

Spectral Medical Announces Third Quarter 2025 Financial Results and Provides Corporate Update

- PMA submission targeted for Q1 2026 following positive Tigris results and ongoing FDA interactions
 - Company to host Corporate Update call on Wednesday, December 10, 2025

TORONTO, Nov. 07, 2025 -- **Spectral Medical Inc. (“Spectral” or the “Company”)** (TSX: EDT), a late-stage theranostic company advancing therapeutic options for sepsis and septic shock, today announced its financial results for the third quarter and provided a corporate update.

The third quarter of 2025 marked a pivotal period for Spectral, highlighted by the announcement of topline results from the Tigris trial – a confirmatory, Phase 3 study evaluating PMX for the treatment of endotoxic septic shock. The Tigris study met its prespecified primary endpoint, achieving a 95.3% posterior probability of benefit for 28-day all-cause mortality with an adjusted odds ratio of 0.67 [0.39–1.08], and demonstrated a >99% posterior probability of benefit for 90-day mortality with an adjusted odds ratio of 0.54 [0.32–0.87], representing a 17.4% absolute mortality reduction.

Consistent with US Food & Drug Administration (“FDA”) guidance and Bayesian statistical principles, both adjusted and unadjusted analyses were presented, with the adjusted analysis accounting for key covariates such as baseline severity of illness. These results reinforce the clinical and statistical robustness of PMX as a life-saving therapy for endotoxic septic shock.

Dr. John Kellum, Chief Medical Officer of Spectral Medical, stated, “The positive Tigris results confirm a clinically meaningful survival benefit with PMX, validating our Bayesian approach and years of development. We are now focused on completing the regulatory submission package.”

Spectral is in interactive discussions with the FDA to advance toward its Premarket Approval (“PMA”) submission, now targeted for Q1 2026 (previously Q4 2025). Discussions are focused on non-clinical components of the PMA to ensure a complete, high-quality submission and an efficient review process.

Corporate Highlights During & Subsequent to the Third Quarter of 2025

Tigris

- Announced positive topline Tigris results on August 12, 2025:
 - The trial met its prespecified primary endpoint, achieving a 95.3% posterior probability of benefit for 28-day all-cause mortality (adjusted odds ratio 0.67 [0.39–1.08]).
 - The key secondary endpoint demonstrated a >99% posterior probability of benefit for 90-day mortality, with a 17.4% absolute mortality reduction and number needed to treat of 8.1.
- PMA submission:
 - The Company’s Premarket Approval submission follows a modular submission strategy, with non-clinical components already submitted and under FDA evaluation.
 - Full PMA submission, including the clinical results, is now targeted for submission in Q1 2026.
 - The updated timing reflects ongoing interactive feedback with the FDA, and as the Company works to incorporate agency feedback on non-clinical module items, including updated standards and human factors testing.
 - Allows for a complete and compliant PMA submission – positioning PMX for the most efficient review possible.
 - This short deferral in timing is not expected to impact the overall commercialization trajectory and positions Spectral for a strong, high-quality submission.
- EDEN Study manuscript published September 16, 2025:
 - The prospective, multicenter observational study of 90 patients demonstrated that those with endotoxic septic shock (“ESS”) – defined as endotoxin activity assay (“EAA”) ≥ 0.6 combined with a Multiple Organ Dysfunction Score (“MODS”) > 9 or a Sequential Organ Failure Assessment (“SOFA”) > 11 – had a 28-day mortality rate of 57.1%, compared with only 15.9% in other septic shock patients.
 - Criteria used in the study to define ESS directly align with Tigris trial enrollment parameters.
 - These data will inform subsequent discussions with the FDA on potential labelling for PMX, as well as provide the medical community and the Company a better picture of the addressable population in the U.S. for PMX.

PMX Commercialization

- Ongoing collaboration with Vantive on commercialization planning.
- Vantive intends to submit 510(k) application for its PrisMax system, expected to be the primary ICU platform for PMX treatment.
- Market readiness efforts are aligned with potential FDA approval timelines.

