

Aeromedical Box Ticked; Pivotal Readout Ahead

EMVision Medical Devices Ltd.

EMVision yesterday reported successful completion of the First Responder Brain Scanner aeromedical feasibility and usability study with the Royal Flying Doctor Service. Across 15 dispatches and 12 unique airstrips spanning 125–371 km from Adelaide, scan data quality was unaffected by flight conditions, flight nurse operators rated the device favourably across device preparation, patient set-up and scanner operation, and 100% of participants indicated they would be comfortable seeing the scanner used on a family member. The final A\$400k MRFF/ASA milestone has been received.

We view the readout as supportive for the rural/remote pre-hospital use case underpinning our First Responder market potential assumptions, but not catalytic on its own – diagnostic accuracy was not an endpoint, and the device tested was the advanced prototype rather than the production-equivalent commercial unit that will support the 510(k) substantial-equivalence pathway.

The more important signal sits in what today's announcement does not say.

Since our August 2025 initiation, the pivotal emu™ validation trial timeline has slipped materially – full enrolment is now guided to late CY26/early CY27, against our initiation assumption of Q3 FY26 study finalisation and FY26-end De Novo submission. Management has separately added an acute ischaemia detection endpoint to the pivotal trial (announced 10 May 2026), which expands clinical and commercial scope but introduces incremental execution and regulatory risk. We retain our Spec Buy rating and \$2.92 fair value but flag that the FY27 commercialisation timing in our model is now demonstrably tight.

Refreshed Catalyst Calendar

The table below maps our initiation catalyst guidance against the current state of disclosure. The principal change is the 12-month slip in the pivotal trial enrolment timeline and corresponding compression of the FDA submission.

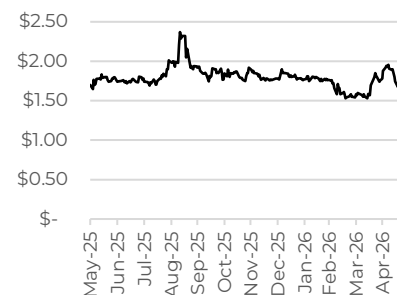
Event	Initiation guide	Current guide	Status
RFDS aeromedical study readout	Late 2025	Delivered 27-May-26	Delivered; supportive but not catalytic.
First Responder MSU Stage 1 (Melbourne)	Q4 CY25	Imminent	"Nearing conclusion" per today; key near-term readout.
Standard road ambulance study	Not specified	Preparations advanced	Confirms breadth of pre-hospital evidence base.
Pivotal emu™ enrolment complete	Q1 CY26	Late CY26/early CY27	12-month slip vs initiation. ~125/300 patients enrolled.
Ischaemia endpoint added to pivotal	Not modelled	Confirmed 10-May-26	Expands label scope; introduces complexity.
FDA De Novo submission	Late FY26	Mid-late CY27 likely	Sequenced behind enrolment + analysis.
emu™ US commercialisation	Q1 FY27	CY28E	12–18 month slip in commercial revenue start.

Recommendation	SPEC BUY
Price Target	\$2.92
Share Price	\$1.77
TSR	+65%

Company Profile

Market Cap	\$164.5M
Enterprise Value	\$146.1M
SOI (diluted)	100.8M
Free Float	66.8%
ADV (3-month)	\$78.6k
52-Week Range	\$1.48-2.43

Price Performance



%	1M	3M	12M
Absolute	-1.7%	1.1%	4%
ASX/S&P200	-0.8%	-4.0%	3.7%

Company Overview

EMVision Medical Devices (ASX:EMV) is an Australian commercial-stage medical device company developing portable, radiation-free electromagnetic brain scanners for point-of-care stroke diagnosis, with two products in clinical development: the cart-based emu™ for hospital ED and ICU use, and the backpack-portable First Responder for road and air ambulance deployment. The company is currently progressing its pivotal validation trial across six US and Australian sites to support an FDA De Novo clearance pathway for emu™, with First Responder to follow via 510(k) substantial equivalence.

