EMVision Medical Devices Ltd
ASX:EMV

# FY26 Results Presentation

August 2026

**First Responder**
Portable Neurodiagnostic Device

**emu™**
Bedside Brain scanner

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# INTRODUCTION TO EMVISION

Building a new category of point of care neurodiagnostic devices for acute neurological emergencies

## Novel Technology

– Foundation research at the University of Queensland

– >8 years and >A$75M invested under EMVision

– 14+ patent families across hardware and software

## Differentiated Solution

– World-first portable and rapid neurodiagnostic solution

– Deployable across diverse patient settings

– Enables faster triage, transfer and treatment decisions

## Large Addressable Markets

– Multi-billion-dollar opportunity in stroke care

– 2nd planned indication: traumatic brain injury (TBI)

– Both large and growing global healthcare burdens

## Encouraging Clinical Data

– 300-patient multi-site Australian study met endpoints

– High diagnostic accuracy for both stroke subtypes

– Pivotal trial underway for FDA De Novo clearance

## Strong Clinical Engagement

– Technology partner of the Australian Stroke Alliance

– Leading academic centres involved in validation include Mayo Clinic, Memorial Hermann, Mt Sinai and UCLA Health

**emu™**

*In-hospital device*

**First Responder**

*Pre-hospital device*

*Advanced prototype pictured, production equivalent units in progress*

# WHY WE ARE STARTING IN STROKE

Stroke remains a large and growing cause of mortality and disability globally

**1 in 4** people will have a stroke in their lifetime

Around **two-thirds** of survivors suffer permanent disability

Annual stroke incidence forecast to grow by **+80%** by 2050

Annual direct and indirect costs of stroke expected to grow to over **US$1.6 trillion** by 2050

## Time is brain

Every minute that a stroke goes untreated, approximately **2 million** brain cells are lost.

Modern stroke treatments are highly effective but depend on **speed** of access and determination of **stroke type** (clot vs bleed).

The earlier a stroke is treated, the greater the likelihood of **survival** and functional **independence**.

With stroke every minute matters, yet bottlenecks in care pathways continue to delay access to life-saving treatments

*Sources: NIH National Library of Medicine, World Stroke Organisation, Global Stroke Action Coalition, Stroke Foundation.*

# STROKE AND TBI REQUIRE URGENT DIAGNOSIS

Conventional CT imaging is critical in stroke and TBI diagnosis but not widely accessible at the point of care

## Conventional CT

- Fixed location (hospital only)
- Heavy (1,800 – 2,700 kg)
- Ionizing radiation
- Complex to operate
- Considerable capex and opex

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

## Mobile CT Scanner

- Mobile (pre-hospital)
- Heavy (450 – 1,000 kg)
- Ionizing radiation
- Complex to operate
- Considerable capex and opex


EMVision devices are designed to complement CT/MRI and fill gaps where they are inaccessible or unavailable

# EMVISION IN THE STROKE CARE PATHWAY

Rapid neurodiagnostic insight at the point of care to accelerate decision making and care pathway activation

| | Stroke onset (pre-hospital) | Hospital arrival & triage | Monitoring & recovery |
|---|---|---|---|
| Use case | **In-field stroke detection & classification** | **Initial scan in emergency departments** | **Routine monitoring in ICU / stroke ward** |
| |  |  |  |
| Benefit | Optimise hospital selection, pre-notification, initiate earlier triage & treatment decisions | Faster in-hospital transfer to specialist units (e.g. direct-to-angio), patient management, or inter-hospital transfers | Detection of perioperative stroke or monitoring of patients at risk of complications or acute neurological deficits on the wards |

# MARKET OPPORTUNITY

Multi-billion-dollar addressable market for emu™ and First Responder devices

## US First Strategy

### Initial Launch Strategy

– Concentrated, high need geography

– Established Pivotal Trial site relationships

– Proof of concept for national rollout

### The US 'Stroke Belt'

**22%**

**higher stroke death rate than rest of US**

Thirteen US states with consistently higher stroke incidence and mortality, where long rural transfers routinely delay definitive care and where we have established clinical champions in the region, makes the Stroke Belt the natural home for our initial commercial launch

## emu™ (In-Hospital)

**US Stroke Belt: High Priority Targets**

| 70 | 400 | 330 |
|---|---|---|
| **Comprehensive Stroke Centers** | **Primary Stroke Centers** | **Critical Access Hospitals** |
| *Highest acuity* | *Volume market* | *Remote access* |

