14/11/2024

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ASX Release

AGM CHAIR'S ADDRESS & MANAGING DIRECTOR PRESENTATION

EMVision Medical Devices Limited (ASX:EMV) ("EMVision" or the "Company") is pleased to provide copies of the Chair's Address and Managing Director Presentation to be given at its Annual General Meeting held at 2.00PM (AEST) on 14 November 2024.

Chair's Address – John Keep

At EMVision we are committed to our mission of playing a pivotal role in reducing the significant global burden of stroke and traumatic brain injury.

We know that healthcare professionals can make a powerful difference in the outcomes of their patients when they have timely access to the right diagnostic information. It is becoming increasingly clear, particularly on the back of our latest trial results, that we are on the pathway to provide this.

Our value proposition is compelling – our scanners represent an opportunity to revolutionise patient care by offering reliable, portable, easy to use and cost effective neurodiagnostic capability at the point-of-care. This can open the door to earlier triage, transfer or treatment decision making, which in medical emergencies like stroke, means significantly better outcomes for patients and less enduring disability.

The Company has enjoyed another successful year, underpinned by strong product and clinical development progress.

Advancing and commercialising our pipeline of portable brain scanner products, one for use at the bedside, the emu™, and the other for use out in the field by first responders, remains the central goal of EMVision's existence.

To that end, during the year we completed a successful clinical trial, with our emu™ bedside device, which enrolled over 300 participants at three major stroke centres in Australia. This week we were thrilled to share incredibly encouraging diagnostic performance test data and case studies, including the detection of very small haemorrhages, from this trial. A standout highlight was the emu™ scanner's ability to detect and classify haemorrhagic stroke with 92% sensitivity and 85% specificity in this cohort. This great result allows us to confidently proceed into our upcoming validation trials anticipated to commence early in the new year, including four influential sites in the United States to ultimately support FDA approval and commercialisation of our product. Currently we have 2 of our senior team members in the States preparing the sites for the trials.

We see enormous market potential for our scanners to improve the timely diagnosis and treatment of stroke and there is a clear path ahead to capitalise on this opportunity. In doing so we can help reduce the enormous health economic burden associated with stroke and importantly improve many lives.

Earlier this year, we unveiled a proof-of-concept prototype of our other portable brain scanner, the First Responder device. This is an ultra-lightweight iteration of our technology, with more antennas, that can be carried in a backpack and easily operated by paramedics at the scene.

Based on initial bench testing to date, we expect its performance capabilities to be at least equivalent, if not superior, to our emu™ device. It represents a genuine step change, that has the potential to alter the landscape of pre-hospital care, particularly as we see treatments move into the field at the scene of an incident.

We are fortunate to have an excellent collaboration with the Australian Stroke Alliance. Their experts are intimately involved in the development and validation of our technology, to help ensure that we are building products that will be both clinically useful and have a substantial positive impact. As our First Responder device hits the roads and skies next year in clinical studies, we are looking forward to the next exciting stage of our collaboration, focusing on implementation.

We are immensely grateful for the strategic investment and ongoing relationship with Keysight Technologies (NYSE:KEYS), a long-term technology collaborator, and a leader in test and measurement technology. Earlier this year Keysight made a strategic $15.3m investment in EMVision to help accelerate our path to market.

We are also very appreciative for the support of Federal and State grant programs, which have totalled close to $20m in awarded funding since inception. This highlights the Government's recognition of the importance of our innovative home-grown technology and our potential to reduce the burden of stroke. We continue to pursue non-dilutive grant programs available to us.

Thank you to our very talented and capable team here at EMVision, competently led by Scott Kirkland, EMVision Managing Director & CEO and thank you to my fellow Directors for their dedication and hard work during the year and finally to our fellow shareholders, thank you all for your continued support of EMVision.

We look forward to keeping you updated on our progress and another productive year ahead as we move closer to achieving our mission in reducing the significant global burden of stroke and traumatic brain injury.

Authorised for release by the Board of the Company.

[ENDS]

For further information, media or investor enquiries, please contact:

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About EMVision Medical Devices

EMVision Medical Devices Limited (ASX:EMV) is an innovative Australian medical device company developing a novel approach to looking inside the human body. Our product pipeline includes portable, non-invasive, affordable and safe neuroimaging devices.

Our vision is to help transform and improve the timely diagnosis and treatment of stroke and other time sensitive medical emergencies, at the point-of-care.

EMVision has offices in Sydney and Brisbane www.emvisionmedical.com

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.

