further FDA Engagement

A larger dataset will be required to draw conclusions on sensitivity/specificity for blood and ischemia. The algorithms may be subject to further refinement and investors should note there is no guarantee the algorithms will replicate the same level of accuracy on larger data sets without further refinement, or at all. Five datasets where pathologies were estimated to fall outside of the anticipated prototype hardware range were identified and accuracy figures presented here are with, and without, the 5 excluded datasets for completeness. The indicative milestone timetable is a guide of EMVision's intentions at the date of this presentation only.

1ST GENERATION DEVICE UNDER DEVELOPMENT

IMPROVING USER INTERFACE, USABILITY, SOFTWARE INTEGRATION AND HARDWARE

DESIGNING FOR MANUFACTURE AND REGULATORY SUBMISSIONS

ACCESSORIES AND ALGORITHM DEVELOPMENT PROGRESSING WELL

NEXT GENERATION R&D PROGRAM

In collaboration with the University of Queensland, R&D continues to progress positively in the background on next gen first responder potential solutions, including a wearable early stage pre-clinical prototype.

Artistic impression of first-generation commercial device. Device under development and subject to clinical validation.

CLINICAL & ECONOMIC VALUE OF EMVISION'S 1ST GENERATION DEVICE

IN-HOSPITAL STUDY OVERVIEW

STUDY OBJECTIVES

- Identify the clinical applications of in-hospital stroke patient monitoring using EMVision technology that may impact clinical outcomes and deliver economic value.
- Identification of deficiencies within the current stroke management paradigm that may be addressed with the EMVision technology.
- Model for the use of EMVision product in-hospital setting with projected clinical outcomes and economic benefits for further testing at a wider number of hospitals.

STUDY METHODOLOGY

- Primary Market Research at two large tertiary public hospitals.
- Map the flow of stroke patients from admission to discharge.
- Capturing no. of patients, type of stroke, length of stay, monitoring, diagnostic interventions, therapeutic interventions, complications arising, location within hospital etc.

STAKEHOLDERS INTERVIEWED

- Emergency
- Neurology
- Radiology
- Intensive Care
- Nurse Specialists
- Hospital Payments

To be completed;

- Interventional Neuroradiology (Emergency Clot Retrieval)
- Neurosurgery

Research & Modelling conducted by;

IMPACT HEALTH
ACCELERATING HEALTH INNOVATION

FINDINGS DO NOT INCLUDE ANY POTENTIAL VALUE ATTRIBUTED FROM A POTENTIAL REDUCTION IN PATIENT DISABILITY SCORES

Research & Modelling conducted by;

IMPACT HEALTH
ACCELERATING HEALTH INNOVATION

INTERIM FINDINGS

GAPS IN CURRENT STROKE MANAGEMENT

- Clinical assessments are done frequently but can be rudimentary (visual assessment, questionnaire). Within an hour a patients condition can go from fairly good to critical.
  - *Unlikely a bleed will be detected before the onset of clinical symptoms.*
  - *Not possible to differentiate between vasospasm and a bleed post surgery without moving patient to CT*
  - *Monitoring for changes in oedema in ICU patients can be difficult to evaluate clinically (until it has progressed / the patient's condition deteriorates)*
- At the two large tertiary hospitals where the interviews were conducted, approximately 30% of stroke patients are transferred from rural hospitals, they cannot be transferred without a CT, access to CT in remote and rural hospitals is limited lengthening time to treatment.
- Patients that receive treatment for stroke require 2 or more follow up CT scans during their stay. It is resource intensive transporting these patients to radiology department and back.

IN-HOSPITAL OPPORTUNITY FOR EMVISION

- Bedside imaging could reduce resource intensive and time consuming transportation to imaging department for follow up CTs, freeing CT time for other patients.
- In patients monitored post treatment, EMVision system could give significantly more detail than clinical assessments , potentially identifying worsening conditions before symptoms present and enabling more rapid intervention
  - *A bleeding event is catastrophic, Detect a bleed before the onset of clinical symptoms.*
  - *Differentiate between vasospasm and a bleed post surgery at the bedside*
  - *Monitoring for changes in oedema at the bedside, before clinical symptoms present*
- Significant opportunity to improve clinical outcomes through accelerating triaging, transport and treatment of patients in rural and remote locations where CT is not readily accessible,

POTENTIAL ECONOMIC VALUE TO HOSPITAL*

- There is economic value in the early identification of worsening conditions, enabling earlier intervention. It is estimated, direct budgetary impact could materialize through reduced ICU time or reduced length of stay (LOS) . For each 24 hours reduced LOS, the potential budget impact is a reduction of $750 - $5,323. If LOS is reduced by 24 hours in 5% (being the complication rate post thrombolysis treatment) of patients the budget impact results in a savings of $18K-$75K per annum.
- Further, each follow up CT scan that could be avoided with the use of the EMVision device could displace a direct cost of between $320 - $513.
- For a public hospital with 500 stroke patients per annum, the budget impact of displacing the follow up CT scans is anticipated to be $112K - $145K per annum. This is a lower to mid range estimate based on EMVision only being used in patients who have received treatment for stroke.

