



SPECTRAL MEDICAL ANNOUNCES FIRST QUARTER RESULTS AND PROVIDES CORPORATE UPDATE

NEW TRIAL SITES ENROLL 60% OF NEW PATIENT ENROLLMENTS SINCE THE BEGINNING OF APRIL

TIGRIS PATIENT ENROLLMENT AT 58 PATIENTS

TORONTO, Canada – May 12, 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 first quarter ended March 31, 2023 and provided a corporate update.

During the first quarter the Company implemented a number of business initiatives, as outlined in Spectral’s [investor update](#) call held on April 6, 2023, that are targeted to enhance and accelerate Tigris enrollment. Management is pleased to report positive progress on these initiatives, including:

- enrolled an additional five patients, three of whom were enrolled at the University of California San Francisco (“UCSF”), a site that was onboarded and started actively enrolling in March 2023;
- currently 58 patients enrolled to date and continue to close in on our interim target of 90 patients, an important milestone as our strategic commercial partner, Baxter, will have the opportunity to view the data as well as provide a second milestone payment to Spectral;
- remain on track to have 25 active trial sites open by the end of September 2023, with multiple new sites conducting site initiation visits (“SIV”) at the Company’s Tigris Investigator Meeting next week;
- new CRO transition progressing on schedule, with full transition complete by end of June;
- Tigris Investigator Meeting set for May 17th and 18th in Charlotte, North Carolina, including pipeline sites, with more than 20 sites to be represented; and
- clinician focused PMX media pre-production progressing well, with production crew attending and filming at the Tigris Investigator Meeting.

Dr. John Kellum, Chief Medical Officer of Spectral Medical, stated, “We are witnessing an increase in enrollment as a result of onboarding additional trial sites, with 3 of the 5 enrollments since April coming from a new site - UCSF. This is the fastest we’ve seen a new site enroll patients within a forty-day period. To further assist our efforts, we are conducting site initiation visits for two additional sites during the second quarter and expect to have a total of 19 sites onboarded by June. With the help of our new CRO, Beaufort, who brings a significant number of clinical field resources, we believe we are on an accelerated enrollment path, allowing us to more swiftly reach key enrollment milestones. Importantly, Tigris mortality data continues to exceed our expectations and has been consistent with our recent announcement of the EUPHAS-2 [study results](#). The EUPHAS-2 data further validates our confidence in the outcome of Tigris and our potential for FDA approval, which would bring a much-needed personalized therapy to those suffering from endotoxemic septic shock.”

Chris Seto, Chief Executive Officer of Spectral Medical, stated, “We are hosting an Investigator Meeting in mid-May and anticipate very robust attendance, including existing sites, new and pipeline sites,

principal investigators, clinical research coordinators, our new CRO (Beaufort), our safety committee (ISAC), and our strategic commercial partner, Baxter. This is a very important event as we are bringing together key healthcare professionals for training on how to participate in the clinical trial, further assisting in the advancement of Tigris. Furthermore, we are developing educational tools, including videos, to assist in educating healthcare professionals as well as patients and the public on endotoxemic septic shock and our PMX therapy. We believe these materials will aid in supporting commercial adoption of PMX, assuming FDA approval. We are very proud of our progress and continue to execute on our strategy. While we are witnessing initial benefits of our efforts, we believe that we will realize the full impact of these initiatives over time. We look forward to reporting our progress as material developments unfold.”

Corporate Highlights During & Subsequent to the First Quarter Ended March 31, 2023

Tigris

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

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. Transition activities are progressing well, with full change from the incumbent CRO expected by the end of the second quarter. 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 58 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. The Company continues to close in on its interim target of 90 patients, an important milestone.

Last twelve-month enrollment rate has stabilized at 0.182 patients per site per month. Through the previously announced initiatives to enhance Tigris enrollment, Management is targeting an enrollment rate of 0.25 patients per site per month.

- **Tigris Sites**

There are currently 16 active Tigris sites. The Company remains on schedule to onboard an additional 9 new sites over the next two quarters bringing the total sites to 25. Should suitable sites over and above the 25 be identified, FDA approval would be required to approve incremental sites. Management believes the FDA would be amenable to requests for additional Tigris sites, based on historical interactions.

- **Timing**

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

- **Investigator Meeting**

A Tigris study Investigator Meeting (in-person) is scheduled for May 17th and 18th 2023 in Charlotte, North Carolina. This represents the first in-person investigator meeting since August 2019 with agenda set and attendance being confirmed. Robust attendance is expected with more than 65 key stakeholders of the Tigris Trial and including pipeline sites more than 20 sites will be represented. Historically, patient enrollment increases post-investigator meeting.

- **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 51 patients into the observational study.

EUPHAS-2

On April 6, 2023, the Company reported positive results from the EUPHAS-2 clinical trial. This study included 50 critically ill Endotoxemic Septic Shock patients assessed with Spectral's EAA diagnostic and treatment with PMX. The study reported a 28-day mortality of just 36% with the treated patients versus a predicted 75% mortality utilizing the widely accepted SAPS II mortality estimation tool. This represents more than a 50% estimated relative mortality reduction with the use of PMX. The patient population of the EUPHAS-2 study aligns with the patient population of the Tigris Trial.

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.
- The Company is working with Baxter on a sub-study to obtain FDA approval for hemoperfusion for Baxter's Prismax device; the Prismax with its leading installed base, is anticipated to be the primary device utilized for PMX treatments on commercial launch.
- 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 a third-party produced video focused on Endotoxemic Septic Shock (ESS), PMX and positive patient outcomes. This video will be targeted at 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 increase the 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.

Financial Review

Revenue for the three-months ended March 31, 2023 was \$530,000 compared to \$484,000 for the same three-month period last year, representing an increase of \$46,000, or 9.5%. This increase was mainly due to an increase in proprietary biochemicals product revenue.

