



SPECTRAL MEDICAL ANNOUNCES SECOND QUARTER RESULTS AND PROVIDES CORPORATE UPDATE

Tigris Trial Enrollment Reaches 71 Patients

TORONTO, Canada – August 10, 2023 – 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 second quarter ended June 30, 2023 and provided a corporate update.

During the second quarter, the Company continued to execute on a number of key business initiatives that are targeted at enhancing and accelerating Tigris enrollment. Management is pleased to report positive progress on these initiatives, specifically:

- During and subsequent to the second quarter the Company enrolled an additional 18 patients, nearly half of which came from new sites opened for enrollment in 2023;
- 71 patients enrolled to date and the Company continues to close in on its interim target of 90 patients, an important milestone as Spectral’s strategic commercial partner, Baxter, will have the opportunity to view the data as well as provide a second milestone payment to Spectral;
- On track to have 25 active trial sites open by the end of September 2023, with three new sites opened for enrollment during the second quarter bringing current total active trial sites to 18;
- New CRO transition progressing on schedule, with full transition expected to be complete by August 2023;
- Held first in-person Tigris Investigator Meeting since 2019 in May 2023 in North Carolina, which was well attended by approximately 70 attendees;
- Clinician-focused PMX media production nearing completion, with the video expected to be released in September 2023; and
- On August 9, 2023, the Company launched a Bought Deal Private Placement with Paradigm Capital Inc. acting as the underwriter. Expected minimum gross proceeds are C\$5,000,000 issuable in the form of convertible senior notes (the “notes”) with a maturity of November 1, 2026 and a coupon rate of 9% payable semi-annually. The notes will have certain conversion rights, with an expected conversion price of \$0.40 per share.

Dr. John Kellum, Chief Medical Officer of Spectral Medical, stated, “We have seen a surge of new enrollment activity since April 2023, which I believe is due in part to the new sites we have onboarded, as well as the success of our Tigris Investigator meeting held this past May. The meeting provided the principal investigators, clinical research coordinators, the Company’s CRO and other key team members with educational resources and training tools, while reinvigorating and reinforcing the importance of this trial and the potential of bringing the PMX therapy to market.”

Chris Seto, Chief Executive Officer of Spectral Medical, stated, “I am encouraged by the momentum and pace of patient enrollment in the Tigris study during the second quarter and in the weeks thereafter, which I believe is the direct result of the business initiatives we have undertaken. We will continue to monitor our progress, and assuming we maintain this enrollment momentum, we expect to be on track to reach the important interim milestone of 90 patients enrolled by the end of 2023. At the same time, we continue to work closely with Baxter, our strategic commercial partner, to advance post-approval, commercial marketing plans for PMX.”

Corporate Highlights

Tigris

- **New Contract Research Organization (“CRO”) - Beaufort**

On March 23, 2023, the Company engaged a new contract research organization (“CRO”), Beaufort. Beaufort has extensive experience with ICU clinical trials and brings a strong regulatory group, experienced biostats personnel, and additional clinical field resources. Onboarding activities are progressing well, with complete transition from the incumbent CRO expected by August 2023. As part of its engagement, Beaufort is reviewing and evaluating recruitment and enrollment processes on a site-by-site basis of Tigris sites.

- **Patient Enrollment**

Total of 71 patients randomized to date out of the 150 total patients to be enrolled in the Tigris trial. Patient screening activities at the sites are increasing and results to date of those enrolled in the study continue to exceed expectations.

Enrollment rate has increased to 0.25 patients from 0.182 patients per site per month, following initiatives to enhance Tigris enrollment since April 1, 2023, and is now at the Company’s previously stated target.

- **Tigris Sites**

There are currently 18 active Tigris sites onboarded. The Company remains on schedule to onboard an additional 7 new sites over the next quarter bringing the total sites to 25. Should suitable sites over and above the 25 be identified, FDA approval would be required to approve the addition of these incremental sites.

- **Timing**

The Company continues to focus on finalizing the Tigris trial within the reasonably shortest timelines while continuing to maintain the highest clinical standard. The Company targets reaching interim enrollment of 90 patients around the end of 2023.

- **Investigator Meeting**

A Tigris study Investigator Meeting was held on May 17th and 18th 2023 in Charlotte, North Carolina. The in-person meeting was attended by principal investigators and clinical research coordinators from all existing and new trial sites, as well as the Company’s new CRO, Beaufort. Also in attendance were representatives from the Company’s strategic partner Baxter and members of the Balancing Act. This successful Investigator Meeting has already helped to bolster ongoing enrollment activities related to the Tigris trial.

- **EDEN Observational Study**

In March 2022, the Company launched an ancillary observational study, EDEN, to collect data on patients with sepsis even if ineligible for Tigris. EDEN will capture much-needed data on the full range of septic shock and its relation to organ failure and endotoxin activity. These data will inform subsequent discussions with the FDA on labeling for PMX, as well as to provide the medical community and the Company a better picture of the addressable population in the U.S. for PMX.