**Stroke Belt Total: 800 hospitals**

Key Global Addressable Market: Hospital settings

| 10,200 | 5,960 | 545 | 12,850 |
|---|---|---|---|

## First Responder (Pre-Hospital)

**US Stroke Belt: High Priority Targets**

| 980 | 1,600 | 4,000 |
|---|---|---|
| **Aeromedical Ambulances** | **Academic EMS & Special Units** | **Advanced Life Support** |
| *Remote access* | *KOL networks* | *Highest acuity* |

**Stroke Belt Total: ~6,580 vehicles**

Key Global Addressable Market: Road & Air Ambulances

| 60,000 | 58,000 | 5,200 | 8,300 |
|---|---|---|---|

*Stroke Belt Incidence Source: National Center for Chronic Disease Prevention and Health Promotion, Division for Heart Disease and Stroke Prevention.*
*EMV cautions investors that there are regulatory barriers and unique access challenges to each market and can be subject to varying rates of penetration. The High Priority Targets have been identified by the Company as part of its target addressable market, which will inform the Company's long-term development and commercialisation strategy and are not indicative of future sales. Investors are cautioned that there are no guarantees that the high priority targets will be converted into future sales.*
*Addressable market sources: estimates based on ABS, U.S Census Bureau, WHO, AHA, EMS data and other publicly available data. Number of devices per setting will vary depending on clinical demand and onsite capabilities.*

# Highlights & Financials


*Advanced prototype pictured*

# FY2026 HIGHLIGHTS

Significant progress across clinical programs, product development and commercial priorities

## 1 emu™ (in-hospital)

- Pivotal (Validation) Trial, to support FDA De Novo approval, recruiting at several leading domestic and international stroke hospitals, with enrolment surpassing key milestones.
- Following R&D progress in the parallel Continuous Innovation Study, ischaemia detection endpoint in progress, pending FDA consultation, to be added to Pivotal Trial.
- Enrolment completion targeted in early CY2027, followed by endpoint readouts and FDA submission.
- Regional Benefits Study progressing toward ethics submission.

## 2 First Responder (pre-hospital)

- Aeromedical Retrieval Study completed, with favourable results reported for device feasibility and usability in aeromedical environment.
- Mobile Stroke Unit Study Stage 1 enrolment complete, with reporting expected in 3Q CY26.
- Experience and feedback from these studies has fed into the commercial First Responder product design (lower component count, lighter, with superior capability) ahead of data collection and testing to support regulatory clearance.

## 3 Commercial & Market

- Strong balance sheet position, with $17.1m cash and $4.6m grant funding remaining, in addition to expected R&D Tax Incentive of $4.3m.
- Growing international interest reflected in featured presentations at several industry events including:
  - European Stroke Organisation Conference
  - Int. Conference on Emergency Medicine
  - Novel Acute Brain Injury Conference
  - Military Health System Research Symposium
- Pilot diagnostic performance data from ‘EMView’ study published in npj Digital Medicine (Nature Portfolio), a leading, high impact peer-reviewed journal in digital health.

# PROFIT AND LOSS

For the year ended 30 June 2026

| AUD | FY26 | FY25 |
|---|---|---|
| **Income** | | |
| Grant income | 3,269,373 | 1,749,240 |
| Other income | 82,984 | 164,500 |
| R&D rebate | 5,005,595 | 3,137,983 |
| Interest income | 491,133 | 576,710 |
| | | |
| **Expenses** | | |
| Administration expenses | (2,114,553) | (1,802,768) |
| Employee expenses | (7,791,862) | (7,073,648) |
| Research & development | (4,961,616) | (4,035,236) |
| Finance costs | (203,443) | (88,567) |
| Share-based payments | (1,645,664) | (575,138) |
| Depreciation & amortisation | (416,901) | (408,485) |
| | | |
| **Net loss before tax** | **(8,284,954)** | **(8,355,409)** |
| Income tax expense | (31,396) | (1,450,127) |
| **Net loss after tax** | **(8,316,350)** | **(9,805,536)** |

## Commentary

- Total non-dilutive grant income and R&D tax incentive income of $8.3 million for the year.
- The Company effectively managed expenses during the year, despite higher levels of clinical trial and R&D activity on the emu™ and the First Responder device as these devices progress towards commercialisation.
- Share-based payments increased during the year to $1.6 million and is a non-cash expense.