Balance Sheet and Financing Update

- On August 22, 2025, Vantive advanced the second tranche of US\$3 million under the US\$10 million promissory note agreement signed in May 2025.
 - Under the terms of the promissory note agreement, Vantive may advance funds to Spectral in up to four separate tranches.
 - With the US\$3 million Tranche B advance, together with the initial US\$4 million Tranche A advance, the current cumulative draw of the promissory note is US\$7 million.
- During Q3 2025 and through to November 2, 2025, the Company received net proceeds of \$2.5 million from the exercise of warrants.
- Spectral balance sheet was further strengthened with warrant exercise proceeds and the Vantive Tranche B advance – providing the Company additional flexibility to execute on its regulatory pathway and into PMX commercialization.
- On September 29, 2025, Spectral filed a final short form base shelf prospectus.
 - Given upcoming milestones and catalysts which may be impactful to the Company, the base shelf prospectus provides optionality and maximum flexibility to opportunistically optimize Spectral's balance sheet.

"This was a transformative quarter for Spectral, highlighted by the positive topline results from Tigris," said Chris Seto, CEO of Spectral Medical. "The totality of evidence continues to build in support of PMX as the first targeted therapy for endotoxic septic shock. With our PMA submission in sight, we are continuing to work closely with our commercialization partner Vantive."

Financial Review

Total revenue for the three months ended September 30, 2025, increased to \$675,000 compared to \$502,000 for the same period in 2024, representing an increase of \$173,000 or 34%. Total revenue for the nine months ended September 30, 2025, was \$2,060,000 compared to \$1,641,000 for the same period in 2024, representing an increase of \$419,000 or 26%. The period-over-period increase in total revenue for both the three- and nine-month periods was primarily driven by higher Product revenue, reflecting the timing of EAA diagnostic order fulfillment, expanded EAA commercialization activities, and increased PMX pre-commercialization launch activities in collaboration with Vantive.

Specifically, EAA diagnostic and instrumentation revenue for the three months ended September 30, 2025, totaled \$232,000 compared to \$68,000 for the same period in 2024, representing an increase of \$164,000 or 241%. For the nine-month period, EAA diagnostic and instrumentation revenue totaled \$432,000 compared to \$356,000 for the same period in 2024, representing an increase of \$76,000 or 21%. PMX-related revenue for the three- and nine-month periods was \$109,000 and \$136,000, respectively, compared to \$79,000 and \$100,000 in the prior year. The PMX revenue is attributed to Vantive's pre-commercialization launch activities for PMX, as PMX remains a non-FDA cleared product and there is no commercial activity in Canada to-date.

Operating expenses for the three-months ended September 30, 2025, were \$30,800,000 compared to \$ 10,409,000 for the same period in the preceding year, an increase of \$ 20,391,000, or 196%. The increase in operating expenses was primarily attributable to the fair value adjustment of derivative liabilities, which is a non-cash item. The change in fair value reflects the increase in Spectral's share price from approximately \$0.81 at June 30, 2025 to \$1.46 at September 30, 2025, which increased the theoretical value of conversion features embedded in the Company's outstanding convertible notes. As the Company's market capitalization rises, these conversion options become more valuable to noteholders, resulting in a higher fair value liability and a corresponding non-cash loss recognized in the income statement.

Excluding the derivative adjustment, underlying cash-based operating costs were largely stable year-over-year. Consulting and Professional fees rose slightly for the three-months ended September 30, 2025, to \$1,375,000 compared to \$1,282,000 an increase of \$93,000 or 7%. This increase reflects increased statistical and regulatory consulting activities associated with the completion of the Tigris trial and the Company's ongoing FDA PMA submission activities.

Interest expense for the three-months period ended September 30, 2025 was \$1,364,000 compared to \$970,000 for the three-months period ended September 30, 2024. The increase in interest expense reflects higher outstanding debt related to the Company's convertible notes and Vantive promissory note, including a full-quarter accrual of paid-in-kind interest. The principal amount of convertible notes issued in 2024 was \$9,880,000. The principal amount of promissory note issued in 2025 was \$9,669,000. Interest expense in the three-months period ended September 30, 2025 was offset by Finance income of \$2,252,000 recognized on the promissory note. Finance income represents the fair value discount upon initial recognition of the second tranche advanced on August 22, 2025.

