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A Stroke of Innovation: Brain Imaging Beyond the Hospital

30 October 2026

Company Snapshot

Company	EMVision Medical Devices Ltd
Core offering	Portable, non-invasive brain imaging platform
Key markets	Stroke diagnosis and monitoring, emergency and pre-hospital care, and other neurological imaging applications
Shares on issue	93.0m
Share Price (28 Oct 2026)	A$1.50
Market Capitalisation	A$139.4m
Net Cash (30 Sep 2026)	A$18.1m

Stroke represents a significant and growing global healthcare challenge. Approximately one in four people will experience a stroke during their lifetime. Global stroke incidence reaches approximately 12 million cases annually. In the United States alone, more than 795,000 people suffer a stroke each year, including approximately 610,000 first-time events. Stroke is also a leading cause of serious long-term disability, with approximately two-thirds of survivors experiencing some degree of disability.

The burden is expected to increase considerably over the coming decades. Annual stroke incidence in the US is forecast to rise by approximately 80% by 2050, while the combined direct and indirect economic costs could exceed US$1.6 trillion annually, highlighting the significant financial implications of delayed diagnosis, treatment and prolonged rehabilitation.

Timely diagnosis is a critical determinant of stroke outcomes. Modern treatments can substantially improve recovery, but their effectiveness depends on rapid intervention and, crucially, the ability to distinguish between the two main types of stroke: ischaemic stroke, caused by a blood clot, and haemorrhagic stroke, caused by bleeding in the brain. These conditions require different treatment approaches, making accurate identification essential before appropriate treatment can be initiated.

The clinical consequences of delays are significant. During a stroke, the brain can lose approximately 1.9 million neurons every minute. In ischaemic stroke, each 15-minute reduction in treatment time has been associated with approximately 4–5% higher odds of independent walking at three months, while each hour saved may increase the chances of functional independence by 22–25%. In haemorrhagic stroke, early anticoagulation reversal (reversing the effects of blood-thinning medications) is also critical, with treatment within 60 minutes of hospital arrival associated with improved outcomes (18% reduction in odds of death).

These time-sensitive interventions underscore the importance of shortening the interval between symptom onset, diagnosis and treatment. Fewer than 5% of patients receive thrombolytic treatment (blood clot dissolution) within the first hour after symptom onset, highlighting the difficulties of delivering early stroke care. This period is known as the “golden hour”, when treatment is most effective. In haemorrhagic stroke, the challenge is also evident in anticoagulation reversal, with only around one-third of eligible patients reportedly receiving treatment within 60 minutes of hospital arrival.

Access to timely stroke assessment remains constrained by the limitations of existing infrastructure. CT and MRI scanners are typically located in fixed hospital facilities, often requiring patients to be transported to dedicated imaging departments before treatment decisions can be made. This can create significant bottlenecks, particularly in emergency settings and for patients located far from specialised stroke centres. As a result, many patients do not receive appropriate treatment within the critical early window.

EMVision Medical (ASX: EMV) aims to address this gap by bringing brain imaging closer to the patient. Founded out of research at the University of Queensland, the company is developing portable brain-scanning technology designed to enable rapid, accessible assessment at the point of care. Its non-ionising approach has the potential to reduce reliance on conventional imaging infrastructure and support faster clinical decision-making in emergency departments, ambulances and other settings where access to CT or MRI may be limited.

By enabling stroke assessment closer to where patients first receive medical attention, EMVision seeks to help clinicians identify stroke type earlier, accelerate treatment and improve patient outcomes. The company's longer-term ambition extends beyond stroke to other time-critical neurological conditions, positioning its technology as a potential alternative diagnostic tool in settings where speed and accessibility are essential.

Brain Imaging Solutions at the Point of Care

EMVision is developing portable brain-scanning devices designed to complement conventional CT and MRI systems, addressing gaps in access to neuroimaging where traditional equipment is unavailable, difficult to access or impractical to deploy. The company's technology aims to deliver rapid neurodiagnostic insights at the point of care.

Unlike conventional CT, the technology does not use ionising radiation. Its non-ionising approach is designed to enable bedside scanning without the special protection required for ionising imaging equipment. The portable format also aims to reduce the need to move patients or transport them to dedicated imaging departments. Scanning and the generation of neurodiagnostic outputs are intended to take only a few minutes, potentially enabling clinicians to obtain actionable information earlier in the care process.

Traditional CT scanners provide established diagnostic capabilities but are generally installed in fixed hospital locations. They are heavy systems, typically weighing approximately 1,800–2,700 kg, and require substantial capital investment, ongoing operating expenditure and specialised infrastructure. Mobile CT systems extend imaging access into pre-hospital settings, but remain comparatively heavy, at approximately 450–1,000 kg, while retaining the need for ionising radiation and relatively complex operating requirements.