# BALANCE SHEET

As at 30 June 2026

| AUD | 30 June 2026 | 30 June 2025 |
|---|---|---|
| Cash | 17,103,760 | 10,456,814 |
| Other financial assets | - | 73,651 |
| Other current assets | 295,924 | 272,084 |
| R&D receivable | 4,296,599 | 3,137,983 |
| Intangibles | 558,423 | 605,250 |
| Plant and equipment | 174,565 | 154,403 |
| Right-of-use assets | 608,778 | 874,797 |
| **Total assets** | **23,038,049** | **15,574,982** |
| Payables | 2,313,644 | 1,317,803 |
| Deferred income | 812,214 | 874,261 |
| Borrowings | 2,736,390 | 2,652,500 |
| Employee benefits | 737,723 | 565,641 |
| Lease liabilities | 669,367 | 881,813 |
| **Total liabilities** | **7,269,338** | **6,292,018** |
| Capital | 53,654,265 | 41,752,047 |
| Reserves | 3,284,309 | 2,347,123 |
| Accumulated losses | (41,169,863) | (34,816,206) |
| **Total equity** | **15,768,711** | **9,282,964** |

## Commentary

- Cash balance increased following completion of $14.0 million capital raising (pre-costs) in H1 FY26.
- R&D receivable of $4.3 million for eligible FY26 expenditure which will be received in FY27.
- Borrowings relate to non-dilutive funding from the NSW Medical Devices Fund.*
- Financial resources including secured grants and R&D tax rebate leaves EMVision well capitalised to deliver on upcoming clinical and regulatory milestones.

| Grant Program | Total Funding | Funding Remaining |
|---|---|---|
| Industry Growth Program | $5.0m | $2.8m |
| CRC-P Program | $3.0m | $1.8m |
| **Total** | **$8.0m** | **$4.6m** |

** Repayment of grant is triggered upon a "commercial success" milestone defined as achieving $500,000 cumulative positive EBITDA.*

# CASHFLOW

For the year ended 30 June 2026

| AUD | FY26 | FY25 |
|---|---|---|
| Receipts from grants (inc. GST) | 7,375,124 | 3,856,285 |
| Receipts of other income | 37,017 | 178,297 |
| Payments to suppliers & employees (inc. GST) | (13,983,498) | (12,431,314) |
| Interest received | 425,966 | 576,710 |
| Interest & other finance costs paid | (69,689) | (15,975) |
| Income tax paid | (31,396) | - |
| **Net cash used in operating activities** | **(6,246,476)** | **(7,835,997)** |
| Payments for plant and equipment | (124,216) | (50,373) |
| **Net cash used in investing activities** | **(124,216)** | **(50,373)** |
| Proceeds from issuance of shares (net) | 13,156,433 | (2,384) |
| Placement of term deposits | 73,651 | - |
| Repayment of lease liabilities | (212,446) | (255,956) |
| **Net cash provided by/(used in) financing activities** | **13,017,638** | **(258,340)** |
| Net increase/(decrease) in cash and cash equivalents | 6,646,946 | (8,144,710) |
| Cash and cash equivalents at the beginning of the year | 10,456,814 | 18,601,524 |
| **Cash and cash equivalents at the end of the year** | **17,103,760** | **10,456,814** |

## Commentary

- Proceeds from issuance of shares reflect the Company's placement and share purchase plan completed in H1 FY26.
- Effective management of cashflow despite higher levels of clinical trial and R&D activity on the emu™ and First Responder device, including an international study to support FDA De Novo clearance, as these devices progress towards commercialisation.


# Outlook

# OUTLOOK

Key priorities for the next twelve months

## emu™ In-Hospital

### Complete pivotal trial enrolment

Continue to hit recruitment milestones, culminating in recruitment completion across training verification and primary analysis cohorts.

### FDA Engagement

Parallel consultation with FDA via Q-Sub process for ischaemia detection addition, supported by AI model development from 'Continuous Innovation Study'

### Pivotal trial read out & FDA De Novo Submission

Complete pivotal trial readout on pre-specified endpoints, triggering FDA De Novo submission upon success.

### Regional Benefits Study

Begin gathering evidence in regional and rural hospitals, demonstrating how the emu™ can improve outcomes, particularly where access to CT or MRI may be delayed.

## First Responder Pre-Hospital

### Build commercial production equivalent units

First Responder production equivalent units in process, expected first build to complete early CY27, enabling verification, validation and market access preparation.

