Thesis Intact; Waiting on Pivotal Study Progress

EMVision Medical Devices Ltd.

Recommendation	**SPEC BUY**
Price Target	**$2.94**
Share Price	**$1.80**
TSR	**+63%**

EMVision released its FY26 annual report on 24 August. The loss narrowed 15% to A$8.3M on income of A$8.8M, up 57% and sourced entirely from grants (A$3.3M) and the R&D tax incentive (A$5.0M). Operating cash outflow was A$6.2M. The company closed the year with A$17.1M cash and A$4.6M of committed non-dilutive funding still to be drawn, having raised A$14.0M at $1.94 through a September 2025 placement and share purchase plan.

There is no clinical data in this result and no guidance the market did not already hold. The one new disclosure of substance sits in the business risk section, which puts primary analysis of the emu™ pivotal validation trial in CY2027. That is the first completion date the company has committed to in a statutory document, and it corroborates the slip we flagged in May.

Pivotal Study Updates

Recruitment for the pivotal study is still an outstanding item. The last disclosed number was more than 125 patients against a 300-participant target, on 10 May 2026. Seventeen months after the study opened, against an enrolment window originally guided at six to twelve months, we would have liked an updated count. Its absence does not change our view. The CY2027 primary analysis target disclosed in the same document is consistent with the late CY26/early CY27 full enrolment guidance given in May, and all six sites are now recruiting.

We retain Spec Buy with fair value at $2.94, against $2.92 in May. The headline barely moves but the inputs behind it have. We have lifted our discount rate to 15% and restaged the capital raising profile across three years. The substantive change is funding: on our numbers EMVision exits FY27 with A$1.4M, so the raise is an FY27 event, not FY28 as we previously had it.

Refreshed Catalyst Calendar

Event	May-26 guide	Current guide	Comment
First Responder MSU Stage 1 data	Imminent	Stage 1 concluded, analysis underway	Nearest readout carrying paired CT ground truth
Mayo Clinic Stroke Review paper	Not flagged	14–17 Oct 2026	Confirmed. Workflow integration, not diagnostic accuracy
Pivotal emu™ enrolment complete	Late CY26/early CY27	Unchanged	No recruitment count disclosed since 10-May-26
Pivotal primary analysis	Not specified	CY2027	First appearance in a statutory document
FR production-equivalent units	Not specified	Early CY27	Gates the next phase of the FR study program
FDA De Novo submission	Mid-late CY27 likely	FY27 per CEO letter	We retain mid-late CY27
emu™ US clearance	CY28E	CY28E	Unchanged. 312-day average breakthrough review

Company Profile

Market Cap	$167.3M
Enterprise Value	$153.3M
SOI (diluted)	100.8M
Free Float	71.3%
ADV (3-month)	$66.8k
52-Week Range	$1.47 – $2.43

Price Performance

%	1M	3M	12M
EMV	10.1%	7.8%	-5.3%
ASX/S&P200	3.2%	5.2%	1.6%

Company Overview

EMVision Medical Devices (ASX:EMV) is an Australian 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 four US and two Australian sites to support an FDA De Novo clearance pathway for emu™, with First Responder to follow via 510(k) substantial equivalence.

Analyst

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Analyst

What the Result Contained

Income of A$8.8M was entirely non-commercial. Grant income of A$3.3M came from the Australian Stroke Alliance Golden Hour project (A$0.8M), the Industry Growth Program (A$1.3M) and CRC-P Round XVII (A$1.1M), the last from a A$3.0M award executed during the year for the emu™ Regional Benefits Study. The R&D tax incentive contributed A$5.0M against A$3.1M. Total expenses of A$17.1M rose 23%, on employee costs of A$7.8M, R&D of A$5.0M and a share-based payment charge of A$1.6M that nearly tripled.

Operationally the year delivered process rather than data. The pivotal trial is recruiting at four US and two Australian sites, with Mayo Clinic, UCLA, The Royal Melbourne and Mount Sinai named. A paper on emu™ workflow integration in emergency departments will be presented at Mayo Clinic's 18th Annual Stroke and Cerebrovascular Disease Review on 14 to 17 October. On First Responder, the RFDS aeromedical study completed and Stage 1 of the Mobile Stroke Unit study with Ambulance Victoria and The Royal Melbourne concluded, with analysis underway and management describing early observations as encouraging. Neither has released data.

