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# **COMPANY OVERVIEW**



**EMVision (ASX:EMV)** is a medical device company developing and commercialising world-first portable brain scanner products to address significant unmet clinical needs

- Founded in 2017 to advance and commercialise a decade of groundbreaking research out of the University of Queensland.
- EMVision has two distinctive portable brain scanner products to deploy in-hospital (emu™) or in the field (first responder) to enable earlier diagnosis and earlier triage, transfer or treatment decisions
- First indication targeted for stroke care, a multi-billion-dollar market opportunity, with a second planned indication in traumatic brain injury.
- Over \$50m invested in 'world first' product development since inception, including approximately \$20 million of funding from non-dilutive grants.
- Executed several best-in-breed clinical and industry collaborations, including strategic investment from Keysight Technologies (NYSE:KEYS).
- **Experienced** board and management team, with a strong execution and shareholder value creation track record.







# MEET THE TEAM



# Significant medical device development and global commercialisation expertise across the group

# **Executive Leadership Team**



Scott Kirkland CEO, Managing Director, Co-founder

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



Forough Khandan Chief Technology Officer

Over 15 years medical device development expertise. Former Head of Program Management Nanosonics (ASX:NAN), a \$1.1bn medical device success story.



Prof. Stuart Crozier Chief Scientific Officer, Co-inventor

Pioneer in medical imaging innovation. Professor Crozier's advancements in MRI technology are 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

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



Emma Waldon Chief Financial Officer, Company Secretary

Over 20 years corporate advisory, capital market and corporate 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 Philip Dubois Independent Non-Executive Director

Neuroradiologist, former CEO of Sonic Healthcare Imaging (ASX:SHL), \$13 bn 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), \$3.4 bn 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. Previously Chairman of Argenica Therapeutics (ASX:AGN), developing neuroprotective therapies to reduce brain damage after stroke.



Patryk Kania Independent Non-Executive Director

Medical device executive with over 20 years commercialisation experience across US, Europe and APAC, within sales, marketing and general management. Current CEO of Field Orthopaedics, previously held senior roles at Abbott, J&J and Roche.

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



# First indication

# **Stroke**

- 1 in 4 adults will suffer from a stroke in their lifetime<sup>1</sup>.
- 60% of stroke patients suffer permanent disability after their stroke<sup>2</sup>.
- The annual economic impact of stroke currently represents 0.66% of global GDP, estimated to exceed US\$1 trillion by 2030¹.
- Treatment within 3 hours of symptom onset improve chances of recovery with little or no disability.
  - Only around 23.5% of patients receive tPA (clotdissolving medication) in the US, partially due to the narrow treatment window of 4.5 hours from onset<sup>3</sup>.
  - Thrombectomy is used in about 27% of all patients with vascular occlusions in the US<sup>4</sup>, indicating an opportunity for growth.

# Types of Stroke Hemorrhagic Ischemic Stroke

20 million brain cells are saved for every 10 minutes earlier treatment is initiated

### Second indication

# **Traumatic brain injury** (TBI)

- 50 to 60 million people worldwide will suffer a TBI this year.
- TBIs are estimated to cost the world economy upwards of US\$400 billion per annum.
- TBI is classified as mild, moderate or severe based on the severity of injury and its effects.
- For patients with suspected traumatic brain injuries, quick evaluation is critical.
  - Most patients with suspected traumatic brain injury are examined using neurological scales which are subjective and may lead to biases in care.

World Stroke Organisation

<sup>2.</sup> Poomalai et al., Functional Ability and Health Problems of Stroke Survivors, 2023

<sup>.</sup> Rai et al., Updated estimates of large and medium vessel strokes, mechanical thrombectomy trends..., 2022

<sup>4.</sup> Mikulik et al., Stroke 20 20: Implementation goals for intravenous thrombolysis, 2021

# CT SCANNERS ARE VITAL IN STROKE CARE, BUT ARE NOT READILY AVAILABLE AT THE POINT-OF-CARE



CT scanners cannot be widely deployed at the bedside, or in remote locations, or in every ambulance. EMVision's products can address this unmet need.

