



SPECTRAL MEDICAL ANNOUNCES THIRD QUARTER RESULTS AND PROVIDES CORPORATE UPDATE

Tigris Trial Enrollment at 135 Patients

Strengthened Balance Sheet with Expected Funds to Complete Tigris Trial Enrollment

TORONTO, Canada – November 8, 2024 – 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 ended September 30, 2024, and provided a corporate update.

Spectral has continued its significant progress throughout the third quarter of 2024 both clinically and operationally and year-to-date enrolled 54 patients for a total of 135 patients out of the 150 total patients target. The Company is focused on the final push to fully enroll and finish the Tigris trial, bringing the Company closer to FDA submission and potential FDA approval. In parallel to its clinical trial, the Company continues to work closely with its commercialization partner, Baxter.

Dr. John Kellum, Chief Medical Officer of Spectral Medical, stated, “We continue to witness robust enrollment activity in 2024, with record enrollment rates over several months of the year. Screening rates have been at approximately 50% higher throughout the year compared to 2023. Tigris is approaching the final phase of the trial, and we have very dedicated investigators who believe in the project. In October, we experienced some disruptions due to Hurricane Helene – mainly the national saline shortage (required to prepare the device for treatment). Our clinical team is focused on trial site support and is working to help resolve this issue. We are committed alongside our trial sites to advancing Tigris and believe PMX, if ultimately approved, will play a major role in reducing the tragic rates of mortality caused by sepsis.”

“I am pleased with the increased level of activity across the Company and the resultant ramp up of patient enrollment throughout 2024. With the recent medical supply chain events negatively impacting enrollment, we anticipate a slight shift in finalizing Tigris enrollment into the early 2025 timeframe,” said Chris Seto, Chief Executive Officer of Spectral. “That being said, with the receipt of gross proceeds of approximately \$11 million since the beginning of April, we believe we have secured funding to finalize Tigris enrollment.”

Corporate Highlights During & Subsequent to Third Quarter 2024

Tigris Trial and Regulatory Program

- **Patient Enrollment**

Total of 135 patients randomized to date out of the target 150 total patients to be enrolled in the Tigris trial.

- Year-to-date enrollment experienced in 2024 has been robust with 54 patients enrolled so far.
- Record monthly enrollment to start Q3 2024, with nine patients enrolled in July; followed by anticipated slowdown in August and September with lighter enrollment activity due to site vacation schedules.
- Experienced significantly lower patient enrollment in October due to the impact of Hurricane Helene on the medical supply chain. The disruption in production of critical intravenous fluids has led to a rationing of saline, which is required to prepare PMX for treatment, negatively impacted patient enrollment, despite record patient screening levels. Our clinical team is working to help sites resolve this issue.
- For more information on Hurricane Helene's impact on the supply of critical intravenous fluids, see the following link: [Letter to Health Care Leaders and Stakeholders on Impacts of Hurricane Helene from Secretary Becerra | HHS.gov](#)

- **Tigris Sites**

Currently 22 Tigris sites participating.

- Spectral clinical team focused on trial site management activities to ensure that Tigris sites have the support and resources to enroll patients as efficiently as possible.

- **Timing**

The Company continues to focus on finalizing the Tigris trial within the reasonably shortest timelines. Based on the current rate of enrollment, management believes Tigris should be completed in first quarter of 2025.

PMX Commercialization

- **Baxter Partnership Activities**

In anticipation of a positive Tigris trial outcome, the Company has been working closely with Baxter on post-approval marketing plans for PMX commercialization. This includes developing product branding, pricing and roll-out plans with numerous Baxter departments, including marketing, regulatory, clinical and reimbursement. Baxter has communicated its intention to undertake a broad marketing campaign on day one of FDA approval for PMX.

- **Prismax Sub-study**

The Company is also working with Baxter on a sub-study to obtain FDA clearance for hemoperfusion for Baxter's Prismax device. The Prismax, with its leading installed base in ICUs throughout the U.S., is anticipated to be the primary ICU device utilized for PMX treatments on commercial launch.

Funding

- **Exercise of Anti-Dilution Pre-emptive Rights**

On July 19, 2024 the Company completed an additional non-brokered offering of US\$1 million of 9% convertible notes of the Company (the "Notes") at a price of US\$1,000 per convertible note due on May 1, 2028 (the "Offering"). The Notes were sold to one of the Company's largest

shareholders pursuant to the exercise of their anti-dilution pre-emptive rights relating to the closing of the offering of the approximately CAD\$8.5 million offering of Notes that was completed on May 30, 2024.

- **Share Warrant Exercise / Expired Warrants**

In the third quarter 232,500 share warrants were exercised for gross proceeds of approximately \$114,250. These warrants were issued in conjunction with the Company's July 27, 2021 and November 2, 2022 unit offerings.

On July 29, 2024, 10,982,500 share warrants expired. These expired share warrants were issued in conjunction with the Company's approximately \$10 million unit offering which closed on July 27, 2021. As at the time of this MD&A, the Company has 7,730,464 share warrants outstanding.