EMVISION

emvision.com.au

ASX:EMV

CEO PRESENTATION

AGM 2024

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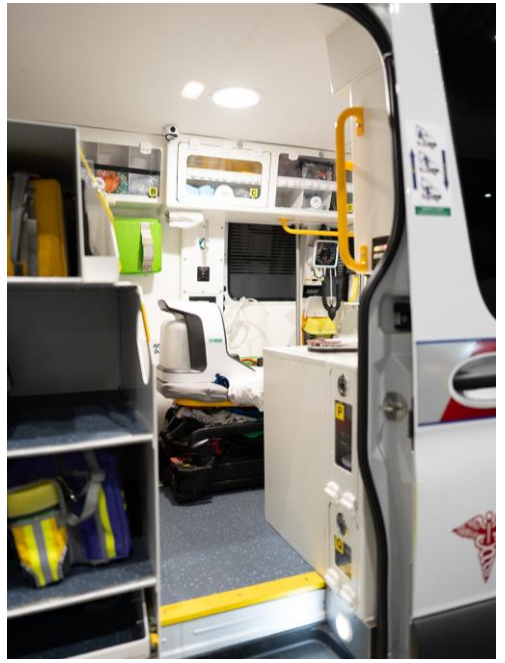
OVERVIEW

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

- **Founded in 2017 after 10 years of R&D at University of Queensland**
- **Best-in-breed partnerships and clinical collaborations**
- **“Zero to one” technology**
- **Multi-billion-dollar market opportunity**
- **Significant non-dilutive federal and state grant funding**
- **Approximately 40 Staff between Sydney and Brisbane offices**
- **First Indication**
  Stroke care
- **Second Indication**
  Traumatic brain injury



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 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.
	**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.

2024 HIGHLIGHTS

Exceptional neurodiagnostic performance demonstrated

The **EMView** study provided very encouraging real-world evaluation of diagnostic algorithm performance on suspected stroke patients.

First Responder unveiled

Ultra-light weight First Responder proof-of-concept prototype brain scanner fabricated, with game changing potential.

Keysight Technologies (NYSE:KEYS) strategic $15.3m investment

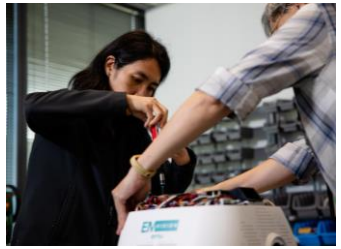
Strategic investment from long-term collaborator to accelerate clinical trials and production capacity.

Positive FDA engagement

FDA meeting reinforced confidence that EMVision's strategic direction is appropriate aligned with FDA requirements.

EMVision scanner showcases

Encouraging Federal Health Minister engagement at ASPC 2024. Strong interest at *Asia Summit on Global Health*, *Advancing Stroke in Top End* and CAA *Congress* events.



Pilot production line established

Under current configurations, the production line is anticipated to have capacity for the build, test and release of up to three emu™ devices per week, with modest personnel additions.

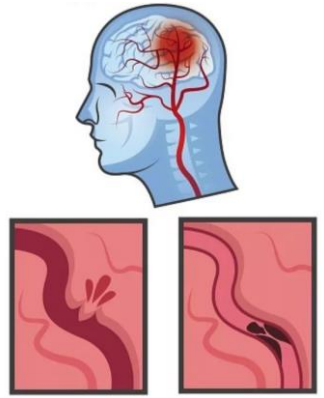
OUR VISION IS TO REDUCE THE GLOBAL BURDEN OF **STROKE** AND OTHER **TIME SENSITIVE MEDICAL EMERGENCIES**

First indication

Stroke

- 1 in 4 adults will suffer from a stroke in their lifetime[1].
- 60% of stroke patients suffer permanent disability after their stroke[2].
- The annual economic impact of stroke currently represents 0.66% of global GDP, estimated to exceed US$1 trillion by 2030[1].
- Treatment within 3 hours of symptom onset improve chances of recovery with little or no disability.
  - Only around 23.5% of patients receive tPA (clot-dissolving medication) in the US, partially due to the narrow treatment window of 4.5 hours from onset[3].
  - Thrombectomy is used in about 27% of all patients with vascular occlusions in the US[4], indicating an opportunity for growth.

Types of 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 the 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 a neurological scale which are subjective and may lead to biases in care.