### Data collection to advance AI models

Next generation enhanced hardware is designed to exceed emu™'s diagnostic performance. Multi-site clinical data collection will train and validate AI models to demonstrate this performance in patients.

### Build out the pilot manufacturing line

Establishment of pilot production line at our Macquarie Park HQ, which, beyond clinical studies, forms the base for scaling up to commercial volumes.

### Expanded pre-hospital studies

Production equivalent First Responder units will move into expanded pre-hospital studies with front-line emergency services

## Commercial & Corporate

### Prepare for US launch

Progress US commercialisation readiness across regulatory strategy, reimbursement pathway, evidence generation. Establish GTM infrastructure including initial sales, marketing and customer support.

### Cultivate customer & strategic relationships

Continue to expand relationships with US hospitals, health systems and strategic partners to hit the ground running post FDA clearance

### Grow non-dilutive grant funding pipeline

Pursue grant opportunities to top up R&D funding, including for our second target indication (traumatic brain injury) and to support further clinical evidence generation.

### Clinical leader and KOL engagement

Continue to deepen engagement with leading stroke neurologists, emergency physicians and prehospital clinicians in Australia and key international markets to build clinical advocacy ahead of commercialisation

*The priorities and timelines on this slide reflect current plans and expectations only, are subject to risks and uncertainties (including clinical, regulatory and manufacturing risks), and may change. Actual outcomes may differ materially.*

# emu™ PATHWAY

Pivotal (Validation) Trial gaining momentum

## Recruitment Surpassing Key Milestones

- Recently introduced enrolment acceleration initiatives supporting recruitment momentum.
- emu™ device continues to integrate seamlessly into hospital code stroke workflows, with no device related adverse events reported.
- Additional site activations in progress, reflecting strong clinical interest.

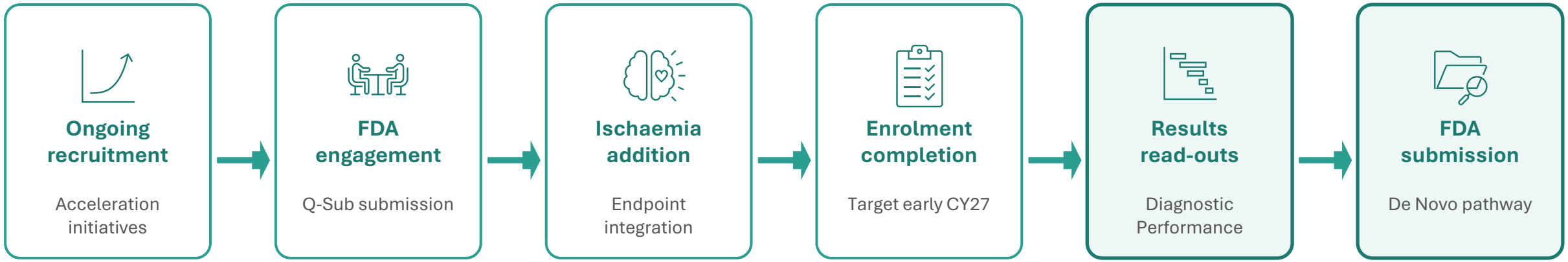
## Adding Ischaemia Detection Feature

- Preparations are underway to add acute ischaemia detection to Pivotal Trial.
- Simultaneous validation with haemorrhage detection strengthens commercial opportunity from first release and streamlines regulatory process and costs.
- FDA pre-submission (Q-Sub) engagement planned in the coming months.

**FORWARD ROADMAP**

*Progressing through CY26*

*Readouts & FDA Submission*



# FIRST RESPONDER PATHWAY

Progressing toward commercial production equivalent units, clinical data collection, alongside validation and substantial equivalence testing

*Pre-hospital feasibility and usability studies with advanced prototype · Production equivalent device design and development · Data collection · AI Model training · Diagnostic performance · Validation*

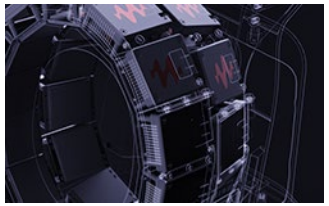
**FY26** | **FY27** | **FY28**

Aeromedical

Mobile Stroke Unit

Stage 1 Complete Reporting Q3 CY26

Production Equivalent hardware



Data Collection (algorithm training)

Validation & Substantial Equivalence testing - 510(k)

Expanded Pre-Hospital Studies


"The First Responder integrated smoothly into our retrieval workflow, our flight nurses found it intuitive to set up and operate, and importantly the scanner held up under the realities of flight. This study is a meaningful step toward bringing advanced neurodiagnostics to patients who today often have to wait many hours for a CT."

