



SPECTRAL MEDICAL ANNOUNCES FOURTH QUARTER AND FISCAL 2023 RESULTS AND PROVIDES CORPORATE UPDATE

97 patients enrolled

TORONTO, Canada – March 28, 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 fourth quarter and for the year ended December 31, 2023 and provided a corporate update.

The Company made significant progress throughout 2023, both clinically and operationally. Specifically, regarding its Tigris trial, a Phase III clinical trial evaluating PMX for endotoxic septic shock. The Company has successfully enrolled 97 patients to date, out of the 150 total patients to be enrolled, and focused on the final push to fully enroll and finish the Tigris trial. The Company believes that the continued onboarding of new Tigris sites since the fourth quarter of 2023 could further accelerate enrollment experienced to date and allow Spectral to rapidly reach the 150-patient target, 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. Recently, Baxter exercised its right to maintain its exclusive distribution rights for PMX products in the U.S. and Canada and paid Spectral a non-dilutive milestone payment. Additionally, the Company and Baxter mutually agreed to amend the initial term of their commercial partnership to ten years post-FDA approval of PMX. The Company believes this amendment provides a mutually beneficial runway for the parties to maximize PMX commercial economics, while providing motivation for continued support and allocation of resources to the PMX partnership.

Dr. John Kellum, Chief Medical Officer of Spectral Medical, stated, “We have witnessed robust enrollment activity to start 2024. This pace of enrollment continues the momentum since we communicated our enhanced recruitment initiatives last April, and it’s fair to say that our steady enrollment over the last twelve months is a culmination of many of these initiatives, which the Company implemented throughout 2023. As we enter the final push to fully enroll and finish Tigris, our clinical team is focused on trial site management activities such as site visits, refresher training, and clinical communications, workshops, and roundtables. Ultimately, we want to ensure that our Tigris sites have the support and resources to enroll patients as efficiently as possible. We are committed to advancing Tigris and believe PMX, if ultimately approved, will play a major role in reducing the tragic rates of mortality caused by sepsis.”

Corporate Highlights During & Subsequent to the Fourth Quarter and Fiscal Year Ended December 31, 2023

Tigris:

- Total of 97 patients randomized to date out of the 150 total patients to be enrolled in the Tigris trial.
 - accelerated enrollment experienced in 2024 to date, with 16 patients enrolled so far – represents the most robust enrollment rates since the start of the Tigris trial.
- Currently 22 Tigris sites onboarded
 - addition of two new trial sites in the fourth quarter – the Mayo Clinic and Emory Healthcare.
 - subsequent to the fourth quarter, the Company added three new sites – University of

Texas Health Sciences Center at Houston, The Institute for Extracorporeal Life Support (San Antonio, TX), and UCLA, with two additional sites in the pipeline.

- Investigator Meeting held March 12th and 13th
 - The Company held a Tigris trial Investigator Meeting in conjunction with the *29th International Conference on Advances in Critical Care Nephrology* in San Diego.
 - In-person meeting well attended with multiple stakeholders present, including: principal investigators and clinical research coordinators from existing and new trial sites; CRO, Beaufort; and representatives from the Company's strategic partner Baxter.
 - Focus of the meeting was on the practical aspects of diagnosing endotoxic septic shock and treating with PMX, as well as featuring several talks from trial sites on how EAA and PMX could be implemented into routine clinical practice after potential regulatory approval of PMX.
- Completion of EDEN Observational Study
 - The Company completed its EDEN study in the fourth quarter with 92 patients enrolled. The ancillary observational study collected data on patients with sepsis even if ineligible for Tigris, and captured 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 labelling 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. The Company expects final analysis of the data in mid-2024.

PMX Commercialization:

- 90 patient enrollment interim milestone achieved
 - On February 15, 2024, Spectral announced that it had reached the 90-patient enrollment threshold and provided written notification to Baxter of this achievement. Subsequently, Baxter exercised its option to maintain exclusive distribution rights and paid Spectral an ~C\$2 million non-dilutive payment.
 - Since inception of partnership, funding support from Baxter has amounted to ~C\$15 million – comprised of non-dilutive payments and convertible notes subscriptions.
- Amendment of Initial Term of Exclusive Distribution Agreement
 - In February 2024, the Company and Baxter mutually agreed to amend the initial term of the exclusive distribution agreement to 10 years post-FDA approval; the Company believes the 10-year term provides mutually beneficial runway to maximize PMX commercial economics.
- Commercialization 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.
 - 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.

i-Dialco Inc.:

Throughout 2023, the Company became aware of significant changes in the iDialco business plan that impacted the ability of the Company to forecast the recoverability of the investment. Accordingly, the net investment was assessed for a non-cash impairment loss. As part of this assessment the Company noted significant changes from the initial business plan at inception, including the identification that the period of negative cash flows for the entity increased substantially as a result of shift in both the regulatory and commercialization timelines mainly due to further device developments and improvements required for clinical adoption of the SAMI and DIMI devices. The Company maintains a 30% ownership and voting rights within iDialco, and will continue to track any future losses or gains booked by iDialco.