1. World Stroke Organisation
2. Poomalai et al., *Functional Ability and Health Problems of Stroke Survivors*, 2023
3. Rai et al., *Updated estimates of large and medium vessel strokes, mechanical thrombectomy trends...*, 2022
4. 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
Ionizing radiation
Specialist operator

$$$$$

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

Mobile CT Scanner

450 – 1,000 kg
Mobile
Ionizing radiation
Specialist operator

$$$$$

880 mm

emu™

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

$$

430 mm

First Responder

< 12 kg
Portable, pre-hospital
Non-ionizing
Trained healthcare professional

$

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 / per scan

Coupling media

Disposable cap

First Responder consumables ~US$50 / per scan

Total Addressable Market

emu ADDRESSABLE MARKET ~$15B

US	GER, FRA, UK	AUS	ROW
10,200	5,960	545	86,000

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

US	GER, FRA, UK	AUS	ROW
60,000	58,000	52,000	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 the rest of the world (e.g., China, Japan, Brazil, Mexico, South Korea, Spain, Italy, India and Canada)

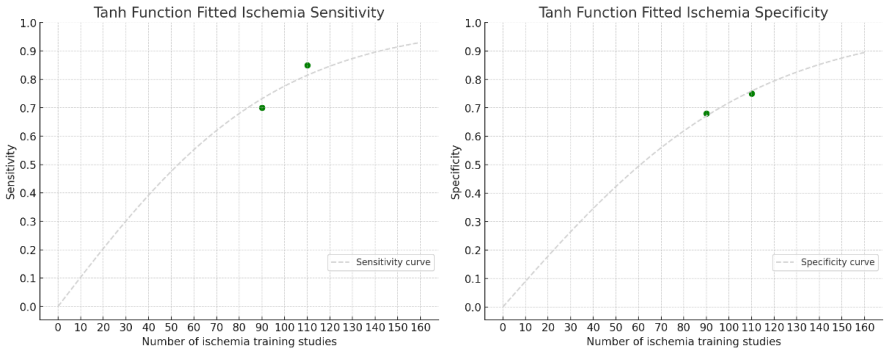
EMView PRE-VALIDATION CLINICAL TRIAL RESULTS

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**

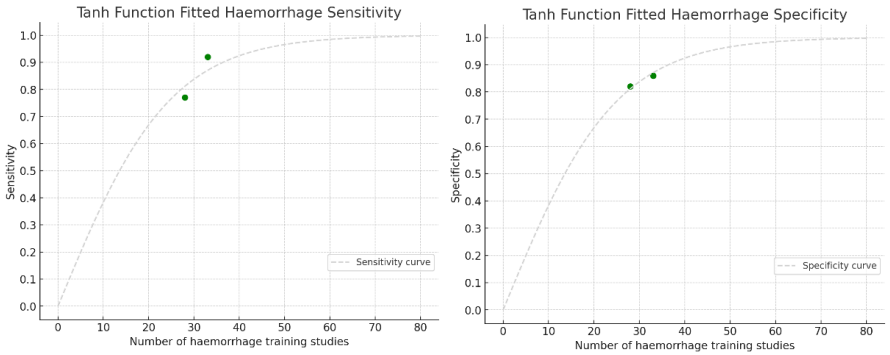
Including 20 ischaemic,
15 stroke mimics,
20 healthy patients



‘*Ischemia (clot)* or not’

	Ischemic	Not Ischemic
Total Test Cases	20	32
Correctly Identified Cases	12	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

Stroke Scales

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.

CT Scans

NCCT for AIS
39% - 70% Sensitivity

CTP for AIS
80% - 90% Sensitivity

NCCT for haemorrhage
90% - 100% Sensitivity

AIS = Acute Ischemic Stroke

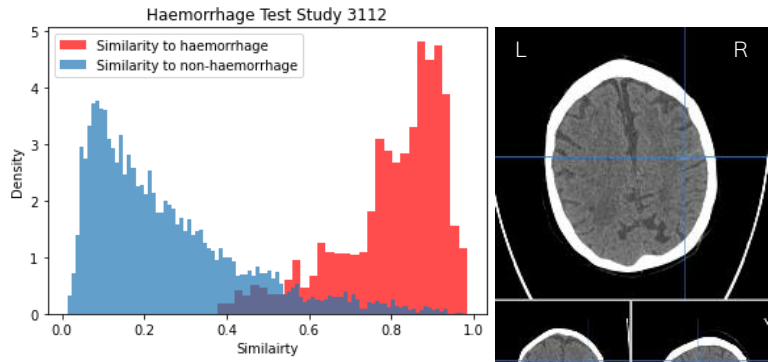
See November 2024 ASX Release ‘*Algorithms Deliver Excellent Results in EMView Study*’ for further details.