Furthermore, patients enrolled in EDEN will also be considered for entry into the Tigris study, which provides another tool to support enrollment.

The Company has onboarded 4 EDEN sites and enrolled 64 patients into the observational study.

PMX Commercialization

- In anticipation of a positive Tigris trial outcome, the Company has been working closely with Baxter, the Company's strategic commercial partner, 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 1 of FDA approval for PMX.
- May 5, 2023, Baxter announced a new CEO of its proposed Kidney Care business. For more information, please visit: [Baxter Names Chris Toth CEO of Proposed Kidney Care Spinoff | Baxter](#)

Clinical Team Focused PMX Media

The Company commissioned The Balancing Act to produce a video focused on Endotoxemic Septic Shock (ESS), PMX and positive patient outcomes. This video will target a number of Tigris study stakeholders, including CRCs, trial treatment staff, and potential patients. The nature of the PMX video will be to inspire and further increase awareness of the PMX therapy. Management believes that the video can act as an enrollment catalyst by inspiring research staff and front-line providers, as well as improve patient/family awareness of ESS and PMX. Production is nearing completion with the video expected to be completed in September 2023.

Financial Review

Revenue for three months ended June 30, 2023, was \$306,000 compared to \$276,000 for the same period last year, representing an increase of \$30,000, or 10.9%. Revenue for six months ended June 30, 2023, was \$836,000 and \$760,000 for the same period last year, representing an increase of \$76,000, or 10.0%. This increase was mainly due to an increase in proprietary EAA biochemicals product revenue.

Operating expenses for the three months ended June 30, 2023, were \$4,294,000, compared to \$2,331,000 for the same period in the prior year, an increase of \$1,963,000, or 84.2%. The change is primarily due to an increase in share-based compensation of \$891,000 due to the grant of certain stock awards in May 2023, which were not issued during the second quarter in the prior year. In addition, consulting and professional fees increased by \$755,000 primarily due to increased site and patient fees related to the Tigris trial and Eden observational study. Lastly, interest expense increased \$121,000 primarily related to the Notes Payable, which was not outstanding in the same period in the prior year. Operating expenses for the six months ended June 30, 2023, were \$6,558,000, compared to \$4,851,000 for the same period in the preceding year, an increase of \$1,707,000, or 35.2%. The change is due to an increase in share-based compensation of \$172,000. In addition, consulting and professional fees increased by \$954,000 primarily due to increased site and patient fees related to the Tigris trial and Eden observational study. Lastly, interest expense increased \$242,000 primarily related to the Notes Payable, which was not outstanding in the same period in the prior year.

Loss for the three months ended June 30, 2023 was \$3,939,000, or \$0.01 per share, compared to a loss of \$2,954,000, or \$0.01 per share, for the same quarter last year. The increased loss of \$985,000 was due to increased operating expenses, partially offset by a reduction in loss from discontinued operations of \$948,000 related to the reduction in Dialco operating expenses. Loss for the six months ended June 30, 2023 was \$5,716,000, or \$0.01 per share, compared to a loss of \$5,639,000, or \$0.01 per share, for

the same quarter last year. The increased loss of \$77,000 was due to increased operating expenses, partially offset by a reduction in loss from discontinued operations of \$1,554,000 related to the prior Dialco operating expenses.

The Company concluded the second quarter of 2023 with cash of \$2,521,000 compared to \$8,414,000 of cash on hand as of December 31, 2022.

The total number of common shares outstanding for the Company was 278,576,261 at June 30, 2023.

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 endotoxemic septic shock. Approximately 330,000 patients are diagnosed with septic shock in North America each year.

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 company's ability to raise capital and the availability of funds and resources to pursue R&D projects, the recruitment of additional clinical trial sites, the rate of patient enrollment, the successful and timely completion of clinical studies, the success of Baxter's commercialization efforts, 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)

	June 30, 2023	December 31, 2022
	\$	\$
Assets		
Current assets		
Cash	2,521	8,414
Trade and other receivables	742	1,056
Inventories	288	340
Prepayments and other assets	1,142	276
	4,693	10,086
Non-current assets		
Right-of-use-asset	417	464
Property and equipment	191	237
Intangible asset	196	211
Investment in iDialco	834	998
Total assets	6,331	11,996
Liabilities		
Current liabilities		
Trade and other payables	2,724	3,167
Current portion of contract liabilities	698	696
Current portion of lease liability	98	96
	3,520	3,959
Non-current liability		
Lease liability	374	420
Non-current portion of contract liabilities	3,676	4,011
Notes payable	6,039	6,129
Total liabilities	13,609	14,519
Shareholders' deficiency		
Share capital	87,061	87,050
Contributed surplus	8,773	8,773
Share-based compensation	9,858	8,908
Warrants	2,490	2,490
Deficit	(115,460)	(109,744)
Total shareholders' deficiency	(7,278)	(2,523)
Total liabilities and shareholders' deficiency	6,331	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)