EMVision's portable approach is intended to address these limitations through a more accessible, lightweight and potentially cost-effective imaging solution. Its non-ionising technology, bedside deployment and reduced infrastructure requirements could make it particularly useful in settings where conventional scanners are difficult to access. Rather than replacing CT or MRI, EMVision aims to complement existing imaging infrastructure and help clinicians make earlier triage and treatment decisions.

The company’s portable brain scanners aim to support faster stroke assessment across the care pathway, from pre-hospital triage and hospital selection to treatment planning, specialist transfers and bedside monitoring. By providing rapid neurodiagnostic insights without requiring patients to be transported to dedicated imaging facilities, the technology could help accelerate clinical decision-making and identify neurological deterioration earlier.

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The emu Scanner

The emu is EMVision's flagship product. The bedside scanner is currently undergoing a pivotal clinical trial, with strong recruitment across leading stroke centres in the US and Australia. The trial is collecting paired clinical data to assess the scanner's accuracy in identifying stroke type, providing the key evidence needed to support the company's FDA De Novo submission.

Beyond generating clinical evidence, the trial is helping build relationships across the US and Australian healthcare communities. Clinicians, nurses and research teams at leading stroke institutions are gaining hands-on experience with the emu, increasing familiarity with the technology and helping establish a foundation for future adoption. Early experience integrating the device into emergency department workflows has also informed a research paper and a presentation at Mayo Clinic's 18th Annual Stroke and Cerebrovascular Disease Review in 2026.

A successful FDA De Novo request would establish a new regulatory classification for the emu, potentially creating a pathway for future products, including the First Responder, and supporting the company's broader commercialisation strategy.

First Responder Platform

The First Responder is EMVision's pre-hospital imaging platform, designed to bring brain scanning into ambulances and settings where conventional CT and MRI systems are impractical due to their size, weight and infrastructure requirements. The overall scanning workflow takes approximately five minutes, which could support faster neurological assessment before patients reach hospital.

There was further progress in FY26 through feasibility and usability studies with the Royal Flying Doctor Service, SAAS, Ambulance Victoria and the Australian Stroke Alliance. Testing in aeromedical environments received positive feedback from flight nurses and patients. The Mobile Stroke Unit study, conducted with Ambulance Victoria, The Royal Melbourne Hospital and the Australian Stroke Alliance, has completed Stage 1, with analysis underway and early findings described as encouraging.

Insights from these studies are informing the next generation of the device. Production-equivalent units currently under development are expected to be lighter than the prototypes used in field testing, with the company aiming to deliver diagnostic performance that exceeds that of the emu. These units are expected to be ready in early CY27, with clinical and operational preparations already underway to support the next phase of studies and progress towards commercialisation. A key advantage is the potential for the device to be operated by healthcare professionals such as nurses and paramedics, rather than requiring dedicated imaging technicians or specialist operators.

Regulatory Pathway

The company has conducted multi-site studies for the emu product, building a proprietary dataset to develop and train its AI models. Initial results from 307 participants, including 277 patients with suspected stroke and 30 healthy participants, have been encouraging, with the technology achieving 92% sensitivity and 85% specificity for detecting haemorrhage, and 95% sensitivity and 80% specificity for ischaemic stroke.

Conventional stroke assessment tools vary considerably in diagnostic performance. Pre-hospital stroke scales, such as LAMS (Los Angeles Motor Scale), have an estimated sensitivity of 69% and specificity of 81% for identifying patients with a higher likelihood of large vessel occlusion (LVO). For acute ischaemic stroke, non-contrast CT has a sensitivity of approximately 39–70%, with specificity above 90%, while contrast-

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enhanced CT improves sensitivity to 80–90% and specificity to above 95%. For haemorrhagic stroke, non-contrast CT performs particularly well, with sensitivity of 90–99% and specificity above 95%. It's important to note that these figures are drawn from separate studies with different populations and endpoints and are not directly comparable

A larger pivotal clinical trial has been underway since March 2025, designed to validate the device's diagnostic performance and support its FDA De Novo submission. The study design has been aligned with the FDA, with the primary analysis targeting 300 patients, including 150 with intracranial haemorrhage. The goal is to demonstrate sensitivity and specificity above 80% for haemorrhage detection, with statistical success requiring the lower bound of the 95% confidence interval for both measures to exceed this threshold. Recruitment is underway across leading stroke centres in the US and internationally, with enrolment progressing towards completion in early CY27.

EMVision is also working to expand the trial to include acute ischaemic stroke (blood clot) detection. This addition is subject to further FDA consultation, with pre-submission engagement planned in the coming months. Validating both haemorrhagic and ischaemic stroke detection could broaden the commercial opportunity from its initial launch while potentially reducing the need for separate regulatory studies.