Operating expenses for the three-months ended March 31, 2023, were \$2,264,000, compared to \$2,520,000 for the same period in the preceding year, a decrease of \$256,000, or 10%. The reduction in operating expenses was primarily due to a reduction in stock-based compensation due to the issuance

timing of annual grants partially offset by an increase in professional services, supporting increased Tigris trial activity and salaries and benefits.

Loss for the three-months ended March 31, 2023 was \$1,777,000, or \$0.01 per share, compared to a loss of \$2,685,000, or \$0.01 per share, for the same quarter last year.

The Company concluded the first quarter of 2023 with cash of \$4,886,000 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 278,547,804 at March 31, 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 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)

	March 31, 2023 \$	December 31 2022 \$
Assets		
Current assets		
Cash	4,886	8,414
Trade and other receivables	1,104	1,056
Inventories	349	340
Prepayments and other assets	853	276
	7,192	10,086
Non-current assets		
Right-of-use-asset	440	464
Property and equipment	213	237
Intangible asset	200	211
Investment in iDialco	913	998
Total assets	8,958	11,996
Liabilities		
Current liabilities		
Trade and other payables	2,135	3,167
Current portion of contract liabilities	669	696
Current portion of lease liability	97	96
	2,901	3,959
Non-current liability		
Lease liability	397	420
Non-current portion of contract liabilities	3,844	4,011
Notes payable	6,142	6,129
Total liabilities	13,284	14,519
Shareholders' (deficiency) equity		
Share capital	87,050	87,050
Contributed surplus	8,773	8,773
Share-based compensation	8,882	8,908
Warrants	2,490	2,490
Deficit	(111,521)	(109,744)
Total shareholders' deficiency	(4,326)	(2,523)
Total liabilities and shareholders' (deficiency) equity	8,958	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 March 31, 2023 \$	Three-months ended March 31, 2022 \$
Revenue	530	484
Expenses		
Changes in inventories of finished goods and work-in-process	-	(36)
Raw materials and consumables used	137	181
Salaries and benefits	956	806
Consulting and professional fees	628	429
Regulatory and investor relations	108	142
Travel and entertainment	84	55
Facilities and communication	82	67
Insurance	87	119
Depreciation and amortization	61	59
Interest expense	128	7
Foreign exchange (gain) loss	(61)	4
Share-based compensation	(26)	693
Other income/expense	(5)	(6)
Net loss on joint arrangement	85	-
	2,264	2,520
Loss and comprehensive loss for the year from continuing operations	(1,734)	(2,036)
Loss from discontinued operations	(43)	(649)
Loss and comprehensive loss for the year	(1,777)	(2,685)
Basic and diluted loss from continuing operations per common share	(0.01)	(0.01)
Basic and diluted loss from discontinued operations per common share	(0.00)	(0.00)
Basic and diluted loss per common share	(0.01)	(0.01)
Weighted average number of common shares outstanding – basic and diluted	278,547,804	267,980,359

Spectral Medical Inc.

Condensed Interim Consolidated Statements of Changes in Shareholders' Equity

In CAD (000s)

(Unaudited)

	Number of Shares	Share Capital \$	Contributed surplus \$	Share-based compensation \$	Warrants \$	Deficit \$	Total Shareholders' (deficiency) equity \$
Balance, January 1, 2022	267,886,408	84,357	7,985	7,984	2,251	(98,494)	4,083
Share options exercised	211,335	114	-	(51)	-	-	63
RSU released	49,038	31	-	(31)	-	-	-
Loss and comprehensive loss for the year	-	-	-	-	-	(2,688)	(2,688)
Share-based compensation	-	-	-	693	-	-	693
Balance, March 31, 2022	268,146,781	84,502	7,985	8,595	2,251	(101,182)	2,151

	Notes	Number of Shares	Share Capital \$	Contributed surplus \$	Share-based compensation \$	Warrants \$	Deficit \$	Total Shareholders' (deficiency) equity \$
Balance January 1, 2023		278,547,744	87,050	8,773	8,908	2,490	(109,744)	(2,523)
Loss and comprehensive loss for the year		-	-	-	-	-	(1,777)	(1,777)
Share-based compensation		-	-	-	(26)	-	-	(26)
Balance, March 31, 2023		278,547,744	87,050	8,773	8,882	2,490	(111,521)	(4,326)

Spectral Medical Inc.

Condensed Interim Consolidated Statements of Cash Flows

In CAD (000s)

(Unaudited)

	Three- months ended March 31, 2023 \$	Three- months ended March 31, 2022 \$
Cash flow provided by (used in)		
Operating activities		
Loss for the year	(1,777)	(2,688)
Adjustments for:		
Depreciation on right-of-use asset	24	24
Depreciation on property and equipment	24	45
Amortization of intangible asset	11	4
Amortization of deferred financing fees	44	
Interest expense	129	7
Unrealized foreign exchange loss (gain)	(31)	6
Share-based (reversal) compensation	(26)	693
Loss on investment in iDialco	85	-
Changes in items of working capital:		
Trade and other receivables	(48)	(81)
Inventories	(9)	(226)
Prepayments and other assets	(577)	(262)
Trade and other payables	(1,150)	148
Contract liabilities	(194)	(114)
Net cash used in operating activities	(3,495)	(2,444)
Investing activities		
Purchases of property and equipment	-	(2)
Net cash used in investing activities	-	(2)
Financing activities		
Lease liability payments	(33)	(29)
Share options exercised	-	63
Net cash provided by financing activities	(33)	34
Increase (decrease) in cash	(3,528)	(2,410)
Effects of exchange rate changes on cash	-	(6)
Cash, beginning of year	8,414	8,890
Cash, end of year	4,886	6,472