Operating expenses for the nine months ended September 30, 2025 were \$46,364,000 compared to \$19,830,000 for the same period in 2024, representing an increase of \$26,534,000 or 134%. The increase was primarily driven by the non-cash fair-value adjustment of derivative liabilities, which rose significantly during the period as a result of the increase in the Company's share price. Additionally, there was an increase in interest expense, in relation to the full period impact of convertible notes previously issued on May 30, 2024 and July 19, 2024 in addition to the Tranche 1 and Tranche 2 draw downs of the Vantive promissory note in May 2025 and August 2025 Tranche 2. The interest expense for the nine-months ended September 30, 2025 was \$3,622,000 compared to \$2,178,000 for the nine-months period ended September 30, 2024.

The increase in operating expenses was partially offset by non-cash finance income recognized on the Vantive promissory note. Finance income of \$5,389,000 was recognized in connection with the fair value discount upon initial recognition of the first tranche drawn in May 2025 and the second tranche drawn in August 2025.

Excluding these non-cash and financing-related items, the Company's underlying cost structure remained relatively stable.

Loss for the three-months ended September 30, 2025 was \$30,316,000 \$(0.11) per share compared to a loss of \$9,995,000, \$(0.04) per share for the same period in the prior year. The increased loss of \$20,321,000 was due to increased operating expenses, primarily due to increase in fair value adjustments of derivative liabilities.

Loss for the nine-months ended September 30, 2025 was \$ 44,855,000, \$(0.16) per share, compared to a loss of \$18,556,000 \$(0.07) per share, for the same period in the prior year. The increased loss of \$26,299,000 was primarily attributable to the non-cash fair value adjustment of the derivative liability as at September 30, 2025. In addition, interest expense rose compared to the prior year, reflecting the full-period impact of the convertible notes issued in May and July 2024 and the interest accrued on drawdowns under the Vantive promissory note facility, including the first tranche advanced in May 2025 and the second tranche advanced in August 2025.

The Company concluded the third quarter of 2025 with cash of \$5,892,000 compared to \$2,988,000 of cash on hand as of December 31, 2024.

The total number of common shares outstanding for the Company was 289,138,820 at September 30, 2025.

Spectral Medical Corporate Update Call

Chris Seto, Chief Executive Officer, and Dr. John Kellum, Chief Medical Officer, will host the call followed by a question-and-answer session. All interested parties are invited to participate.

CONFERENCE CALL DETAILS:

Date: Wednesday, December 10, 2025

Time: 10:00 a.m. ET

Dial-in: 1-877-407-0792 or 1-201-689-8263

Call me™: <https://callme.viavid.com/viavid/?callme=true&passcode=13757127&h=true&info=company&r=true&B=6>

*Participants can use Guest dial-in #s above and be answered by an operator OR click the Call me link for instant telephone access to the event. *Available 15 minutes prior to scheduled start time.*

Replay Dial-in: 1-844-512-2921 or 1-412-317-6671

Access ID: 13757127

Replay Available until 11:59 p.m. ET, Wednesday, December 24, 2025

About Spectral

Spectral is a Phase 3 company seeking U.S. FDA approval for its unique product for the treatment of patients with septic shock, Toraymyxin™ ("PMX"). PMX is a therapeutic hemoperfusion device that removes endotoxin, which can cause sepsis, from the bloodstream and is guided by the Company's FDA cleared Endotoxin Activity Assay (EAA™), the clinically available test for endotoxin in blood.

PMX is approved for therapeutic use in Japan and Europe, licensed by Health Canada, and has been used safely and effectively with over 360,000 units sold worldwide to date. In March 2009, Spectral obtained the exclusive development and commercial rights in the U.S. for PMX, and in November 2010, signed an exclusive distribution agreement for this product in Canada. In July 2022, the U.S. FDA granted Breakthrough Device Designation for PMX for the treatment of endotoxic septic shock. Approximately 330,000 patients are diagnosed with septic shock in North America each year.

The Tigris Trial is a confirmatory study of PMX in addition to standard care vs standard care alone and is designed as a 2:1 randomized trial of 150 patients using Bayesian statistics. Endotoxic septic shock is a malignant form of sepsis <https://www.youtube.com/watch?v=6RANrHHi9L8>.

The trial methods are detailed in "[Bayesian methods: a potential path forward for sepsis trials](#)".