The company is targeting enrolment completion in early CY27, followed by an FDA De Novo submission. The FDA's official review goal for a De Novo classification request is 150 days. However, the actual review period will depend on the FDA's assessment and whether additional information is required, with the process potentially taking 9–12 months.

The De Novo pathway is necessary because the emu introduces a novel technology without an established equivalent device classification. This requires EMVision to demonstrate the device's safety and effectiveness to support its proposed classification. While this creates a more demanding initial regulatory process, it may also create a competitive advantage by raising the evidence requirements for potential entrants.

Importantly, De Novo clearance for the emu could also support the regulatory strategy for future products, including the First Responder. If the FDA determines that the relevant requirements are met, subsequent devices may be eligible for the 510(k) pathway, which can be more straightforward than De Novo. This could reduce the time, cost and evidence required to bring future products to market.

Recent Milestones

The emu pivotal trial continued to recruit at leading stroke centres in the US and Australia. By early October, recruitment had surpassed 230 patients, with no device-related adverse events reported to date.

Clinical evidence also continued to build during the year. EMVision's pilot diagnostic performance data from the EMView study was published in *Digital Medicine*, a peer-reviewed journal, supporting the scientific foundation of its technology.

The First Responder also reached important milestones in pre-hospital care. The aeromedical feasibility and usability study reported encouraging results.

Potential Market Expansion

EMVision's relationship with Keysight Technologies, a global leader in electronic test and measurement technology, could provide strategic and technical support as the company progresses towards

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commercialisation. Keysight established a strategic equity stake in EMVision in February 2024 through a US$10m investment, following a longstanding technical collaboration.

Beyond its investment, Keysight has collaborated with EMVision on specialised components used to generate and measure the electromagnetic signals at the core of its brain-imaging technology. This relationship combines EMVision's medical-imaging development with Keysight's expertise in radiofrequency measurement and instrumentation, potentially supporting further product development.

Outside stroke, traumatic brain injury (TBI) represents a potential expansion opportunity. Patients who experience falls or head impacts may require assessment to rule out intracranial bleeding. EMVision's portable, non-invasive and non-ionising technology could potentially help clinicians assess these patients and identify those who may need further investigation, subject to clinical validation and regulatory approval.

The potential market is significant, with approximately 12 million strokes and 27 million traumatic brain injury events occurring worldwide each year. EMVision believes that its existing hardware could support additional applications through software upgrades, potentially expanding its addressable market without requiring an entirely new imaging platform. This could provide a pathway to broaden the technology's use beyond stroke and across a wider range of neurological conditions.

The Commercial Opportunity Ahead

EMVision is prioritising the US Stroke Belt as a key target market for commercialisation. According to the company, this region comprises 13 states that have historically experienced elevated stroke incidence and mortality, with stroke death rates reported to be approximately 22% higher than in the rest of the US. Rural communities and long transfer distances can make timely access to specialised stroke services particularly challenging, creating a potential use case for portable brain imaging. EMVision has also established relationships with clinical specialists in the region, which could support the introduction and evaluation of its technology.

The company's initial hospital opportunity in the Stroke Belt is estimated at approximately 800 facilities, comprising 70 Comprehensive Stroke Centres, 400 Primary Stroke Centres and 330 Critical Access Hospitals. These institutions offer different potential use cases, ranging from severe stroke assessment to improving access to diagnostic capabilities in more remote settings.

Beyond the initial US launch market, EMVision estimates a broader market opportunity of approximately 10,200 facilities in the US, 5,960 in Europe and 545 in Australia.

The First Responder could offer an even broader opportunity by extending brain imaging into ambulances and aeromedical services. Within the US Stroke Belt, EMVision identifies an estimated 6,580 potential vehicle targets, comprising 980 aeromedical and ambulance units, 1,600 academic EMS (Emergency Medical Services) and specialised units, and 4,000 Advanced Life Support vehicles. The broader estimated addressable market includes approximately 60,000 road and air ambulances in the US, 58,000 in Europe and 5,200 in Australia.

Pre-hospital imaging could represent the company's most impactful application because it addresses delays that occur before patients reach a hospital equipped to provide definitive stroke care. However, adoption will depend on clinical performance, regulatory clearance, workflow integration, procurement decisions and evidence that the technology improves patient management.

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EMVision's proposed commercial model combines device sales with per-scan revenue and ongoing service costs. Based on the indicative assumptions provided by the company, the emu could be priced at approximately US$150,000–200,000 per device, with a US$25 fee per scan and annual operating costs equivalent to around 10% of the device's purchase price.

For the First Responder, the corresponding assumptions are approximately US$50,000–100,000 per device, US$50 per scan and annual service costs of around 10% of the purchase price. Actual profitability will depend on device utilisation, reimbursement arrangements, manufacturing costs and service requirements.

