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# ASX:EMV

BELL POTTER  
HEALTHCARE CONFERENCE 2023

Portable brain imaging, anywhere, anytime



NOVEMBER 2023

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# OVERVIEW

EMVision is an innovative medical device company developing world first electromagnetic portable brain scanner products to address significant unmet clinical needs.

Originally spun out of the University of Queensland.



- ▶ Founded in 2017 after 10 years of R&D at UQ
- ▶ Experienced team
- ▶ “Zero to one” technology
- ▶ Best-in-breed partnerships and clinical collaborations
- ▶ Significant non-dilutive Federal and State grant funding
- ▶ Multi-billion-dollar market opportunity
- ▶ First indication – stroke care
- ▶ Second indication – traumatic brain injury (TBI)
- ▶ 15m strokes and 27m medically treated TBI incidents worldwide each year

# THE TEAM

SIGNIFICANT MEDICAL DEVICE DEVELOPMENT AND GLOBAL COMMERCIALISATION EXPERTISE ACROSS THE GROUP

## Executive leadership team



**Scott Kirkland**  
CEO and Managing  
Director  
Co-founder

Sales and marketing executive, former Head of Client Sales at US-venture backed global AI advertising company Quantcast



**Forough Khandan**  
Chief Technology  
Officer

Over 15 years medical device development expertise. Former Head of Program Management Nanosonics (ASX:NAN), a \$1.3bn medical device success story.



**Professor Stuart Crozier**  
Chief Scientific Officer  
Co-inventor

Pioneer in medical imaging innovation. Prof Crozier's advancements in MRI technology now central to 65% of all MRI machines.



**Robert Tiller**  
Head of Design

Over 25 years in medical device product design and commercialization, previously CEO of Tiller Design



**Dr. Christian Wight**  
Head of Regulatory  
Affairs

Previously Regulatory Manager at Corin. Multiple successful FDA, CE and TGA registrations



**Emma Waldon**  
CFO, Company  
Secretary

20+ years corporate advisory, capital market and cooperate governance experience in Australia and UK

## Board of Directors



**John Keep**  
Independent  
Non-Executive  
Chairman

As former CEO of Queensland Diagnostic Imaging, John grew the business to become one of the state's leading private imaging group and led the successful trade sale of the group



**Dr Ron Weinberger**  
Strategic advisor,  
Non-Executive  
Director

Former Executive Director and CEO of Nanosonics (ASX:NAN). Former CEO of EMVision. Over 20-years' experience developing and commercializing medical devices.



**Dr Philip Dubois**  
Independent  
Non-Executive  
Director

Neuroradiologist, former CEO of Sonic Healthcare Imaging (ASX:SHL), \$14bn market cap. Currently an Associate Professor of Radiology at the University of Queensland Medical School. Has served on numerous government and radiology group bodies



**Tony Keane**  
Independent  
Non-Executive  
Director

Non-executive Chairman of National Storage Holdings Ltd (ASX:NSR), \$3bn market cap. Previously held numerous roles with a major trading bank principally in business, corporate and institutional banking.



**Geoff Pocock**  
Independent  
Non-Executive  
Director

Over 20 years' experience in commercialisation, corporate finance. Chairman of Argenica Therapeutics (ASX:AGN).

# OUR VISION IS TO REDUCE THE GLOBAL BURDEN OF STROKE AND OTHER TIME SENSITIVE MEDICAL EMERGENCIES

## FIRST INDICATION - STROKE

- 1 in 4 adults will have a stroke in their lifetime
- 2 out of 3 strokes result in permanent disability
- 34% of total global healthcare expenditure is spent on stroke
- The average healthcare cost of stroke per person in the United States is USD \$140,048

Every 10 minutes can **SAVE** up to **20 MILLION** brain cells



## SECOND INDICATION - TRAUMATIC BRAIN INJURY (TBI)

- An estimated 50-60 million people, worldwide, will suffer a TBI this year.
- Those TBIs each year are estimated to cost the world economy upwards of \$US400 billion
- One of the most common severe types of TBI is acute subdural hematoma, caused by rupture of blood vessels
- For patients with suspected traumatic brain injuries, quick evaluation is critical
- Most patients with suspected traumatic brain injury are examined using a neurological scale (GCS) which is imprecise and can lead to biases in care (Matney C 2022).



## EMVISION'S PORTFOLIO OF WORLD FIRST POINT-OF- CARE BRAIN SCANNERS IS THE SOLUTION

Neuroimaging as is  
accessible today.

- Large
- Expensive
- For most part stationary
- Ionizing radiation (CT) and ferromagnetism (MRI)
- Requires special infrastructure
- Requires specialist operators



1st Gen (Bedside)

EMVision,  
Neuroimaging  
anywhere.