Analyst

Jacob Hoenig jh@eveq.com
Healthcare Analyst

What the RFDS Study Tested & What It Found

The study was a single-arm workflow integration design with seventeen adult participants enrolled. The First Responder was dispatched on 15 transfers across 12 unique airstrips, with scans conducted on tarmac, on-board stationary aircraft, and in clinic settings. Several environmental variables were logged in parallel with scan data: temperature, vibration, tilt angle, device motion, and inflation pressure. The headline conclusion was that scan data quality across 13 transfers was comparable with scans conducted at EMVision's Sydney facility and was not materially impacted by aeromedical conditions.

Operator usability was assessed via a five-point Likert survey across three domains. Positive response rates ("Strongly Agree" or "Agree") were 100% for device preparation, ~83% for participant set-up, and ~92% for scanner operation. Median scan time was 5 minutes 7 seconds, inclusive of a 3-minute redundant sequence that management expects to remove from the production-equivalent commercial device. Patient experience metrics were favourable: 92% of participants indicated they felt calm during the scan and 100% would be comfortable seeing the scanner used on a family member.

The final A\$400k non-dilutive milestone under the Australian Stroke Alliance MRFF-funded project has been received, closing out that funding stream. We had already accounted for prior ASA tranches in our model; this final receipt is consistent with the schedule assumed at initiation.

Does the Aeromedical Readout Meaningfully De-Risk First Responder?

First, hardware robustness in real-world conditions speaks directly to the AI generalisability concern flagged in our initiation. The diagnostic algorithms have been trained on data from controlled hospital environments; demonstrating that scan data remains comparable across temperature, vibration, tilt and motion logged in flight is the first piece of evidence that the system can perform outside its training distribution. The Continuous Innovation Study sites at Princess Alexandra and John Hunter will provide further data on this axis, but the RFDS data is the first published evidence in an environment that genuinely stresses the hardware.

Second, our pre-hospital TAM construction assumed First Responder could be operated by paramedics with minimal additional training – a critical assumption given Mobile Stroke Units require a CT-qualified radiographer onboard and Micro-X's Head CT will likely face similar staffing constraints. The 100% positive response rate on device preparation by Royal Flying Doctor Service flight nurses (a non-radiographer workforce) is the first direct evidence supporting that assumption. It does not validate the full road-ambulance paramedic use case, but the population scanning in this study is reasonably representative of the pre-hospital end-user.

Third, the announcement explicitly anchors the next development step: "production equivalent commercial units, currently in development" will support "subsequent data collection and diagnostic performance and substantial equivalence testing to progress along the regulatory pathway." This keeps First Responder on the 510(k) substantial-equivalence path, which is dependent on prior emu™ De Novo clearance. The bottleneck for First Responder is now sequential to emu™, not parallel.

Our view: the readout incrementally de-risks the rural and remote stroke care use case and lends support to the 80% air-ambulance market potential assumption in our S-curve. It does not move our blended Probability of Success factor (65%), because regulatory clearance depends on the pivotal emu™ validation study and subsequent substantial equivalence testing, neither of which were tested today. Investors looking for the readout that materially de-risks First Responder should wait for the Mobile Stroke Unit (MSU) Stage 1 data – that study has paired ground-truth CT comparison and is the closer analogue to a diagnostic performance dataset.



emu™ Pivotal Readout

Our initiation set the pivotal validation study timeline as commencement in late March 2025, a 6–12 month enrolment period, and study finalisation in Q3 FY26 (early CY26), with the FDA De Novo submission slated for end of FY26 and emu™ commercialisation in Q1 FY27. The current trajectory differs materially on every leg of that path.

Recruitment status. The most recent update from the company (10 May 2026) puts recruitment at over 125 patients against the 300-participant target across the haemorrhage and non-haemorrhage arms. Six sites are active: Royal Melbourne Hospital, UHealth Memorial Hermann, Mayo Clinic Florida, Mount Sinai, Liverpool Hospital, and UCLA Health (the West Coast site activated in late August 2025, around the time of our initiation). Full enrolment is now guided to late CY26 or early CY27.