Spectral is listed on the Toronto Stock Exchange under the symbol EDT. For more information, please visit www.spectraldx.com.

Forward-looking statement

Information in this news release that is not current or historical factual information may constitute forward-looking information within the meaning of securities laws. Implicit in this information, particularly in respect of the future outlook of Spectral and anticipated events or results, are assumptions based on beliefs of Spectral's senior management as well as information currently available to it. While these assumptions were considered reasonable by Spectral at the time of preparation, they may prove to be incorrect. Readers are cautioned that actual results are subject to a number of risks and uncertainties, including the availability of funds and resources to pursue R&D projects, the successful and timely completion of clinical studies, the ability of Spectral to take advantage of business opportunities in the biomedical industry, the granting of necessary approvals

by regulatory authorities as well as general economic, market and business conditions, and could differ materially from what is currently expected.

The TSX has not reviewed and does not accept responsibility for the adequacy or accuracy of this statement.

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Spectral Medical Inc.

Condensed Interim Consolidated Statements of Financial Position
In CAD (000s), except for share and per share data
(Unaudited)

	Notes	September 30, 2025 \$	December 31, 2024 \$
Assets			
Current assets			
Cash		5,892	2,988
Trade and other receivables		433	451
Inventories		218	229
Prepayments and other assets		711	790
		7,254	4,458
Non-current assets			
Right-of-use-asset		352	444
Property and equipment		172	243
Intangible asset		347	175
Total assets		8,125	5,320
Liabilities			
Current liabilities			
Trade and other payables		2,978	2,769
Current portion of contract liabilities	6	759	380
Current portion of lease liability		134	129
Notes payable	7	16,087	14,425
Derivative Liability	7	47,411	9,742
		67,369	27,445
Non-current liability			
Lease liability		270	371
Non-current portion of contract liabilities	6	4,685	5,049
Promissory Note	8	4,221	-
Non-current interest accrual promissory note		244	-
Total liabilities		76,789	32,865
Shareholders' (deficiency) equity			
Share capital	10	93,774	90,566
Contributed surplus		10,149	10,149
Share-based compensation		12,061	11,196
Warrants		1,046	1,383
Deficit		(185,694)	(140,839)
Total shareholders' (deficiency) equity		(68,664)	(27,545)
Total liabilities and shareholders' (deficiency) equity		8,125	5,320

Spectral Medical Inc.

Condensed Interim Consolidated Statements of Loss and Comprehensive Loss
In CAD (000s), except for share and per share data

(Unaudited)

			Reclassified (Refer Note17)	Reclassified (Refer Note17)	
	Notes	Three months ended	Three months ended	Nine months ended	Nine months ended
		September 30, 2025	September 30, 2024	September 30, 2025	September 30, 2024
		\$	\$		\$
Revenue	6	675	502	2,060	1,641
Expenses					
Cost of goods sold		191	88	548	364
Gross Profit		484	414	1,512	1,277
Raw materials and consumables used		163	293	364	852
Salaries and benefits	14	1,046	1,065	3,127	3,046
Consulting and professional fees		1,375	1,282	3,956	3,652
Regulatory and investor relations		393	284	659	585
Travel and entertainment		63	136	238	407
Facilities and communication		91	62	178	239
Insurance		98	105	281	315
Depreciation and amortization		53	51	121	138
Interest expense	7	1,364	970	3,622	2,178
Finance income promissory note	8	(2,252)	-	(5,389)	-
Foreign exchange(gain) loss		551	(399)	(1,032)	129
Share-based compensation	10	336	241	1,903	1,497
Other expense		46	163	161	704
Fair value adjustment derivative liabilities	7	27,473	6,156	38,175	6,088
		30,800	10,409	46,364	19,830
Loss and comprehensive loss for the period from continuing operations		(30,316)	(9,995)	44,852)	(18,553)
Loss from discontinued operations	4	-	-	(3)	(3)
Loss and comprehensive loss for the period		(30,316)	(9,995)	(44,855)	(18,556)
Basic and diluted loss from continuing operations per common share	11	(0.11)	(0.04)	(016)	(0.07)
Basic and diluted loss from discontinued operations per common share	11	(0.00)	(0.00)	(0.00)	(0.00)
Basic and diluted loss per common share	11	(0,11)	(0.04)	(016)	(0.07)
Weighted average number of common shares outstanding - basic and diluted	11	286,966,412	281,705,359	285,687,827	280,269,516

Spectral Medical Inc.