- ✓ Portable, compact
- ✓ Cost effective
- ✓ Non-invasive
- ✓ Faster diagnosis, faster treatment
- ✓ Better monitoring
- ✓ Less disability
- ✓ Improved quality of life
- ✓ Significant healthcare & insurer savings



2nd Gen (First responder)



# OVERVIEW OF 1<sup>ST</sup> GEN AND 2<sup>ND</sup> GEN CLINICAL VALUE

## UNMET NEED FOR PRE-HOSPITAL AND BEDSIDE IMAGING ACROSS THE ENTIRE PATIENT JOURNEY

A typical stroke patient journey & timeline in an urban setting



2nd GEN



Potential clinical use cases


- Reliably distinguish between haemorrhagic stroke versus ischaemic stroke. Open the door to in-field tPA opportunity
- Reliably segment LVOs & potential ECR candidates - to assist decision making on transfer to clot retrieval center versus local stroke unit or hospital

● Ischemia present

● Blood present

● Undetermined (wait until CT)

1st GEN



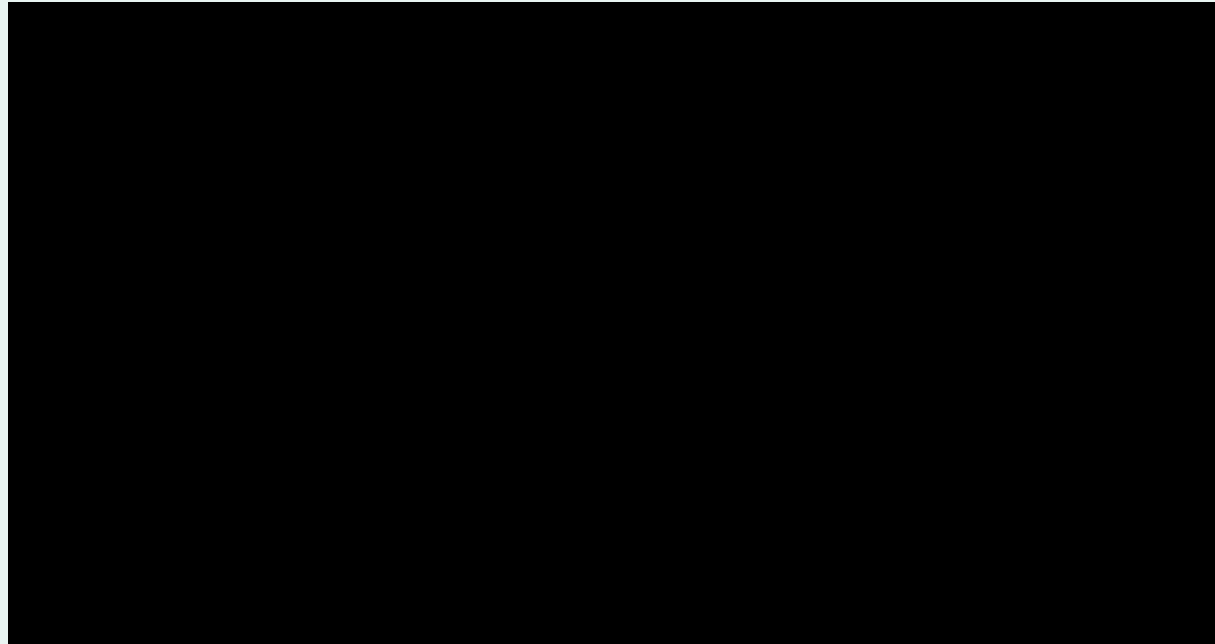
Potential clinical use cases

- Front line decision support where there is limited access to CT (e.g. rural and remote) - inform patient triage and transfer decision making
- Monitor response to therapy or surgical intervention & complications
- Detect secondary bleeding earlier – routine brain scan to assess haemorrhagic transformation of ischaemic stroke
- Monitoring for post stroke oedema to allow earlier clinical detection and intervention
- Monitoring response to reperfusion therapy including restoration of blood flow and complications
- Assist in the earlier identification of perioperative stroke

Gen 1 and 2 devices under development and their potential clinical utility is subject to successful clinical testing and validation.

# POINT-OF-CARE BRAIN IMAGING, ANYWHERE, ANYTIME

Product demonstration video (<https://youtu.be/BYtjYcJvoVs>)



*"This is an exciting development in stroke and neurological care. We have found the EMVision scanner to be a very user-friendly portable imaging modality. The EMVision scanner has potential for wide application in both the prehospital and acute hospital settings."*

**Dr Dennis Cordato**

Stroke neurologist, Principal Investigator 'EMView' trial



*"It cannot be underestimated how important this cutting-edge technology could become for future stroke management."*

**Professor Geoffrey Donnan AO**

Stroke neurologist

Co-chair ASA, Past-president of World Stroke Organization



*"The concept of bringing imaging to the patient will dramatically reduce times to administer life saving interventions such as thrombolysis and thrombectomy."*

**Professor Stephen Davis AO**

Stroke neurologist

Co-chair ASA, Past-president of World Stroke Organization



*"Equitable healthcare for Australians in remote areas needs to overcome the tyranny of distance. Portable brain imaging is a crucial next step in bringing critical care to patients sooner."*