Trial expansion. On 10 May 2026, management announced the addition of an acute ischaemia detection endpoint to the pivotal trial. The case for adding ischaemia is sound – it broadens the De Novo clearance label from haemorrhage detection alone to include the larger ischaemic stroke segment (~80% of stroke cases), and management estimates it saves up to two years versus running a separate standalone study. The cost is incremental execution and regulatory complexity: ischaemia detection is a harder signal-processing problem than haemorrhage detection, and the FDA review will now need to satisfy itself on a more complex evidence base. No performance data on the ischaemia endpoint has yet been disclosed.

Implication for FDA submission and commercialisation timing. With full enrolment now late CY26/early CY27, data analysis and dossier preparation pushing into mid CY27, and a 312-day average FDA De Novo review for breakthrough devices (390 days standard), realistic clearance lands in mid-to-late CY28 – twelve to eighteen months later than our initiation model assumed. Commercialisation in Q1 FY27, as our initiation modelled, is no longer credible on the current trajectory.

Our view: the pivotal trial slip and ischaemia endpoint expansion are the dominant events for the EMV thesis since our initiation, and they cut both ways. The slip pushes out revenue and probably necessitates a larger or earlier capital raise. The ischaemia endpoint, if successfully validated, lifts the addressable label and the commercial argument – our initiation TAM was explicitly built on haemorrhage triage, so a dual-indication clearance would be additive to fair value. We retain the headline \$2.92 price target until pivotal data reads out, at which point we will refresh the model for both the timing slip and any incremental ischaemia performance data. Investors should size positions with that two-sided risk in mind.

Funding

Cash of A\$18.4M at 31 March 2026 plus A\$6.2M remaining non-dilutive grants gives roughly 18 months of runway at current burn – adequate to reach pivotal readout but not to fund the commercial sales build-out and inventory we modelled. Our initiation assumed a A\$20M raise in late FY26; with the timeline slip, the timing and likely size of that raise both warrant review.

Competitive Update

One competitive development warrants flagging. Micro-X (ASX:MX1) activated the first human trial site for its 70 kg portable Head CT stroke scanner at Royal Melbourne Hospital in February 2026 – the same hospital running EMV's pivotal validation trial. The Micro-X study is initially a hospital-based phantom and imaging study to generate regulatory submission data, with a stated intent to follow with an in-ambulance trial. Royal Melbourne is also the base for Australia's only Mobile Stroke Unit, where EMV's First Responder MSU Stage 1 study is concurrently running.



At this point, the competitive overlap does not change our position. Micro-X's Head CT remains a radiation-based modality requiring trained operators, whereas EMV's electromagnetic approach is radiation-free and designed for non-radiographer operation. The use cases diverge on those two attributes: high-frequency ICU monitoring (where radiation precludes routine use) and scaled paramedic deployment (where radiographer staffing is impractical) remain structurally favourable to EMV. Micro-X is the more credible competitor for definitive bedside diagnosis in higher-acuity centres, but that is not where EMV's primary TAM sits.

The more meaningful read-across is that Royal Melbourne Hospital is now hosting two parallel point-of-care stroke imaging programs. This validates institutional clinical demand at the most engaged comprehensive stroke centre in Australia and signals that the category is competitive but not winner-take-all. We are not adjusting forecasts.

Financial Summary

Income Statement					
A\$Ms	FY24a	FY25a	FY26e	FY27e	FY28e
Revenue	-	-	-	-	3.48
Other Income	11.22	5.05	4.39	3.59	3.92
Total Revenue	11.22	5.05	4.39	3.59	7.39
Operating expenses	-13.07	-13.49	-17.25	-18.75	-22.59
EBITDA	-1.85	-8.44	-12.86	-15.16	-15.20
D&A	-0.41	-0.41	-0.56	-0.21	-0.21
EBIT	-2.26	-8.84	-13.42	-15.37	-15.41
Net Interest	0.23	0.49	0.21	0.48	0.17
NPBT	-2.03	-8.36	-13.21	-14.89	-15.24
Tax expense	-0.70	-1.45	-	-	-
Discontinued operations	-	-	-	-	-
NPAT	-2.73	-9.81	-13.21	-14.89	-15.24