EMView PRE-VALIDATION CLINICAL TRIAL RESULTS

Exemplar case studies

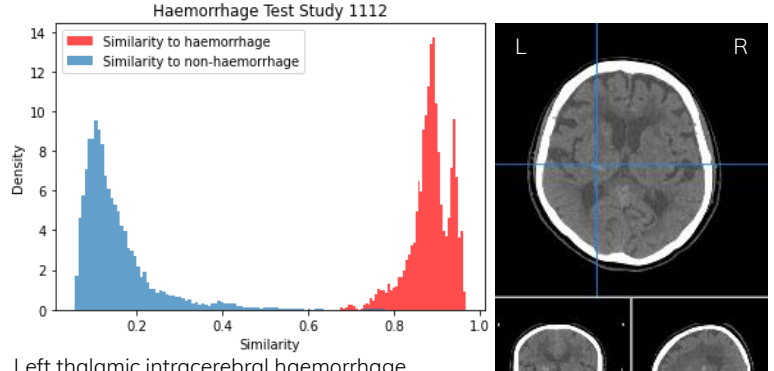
Very small haemorrhages successfully detected and classified

Case #1



Right convexity subarachnoid haemorrhage (1.7 mL) successfully detected and classified as haemorrhage

Case #2

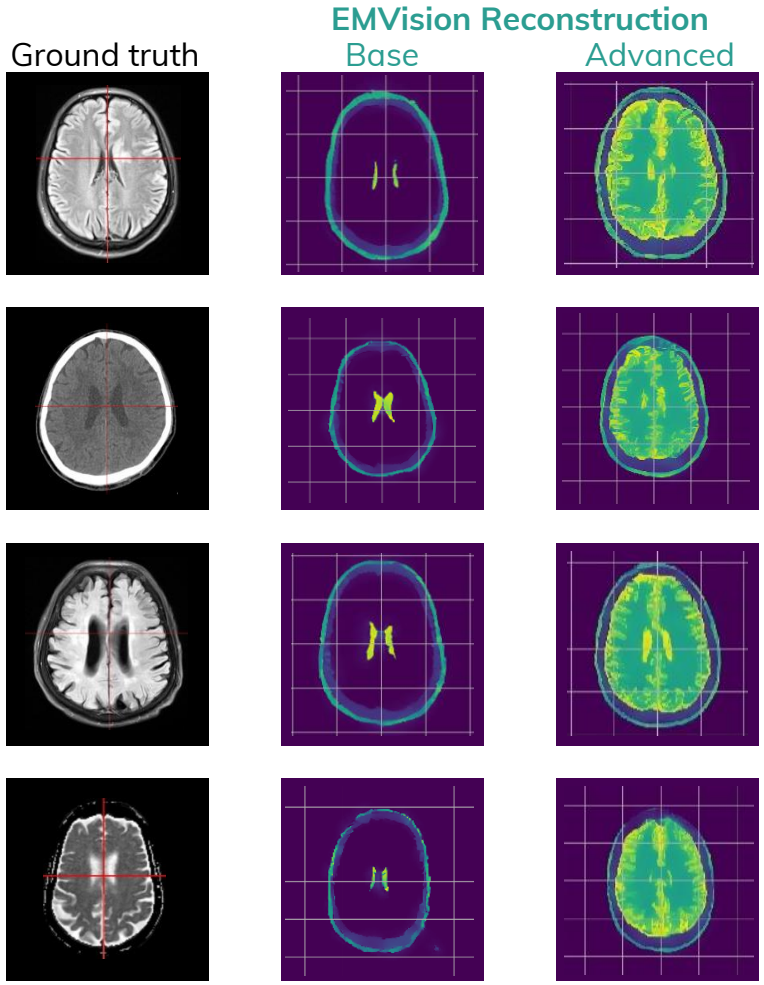


Left thalamic intracerebral haemorrhage (0.7 mL) successfully detected and classified as haemorrhage

Median reported haemorrhage volume in haemorrhagic stroke is 14.0 mL and 75% of haemorrhage volumes exceed 3.8 mL

Robinson et al., *What is the median volume of intracerebral hemorrhage and is it changing?*, 2021

Probabilistic anatomical imaging case studies



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

See November 2024 ASX Release '*Algorithms Deliver Excellent Results in EMView Study*' for further details.