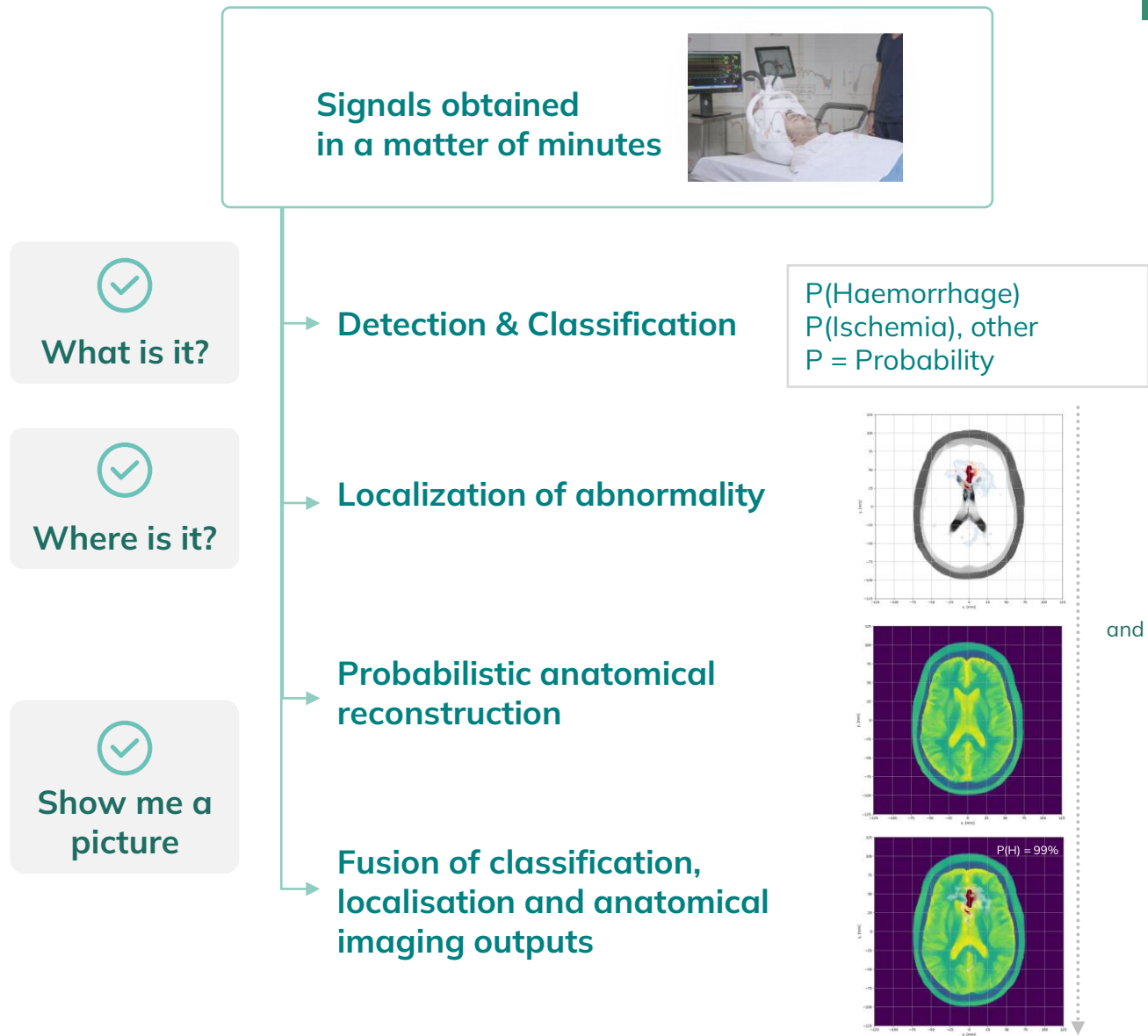
**Dr Mardi Steere**

Executive General Manager Medical and Retrieval Services,  
Royal Flying Doctor Service



# HOW EMVISION'S IMAGING COMES TOGETHER

EMVision is developing a “zero to one” medical imaging technology with a series of algorithms that are combined to help answer important clinical questions in acute stroke care:



*Probabilistic anatomical reconstruction is intended as a fiducial and orientation tool.  
Algorithms are subject to further development, verification and validation.*

# INNOVATING AT PACE

- Safe, portable, fast, cost effective and easy to use imaging modality
- IP portfolio spans software, hardware and multiple indications
- EMVision's unique technology has been published in:

**Stroke**  
An American Heart Association Journal

**International  
Journal of Stroke**  
OFFICIAL JOURNAL OF THE WORLD STROKE ORGANIZATION

**frontiers  
in Neurology**

**nature  
SCIENTIFIC  
REPORTS**

Successful proof-of-principle study completed with 50 confirmed stroke patients at Brisbane's Princess Alexandra hospital in 2020-21 with an earlier clinical prototype. Algorithms refined in this study and observed to accurately classify stroke type (98%) and localise quadrant of stroke (78%). Larger multi-centre clinical trials with commercial unit are underway.

