Spectral Medical Announces First Quarter 2026 Financial Results and Provides Corporate Update

- *PMA submission targeted for May 29, 2026 in alignment with FDA*
- *Vantive commits to additional funding support ahead of PMA acceptance milestone*

TORONTO, May 08, 2026 -- **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 first quarter ended March 31, 2026 and provided a corporate update.

The first quarter of 2026 marked continued progress across regulatory, clinical and commercial readiness initiatives as the Company advances toward submission of its U.S. Food and Drug Administration ("FDA") Premarket Approval ("PMA") application for Toraymyxin™ ("PMX"). During the quarter and subsequent to quarter-end, Spectral further strengthened the clinical and scientific foundation supporting PMX, highlighted by the publication of the Tigris trial in *The Lancet Respiratory Medicine* and presentation at the Society of Critical Care Medicine Annual Congress in Chicago

The Company is targeting a PMA submission date of May 29, 2026, a timeline established in coordination with the FDA to support both submission readiness and efficient allocation of review resources. The timing reflects incorporation of complete 12 -month mortality data from the Tigris study, as well as completion of key non-clinical modules, including human factors engineering testing, to support a complete and compliant submission.

"Our focus remains on executing a high-quality and comprehensive PMA submission while advancing commercialization readiness alongside our partner Vantive," said Chris Seto, Chief Executive Officer of Spectral Medical. "We are encouraged by the continued support from Vantive, including their decision to provide additional funding ahead of the PMA acceptance milestone. We believe this reflects a shared commitment to the PMX program and provides additional flexibility as we execute against this important regulatory step. The progress achieved during the quarter reinforces the strength of the Tigris data and the totality of evidence supporting PMX as we move toward submission and, ultimately, potential approval in the United States."

John A. Kellum, Chief Medical Officer of Spectral Medical, added, "The consistency of benefit observed across endpoints, particularly at later timepoints, supports the concept that treatment effects become more apparent as patients recover beyond the acute phase of septic shock."

Corporate Highlights During & Subsequent to the First Quarter of 2026

Tigris

- **Tigris manuscript published on March 23, 2026:**
  - The Tigris manuscript was published in *The Lancet Respiratory Medicine*, one of the world's leading peer-reviewed journals in critical care and respiratory medicine.
  - The publication confirms the previously reported positive findings for the primary and key secondary endpoints announced in August 2025, while providing additional analyses on survival, safety, secondary and sensitivity analyses:
    - Confirms positive results for primary and key secondary endpoints with 95.3% and 99.4% probability of benefit for PMX at 28-day and 90-day mortality
    - After adjusting for baseline severity, absolute risk reduction for mortality of 10.3% at 28-days and 15.5% at 90-days
    - Kaplan-Meier survival curves demonstrated continued separation beyond day 28, indicating that the survival benefit observed with PMX was sustained over time.
    - Safety profile consistent with standard of care with no significant difference in adverse events
  - The findings further suggest that treatment effects observed at earlier timepoints are sustained and may become more apparent over longer-term follow-up, consistent with the recovery trajectory of critically ill septic shock patients.
- **Society of Critical Care Medicine ("SCCM") Critical Care Congress, Chicago March 24, 2026:**
  - Results from the Tigris study presented on March 24, 2026 at the SCCM Annual Congress in the *Late-Breaking Studies Affecting Patient Outcomes* session
  - Presented by Dr. Javier Neyra, first author of the Tigris paper
- **PMA Submission:**
  - PMA submission date targeted for May 29, 2026.
  - Timing established in coordination with the FDA
    - Supports submission readiness and efficient allocation of review resources

- Based on FDA feedback, 12-month mortality data from the Tigris study is to be incorporated into the PMA submission
- The Company believes the inclusion of complete 12-month mortality outcomes will further inform the FDA's review and contribute to the totality of clinical evidence supporting PMX for the treatment of endotoxic septic shock.
- Spectral currently anticipates being in a position to report topline 12-month mortality data in June 2026, subject to the completion of additional data analysis.

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.

Financing

- On May 07, 2026, the Company entered into a side letter agreement with Vantive US Healthcare LLC in respect of its existing senior secured promissory note.
- Under the agreement, Vantive agreed, at its sole discretion, to advance US$1.0 million as a partial funding of the US$2.0 million Tranche D, notwithstanding that the related milestone (PMA filing acceptance) had not yet been satisfied.
- Upon funding, the advance is treated as an amount drawn under the promissory note.
- The remaining US$1.0 million of Tranche D remains subject to the original milestone conditions, and Vantive has no obligation to fund any further amounts unless such conditions are satisfied or otherwise agreed.