- **Early conversion of Convertible notes issued on September 7, 2023**

On August 19, 2024, 150 Notes having a face value of USD \$1,000 were converted into 509,850 Common Shares at a conversion rate of 3,399 Common Shares per USD\$1,000 principal amount of the Notes.

On September 25, 2024, 225 Notes having a face value of USD \$1,000 were converted into 764,755 Common Shares at a conversion rate of 3,399 Common Shares per USD \$ 1,000 principal amount of the Notes.

Change of Auditors

- On July 11, 2024, the Company announced that MNP had been appointed as the auditors of the Company following the decision by PricewaterhouseCoopers LLP ("PWC") to resign as the auditor of Spectral. The PWC resignation was not the result of any disagreement between the Company and PWC on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure.

Financial Review

Revenue for the three-months ended September 30, 2024 was \$502,000 compared to \$397,000 for the same three-month period last year, representing an increase of \$105,000 or 26%. Revenue for nine-months ended September 30, 2024, was \$1,641,000 and \$1,233,000 for the same period last year, representing an increase of \$408,000 or 33%. Royalty revenue for the three-months ended September 30, 2024 was \$NIL and \$NIL for the same period prior year. Royalty revenue for the nine-months ended September 30, 2024 was \$135,000 compared to \$126,000 for the same nine-month period last year. This is due to an increase in usage of the Company's IP from one customer. Product Revenue for the three-months ended September 30, 2024 was \$274,000 compared to \$186,000 for the same three-month period last year, representing an increase of \$88,000 or 47% Product revenue for nine-month ended September 30, 2024 was \$841,000 and \$562,000, representing an increase of \$279,000 or 50%.

Operating expenses for the three-months ended September 30, 2024, were \$10,497,000, compared to \$4,072,000 for the same period in the preceding year, an increase of \$6,425,000 or 158%. The increase is majorly due to the change in Fair value adjustment for derivative liabilities which increased by \$6,075,000 and also the Interest expense increased by \$628,000 due to convertible notes payable issued on September 7, 2023, May 30, 2024 and July 19, 2024.

Operating expenses for the nine-months ended September 30, 2024 were \$20,194,000 compared to \$10,292,000 for the same period in the preceding year, an increase of \$9,902,000 or 96%. The change is primarily due to an increase in interest expense by \$1,339,000 and Fair value adjustment in derivative liability increased by \$6,530,000. All these increases are due to the funding received during September 2023, May 2024 and July 19, 2024. In addition, share-based compensation expense increased by \$197,000. Lastly, consulting and professional fees increased by \$352,000 due to increased site and

patient fees related to the Tigris trial.

Clinical development and regulatory program costs (as disclosed in Note 13 of the condensed interim consolidated financial statements) were \$638,000 for the three-months ended September 30, 2024 compared to \$1,263,000 for the same period in the prior year. For the nine-months ended September 30, 2024, clinical development costs are \$3,015,000 compared to \$3,258,000 for the corresponding 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 costs reflects decreased start up activity with respect to the initialization of new clinical sites and the absence of upfront CRO switching costs which were experienced in 2023.

Loss for the three-months ended September 30, 2024 was \$9,995,000, \$(0.04) per share compared to a loss of \$3,804,000, \$(0.01) per share for the same period in the prior year. The increased loss of \$6,191,000 was due to increased operating expenses, partially offset by a reduction in loss from discontinued operations of \$130,000 related to the reduction in Dialco operating expenses.

Loss for the nine-months ended September 30, 2024 was \$18,556,000, \$(0.07) per share, compared to a loss of \$9,184,000 \$(0.03) per share, for the same period in the prior year. The increased loss of \$9,372,000 was due to operating expenses, partially offset by a reduction in loss from discontinued operations of \$122,000 related to the reduction in Dialco operating expenses.

The Company concluded the third quarter of 2024 with cash of \$5,759,000 compared to \$2,952,000 of cash on hand as of December 31, 2023.

The total number of common shares outstanding for the Company was 282,815,223 at September 30, 2024.

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 Endotoxin Activity Assay (EAA™), the only FDA cleared diagnostic for the risk of developing sepsis.

PMX is approved for therapeutic use in Japan and Europe and has been used safely and effectively on more than 340,000 patients 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, 2024	December 31, 2023 (Refer Note 3)	January 1, 2023 (Refer Note 3)
		\$	\$	\$
Assets				
Current assets				
Cash		5,759	2,952	8,414
Trade and other receivables		337	186	1,056
Inventories		318	366	340
Prepayments and other assets		882	621	276
		7,296	4,125	10,086
Non-current assets				
Right-of-use-asset		475	567	464
Property and equipment		268	326	237
Intangible asset		180	193	211
Investment in Dialco		-	-	998
Total assets		8,219	5,211	11,996
Liabilities				
Current liabilities				
Trade and other payables		3,004	2,820	3,087
Current portion of contract liabilities	7	502	727	696
Current portion of lease liability		126	121	96
Notes Payable	8&3	12,890	7,940	3,566
Derivative Liability	8&4	17,405	6,310	2,674
		33,927	17,918	10,119
Non-current liability				
Lease liability		404	500	420
Non-current portion of contract liabilities	7	5,170	3,342	4,011
Total liabilities		39,501	21,760	14,550
Shareholders' (deficiency) equity				
Share capital	10	89,871	87,061	87,050
Contributed surplus		10,148	8,916	8,773
Share-based compensation		11,308	10,385	8,908
Warrants		1,384	2,526	2,490
Deficit		(143,993)	(125,437)	(109,775)
Total shareholders' (deficiency) equity		(31,282)	(16,549)	(2,554)
Total liabilities and shareholders' (deficiency) equity		8,219	5,211	11,996