EMVision intends to provide actionable insights to clinicians for time sensitive medical emergencies, such as stroke and traumatic brain injury, in environments where access to CT/MRI is limited or not practical, by the bedside and in the pre-hospital environment.



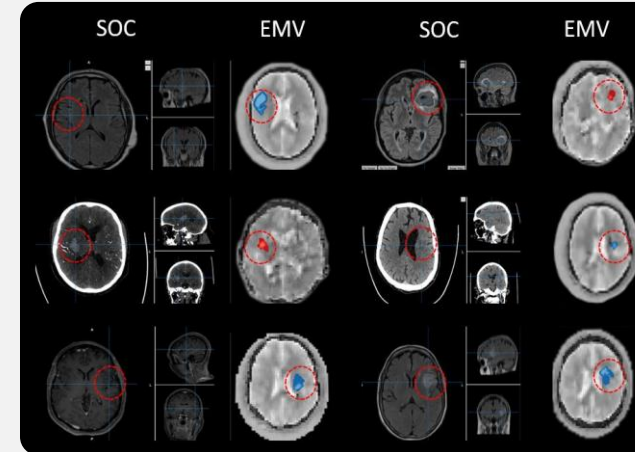
**EMVision has been named the top innovator in the health category in the 2023 AFR BOSS Most Innovative Companies List**

*Please refer to the Company's ASX announcement titled "EMVision Reports Very Encouraging Pilot Clinical Trial Data" released on 28th October 2020 and "Clinical Trial Data Drives Further Confidence for Expanded Studies" released 30th May 2021 for further details on the study. 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.*

*Please refer to the Company's ASX announcement titled "Latest imaging and clinical trial insights" released on 22nd August 2023 for further details on the AI powered probabilistic imaging technique (right).*

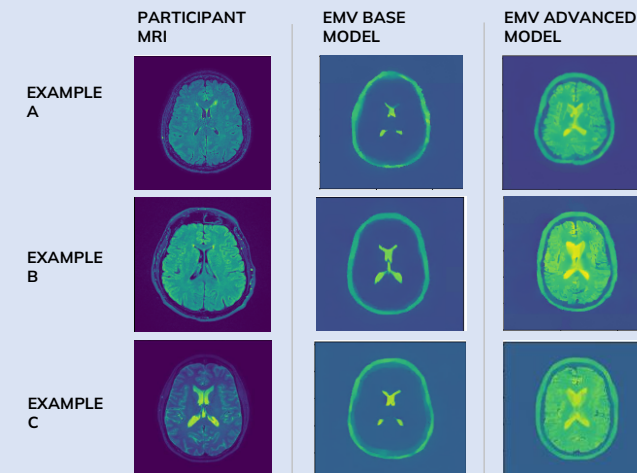
## IMAGING EXAMPLES

### PROOF-OF-PRINCIPLE STUDY



Patient examples from proof of principle pilot trial (left). Pathologies highlighted blue were classified as ischemic stroke and those highlighted red were classified as haemorrhagic. SOC = Standard of Care, EMV = EMVision Clinical Prototype 1 (CP1)

### AI POWERED PROBABILISTIC IMAGING EXAMPLES (NON-STROKE BRAINS)



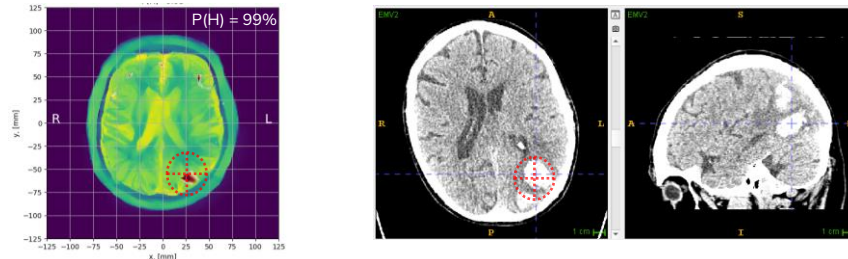
The ground truth 'MRI' slice is an approximate reference point to the EMV scan acquisition (Stage 1 study insights, Gen 1 commercial unit), and not the identical plane. It is intended for this background anatomical reconstruction to be combined with a separate series of algorithms to aid in the classification and localisation of stroke type.