Balance Sheet					
A\$Ms	FY24a	FY25a	FY26e	FY27e	FY28e
Cash	18.60	10.46	24.07	8.44	34.55
Receivables	0.02	-	-	-	-
Inventory	-	-	-	0.53	0.50
R&D Incentive Receivable	2.78	3.14	2.39	2.61	2.52
Other	0.47	0.35	-	-	-
Current assets	21.87	13.94	26.46	11.58	37.57
Intangibles	0.65	0.61	0.56	0.52	0.47
PPE	0.24	0.15	0.19	0.22	0.26
Other	1.22	0.87	-	-	-
Non-current assets	2.10	1.63	0.75	0.74	0.73
Total Assets	23.97	15.57	27.21	12.32	38.30
Accrued Liabilities	0.93	1.32	1.23	1.33	1.60
Borrowings	0.82	-	-	-	-
Lease Liabilities	0.25	0.21	-	-	-
Other	1.42	1.31	-	-	-
Current liabilities	3.41	2.84	1.23	1.33	1.60
Borrowings	1.77	2.65	3.11	3.50	4.01
Other liability	0.27	0.80	2.83	2.34	1.41
Non current liabilities	2.04	3.45	5.95	5.84	5.42
Total Liabilities	5.46	6.29	7.17	7.17	7.02
Net Assets	18.52	9.28	20.04	5.15	31.28
Contributed Equity	41.57	41.75	66.11	66.11	107.5
Retained earnings	-26.52	-34.82	-48.87	-63.76	-79.00
Reserves/Other	3.46	2.35	2.80	2.80	2.80
Total Equity	18.52	9.28	20.04	5.15	31.28

Cashflow Statement					
A\$Ms	FY24a	FY25a	FY26e	FY27e	FY28e
Net profit for period	-2.73	-9.81	-13.21	-14.89	-15.24
D&A	0.41	0.41	0.56	0.21	0.21
Changes in working cap.	-4.65	0.99	-2.71	0.86	0.15
Other	0.98	0.58	0.14	0.11	0.12
Operating cash flow	-5.99	-7.84	-9.80	-15.43	-15.06
Payments for PPE	-0.12	-0.05	-0.20	-0.20	-0.20
Other payments	-0.19	-	-	-	-
Proceeds asset sale	-	-	-	-	-
Investing cash flow	-0.30	-0.05	-0.20	-0.20	-0.20
Equity raised, net	15.25	-0.00	24.54	-	41.37
Net borrowings	-	-	-	-	-
Lease repayments	-0.24	-0.26	-0.93	-	-
Other	-0.00	-	-	-	-
Financing cash flow	15.00	-0.26	23.61	-	41.37
Free cash flow	-6.3	-7.9	-10.0	-15.6	-15.3
Net cash flow	8.7	-8.1	13.6	-15.6	26.1
Effects of XR	-	-	-	-	-
Cash year end	18.60	10.46	24.07	8.44	34.55

Ratios					
	FY24a	FY25a	FY26e	FY27e	FY28e
Liquidity					
Current Ratio	6.4	4.9	21.6	8.7	23.4
Quick Ratio	1.0	1.2	2.0	2.4	1.9
Solvency					
Debt to Equity	0.2	0.4	0.3	1.1	0.2
Debt to Assets	0.1	0.2	0.2	0.5	0.1
LT Debt to Assets	0.1	0.2	0.1	0.3	0.1
Profitability					
Net Margin	n/a	n/a	n/a	n/a	n/a
ROA	-11%	-63%	-49%	-121%	-40%
ROE	-15%	-106%	-66%	-289%	-49%
Valuation					
P/E	n/a	n/a	n/a	n/a	n/a
EV/EBITDA	n/a	n/a	n/a	n/a	n/a
P/B	14.1	31.9	14.8	71.5	11.8

Evolution Capital Ratings System

Recommendation Structure

- **Buy:** The stock is expected to generate a total return of >10% over a 12-month horizon. For stocks classified as 'Speculative', a total return of >30% is expected.
- **Hold:** The stock is expected to generate a total return between -10% and +10% over a 12-month horizon.
- **Sell:** The stock is expected to generate a total return of <-10% over a 12-month horizon.

Risk Qualifier

- **Speculative ('Spec'):** This qualifier is applied to stocks that bear significantly above-average risk. These can be pre-cash flow companies with nil or prospective operations, companies with only forecast cash flows, and/or those with a stressed balance sheet. Investments in these stocks may carry a high level of capital risk and the potential for material loss.