emu and First Responder
OUR PATH TO MARKET ENTRY

emu

We are here

	Pre-Validation Trial	Validation Trial (Pivotal)	Regulatory Submission + Market Entry
	COMPLETED CY Q3 2024	TARGET **COMMENCEMENT** CY Q1 2025	LATE 2025+ ONWARDS
Location	Liverpool Hospital, Royal Melbourne Hospital, Princess Alexandria Hospital	**6 sites** 2 in Australia, 4 in United States	FDA De Novo application — Market entry CMS NTAP reimbursement submission
Patients	30 healthy, 277 suspected strokes	Up to 300 suspected strokes	TGA application and approval — Market entry MSAC reimbursement submission
Objectives	Safety, hardware verification, algorithm development, performance test	Efficacy and safety for regulatory approval Human factors engineering and usability validation	MDR CE Marking — Market entry
		ESTIMATED DURATION 6 – 12 MONTHS	

First Responder

We are here

	Feasibility Study	Substantial Equivalence	Regulatory Submission + Market Entry
	TARGET **COMMENCEMENT** CY Q1 2025	2025 ONWARDS	2026+ ONWARDS
Location	Road and air ambulances (RFDS)	Commercial product and clinical development program	Leveraging predicate device regulatory approval processes. e.g., FDA 510(k) Utilise networks and alliances established through commercialisation of emu™.
Patients	30 patients at scene of event		
Objectives	In-field feasibility and usability	Substantial equivalence testing	

Roadmaps are indicative and subject to change.

STRATEGY FOR CONTINUOUS INNOVATION DURING TRIALS

Validation Trials — Pivotal

Target commencement CY Q1 2025

Validation trials are conducted to demonstrate efficacy and safety for regulatory approval.

Validation trials are designed based on FDA feedback

Up to 300 suspected stroke patients (indicative)

Australian Sites
- **Site #1**
- **Site #2**

American Sites
- **Site #3**
- **Site #4**
- **Site #5**
- **Site #6**

V1 Software Validation

Primary objective: "Blood or not"

✚

V2 Software Validation

Additional features
Additional training

Clinical Data Collection — Training for future software upgrades

Completed trials

EMVision Database
- Confirmed strokes
- Stroke mimics

Existing datasets are used to train and lock the V1 algorithm

Conducted in parallel with validation trials

Cost effective data collection

~100+ participants

Australian Sites
- **Site #1**
- **Site #2** + as needed

Datasets are combined to train the V2 algorithm

Parallel collection of data provides opportunities to introduce additional functionality, higher performance capability and de-risks algorithm development

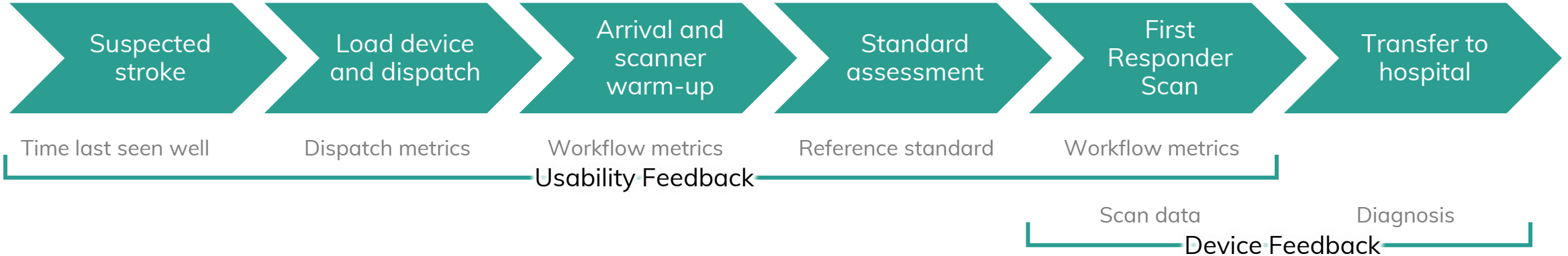
A clear trend was observed in the *EMView* (pre-validation) study where sensitivity and specificity performance steadily improved as additional clinical training data was utilized.

First Responder

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.
Endpoints	· User & patient feedback, EMV First Responder scan data, patient diagnosis. · Time metrics including: 1) symptom onset, 2) scanning metrics



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 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

- Validation (pivotal) trial activation, recruitment and reporting
- First Responder road and air trials activation, recruitment and reporting
- Establishment of go-to-market partnerships and strategic relationships
- Regulatory submissions for approvals