*Algorithms are subject to further development, verification and validation*

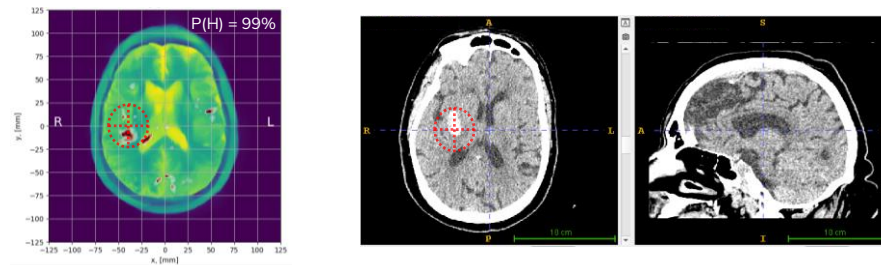
# LATEST PATIENT IMAGING CASE STUDIES

In these examples from EMVision's multi-site clinical trials (pre-validation phase), the EMVision algorithms are able to detect, correctly localize by quadrant ('heatmap' of greatest intensity) and classify intracerebral hemorrhage ('blood or not') and other ('no blood') cases.

Case study A – Intracerebral Hemorrhage (ICH volume ~13.8 mL)



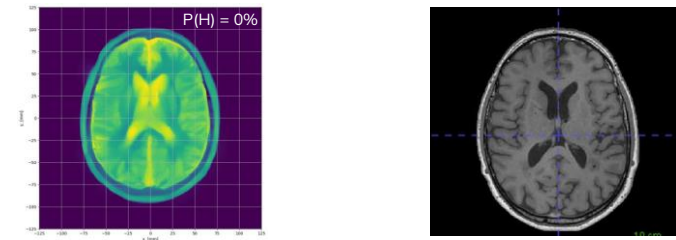
Case study B – Intracerebral Hemorrhage (ICH volume ~4.7 mL)



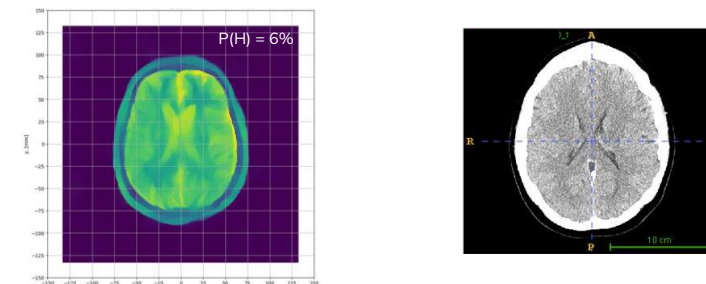
EMVision  
Model output

Ground truth  
Non-contrast CT

Case study C – Healthy volunteer



Case study D – Mimic (migraine)



EMVision  
Model output

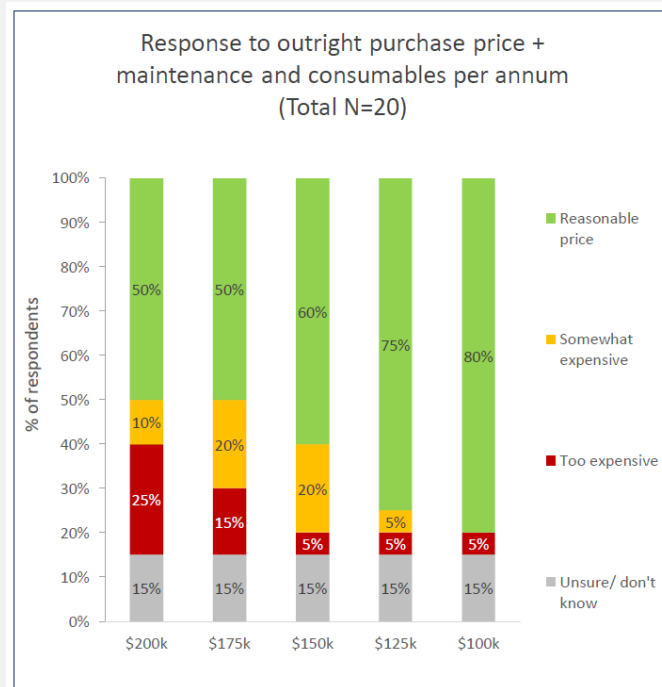
Ground truth  
MRI (top) CT (bottom)

*These 'development in progress' algorithm case studies of patients with intracerebral hemorrhage and other participants are subject to further development, verification and validation. The ground truth 'CT' and 'MRI' slices are an approximate reference point to the EMV scan acquisition, and not the identical plane.*

## POSITIVE MARKET FEEDBACK

US primary market research supports proposed purchasing models

- 20 US based stroke specialists, with involvement in purchasing processes, surveyed by IDR Medical.
- 50% of the sample considered the upper proposed Gen 1 purchase prices reasonable. Only 1 respondent did not accept any of the prices presented.