Financial Review

Revenue for the three-months ended March 31, 2026 was $891,000 compared to $572,000 for the same three-month period last year, representing an increase of $319,000, or 56%. The increase was primarily driven by higher Product revenue, including proprietary biochemical sales, instrumentation sales, and PMX pre-commercialization activities, partially offset by a decrease in Royalty revenue and EAA diagnostic sales mix. Product revenue increased to $386,000 from $176,000 in the prior -year period.

Operating expenses for the three-months ended March 31, 2026, were $3,633,000 compared to $13,049,000 for the same period in the preceding year, a decrease of $9,416,000 or 72 %. The decrease was primarily driven by a lower fair value adjustments on derivative liabilities (a non-cash item), as well as foreign exchange adjustments on derivative liabilities and convertible debentures. These variances resulted largely from changes in market assumptions and the market price used to calculate the option feature. Excluding the derivative fair value adjustment and foreign exchange adjustments on derivative liabilities and convertible debentures, expenses increased period-over-period, primarily due to higher interest expense, regulatory and investor relations costs, facilities costs and share-based compensation. Increase in interest expense reflects higher outstanding debt related to the Company's convertible notes and the Vantive promissory note, including a full-quarter accrual of paid-in-kind (PIK) interest. Interest expense of $1,600,000 which relates to the three months ended March 31, 2026 in relation to convertible notes previously issued and May 2025 and August 2025 promissory notes issued.

Clinical development and regulatory program costs (as disclosed in Note 13 of the consolidated financial statements) were $768,000 for the three-months ended March 31, 2026 compared to $1,585,000 for the same period in the prior year. A significant portion of clinical trial and regulatory costs consists of consulting and professional fees paid to contract research organizations, clinical sites, and other clinical and regulatory consultants .The decrease in clinical costs reflects the completion of Tigris enrollment in April 2025 and reduced clinical site activity, partially offset by an increase in activities related to the Company's ongoing FDA PMA submission, including regulatory consulting, data analysis, and other submission-readiness work. Cumulative trial and regulatory program costs total as of March 31, 2026 was $59,932,000.

Loss for the three-months ended March 31, 2026 was $2,938,000 ($0.01 per share) compared to a loss of $12,605,000 ($0.04 per share) for the same period in the prior year. The decreased loss of $9,667,000 was due to decreased operating expenses, primarily due to decreased fair value adjustment of derivative liability on March 31, 2026.

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	March 31, 2026 $	December 31, 2025 $
Assets			
Current assets			
Cash		1,918	4,071
Trade and other receivables		478	205
Inventories		478	377
Prepayments and other assets		959	640
		3,833	**5,293**
Non-current assets			
Right-of-use-asset		290	321
Property and equipment		135	153
Intangible asset		319	333
Total assets		**4,577**	**6,100**
Liabilities			
Current liabilities			
Trade and other payables		3,460	2,484
Contract liabilities	6	545	693
Lease liability		138	136
Notes payable	7	17,423	16,435
Derivative liability	7	43,929	46,520
		65,495	66,268
Non-current liability			
Lease liability		200	235
Contract liabilities	6	4,443	4,564
Promissory notes	8	4,508	4,285
Interest accrual promissory note		699	470
Total liabilities		**75,345**	**75,822**
Shareholders' deficiency	10		

Share capital	96,685	95,933
Contributed surplus	10,220	10,220
Share-based compensation	13,406	12,266
Warrants	390	390
Deficit	(191,469)	(188,531)
Total shareholders' deficiency	**(70,768)**	**(69,722)**
Total liabilities and shareholders' deficiency	**4,577**	**6,100**