	Three- months ended June 30, 2023	Three- months ended June 30, 2022	Six-months ended June 30, 2023	Six-months ended June 30, 2022
	\$	\$	\$	\$
Revenue	306	276	836	760
Expenses				
Changes in inventories of finished goods and work-in-process	-	-	-	(36)
Raw materials and consumables used	281	187	418	368
Salaries and benefits	976	876	1,932	1,682
Consulting and professional fees	1,472	717	2,100	1,146
Regulatory and investor relations	196	140	304	282
Travel and entertainment	99	66	183	121
Facilities and communication	82	70	164	137
Insurance	101	119	187	238
Depreciation and amortization	55	56	116	115
Interest expense	127	6	255	13
Foreign exchange (gain) loss	(176)	6	(237)	10
Share-based compensation	986	95	961	788
Other expense (income)	17	(7)	12	(13)
Net Loss on joint arrangement	78	-	163	-
	4,294	2,331	6,558	4,851
Loss and comprehensive loss for the year from continuing operations	(3,988)	(2,055)	(5,722)	(4,091)
Income (loss) from discontinued operations	49	(899)	6	(1,548)
Loss and comprehensive loss for the year	(3,939)	(2,954)	(5,716)	(5,639)
Basic and diluted loss from continuing operations per common share	(0.01)	(0.00)	(0.02)	(0.01)
Basic and diluted income (loss) from discontinued operations per common share	(0.00)	(0.00)	(0.00)	(0.00)
Basic and diluted loss per common share	(0.01)	(0.01)	(0.02)	(0.02)
Weighted average number of common shares outstanding – basic and diluted	278,552,182	268,147,683	278,550,005	268,064,079

Spectral Medical Inc.

Condensed Interim Consolidated Statements of Changes in Shareholders' Deficiency

In CAD (000s)

(Unaudited)

	Number of shares	Share Capital	Contributed surplus	Share-based compensation	Warrants	Deficit	Total Shareholders' (deficiency)
		\$	\$	\$	\$	\$	\$
Balance, January 1, 2022	267,886,408	84,357	7,985	7,984	2,251	(98,494)	4,083
Share options exercised	219,546	121	-	(53)	-	-	68
RSUs released	49,038	31	-	(31)	-	-	-
Warrants expired	-	-	788	-	(788)	-	-
Loss and comprehensive loss for the period	-	-	-	-	-	(5,643)	(5,643)
Share-based compensation	-	-	-	788	-	-	788
Balance, June 30, 2022	268,154,992	84,509	8,773	8,688	1,463	(104,137)	(704)
Bought deal offering	10,061,250	2,313	-	-	1,027	-	3,340
Share options exercised	49,251	36	-	(16)	-	-	20
RSU Released	282,311	192	-	(173)	-	-	19
Loss and comprehensive loss for the period	-	-	-	-	-	(5,607)	(5,607)
Share-based compensation	-	-	-	409	-	-	409
Balance, December 31, 2022	278,547,804	87,050	8,773	8,908	2,490	(109,744)	(2,523)
Balance, January 1, 2023	278,547,804	87,050	8,773	8,908	2,490	(109,744)	(2,523)
RSUs released	28,457	11	-	(11)	-	-	-
Loss and comprehensive loss for the period	-	-	-	-	-	(5,716)	(5,716)
Share-based compensation	-	-	-	961	-	-	961
Balance, June 30, 2023	278,576,261	87,061	8,773	9,858	2,490	(115,460)	(7,278)

Spectral Medical Inc.

Condensed Interim Consolidated Statements of Cash Flows

In CAD (000s)

(Unaudited)

	Six-months ended June 30, 2023	Six-months ended June 30, 2022
	\$	\$
Cash flow provided by (used in)		
Operating activities		
Loss and comprehensive loss for the period	(5,716)	(5,643)
Adjustments for:		
Depreciation on right-of-use asset	47	47
Depreciation on property and equipment	46	88
Amortization of intangible asset	15	9
Amortization of deferred financing Fees	87	-
Interest expense	255	13
Unrealized foreign exchange gain	(176)	(7)
Share-based compensation	961	788
Write down of property and equipment to fair value	-	83
Loss on investment in iDialco	163	-
Changes in items of working capital:		
Trade and other receivables	314	105
Inventories	52	(170)
Prepayments and other assets	(866)	(266)
Trade and other payables	(679)	(112)
Contract liabilities	(333)	(355)
Net cash used in operating activities	(5,830)	(5,420)
Investing activities		
Property and equipment acquisitions	-	(21)
Net cash used in investing activities	-	(21)
Financing activities		
Lease liability payments	(63)	(58)
Share options exercised	-	68
Net cash provided by financing activities	(63)	10
Decrease in cash	(5,893)	(5,431)
Effects of exchange rate changes on cash	-	7
Cash, beginning of period	8,414	8,890
Cash, end of period	2,521	3,466