Other Ratings:

- **Under Review (UR):** The rating and price target have been temporarily suppressed due to market events or other short-term reasons to allow the analyst to more fully consider their view.
- **Suspended (S):** Coverage of the stock has been suspended due to market events or other reasons that make coverage impracticable. The previous rating and price target should no longer be relied upon.
- **Not Covered (NC):** Evolution Capital does not cover this company and provides no investment view.

Expected total return represents the upside or downside differential between the current share price and the price target, plus the expected next 12-month dividend yield for the company. Price targets are based on a 12-month time frame.

Disclaimer & Disclosures

Evolution Capital Pty Ltd (ACN 652 397 263) is a corporate Authorised Representative (number 1293314) of Evolution Capital Securities Pty Ltd (ACN 669 773 979), the holder of Australian Financial Services Licence number 551094. The information contained in this report is only intended for the use of those persons who satisfy the Wholesale definition, pursuant to Section 761G and Section 761GA of the Corporations Act 2001 (Cth) ("the Act"). Persons accessing this information should consider whether they are wholesale clients in accordance with the Act before relying on any information contained. Any financial product advice provided in this report is general in nature. Any content in this report does not take into account the objectives, financial situation or needs of any person, or purport to be comprehensive or constitute investment advice and should not be relied upon as such. You should consult a professional adviser to help you form your own opinion of the information and on whether the information is suitable for your individual objectives and needs as an investor. It is important to note that Evolution Capital, or its agents or representatives, engaged and received a financial benefit by the company that is the subject of the research report. The financial benefit may have included a monetary payment or certain services including (but not limited to) corporate advisory, capital raising and underwriting. In addition, the agent or representative drafting the advice may have received certain assistance from the company in preparing the research report. Notwithstanding this arrangement, Evolution Capital confirms that the views, opinions and analysis are an accurate and truthful representation of its views on the subject matter covered. Evolution Capital has used its best endeavours to ensure that any remuneration received by it, or by an agent or representative, has not impacted the views, opinions or recommendations set out in this research report. The content of this report does not constitute an offer by any representative of Evolution Capital to buy or sell any financial products or services. Accordingly, reliance should not be placed solely on the content of this report as the basis for making an investment, financial or other decision.

Recipients should not act on any report or recommendation issued by Evolution Capital without first consulting a professional advisor in order to ascertain whether the recommendation (if any) is appropriate, having regard to their investment objectives, financial situation and particular needs. Any opinions expressed are subject to change without notice and may not be updated by Evolution Capital. Evolution Capital believes the information contained in this report is correct. All information, opinions, conclusions and estimates that are provided are included with due care to their accuracy; however, no representation or warranty is made as to their accuracy, completeness, or reliability. Evolution Capital disclaims all liability and responsibility for any direct or indirect loss, or damage, which may be incurred by any recipient through any information, omission, error, or inaccuracy contained within this report. The views expressed in this report are those of the representative who wrote or authorised the report and no part of the compensation received by the representative is directly related to the inclusion of specific recommendations or opinions. Evolution Capital and / or its associates may hold interests in the entities mentioned in any posted report or recommendation. Evolution Capital, or its representatives, may have relationships with the companies mentioned in this report – for example, acting as corporate advisor, dealer, broker, or holder of principal positions. Evolution Capital and / or its representatives may also transact in those securities mentioned in the report, in a manner not consistent with recommendations made in the report. Any recommendations or opinions stated in this report are done so based on assumptions made by Evolution Capital. The information provided in this report and on which it is based may include projections and / or estimates which constitute forward-looking statements. These expressed beliefs of future performance, events, results, or returns may not eventuate and as such no guarantee of these future scenarios is given or implied by Evolution Capital. Any forward-looking statements are subject to uncertainties and risks that may mean those forecasts made by Evolution Capital are materially different to actual events. As such, past performance is not an indicator of future performance.

Evolution Capital Pty Ltd

Level 8, 143 Macquarie Street Sydney, NSW 2000

Tel: +61 (2) 8379 2960

www.eveq.com