Does the Result Change the Pivotal Timeline?

No. The CY2027 primary analysis target is consistent with the late CY26/early CY27 full enrolment guidance given on 10 May. The CEO letter frames FY27 as completing the trial, reporting results and progressing the De Novo submission, which is the same sequence on the same timetable.

Twelve months of disclosure has produced one recruitment update. Enrolment stood at more than 125 of 300 in May, and if the run rate implied by that figure has held, full enrolment lands inside the guided window. We would have preferred the annual report update the number, but a company recruiting an acute-presentation trial across six sites is under no obligation to report a rolling count, and the CY2027 timetable disclosed alongside the result is the more meaningful commitment.

We are not changing the timeline. Primary analysis in CY2027, dossier preparation into mid CY27 and a 312-day average De Novo review for breakthrough devices still puts realistic clearance in mid to late CY28. The market has had nothing to verify progress against since May, but nothing in this result moves that date. MSU Stage 1 has concluded with analysis underway and is the nearest readout that can move the thesis, carrying paired CT ground truth.

Funding Considerations

This is the material change in our model. EMVision holds A$17.1M with A$4.6M of grant funding still to be drawn, against an FY27 operating outflow we forecast at A$15.1M. On our numbers the company exits FY27 with A$1.4M. A raise inside FY28 is required.

We now carry A$60M of equity raised in three A$20M tranches across FY28, FY29 and FY30 at $1.50. The higher quantum reflects FY26 raising A$14.0M rather than the A$20M we assumed, and closing A$7.0M below our modelled cash. Staging it is the more realistic construction for a company funding through a regulatory review rather than off a revenue base. The timing and price of these raises now matters more to per-share value than any single operating assumption in the DCF. Modelled cash does not exceed A$14M at any point before FY32, so this is a company raising more or less continuously through the regulatory process.

Changes to Valuation and Model

FY26 actuals replace our estimates, FY27 becomes the first forecast year and the valuation date moves to 30 June 2026. The equity bridge now runs off the FY26 balance sheet: cash of A$17.1M less the A$2.7M NSW Medical Devices Fund facility gives A$14.4M net cash, replacing a stale FY24 position.

The discount rate moves to 15%, from 14.6%. The build is a 5.0% risk free rate, a beta of 1.3 and a 6.0% equity risk premium, giving a ~13% cost of equity, to which we add 100bp for size and 100bp for illiquidity. EMVision is a pre-revenue, single-asset developer with a sub-A$200M market capitalisation and thin daily turnover, funding a regulatory process across at least three further equity raises. A discount rate below 15% understates what is actually being underwritten.

Two assumptions we have deliberately left alone. First US emu™ revenue remains in FY28. Pushing it to FY29 would be a notable downside sensitivity in the model and we will make that change at pivotal readout, not on a result release. Second, the ischaemia endpoint stays unmodelled, so our TAM is still built on haemorrhage triage alone and a dual-indication clearance would be additive. The A$4.6M of remaining IGP and CRC-P funding is also excluded from forecast income.

Financial Summary

Income Statement					
A$Ms	**FY25a**	**FY26a**	**FY27e**	**FY28e**	**FY29e**
Revenue	-	-	-	3.48	4.66
Other Income	5.05	8.36	3.59	3.92	3.78
Total Revenue	**5.05**	**8.36**	**3.59**	**7.39**	**8.44**
Operating expenses	-13.49	-16.51	-18.75	-22.59	-24.28
EBITDA	**-8.44**	**-8.16**	**-15.16**	**-15.20**	**-15.84**
D&A	-0.41	-0.42	-0.41	-0.41	-0.22
EBIT	**-8.84**	**-8.57**	**-15.57**	**-15.62**	**-16.06**
Net Interest	0.49	0.29	0.34	0.03	0.09
NPBT	**-8.36**	**-8.28**	**-15.23**	**-15.59**	**-15.97**
Tax expense	-1.45	-0.03	-	-	-
Discontinued operations	-	-	-	-	-
NPAT	**-9.81**	**-8.32**	**-15.23**	**-15.59**	**-15.97**