“I am pleased with the increased level of activity across the Company and its impact on establishing robust trial sites, thus resulting in a significant ramp up of patient enrollment. The recent pace of enrollment, combined with the quality and focus of the current and planned trial sites provide us with confidence in continued robust enrollment activity. The potential to sustain our current pace of enrollment could see us rapidly advance the trial towards completion in the late 2024 to early 2025 timeframe,” said Chris Seto, CEO of Spectral. “During the quarter we took a non-cash impairment charge relating to our investment in iDialco. Consistent with our assessment at the time of spinning-off this business, iDialco has proven to be more challenged with delivering on its business plan based on what was initially envisioned.”

Financial Review

Revenue for the three-months ended December 31, 2023 was \$365,000 compared to \$553,000 for the same three-month period last year. Total revenue for the year ended December 31, 2023 was \$1,598,000 compared to \$1,667,000 for prior year, representing a decrease of \$69,000, or 4%. The decrease in product revenue was mainly due to the timing of orders in addition to certain supply chain constraints.

For the quarter ended December 31, 2023, the Company reported operating expenses of \$6,813,000 compared to \$1,767,000 for the same period in 2022. When excluding the impact of the \$193,000 loss (2022 - \$998,000 gain) on investment in iDialco and \$600,000 impairment loss on Joint venture arrangement, operating expenses for the quarter ended December 31, 2023 were \$6,020,000 compared to \$ 2,766,000 for the same period in the prior year. The increase of \$ 3,254,000 (excluding investment loss and impairment) was due primarily to increased consulting and professional services majorly due to increased site and patient fees related to the Tigris trial and Eden observational study; and a non-cash expense attributed to a Fair Value adjustment on Derivative Liabilities (the increase was primarily due to change in the market assumptions and market price considered for the calculation of the option feature).

Loss for the three-months ended December 31, 2023 was \$6,479,000, or \$0.02 per share, compared to a loss of \$2,537,000, or \$0.01 per share, for the same quarter last year. The loss for the year ended December 31, 2023 was \$15,662,000, or \$0.06 per share, compared to a loss of \$11,281,000 or \$0.04 per share, for 2022.

The Company concluded the 2023 year with cash of \$2,952,000 compared to \$8,414,000 cash on hand as of December 31, 2022.

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

Consolidated Statements of Financial Position

(in thousands of Canadian dollars)

	Notes	Dec-31 2023 \$	Revised (Refer note 15) Dec-31 2022 \$
Assets			
Current assets			
Cash	5	2,952	8,414
Trade and other receivables	6	186	1,056
Inventories	7	366	340
Prepayments and other assets	8	621	276
		4,125	10,086
Non-current assets			
Right-of-use-asset	9	567	464
Property and equipment	10	326	237
Intangible asset	11	193	211
Investment in iDialco	12	-	998
Total assets		5,211	11,996
Liabilities			
Current liabilities			
Trade and other payables	13	2,820	3,087
Current portion of contract liabilities	14	727	696
Current portion of lease liability	9	121	96
Notes Payable	15	264	79
Derivative Liabilities	15	6,310	2,674
		10,242	6,632
Non-current liability			
Lease liability	9	500	420
Non-current portion of contract liabilities	14	3,342	4,011
Notes payable	15	7,676	3,487
Total liabilities		21,760	14,550
Shareholders' (deficiency) equity			
Share capital		87,061	87,050
Contributed surplus		8,916	8,773
Share-based compensation		10,385	8,908
Warrants		2,526	2,490
Deficit		(125,437)	(109,775)
Total shareholders' (deficiency) equity		(16,549)	(2,554)
Total liabilities and shareholders' (deficiency) equity		5,211	11,996

Spectral Medical Inc.