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

	Notes	Three months ended March 31, 2026	Three months ended March 31,2025
		$	$
Revenue	6	**891**	**572**
Expenses			
Cost of goods sold		193	125
Gross Profit		**698**	**447**
Raw materials and consumables used		107	142
Salaries and benefits	14	968	1,056
Consulting and professional fees		859	1,266
Regulatory and investor relations		205	129
Travel and entertainment		76	77
Facilities and communication		99	58
Insurance		104	101
Depreciation and amortization		43	41
Interest expense	7,8	1,600	1,083
Foreign exchange (gain) and loss		1,283	(36)
Share-based compensation	10	1,621	1,260
Other expense		51	59
Fair value adjustment derivative liabilities	7	(3,383)	7,813
		3,633	13,049
Loss and comprehensive loss for the period from continuing operations		**(2,935)**	**(12,602)**
Loss from discontinued operations	4	**(3)**	**(3)**
Loss and comprehensive loss for the period		**(2,938)**	**(12,605)**
Basic and diluted loss from continuing operations per common share	11	(0.01)	(0.04)
Basic and diluted loss from discontinued operations per common share	11	(0.00)	(0.00)
Basic and diluted loss per common share	11	(0.01)	(0.04)
Weighted average number of common shares outstanding - basic and diluted	11	**293,233,056**	**284,760,158**

Spectral Medical Inc.
Condensed Interim Consolidated Statements of Changes in Shareholders' Deficiency
In CAD (000s), except for share and per share data
(Unaudited)

	Notes	Number of Shares	Share Capital	Contributed surplus	Share-based compensation	Warrants	Deficit	Total Shareholders' (deficiency) equity
			$	$	$	$	$	$
Balance January 1, 2025		**284,316,207**	**90,566**	**10,149**	**11,196**	**1,383**	**(140,839)**	**(27,545)**
Share options exercised		431,882	219	-	(74)	-	-	145
RSU released		350,386	100	-	(100)	-	-	-
Warrants exercised		18,750	12	-	-	(3)	-	9

Loss and comprehensive loss for the period		-	-	-	-	-	(12,605)	(12,605)
Share-based compensation		-	-	-	1,260	-	-	1,260
Balance March 31, 2025		**285,117,225**	**90,897**	**10,149**	**12,282**	**1,380**	**(153,444)**	**(38,736)**
Share options exercised		1,379,168	1,345		(607)	-	-	738
RSU released		687,295	268		(268)	-	-	0
Warrants exercised		5,379,225	3,423			(919)	-	2,504
Warrants expired				71		(71)		0
Loss and comprehensive loss for the period							(35,087)	(35,087)
Share-based compensation					859			859
Balance December 31, 2025		**292,562,913**	**95,933**	**10,220**	**12,266**	**390**	**(188,531)**	**(69,722)**
Balance January 1, 2026		**292,562,913**	**95,933**	**10,220**	**12,266**	**390**	**(188,531)**	**(69,722)**
Share Options Exercised	10	549,548	494		(223)			271
RSU released	10	306,530	258		(258)			-
Loss and comprehensive loss for the period							(2,938)	(2,938)
Share-based compensation	10				1,621			1,621
Balance March 31, 2026		**293,418,991**	**96,685**	**10,220**	**13,406**	**390**	**(191,469)**	**(70,768)**

Spectral Medical Inc.
Condensed Interim Consolidated Statements of Cash Flows
In CAD (000s), except for share and per share data
(Unaudited)

	Notes	Three months ended March 31, 2026	Three months ended March 31, 2025
		$	$
Cash flow provided by (used in)			
Operating activities			
Loss for the period		(2,938)	(12,605)
Adjustments for:			
Depreciation on right-of-use asset		31	31
Depreciation on property and equipment		18	25
Amortization of intangible asset		14	4
Amortization and derivative related financing fee	7	64	63
Unrealized foreign exchange (gain) and loss		1,283	(26)
Interest expense on lease liability		5	6
Accreted interest on promissory note	8	151	-
Interest expense on promissory note	8	229	-
Accreted Interest on notes payable	7	1,215	1,076
Share-based compensation	10	1,621	1,260
Fair Value adjustment derivative liabilities	7	(3,383)	7,813
Changes in items of working capital:			
Trade and other receivables		(273)	141
Inventories		(101)	28
Prepayments and other assets		(319)	(289)
Trade and other payables		266	820
Contract liabilities	6	(269)	219
Net cash used in operating activities		(2,386)	(1,434)
Investing activities		-	-
Net cash used in investing activities		-	-

Financing activities			
Lease liability payments		(38)	(38)
Share options exercised	10	271	145
Share warrants exercised	10	-	9
Net cash used in financing activities		232	116
Decrease in cash		(2,153)	(1,318)
Cash, beginning of period		4,071	2,988
Cash, end of period		**1,918**	**1,670**