Condensed Interim Consolidated Statements of Changes in Shareholders' Deficiency

In CAD (000s)

(Unaudited)

	Notes	Number of Shares	Share Capital	Contributed surplus	Share-based compensation	Warrants	Deficit	Shareholders' (deficiency) equity	Total
			\$	\$	\$	\$	\$		\$
Balance January 1, 2024		278,576,261	87,061	8,916	10,385	2,526	(125,437)		(16,549)
Warrants exercised	10	982,500	618	-	-	(121)	-		497
Warrants issued	10	-	-	-	-	211	-		211
Warrants expired		-	-	1,233	-	(1,233)	-		-
Share Options									
Exercised	10	1,867,627	1,163	-	(524)	-	-		639
RSU released	10	114,210	50	-	(50)	-	-		-
Notes Conversion		1,274,625	979	-	-	-	-		979

Loss and comprehensive loss for the period		-	-	-	-	-	(18,556)	(18,556)
Share-based compensation	10	-	-	-	1,497	-	-	1,497
Balance September 30, 2024		282,815,223	89,871	10,149	11,308	1,383	(143,993)	(31,282)
Share Options Exercised	10	39,984	27	-	(11)	-	-	16
Notes Conversion	7	605,022	389	-	-	-	-	389
DSU exercise	10	855,978	279	-	(279)	-	-	-
Income and comprehensive income for the period		-	-	-	-	-	3,154	3,154
Share-based compensation	10	-	-	-	178	-	-	178
Balance December 31, 2024		284,316,207	90,566	10,149	11,196	1,383	(140,839)	(27,545)
Balance January 1, 2025		284,316,207	90,566	10,149	11,196	1,383	(140,839)	(27,545)
Share Options Exercised	10	1,773,216	1,537	-	(670)	-	-	867
RSU released	10	1,037,681	368	-	(368)	-	-	-
Warrants exercised	10	2,011,716	1,303	-	-	(337)	-	966
Loss and comprehensive loss for the period		-	-	-	-	-	(44,855)	(44,855)
Share-based compensation	9	-	-	-	1,903	-	-	1,903
Balance September 30, 2025		289,138,820	93,774	10,149	12,061	1,046	(185,694)	(68,664)

Spectral Medical Inc.

Condensed Interim Consolidated Statements of Cash Flows

In CAD (000s)

(Unaudited)

	Nine months ended September 30, 2025	Nine months ended September 30, 2024
Cash flow provided by (used in)		
Operating activities		
Loss for the period	(44,855)	(18,556)
Adjustments for:		
Finance income on Promissory Note	(5,389)	-
Depreciation on right-of-use asset	92	92
Depreciation on property and equipment	71	85
Amortization of intangible asset	23	13
Amortization and Derivative related financing fee	191	788
Unrealized foreign exchange (gain) and loss	(1,012)	76
Interest expense on lease liability	20	25
Accreted interest on Notes Payable	3,242	2,154
Accreted interest on Promissory Note	115	-
Interest expense on Promissory Note	244	-
Share-based compensation expense	1,903	1,497
Fair value adjustment derivative liabilities	38,175	6,088
Changes in items of working capital:		

Trade and other receivables	18	(151)
Inventories	11	48
Prepayments and other assets	79	(261)
Trade and other payables	240	(24)
Contract liabilities	15	1,603
Net cash used in operating activities	(6,817)	(6,523)
Investing activities		
Purchase of property and equipment	-	(28)
Purchase of Technology	(195)	-
Net cash used in investing activities	(195)	(28)
Financing activities		
Financing charges paid	(207)	(766)
Interest expense paid	(1,263)	(794)
Lease liability payments	(116)	(115)
Share options exercised	867	639
Share warrants exercised	966	497
9% convertible notes issued	-	9,897
Promissory Note issued	9,669	-
Net cash provided by financing activities	9,916	9,358
Increase in cash	2,904	2,807
Cash, beginning of period	2,988	2,952
Cash, end of period	5,892	5,759