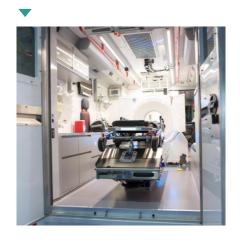


# Conventional CT

1,800 – 2,700 kg Fixed, hospital-only **lonizing radiation** Specialist operator

\$\$\$\$\$

Mobile Stroke Units (MSUs) are custom-built ambulances fitted with a mobile CT



# Mobile CT Scanner

450 - 1,000 kgMobile **lonizing radiation** Specialist operator

\$\$\$\$\$



# emu<sup>TM</sup>

100 kg Portable, in-hospital Non-ionizing Trained healthcare professional

\$\$





430 mm

# First Responder

< 12 kgPortable, pre-hospital Non-ionizing Trained healthcare professional

Time since LSW

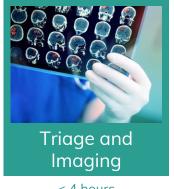
# ACCESSIBLE NEURODIAGNOSTICS AT EVERY STAGE

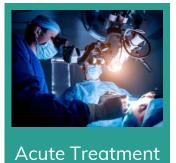














< 4 hours

< 4 hours

< 24 hours

> 3 weeks to lifetime

First commercial product

emu<sup>TM</sup>

Second commercial product

First Responder

# **First Responder**



- Reliably distinguish between haemorrhagic and ischaemic strokes, opening the door to potential in-field thrombolysis opportunities.
- Reliably identify potential endovascular clot retrieval or neurosurgery candidates, assisting decision-making on transfer to appropriate comprehensive stroke-capable hospitals.



### emu™

- Front-line decision support where there is limited access to CT imaging (e.g., in rural and remote areas) to inform patient triage and transfer decision-making.
- Keep a closer eye on potential complications and monitor patients following therapy or surgical intervention.
- Detect secondary bleeding earlier.
- Identification of post-operative stroke.

# Ultimately reducing time from symptom onset to treatment or intervention is a key objective.

# MARKET OPPORTUNITY



# **Attractive Revenue Models**

Traditional CapEx or innovative OpEx selling model offerings to provide buyer flexibility through direct or distributor sales channels.

### emu

# Capital equipment and consumables model

- Capital Equipment Target of ~US\$175,000
- Consumables (disposable cap, coupling media)
   Target of ~US\$25 / per scan
- Preventative maintenance & service contracts
   Target of ~10% of capital equipment p.a.
- Software upgrades (including additional indications)

# Monthly subscription model

- 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 emu and First Responder point-of-care brain scanners.

**emu consumables** ~US\$25/perscan





Disposable cap

First Responder consumables ~US\$50/perscan

# **Total Addressable Market**



**emu** Addressable Market

US GER, FRA, UK



10.200



\* \* \*

**AUS** 

86.000

**ROW** 

Market estimates are calculated on the assumption deployed per relevant department (e.g., emergency department, stroke ward, ICU)

Key Targets

| 1,600 PSC/CSC | 642 PSC/CSC | 93 PSC/CSC |
|---------------|-------------|------------|

CSC = Comprehensive Stroke Centre, PSC = Primary Stroke Centre

### 1,300 Critical Access Hospitals (CAH) in the US:

< 25 inpatient beds, average < 96 hours inpatient stay, located > 35 mi from other hospitals.

Unique reimbursement (allowable costs plus 1% reimbursement)

# First Responder ADDRESSABLE MARKET

60.000

US



GER. FRA. UK

\* \*

**AUS** 

**ROW** 

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. Addressable market sources: estimates based on ABS, U.S Census Bureau, WHO, AHA, EMS data and other publicly available data.. There are further regulatory hurdles to sell into the rest of the world (e.g., China, Japan, Brazil, Mexico, South Korea, Spain, Italy, India and Canada)

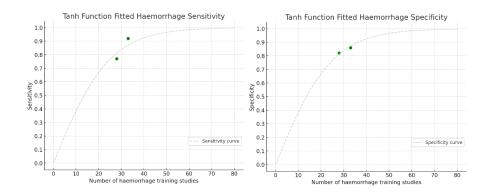


The EMView multi-site study involved 307 participants, including 277 acute suspected stroke patients, enrolled at Liverpool Hospital, Royal Melbourne Hospital, and Princess Alexandra Hospital.

# 'Haemorrhage (bleed) or not'

|                            | Haemorrhage     | Not Haemorrhage |
|----------------------------|-----------------|-----------------|
| Total Test Cases           | 13              | 55              |
| Correctly Identified Cases | 12              | 47              |
| Performance                | 92% Sensitivity | 85% Specificity |

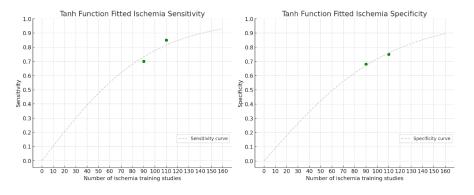
Including 20 ischaemic, 15 stroke mimics, 20 healthy patients



# **'Ischemia** (clot) **or not'**

|                            | Ischemic        | Not Ischemic    |
|----------------------------|-----------------|-----------------|
| Total Test Cases           | 20              | 32              |
| Correctly Identified Cases | 17              | 25              |
| Performance                | 85% Sensitivity | 78% Specificity |

Including 20 haemorrhages, 20 stroke mimics, 2 transient ischaemic attacks



# Reading learning curves

These graphs depict improvements in algorithm performance as the quantity of training datasets increase.