Consolidated Statements of Loss and Comprehensive Loss
For the years ended December 31, 2023 and 2022

(in thousands of Canadian dollars, except for share and per share data)

	Notes	2023 \$	Revised (Refer note 15) 2022 \$
Revenue	20	1,598	1,667
Expenses			
Raw materials and consumables used		936	684
Salaries and benefits	22	3,857	3,767
Consulting and professional fees		4,825	2,653
Regulatory and investor relations		581	567
Travel and entertainment		297	247
Facilities and communication		414	297
Insurance		411	477
Depreciation and amortization		210	225
Interest expense	9,15	1,334	176
Foreign exchange (gain) and loss		(126)	39
Share-based compensation	17	1,488	1,197
Other expense		315	290
Net (gain) loss on joint venture arrangement	12	398	(998)
Impairment loss on joint venture arrangement	12	600	-
Fair Value Adjustment Derivative Liabilities		1,565	(326)
		17,105	9,295
Loss and comprehensive loss for the year from continuing operations		(15,507)	(7,628)
Loss from discontinued operations	4	(155)	(3,653)
Loss and comprehensive loss for the year		(15,662)	(11,281)
Basic and diluted loss from continuing operations per common share	18	(0.06)	(0.03)
Basic and diluted loss from discontinued operations per common share	18	0.00	(0.01)
Basic and diluted loss per common share	18	(0.06)	(0.04)
Weighted average number of common shares outstanding - basic and diluted	18	278,563,241	269,843,447

Spectral Medical Inc.

Consolidated Statements of Changes in Shareholders' (Deficiency) Equity
For the years ended December 31, 2023 and 2022

(in thousands of Canadian dollars)

	Notes	Issued capital Number	\$	Contributed surplus \$	Share-based compensation \$	Warrants \$	Deficit \$	Total Shareholders' (deficiency) equity \$
Balance, December 31, 2021		267,886,408	84,357	7,985	7,984	2,251	(98,494)	4,083
Bought deal offering	21	10,061,250	2,313	-	-	1,027	-	3,340
Share options exercised	15	268,797	157	-	(69)	-	-	88
RSU released		331,349	223	-	(204)	-	-	19
Warrants expired		-	-	788	-	(788)	-	-
Loss and comprehensive loss for the year		-	-	-	-	-	(11,281)	(11,281)
Share-based compensation	15	-	-	-	1,197	-	-	1,197
Revised (Refer note 15) Balance, December 31, 2022		278,547,804	87,050	8,773	8,908	2,490	(109,775)	(2,554)
RSU released		28,457	11	-	(11)	-	-	-
Warrants expired		-	-	143	-	(143)	-	-
Warrants issued		-	-	-	-	179	-	179
Loss and comprehensive loss for the year		-	-	-	-	-	(15,662)	(15,662)
Share-based compensation	15	-	-	-	1,488	-	-	1,488
Balance December 31, 2023		278,576,261	87,061	8,916	10,385	2,526	(125,437)	(16,549)

Spectral Medical Inc.

Consolidated Statements of Cash Flows
For the years ended December 31, 2023 and 2022

(in thousands of Canadian dollars)

	Notes	2023 \$	Revised (Refer note 15) 2022 \$
Cash flow provided by (used in)			
Operating activities			
Loss for the year		(15,662)	(11,281)
Adjustments for:			
Depreciation on right-of-use asset	9	104	94
Depreciation on property and equipment	10	96	161
Amortization of intangible asset	11	18	17
Amortization and Derivative related financing fees		446	324
Unrealized foreign exchange (gain) and loss		(228)	(10)
Interest expense on lease liability	9	25	25
Accreted Interest on Notes Payable		835	151
Share-based compensation	17	1,488	1,197
Disposal of property and equipment		-	167
Net (gain) loss on joint venture arrangement	12	398	(998)
Impairment loss on joint venture arrangement	12	600	
Fair Value Adjustment derivative liabilities		1,565	(326)
Changes in items of working capital:			
Trade and other receivables		870	(851)
Inventories		(26)	(47)
Prepayments and other assets		(345)	599
Right-of-use-asset		-	(26)
Trade and other payables		(267)	1,565
Contract liabilities		(638)	(661)
Net cash used in operating activities		(10,721)	(9,900)
Investing activities			
Purchases of property and equipment	10	(185)	(33)
Net cash used in investing activities		(185)	(33)
Financing activities			
Proceeds from bought deal offering	23	-	4,025
Financing charges paid	15,23	(641)	(1,363)
Note payable	15	4,058	3,802
Lease liability payments		(127)	(91)
Share options exercised		-	88
Derivative liabilities	15	2,154	2,996
Net cash provided by financing activities		5,444	9,457
Increase (decrease) in cash		(5,462)	(476)
Cash, beginning of year		8,414	8,890
Cash, end of year		2,952	8,414