(USD)

Research by:



## ENCOURAGING HEALTH ECONOMIC ASSESSMENT

Estimated Gen 1 potential financial benefits to a public hospital in Australia<sup>1</sup>

Reduction in Transportation Costs **\$120,000**

More efficient CT/MRI Utilization **\$150,000**

Improvement in Endovascular Clot Retrieval Resource Utilization **\$90,000**

Reduction in Length of Stay **\$78,000**

**Estimated Annual Total Financial Benefit of one device**  
(excluding annual cost of imaging system) **\$438,000**



Research & Modelling conducted by:



*The savings estimated is from an Australian public hospital budget impact perspective and does not include post discharge patient outcomes related savings. Investors are cautioned that this study summary dated August 2021 is based on a number of assumptions, which are subject to change and may cause actual results to differ materially from those forecast. Investors should not place undue reliance on these results. The study is not indicative of the proposed unit pricing of EMVision's devices.*

# US REIMBURSEMENT STRATEGY

**Approximately 75% of stroke cases in the United States are covered by Centers for Medicare and Medicaid Services (CMS) via Medicare.**

Under the Inpatient Prospective Payment System (IPPS), Medicare pays for a patient's inpatient hospital stay under a bundled payment (MS-DRG), which covers costs of acute and post-acute care service performed. Examples of costs include radiology, room, supplies, nursing and operating room time. It does not cover physician fees (reimbursed separately), patient out-of-pocket and private health. Although this bundled payment may cover most drugs, devices and supplies, certain qualifying products are eligible for additional payment via the NTAP designation.

## New Technology Add-on Payment (NTAP)

- Announced September 2020
- Intended to support the adoption of cutting-edge technologies that have demonstrated substantial clinical improvement by helping to cover their cost for Medicare patients.

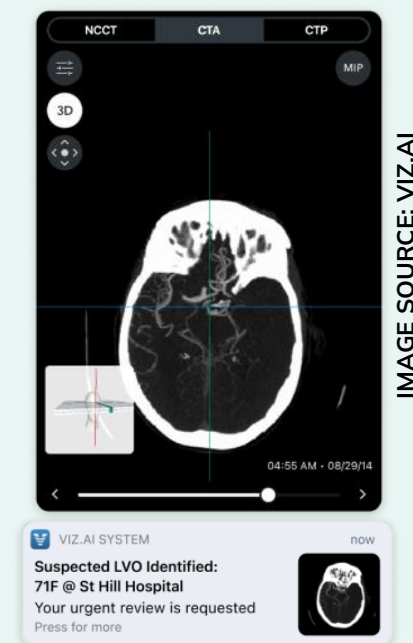
## Requirements

- New technology
- Cost criterion
- Substantial clinical improvement

**For outpatient (including pre-hospital), a similar program exists known as New Technology Ambulatory Payment Classification (APC). Engagement with Early Payor Feedback Program, including CMS and Local Medicare Administrative Contractors (MACs), is planned for H1 CY2024.**

MS-DRG Examples	Description	Medicare Payment USD	Total Charges USD
061	Ischaemic stroke w/ thrombolysis + major complications	\$20k	\$118k
066	Haemorrhagic stroke w/o complications	\$5k	\$43k
023	Thrombectomy w/ major complications	\$39k	\$179k

## NTAP Stroke Care Example



**Viz.AI software is intended to help reduce delays in acute stroke treatment and endovascular therapy.**

**Up to \$1,040 reimbursement per eligible patient beyond MS-DRG reimbursement**



# US MARKET RESPONDENT FEEDBACK ON 1<sup>ST</sup> GEN DEVICE

Commentary from stroke care respondents on use cases in a tertiary hospital setting, remote areas and anticipated scan volumes



## ***Will be used much more often***

*We do way more than 5 scans a day. On the ICU we are monitoring patients every day and sending them for scans, but with this you can do it so much more often, I can imagine wheeling it out on every round.*

***Vascular Neurologist, CSC***

## ***Useful in radiology after intervention***

*"It could be used in the radiology suite straight after the intervention to see if there are any changes and to see if you need to intervene more. On the ward or in the ICU you would use it to see if anything is wrong and then send the patient for a scan to confirm the findings."*

***Neuro-intensivist, CSC***

## ***Could have significant impact in the pre-hospital setting***

*"So pre-stroke treatment, I think it could be of help in the pre-hospital assessment to differentiate between a bleed and an ischemic stroke, to help facilitate transfer to the appropriate place with neurosurgery capabilities; and for transfer to a place that would help in administration of thrombolytics."*

***Vascular Neurologist, CSC***

## ***POC for remote areas with accessibility limitations***

*It's a very interesting thing. It doesn't use radiation, so it can be used anywhere the patient is. It's interesting, I can see how such a device can find use in clinical care. I think it can find a role, but especially in a certain point of care where a CAT scan is not available and that's where I can see it can be very useful. Or in remote areas they have a lot of people that don't have access to a hospital and to a CAT scan. Where you need to make a diagnosis on the spot, this seems to be simple enough to do that. In terms of a big hospital, I can see how you can make use of this in certain situations, it seems easy to bring to the ICU to make sure of things very quickly.*

***Neuro Interventional Radiologist, CSC***

## ***Would do more than 5 scans a day***

*If you had a 36-bed neuro-surgery unit and you had 4 patients having an event, you'd be using this more than 5 times a day.*