Sensitivity and specificity steadily increase as our algorithms 'learn'.

# Comparison thresholds

NIHSS (cut-off of 8) 73% Sens., 79% Spec.

NIHSS (cut-off of 10) 64% Sens., 84% Spec.

LAMS (cut-off of 4) 69% Sens., 81% Spec.

NCCT for AIS 39% - 70% Sensitivity

CTP for AIS 80% - 90% Sensitivity

NCCT for haemorrhage 90% - 100% Sensitivity

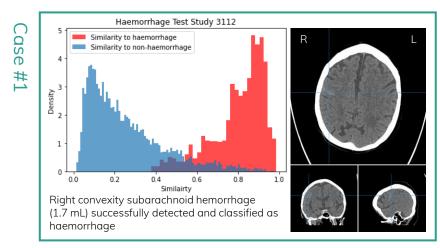
AIS = Acute Ischemic Stroke

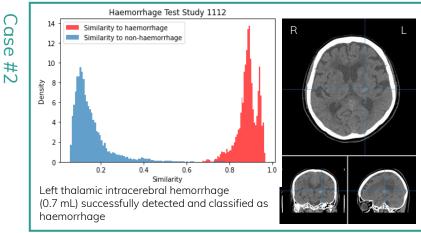
otroke ocdies

# **EMView PRE-VALIDATION CLINICAL TRIAL RESULTS**

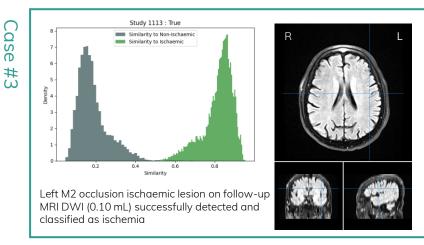


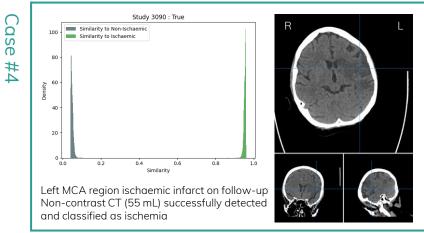
# **Exemplar case studies**





The median reported haemorrhage volume is 14.0 mL. 75% of hemorrhage volumes exceed 3.8 mL (n = 1117, Robinson et al., 2021)
Robinson et al., What is the median volume of intracerebral hemorrhage and is it changing?, 2021





Diffusion-weighted MRI is considered the most accurate imaging modality in the detection of early ischemia however, its utility is often limited due to lack of availability.

# TECHNOLOGY OVERVIEW



# Algorithm portfolio

Signals obtained in a matter of minutes









Localization of abnormality

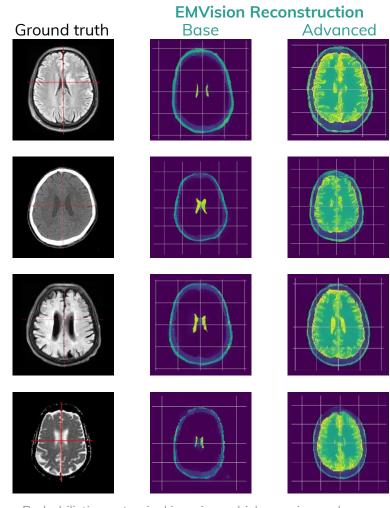


Probabilistic anatomical reconstruction

## **Expansive intellectual property portfolio**

14 patent families across hardware and software 4 design registrations, 2 trademarks Several trade secrets

# Probabilistic anatomical imaging case studies



Probabilistic anatomical imaging, which remains under development, is designed as a fiducial orientation tool.

# emu and First Responder OUR PATH TO MARKET ENTRY



# **emu** First commercial product

| A DI       | vve dre nere  |   |  |
|------------|---|---|--|
|            | Pre-Validation Trial  | Validation Trial (Pivotal)  |  |
|            | COMPLETED CY Q3 2024  | TARGET <b>COMMENCEMENT</b> CY Q1 2025   |  |
| Location   | Liverpool Hospital, Royal Melbourne Hospital,<br>Princess Alexandria Hospital | <b>6 sites</b><br>2 in Australia, 4 in United States  |  |
| Patients   | 30 healthy, 277 suspected strokes   | Up to 300 suspected strokes   |  |
| Objectives | Safety, hardware verification, algorithm development, performance test        | Efficacy and safety for regulatory approval  Human factors engineering and usability validation |  |
|            | 22.3.5p2, p3.101111a1100 t031   | ESTIMATED DURATION 6 – 12 MONTHS  |  |

We are here

# **Regulatory Submission + Market Entry**

### 2025+ ONWARDS





TGA application and approval Market entry

MSAC reimbursement submission



MDR CE Marking

Market entry

# First Responder Second

Second commercial product

# Feasibility Study TARGET COMMENCEMENT CY Q1 2025 Location Road and air ambulances (RFDS) Patients 30 patients at scene of event Objectives Further product development and clinical evaluation dependent on findings from feasibility studies. Substantial Equivalence Substantial Equivalence

# Regulatory Submission + Market Entry

2026+ ONWARDS







Leveraging predicate device regulatory approval processes. e.g., FDA 510(k)

Utilise networks and alliances established through commercialisation of  $emu^{TM}$ .