*Dr Zoe Schofield, Head of Strategic Research Projects at RFDS*

**~5 min**
Median Scan Time
*Rapid scan time demonstrated in real conditions*

**Positive**
Operator Usability
*Operators found it well suited to aeromedical use*

**Positive**
Patient Experience
*100% comfortable seeing scanner used on family*

## Production equivalent First Responder devices are underway

| Design objective | Target |
|---|---|
| **Form factor** | Ultra-lightweight (materially lower component count than earlier 'First Responder' advanced prototype) |
| **Operating environment** | Ruggedised for pre-hospital, aeromedical & military use |
| **Workflow** | Rapid scan; simple operation by non-specialist users |
| **Diagnostic performance** | Diagnostic performance superior to 1st gen emu™ |
| **Power & infrastructure** | Battery power |
| **Regulatory** | Supports FDA substantial equivalence (510(k)) pathway |
| **Pricing & margin** | "Small capital equipment" price point with healthy margin, maximising TAM & penetration rate |

*Timelines and development milestones are indicative only*

# COMMERCIALISATION DRIVERS

Transitioning from R&D focus to market entry preparations

**Regulatory Clearance**
- emu™ → De Novo
- First Responder → 510(k)
- Australia and EU approvals post FDA

**Reimbursement Pathway**
- Clinical & economic benefit evidence
- Early stakeholder engagement
- Temporary & permanent programs

**GTM Strategy & Infrastructure**
- US-first launch (Stroke Belt)
- Phased rollout model
- Australian management & production hub

**Foundation Customers**
- Research & evidence strategy
- Key opinion leader (KOL) adoption
- Academic Medical Centers pilots

emu™

First Responder

| Indicative Revenue Model | | |
|---|---|---|
| Capital | Consumables | Servicing |
| US$150 - $200k | US$25 per scan | ~10% of device cost per year |
| US$50 - $100k | US$50 per scan | ~10% of device cost per year |

** Capex and Opex (subscription) models to be offered to cater for customer preference. Target price range indicative and subject to change. Devices shown are investigational and not yet approved for commercial sale*

# LONGER TERM GROWTH STRATEGY

Initial US launch used as playbook for national scaling, geographic expansion and indication extension

## 1 US National Penetration

- Controlled national rollout, prioritising regions with the greatest unmet need and readiness for adoption.
- Supported by dedicated commercial, clinical, and operational teams.
- Ability to scale salesforce directly or appoint a distributor under a hybrid model.
- Strengthen clinical advocacy by generating post-approval data demonstrating clinical utility and economic benefit to hospitals.

## 2 International Expansion

- Initially targeting European countries with innovative, well-funded healthcare systems ahead of broader penetration.
- In Australia, leverage Australian Stroke Alliance partnership and local clinical relationships to support domestic roll-out.
- Selective expansion in Asia and ROW, targeting countries with clinical needs and health system capacity.

## 3 New Indications

- Traumatic brain injury (TBI) is highly prevalent globally, adding significant new patient populations beyond stroke.
- Expanding into TBI enlarges the clinical utility and addressable markets of both devices, providing a significant consumables opportunity in high volume trauma channels.
- Stroke indication regulatory clearance can also be leveraged, given safety and performance precedents.

# CAPITAL STRUCTURE

Strong capital management track record

| ASX Ticker: EMV | |
|---|---|
| Share Price (21 Aug 2026) | $1.81 |
| Shares on issue | 92.9m |
| Total Options on issue | 7.4m |
| Total Performance Rights on issue | 0.3m |
| Market Capitalisation | $168m |
| | |
| Cash balance (30 Jun 2026) | $17.1m |
| Remaining non-dilutive grants (30 Jun 2026) | $4.6m |
| FY26 R&D Tax Incentive receivable expected in FY27 | $4.3m |
| FY26 quarterly cash burn (net of non-dilutive funding) | ~$1.6m |

## Historic Funding Sources


Major Shareholders:

| | |
|---|---|
| Keysight Technologies (NYSE:KEYS) | 8.8% |
| Scott Kirkland (CEO/Co-founder) | 4.6% |