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 Sep 30, 2024	Revised (Refer Note 16) Three months ended Sep 30, 2023	Nine- months ended Sep 30, 2024	Revised (Refer Note 16) Nine-months ended Sep 30, 2023
		\$	\$	\$	\$
Revenue	7&12	502	397	1,641	1,233
Expenses					
Raw materials and consumables used		327	305	994	722
Salaries and benefits	14	1,078	986	3,101	2,918
Consulting and professional fees		1,282	1,198	3,652	3,300
Regulatory and investor relations		284	110	585	414
Travel and entertainment		136	63	407	245
Facilities and communication		90	81	353	245
Insurance		105	102	315	290
Depreciation and amortization		64	57	191	172
Interest expense	8	970	342	2,178	839
Foreign exchange loss		(399)	46	129	(205)
Share-based compensation		241	340	1,497	1,300
Other expense		163	320	704	289
Net loss on joint arrangement	6	-	41	-	205
Fair value adjustment derivative liabilities	8	6,156	81	6,088	(442)
		10,497	4,072	20,194	10,292
Loss and comprehensive loss for the period from continuing operations		(9,995)	(3,675)	(18,553)	(9,059)
Gain (loss) from discontinued operations	5	-	(130)	(3)	(125)
Loss and comprehensive loss for the period		(9,995)	(3,805)	(18,556)	(9,184)
Basic and diluted loss from continuing operations per common share	11	(0.04)	(0.01)	(0.07)	(0.03)
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	(0.04)	(0.01)	(0.07)	(0.03)
Weighted average number of common shares outstanding - basic and diluted	11	281,705,359	278,604,718	280,269,516	278,569,902

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 \$	Total Shareholders' (deficiency) equity \$
Balance January 1, 2023		278,547,804	87,050	8,773	8,908	2,490	(109,775)	(2,554)
RSU released	10	28,457	11	-	(11)	-	-	-
Warrants issued	10	-	-	-	-	179	-	179
Warrants expired	10	-	-	143	-	(143)	-	-
Loss and comprehensive loss for the period		-	-	-	-	-	(9,184)	(9,184)
Share-based compensation	10	-	-	-	1,300	-	-	1,300
Revised (Refer note 16) Balance, September 30, 2023		278,576,261	87,061	8,916	10,197	2,526	(118,959)	(10,259)
Loss and comprehensive loss for the period		-	-	-	-	-	(6,478)	(6,478)
Share-based compensation	10	-	-	-	188	-	-	188
Balance December 31, 2023		278,576,261	87,061	8,916	10,385	2,526	(125,437)	(16,549)
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	10	-	-	1,232	-	(1,232)	-	-
Share Options Exercised	10	1,867,627	1,163	-	(524)	-	-	639
RSU released	10	114,210	50	-	(50)	-	-	-
Notes Conversion	10	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	10,148	11,308	1,384	(143,993)	(31,282)

Spectral Medical Inc.

Condensed Interim Consolidated Statements of Cash Flows

In CAD (000s)

(Unaudited)

	Nine months ended September 30, 2024	Revised (Refer note 16) Nine months ended September 30, 2023
Cash flow provided by (used in)		
Operating activities		
Loss and comprehensive loss for the period	(18,556)	(9,184)
Adjustments for:		
Depreciation on right-of-use asset	92	73
Depreciation on property and equipment	85	87
Amortization of intangible asset	13	19
Amortization of deferred financing fee	788	373
Unrealized foreign exchange gain/loss	76	(155)
Interest expense on lease liability	25	30
Accreted interest on notes payable	2,154	809
Share-based compensation expense	1,497	1,300
Net loss on joint venture arrangement	-	205
Fair value adjustment derivative liabilities	6,088	(442)
Changes in items of working capital:		
Trade and other receivables	(151)	337
Inventories	48	36
Prepayments and other assets	(261)	(636)
Trade and other payables	(24)	(781)
Contract liabilities	1,603	(647)
Net cash used in operating activities	(6,523)	(8,576)
Investing activities		
Purchase of property and equipment	(28)	(15)
Net cash used in investing activities	(28)	(15)
Financing activities		
Financing charges paid	(766)	(641)
Interest expense paid	(794)	(472)
Lease liability payments	(115)	110
Proceeds from share options exercised	639	-
Proceeds from share warrants exercised	497	-
Proceeds from 9% convertible notes issued	9,897	6,212
Net cash provided by financing activities	9,358	5,209
Change in cash	2,807	(3,383)
Cash, beginning of period	2,952	8,414
Cash, end of period	5,759	5,031