Balance Sheet					
A$Ms	**FY25a**	**FY26a**	**FY27e**	**FY28e**	**FY29e**
Cash	10.46	17.10	1.41	4.59	7.73
Receivables	-	-	-	-	-
Inventory	-	-	0.53	0.50	0.85
R&D Incentive Receivable	3.14	4.30	3.92	3.78	3.02
Other	0.35	0.30	0.30	0.30	0.30
Current assets	**13.94**	**21.70**	**6.16**	**9.16**	**11.89**
Intangibles	0.61	0.56	0.51	0.47	0.43
PPE	0.15	0.17	0.27	0.37	0.46
Other	0.87	0.61	0.34	0.08	-
Non-current assets	1.63	1.34	1.13	0.91	0.89
Total Assets	**15.57**	**23.04**	**7.28**	**10.08**	**12.78**
Accrued Liabilities	1.32	2.31	2.53	3.05	3.28
Borrowings	-	-	-	-	-
Lease Liabilities	0.21	0.27	0.34	-	-
Other	1.31	1.34	1.34	1.34	1.34
Current liabilities	**2.84**	**3.92**	**4.21**	**4.39**	**4.62**
Borrowings	2.65	2.74	2.83	2.93	3.03
Other liability	0.80	0.61	-0.30	-0.99	-1.45
Non current liabilities	**3.45**	**3.35**	**2.54**	**1.94**	**1.59**
Total Liabilities	**6.29**	**7.27**	**6.75**	**6.33**	**6.20**
Net Assets	**9.28**	**15.77**	**0.54**	**3.75**	**6.58**
Contributed Equity	41.75	53.65	53.65	72.45	91.25
Retained earnings	-34.82	-41.17	-56.40	-71.99	-87.96
Reserves/Other	2.35	3.28	3.28	3.28	3.28
Total Equity	**9.28**	**15.77**	**0.54**	**3.75**	**6.58**

Cashflow Statement					
A$Ms	**FY25a**	**FY26a**	**FY27e**	**FY28e**	**FY29e**
Net profit for period	-9.81	-8.32	-15.23	-15.59	-15.97
D&A	0.41	0.42	0.41	0.41	0.22
Changes in WC	-0.99	0.08	0.44	0.00	-0.19
Other	0.58	1.73	0.13	0.12	0.10
Operating cash flow	**-7.84**	**-6.25**	**-15.13**	**-15.06**	**-15.46**
Payments for PPE	-0.05	-0.12	-0.20	-0.20	-0.20
Other payments	-	-	-	-	-
Proceeds asset sale	-	-	-	-	-
Investing cash flow	**-0.05**	**-0.12**	**-0.20**	**-0.20**	**-0.20**
Equity raised, net	-0.00	13.16	-	18.80	18.80
Net borrowings	-	-	-	-	-
Lease repayments	-0.26	-0.21	-0.36	-0.36	-
Other	-	0.07	-	-	-
Financing cash flow	**-0.26**	**13.02**	**-0.36**	**18.44**	**18.80**
Free cash flow	**-7.9**	**-6.4**	**-15.3**	**-15.3**	**-15.7**
Net cash flow	**-8.1**	**6.6**	**-15.7**	**3.2**	**3.1**
Effects of XR	-	-	-	-	-
Cash year end	10.46	17.10	1.41	4.59	7.73

Ratios					
	FY25a	**FY26a**	**FY27e**	**FY28e**	**FY29e**
Liquidity					
Current Ratio	4.9	5.5	1.5	2.1	2.6
Quick Ratio	4.8	5.5	1.3	1.9	2.3
Solvency					
Debt to Equity	0.3	0.2	n/m	0.8	0.5
Debt to Assets	0.2	0.1	0.4	0.3	0.2
LT Debt to Assets	0.2	0.1	0.4	0.3	0.2
Profitability					
Net Margin	n/a	n/a	n/a	n/a	n/a
ROA	-63%	-36%	-209%	-155%	-125%
ROE	-106%	-53%	n/m	-416%	-243%
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	15.1	8.9	n/m	37.4	21.3

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.

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