# **First Responder**

# VISION

# DOMESTIC FEASIBILITY STUDY OVERVIEW

# Targeted commencement CY Q1 2025



Study design Prospective, Convenience Sample, Usability, Pilot Study

Investigational sites Road Ambulance Service

Air Ambulance Service (Royal Flying Doctor Service)

Estimated duration < 6 months

No. of participants 30 total, 20 by road and 10 by air

Study objectives • To evaluate device usability, scan quality, reliability and patient acceptance

- To determine workflow time metrics including those related to scan completion

and emergency dispatch

User & patient feedback, EMV First Responder scan data, patient diagnosis

• Time metrics including: 1) symptom onset, 2) scanning metrics

Suspected stroke

Load device and dispatch

**Endpoints** 

Arrival and scanner warm-up

Standard assessment

First Responder Scan

Transfer to hospital

Time last seen well

Dispatch metrics

Workflow metrics
Usability Feedback-

Reference standard

Workflow metrics

Diagnosis

Device Feedback

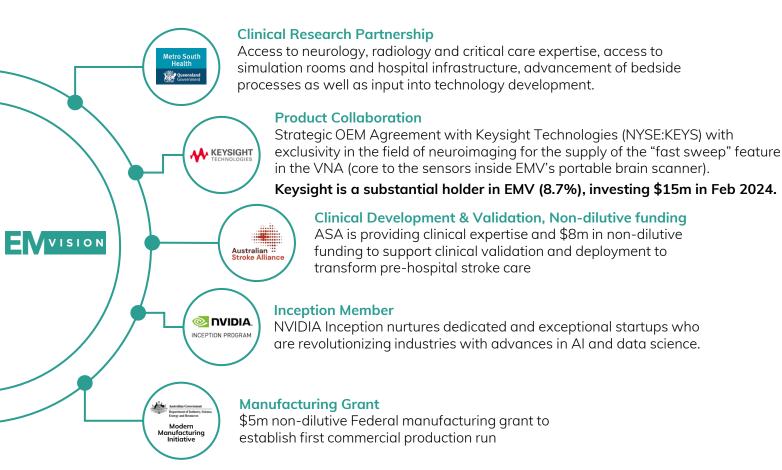
Scan data

13

# 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







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

# **INVESTMENT HIGHLIGHTS**

- ✓ 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 neurological care
- ✓ Multi-billion-dollar market opportunity in stroke care alone
- ✓ Globally there is an increasing demand for point-of-care sensing and imaging solutions
- ✓ Our technology has multiple additional applications for unmet clinical needs of high value, including traumatic brain injury
- ✓ We focus our energies on markets with very little or no competition



### **KEY 2025 CATALYSTS**

emu™

**First Responder** 



Validation (pivotal) trials

Pre-hospital road and air trials

Activation, recruitment, and reporting



Establishment of go-to-market partnerships and strategic relationships



Regulatory submissions for approvals in major markets

# **CAPITAL STRUCTURE**



# **ASX TICKER: EMV**

### Headquarters

4.01, 65 Epping Road, Macquarie Park Sydney, Australia

| Share Price (27th Nov 2024)               | \$1.92 AUD   |
|---|--------------|
| Shares on issue                           | 85,516,535   |
| Total Options on issue                    | 3,900,000    |
| Market Capitalization                     | \$164.2m AUD |
| Enterprise Value                          | \$147.4m AUD |
| Cash balance (30 <sup>th</sup> Sept 2024) | \$16.8m AUD  |
| Remaining non-dilutive staged grants      | \$0.8m AUD   |
|   |              |

# Strong Capital Management Track Record

- Secured ~\$20m in non-dilutive grant funding since inception
- Cash position of \$16.8m (30<sup>th</sup> Sept)
- Modest historical cash burn
- Validation (pivotal) clinical trials capital efficient at ≤\$4m
- Founders, Management, and Directors closely aligned to shareholders, holding approximately 20% of shares on issue
- Keysight Technologies (NYSE:KEYS) substantial shareholder





### **CLINICAL FEEDBACK**



"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 for '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