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Spectral Medical

Approaching the finish line

Spectral, in June, submitted its pre-market approval (PMA) application to the US Food and Drug Administration (FDA) for PMX, its proprietary endotoxin removal therapy for patients with endotoxic septic shock (ESS). The product is supported by positive data from the Phase III Tigris follow-on trial. An FDA regulatory decision, projected in H227, would propel the company towards commercialisation of a differentiated treatment in an area of exceptionally high medical need where mortality rates approach c 50%.

PMX targets endotoxins in septic shock patients

Sepsis is a leading cause of hospitalisation deaths worldwide, with over 350,000 annual deaths in the US alone. Septic shock is a particularly severe form of the condition, affecting c 10–20% of hospitalised sepsis patients but accounting for nearly half of all sepsis deaths. PMX is a single-use therapeutic hemoperfusion device designed to remove endotoxins from the bloodstream, which can contribute to sepsis/septic shock. Treatment is guided by Spectral's FDA cleared endotoxin activity assay (EAA) that tests for endotoxin in blood. Septic shock patients with EAA levels between 0.60 and 0.90 represent the potential treatment base for PMX; at least 30% of septic shock patients are estimated to have EAA levels above 0.60, resulting in a target market of c 150,000 US patients annually, or up to US$2.1bn (assumed total PMX treatment cost of US$15k/patient).

Improved mortality rates confirmed in Tigris

Positive top-line primary efficacy data in Q325 from Spectral's randomised US Phase III Tigris study (n=157) showed that PMX plus standard of care (SoC) in patients with ESS provided a pooled absolute risk reduction of 8.3% (relative risk reduction of 18%) in 28-day mortality, exceeding the prespecified primary endpoint. Results were also published in *The Lancet* and, in June, Spectral reported 12-month survival data from 100% of patients, confirming a continued durability of benefit, with 12-month mortality of 52.8% in the PMX arm versus 66.7% in patients receiving SoC alone, representing an absolute risk reduction of 13.9%.

Valuation: Regulatory catalysts could unlock upside

Spectral's EV of c C$430m reflects the potential for PMX to provide a differentiated and decisive endotoxin treatment to improve ESS outcomes. Regulatory catalysts, including potential US market approval within the next 12–18 months, could significantly de-risk the development trajectory and trigger a re-rating. Commercial partner Vantive (formerly Baxter's renal division, with c $4.5bn revenue) holds strong market positions in the renal and acute care settings.

Consensus estimates

Year end	Total revenues (C$m)	EBITDA (C$m)	PBT (C$m)	EPS (C$)	P/E (x)	EV/EBITDA (x)
12/24	2.3	(10.1)	(15.4)	(0.05)	N/A	N/A
12/25	2.4	(9.4)	(47.7)	(0.16)	N/A	N/A
12/26e	7.3	(9.6)	NA	NA		N/A
12/27e	8.8	(1.3)	NA	NA		N/A

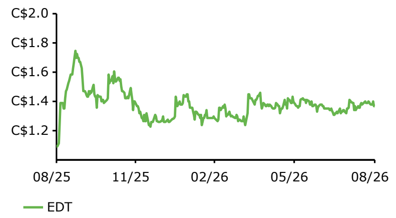
Source: LSEG Data & Analytics

Healthcare

17 August 2026

Price	**C$1.38**
Market cap	**C$405m**

Share price performance



Share details

Code	EDT
Listing	TSXV
Shares in issue	293.6m
Net cash/(debt) at 30 June 2026	C$(23.6)m

Business description

Spectral Medical is advancing Toraymyxin (PMX) for the treatment of patients with endotoxic septic shock. PMX is approved in Japan and Europe, and more than 360k units have been sold worldwide.

Bull points

- Breakthrough Device Designation granted by FDA for PMX for the treatment of ESS.
- Statistically significant positive Phase III Tigris trial results show reduction in ESS mortality vs standard of care across several time periods.
- Commercial strategy largely de-risked through commercial agreement with Vantive.

Bear points

- Regulatory risk remains as path to profitability depends on FDA PMA decision (expected H227).
- Additional fund-raising likely required with c C $24m in debt outstanding at 30 June and given limited near-term revenue sources.
- Potential competition from competing hemoabsorption devices (eg Baxter's oXiris and CytoSorbents' CytoSorb).

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