***Stroke Nurse, TCSC***

# MORE LIVES COULD BE SAVED WITH OUR SCALABLE AND LIGHTWEIGHT 2<sup>nd</sup> GEN BRAIN IMAGING SOLUTION



A Mobile Stroke Unit (MSU) of today



Inside a multi-million dollar Mobile Stroke Unit (MSU)

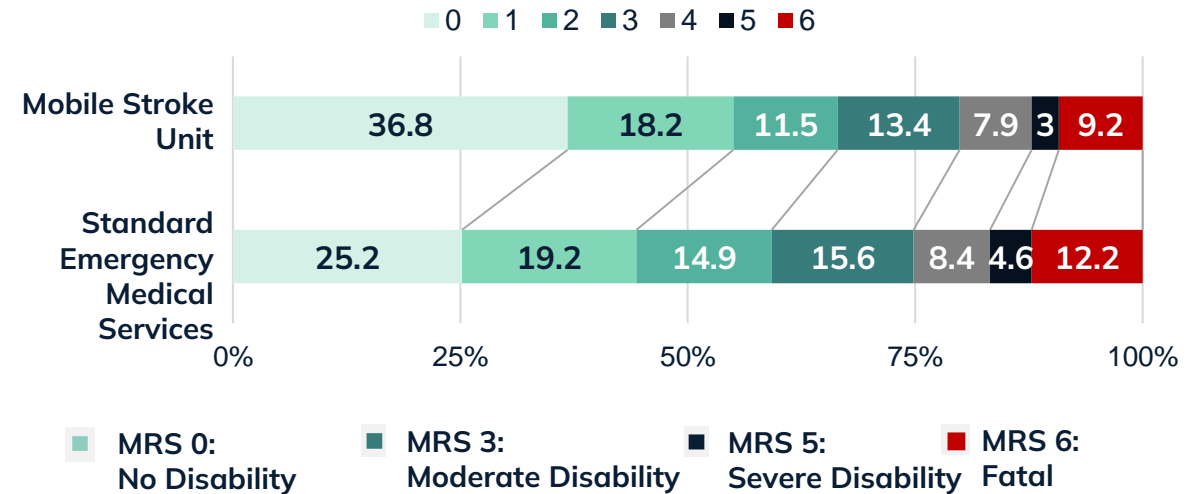


Equipping every standard Road and Air Ambulance with affordable neuroimaging capabilities is our goal  
(2<sup>nd</sup> Gen pictured)

- Mobile Stroke Units (MSU) essentially bring the stroke unit to the patient, providing faster diagnosis and treatment, improving disability outcomes
- However, the model is resource intensive (including radiographer) and requires an expensive specialised vehicle and thus is not generalisable for scale-up
- EMV 2<sup>nd</sup> Gen is designed as a scalable solution that is portable, ultra lightweight and telemedicine enabled, deployable by trained paramedics in any road or air ambulance
- EMV is partnering with the Australian Stroke Alliance (ASA) to develop and validate the Gen 2 to transform pre-hospital stroke care

*Gen 2 value proposition is subject to successful development, clinical testing and validation.*

## MSU vs Standard EMS (1,500 patients) Score on the Modified Rankin Scale (MRS)



Prospective, Multicenter, Controlled Trial of Mobile Stroke Units  
Grotta JC et al. DOI: 10.1056/NEJMoa2103879

# PATHWAY TO MARKET ENTRY (GEN 1 DURING FY25)

## GEN 1



BEDSIDE

**Multi-site clinical trials**  
 Pre-validation phase – Objectives: hardware verification, usability, safety, data for AI models  
**3 key sites activated** (Liverpool, Royal Melbourne and Princess Alexandra Hospitals)  
**Stage 1** (30 healthy patients) *complete ✓*  
**Stage 2** (150 suspected stroke patients) *enrolling – on track to complete during Q4 CY2023*  
**Stage 3** (mechanism to collect any additional datasets, e.g. hemorrhages, that are helpful to achieve objectives)  
**Validation phase** – Objectives: safety and efficacy  
 Sensitivity/specificity validation (*targeted H1 CY2024*)

Notified Body Conformity Assessment (CE Marking)



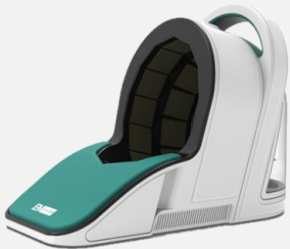
FDA De Novo Clearance



TGA ARTG Listing



## GEN 2



FIRST RESPONDER

**Substantial equivalence testing and road/air trials**

Gen 1 device a predicate for Gen 2

Bench testing underway and healthy volunteer testing - *anticipated to commence coming months*

Road and air testing anticipated to commence H2 CY2024

FDA 510(k) Clearance  
 Streamlined approval pathway



TGA ARTG Listing



Notified Body Conformity Assessment (CE Marking)



*\*See ASX "Latest imaging and clinical trial insights" released 22nd August 2023 for further information on clinical investigations roadmap  
 The indicative studies roadmap and timetable is a guide of EMVision's intentions at the date of this presentation only. EMVision reserves the right to vary this plan and timetable at its discretion, and further notes the above timings are subject to change due to circumstances outside of its control.*

# ATTRACTIVE REVENUE MODELS

Traditional capex or innovative opex selling model offerings to provide buyer flexibility. Direct or distributor sales channels.