M&A Activity in the Sector

Medical-device acquisitions provide useful context for EMVision's potential strategic value, particularly as larger companies seek differentiated technologies and opportunities to expand into adjacent markets.

Boston Scientific agreed to acquire Silk Road Medical for an enterprise value of approximately US$1.16b in 2024, equivalent to 6.5x EV/LTM revenue. Silk Road developed transcarotid artery revascularisation (TCAR), a minimally invasive procedure for stroke prevention in patients with carotid artery disease. The acquisition expanded Boston Scientific's vascular portfolio.

Stryker's acquisition of Mobius Imaging provides a relevant comparison, given Mobius's focus on mobile diagnostic imaging. Mobius developed mobile CT systems for clinical and surgical settings, with Stryker paying approximately US$370m upfront and up to US$130 million in contingent payments for a total consideration of up to US$500m in 2019.

These acquisitions demonstrate that larger medical-device companies may acquire differentiated technologies to expand their portfolios. While this supports the potential strategic relevance of EMVision's portable brain-imaging platform, the acquired businesses had more established commercial operations.

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Upcoming Catalysts

Catalyst	Expected timing	Significance
FDA pre-submission on ischaemia detection and trial protocol modification	Late CY26 / early CY27	Decides whether ischaemia detection can be added to the pivotal trial
emu Regional Benefits Study	After protocol finalisation, ethics approval and site contracting	First evidence of emu's benefit in regional hospitals without ready CT access
emu pivotal trial enrolment complete	Early CY27	Completes patient recruitment for the pivotal trial
First Responder production-equivalent units built	H1 CY27	The production-equivalent design intended for subsequent clinical testing and commercialisation
emu pivotal trial data lock, independent analysis and readout	Mid CY27. After enrolment completes	The main binary event
First Responder data collection starts	Mid CY27. After production-equivalent units are built	The first diagnostic performance signal for the First Responder
FDA De Novo submission for emu	H2 CY27. After the readout	Marks the commencement of the formal FDA review process, subject to acceptance of the submission
First Responder Mobile Stroke Unit Stage 2 and standard road ambulance studies start	H2 CY27. After production-equivalent units are built	Builds the pre-hospital evidence that ambulance services will want before adopting the device
First Responder 510(k) validation: regulatory engagement	H2 CY27	Advances discussions with the FDA regarding a potential 510(k) pathway
FDA De Novo decision for emu	Not guided. After De Novo submission (H2 CY27), typically 9–12 months later	The key value event. Clearance would allow US sales

Indicative timing only. Events may be delayed, modified or may not occur.

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ASX and Global Peer Comparisons

The table below sets out ASX-listed and global companies in diagnostic imaging and monitoring devices.

Assumes 1 USD = 1.42 AUD

Company (Ticker)	Lead Asset / Platform	Indication and Delivery	Most Recent FY Revenue (AUD, m)	Market Cap (AUD, m)
4DMedical (ASX: 4DX)	XV Technology™, CT:VQ™	Lung function and respiratory disease; functional lung imaging and CT-based software	7.1	1,975.3
Ceribell, Inc. (NASDAQ: CBLL)	Ceribell System and Clarity™	Seizure detection and monitoring; point-of-care EEG hardware and AI-powered analysis	126.5	1484.3
EMVision Medical Devices (ASX: EMV)	**emu™; First Responder**	**Stroke and neurological emergencies; portable in-hospital and pre-hospital brain scanning**	**8.9 (non-commercial)**	**139.4**
Hyperfine, Inc. (NASDAQ: HYPR)	Swoop® Portable MR Imaging System	Brain imaging, including stroke and neurological conditions; portable, low-field MRI at the point of care	19.3	101.5
CurveBeam AI (ASX: CVB)	HiRise™ weight-bearing CT; LineUp™ and InReach™ extremity CT; CT-based bone density (BMD) software	Orthopaedics and bone health; standing 3D imaging of the lower limb, hip and pelvis for acute care and joint replacement planning; point-of-care CT systems with SaaS software	8.7	14.7

As of 29 Oct 2026

EMVision is approaching a critical stage in its development, with the focus shifting from technology development towards clinical validation and commercial readiness. The key near-term priorities are to complete enrolment in the emu pivotal trial, report the results and progress towards an FDA De Novo submission. The outcome of this process will be an important determinant of the company's ability to move towards commercialisation in the US.

Overall, EMVision is developing an innovative portable brain-imaging platform, with encouraging early clinical results supporting its potential. Nevertheless, it remains a pre-commercial business, and significant milestones are still ahead. Trial results, regulatory clearance, manufacturing execution, funding position and the ability to establish a viable commercial model will be key factors to monitor moving forward.

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