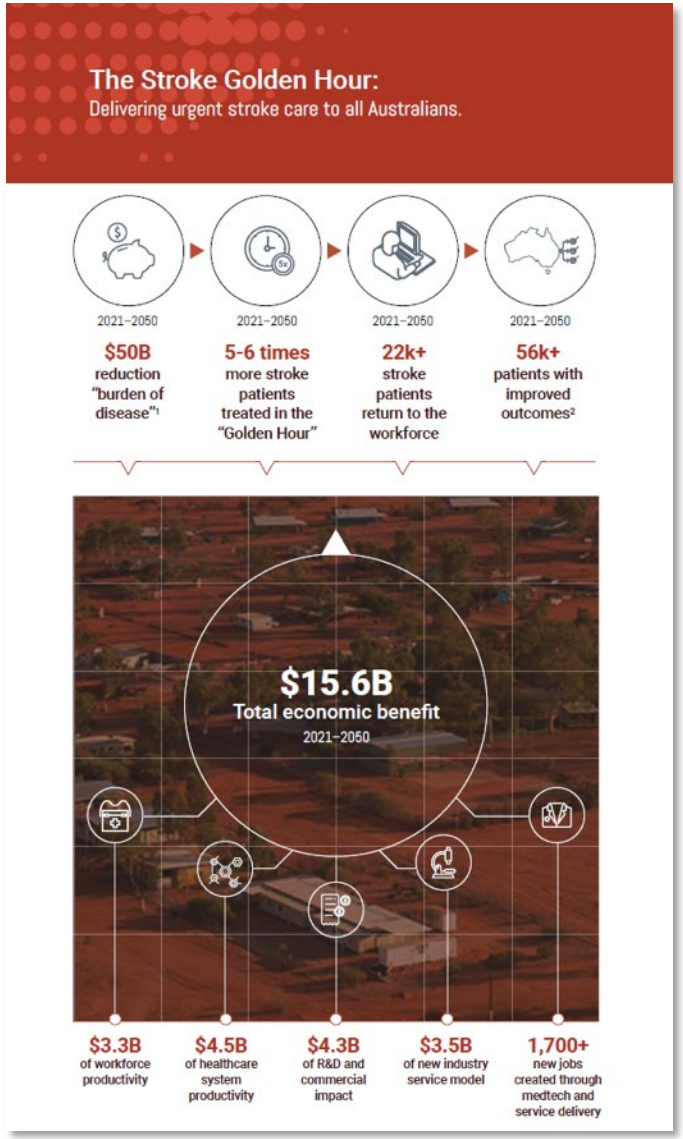
$130k - $220k per annum*

- *Interim analysis estimate of direct cost reduction to Australian Public Hospital – values are subject to change and do not factor in cost of EMVision system. Value to insurer will be modelled in final report.
- These budget impact figures are based on a domestic analysis and may be substantially higher in the United States.

CAUTIONARY NOTE:

The research and modelling in this presentation is based on a number of assumptions, which include but are not limited: to the successful clinical validation of EMVision's first generation device; the performance and availability of the device once operational; the representativeness of the limited sample size; and the availability of suitably trained staff at hospitals capable of both using the EMVision device, and interpreting the results produced. EMVision has not yet obtained definitive clinical validation for its first generation device and, while the Company continues to work towards clinical validation, there are no certainties that validation will be obtained within the 24 months from this Presentation, or at all, or that the device ultimately the subject of clinical validation will be able to perform in the manner assumed in this presentation. The study is not indicative of the proposed unit pricing of EMVision's devices, nor does it assert that there will be demand for EMVision's products at certain prices. Impact Health is a consultant to EMVision and makes no representation regarding, and to the extent permitted by law excludes any responsibility for, any statements in or omissions from any part of this presentation. The assumptions below, including pricing assumptions, are current as at the date of the presentation and are subject to change.

AUSTRALIAN STROKE ALLIANCE – A SHARED VISION



THE PROBLEM

8 million Australians live in rural, remote and indigenous settings with virtually no access to reperfusion therapies

Tyranny of distance and inequality of access to stroke units - 77% urban versus only 3% for rural and remote

65% of stroke survivors experience major disability

This challenge is not unique to Australia

THE SOLUTION

Lightweight, novel and affordable brain scanning technology embedded in standard road and air ambulances

HOW WE ARE WORKING TOGETHER

The ASA team are helping EMVision to plan for its expanded clinical studies and facilitating further validation across additional centers through their expansive network.

We have also collaborated on a Medical Research Future Fund Stage 2 submission. There are ten shortlisted groups in Stage 2 of which one or some are expected to receive funding. It is a competitive grant process that if successful, would allow EMVision to **accelerate** first responder (2nd gen) product development.

source: austrokealliance.org.au / SPP Analysis (2020)

The EMV 2nd Gen image is an artistic concept of a proposed first responder device which is subject to prototype development and clinical testing