## CAPITAL EQUIPMENT & CONSUMABLES MODEL (GEN 1)

- Capital Equipment – Target: ~US\$150,000
- Consumables (disposable cap, coupling media) – Target: ~US\$25 / per scan
- Preventative maintenance & service contracts – Target: ~10% of capital equipment p.a.
- Software upgrades (including additional indications)

## MONTHLY SUBSCRIPTION MODEL (GEN 1)

- Target ~US\$8,000 / month (subject to term)
- Delivery of the unit and training
- Consumables (subject to quota)
- Software upgrades
- Potential integration into PACS and EMR
- Access to cloud storage and viewing
- Routine maintenance included

**Significant consumable opportunity for both Gen 1 and Gen 2 point-of-care brain scanners.**

### Gen 1 consumables (~US\$25 / per scan)



Coupling media



Disposable cap

### Gen 2 consumables (~\$US50 / per scan)



# TOTAL ADDRESSABLE MARKET



## 1st GEN ADDRESSABLE MARKET - ~\$15Bn

US.	GER, FR, UK	AU	ROW
			
10,200	5,960	545	86,000
<b>FIRST TARGETS - ~\$350m+</b>			
1,600 PSC / CSC	642 PSC / CSC	93 PSC / CSC	
PSC = Primary Stroke Centre CSC = Comprehensive Stroke Centre			



## 2nd GEN ADDRESSABLE MARKET

US.	EUROPE	AU	ROW
			
60,000	58,000	5,200	54,000
Road and aeromedical ambulances			

EMV cautions investors that there are regulatory barriers and unique access challenges to each market and can be subject to varying rates of penetration. Estimates based on publicly available data. There are further regulatory hurdles to sell into ROW: China, Japan, Brazil, Mexico, South Korea, Spain, Italy, India and Canada.

# PARTNERS & COLLABORATORS

TRACK RECORD OF SECURING AND ONGOING ACCESS TO NON-DILUTIVE FUNDING PROVIDES GOOD FLEXIBILITY  
GRANT SCHEMES ARE COMPETITIVE AND SUBJECT TO DUE DILIGENCE BEFORE AWARD



## Commonwealth CRC-P Grant Program Collaborators



GE Healthcare

**Princess Alexandra Hospital**  
BRISBANE • AUSTRALIA

CRC-P grant supported an industry-led collaboration, including cash contribution from GE Healthcare, to develop and successfully test EMVision’s earlier proof of principle prototype device

## NSW Medical Devices Fund backing



\$2.5m non-dilutive grant funding awarded in November 2022 to support EMVision’s multi-site clinical trials



# SET UP FOR SUCCESS

- ✓ We have assembled a team of medtech experts that have successfully done this before and created significant shareholder value
- ✓ We have compelling support from the leading minds in stroke care
- ✓ Multi-billion-dollar market opportunity in stroke care alone
- ✓ Globally there is an increasing demand for point-of-care imaging solutions
- ✓ Our technology has additional applications for unmet clinical needs of high value, including traumatic brain injury
- ✓ Our multiple non-dilutive funding sources provide strong endorsement and offer flexibility to accelerate the commercialization of our product portfolio



## KEY UPCOMING CATALYSTS



Generate pre-validation and validation clinical trial data, achieving endpoints and recruitment objectives. Anticipated stage 2 reporting CY Q1 2024. FDA engagement.



Establish commercial partnership/s & strategic relationships



Gen 2 Advanced Prototype bench testing underway & healthy volunteer studies coming months, Gen 2 proof of concept unit build and road & air trials (during CY2024)



Establishment of commercial manufacturing



Regulatory submissions and approvals

# CAPITAL STRUCTURE

## ASX TICKER: EMV

Headquarters:  
4.01, 65 Epping Road, Macquarie Park  
Sydney, Australia

Share Price (14 <sup>th</sup> November 2023)	\$1.64 AUD
Shares on issue	77,957,112
Total Options on issue	5,900,000
Performance Rights	6,044,305
Market Capitalization	\$127.8m AUD
Enterprise Value	\$120m AUD
Cash Balance (30 September)	\$7.8m AUD
Remaining non-dilutive grant funding (as of 30 September)	\$3.8m AUD
Historical R&D Rebate for previous FY	\$2.5m AUD

- Secured ~\$20m in non-dilutive grant funding since inception
- \$3.8m ongoing non-dilutive staged grant funding available
- Modest historical cash burn
- Multi-centre clinical trials capital efficient at less than \$4m
- Founders, Management and Directors closely aligned to shareholders, holding approximately 20% of shares on issue



# THANK YOU

## ASX:EMV



**EMVISION**  
ASX:EMV

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