



SPECTRAL MEDICAL ANNOUNCES FOURTH QUARTER AND FISCAL 2022 RESULTS AND PROVIDES CORPORATE UPDATE

Reports significant enhancements to accelerate Tigris patient enrollment including appointment of new Contract Research Organization

Management to host Investor Day on April 6, 2023

TORONTO, Canada – March 24, 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 fourth quarter and for the year ended December 31, 2022 and provided a corporate update.

The Company made significant progress throughout 2022, both clinically and operationally. Specifically, regarding our Tigris trial, a Phase III clinical trial evaluating PMX for endotoxemia and septic shock. The Company has successfully enrolled 53 patients to date, out of the 150 total patients to be enrolled, and are focused on the interim milestone of enrolling 90 patients. Upon achieving the interim enrollment target, our strategic commercial partner, Baxter, will have the opportunity to view the data, as well as provide a second milestone payment to Spectral, which management believes would provide further validation of the Company’s ongoing efforts. The Company believes that the continued onboarding of new Tigris sites will allow us to more rapidly reach our 150 patient target, bringing us closer to FDA submission and potential FDA approval.

Dr. John Kellum, Chief Medical Officer of Spectral Medical, stated, “While we witnessed a slow pace of enrollment as a result of the COVID-19 pandemic, we have made significant changes to address and accelerate recruitment activities. Importantly, we are in the process of engaging a new Contract Research Organization (“CRO”) to oversee the Tigris trial. This new CRO has extensive experience in ICU clinical trials and will review and evaluate the recruitment and enrollment processes of each Tigris trial site to implement improvements as needed, which we believe will assist in reaching enrollment milestones. Moreover, we have an active pipeline of nine new sites in the clinical trial agreement phase, which should increase our number of sites to a total of 25 sites onboarded by the end of the third quarter of 2023. With a target of 25 sites, we believe we can finalize enrollment for Tigris. 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.”

Chris Seto, CEO, stated, “We announced forming a strategic joint venture with Infomed in December 2022. The new company, i-Dialco, is exclusively focused on advancing commercialization of the SAMI and DIMI dialysis devices in the North American markets. Infomed will fund a multi-year business plan, including all working capital and commercialization costs, as well as planned development, clinical and regulatory activities resulting in the elimination of over \$3 million of annual expenses for Spectral. While Spectral maintains full access to SAMI for

potential use with our PMX column through an exclusive, royalty-free license, we believe Infomed has the resources and knowledge to bring SAMI and DIMI to their full commercial potential.”

“We believe we have implemented important changes, including onboarding a new CRO, and refocusing our clinical team with the spin-off of Dialco that allows us to be laser focused on progressing Tigris. We anticipate our initiatives aimed at enhancing trial recruitment and enrollment will assist in completion of Tigris as expeditiously as possible. Furthermore, given the developments to date, as well as the encouraging mortality data thus far, which has exceeded our expectations, we have been working closely with Baxter to prepare post-approval marketing plans for PMX. Assuming FDA approval, we believe we can quickly penetrate the large U.S. market and bring a personalized therapy to patients suffering from endotoxemic septic shock, which represents a multi-billion-dollar addressable market in the U.S. alone. Overall, we believe the steps we are taking will help maximize value for Spectral and our shareholders while enabling us to increase our focus on PMX and advancing our Tigris trial. We look forward to hosting a virtual investor day on April 6th, to discuss these activities and other developments in more detail,” concluded Mr. Seto.

Initiatives to Enhance Tigris Enrollment

The most impactful initiatives to finalize the Tigris trial are increasing the number of trial sites, and increasing the enrollment productivity at each trial site.

- **Increase Number of Tigris Sites:**

Spectral currently has 16 active sites onboarded, with an active pipeline of 9 new sites in the clinical trial agreement (“CTA”) phase. There is currently line of sight to reach a full complement of 25 sites by end of Sept/23. This pipeline and pace of onboarding new sites is the culmination of the identification and screening of suitable sites since the FDA approved an increase in Tigris sites in August 2022.

Management is targeting 25 productive trial sites to finalize Tigris trial enrollment. The FDA has currently approved 25 sites. We believe reaching 25 active sites enrolling patients will be sufficient to reach 150 total patients to complete the trial. The Company will reassess the need to increase active sites above 25 in Sept/23 as this will require further FDA approval. Management believes the FDA would be amenable to the Company’s request for a further increase in number of sites, based on historical approvals and interactions with the FDA.

Spectral’s clinical team continues to actively monitor recruitment performance on a site-by-site basis, and will prune underperforming sites which do not have a path to enrollment productivity.

- **Initiatives to Increase enrollment productivity at each Tigris site:**

- **New Contract Research Organization (“CRO”).** The new CRO is a global contract research organization that provides a full range of clinical, regulatory and quality solutions, has been engaged to execute the Tigris trial. They have extensive experience in Intensive Care Unit (ICU) clinical trials. As part of the scope of work, the new CRO will provide critical review and evaluate recruitment and enrollment

processes on a site-by-site basis of Tigris sites. The new CRO's immediate assessment priority will be on the new sites and underperforming sites.

The new CRO's engagement adds significant incremental field resources to the Tigris study, including a seasoned project manager and staffing of five additional clinical research associates ("CRA"). This is incremental to Spectral's three existing CRAs and two field trainers. The increased presence at sites allows for site service to reduce site burden, and increase study management presence to maximize exposure, in addition to continuous site monitoring feedback.

- **Investigator Meeting.** The Company has scheduled an in-person investigator meeting for mid-May 2023. This represents the first in-person investigator meeting since August 2019, which will include attendance by principal investigators ("PI") and clinical research coordinators ("CRC") from all existing and new trial sites, as well as the new CRO. Historically, patient enrollment increases post-investigator meeting.
- **Clinical Team Focused PMX Media.** The Company has 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 further 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.

Corporate Highlights During & Subsequent to the Fourth Quarter and Fiscal Year Ended December 31, 2022

Tigris

- **Patient Enrollment**

Total of 53 patients randomized to date out of the 150 total patients to be enrolled in the Tigris trial. Patient screening activities at the sites is robust, and results to date of those enrolled in the study continue to exceed expectations.

- **Tigris Sites**

There are currently 16 Tigris sites onboarded and actively enrolling patients. The Company has an active pipeline of nine new sites in the clinical trial agreement phase, and expects a total of 25 sites onboarded by the end of the third quarter of 2023. The two most recent additional clinical trial sites, the Medical University of South Carolina (MUSC) and the University of California San Francisco (UCSF), were onboarded in February and March, respectively.

- **Timing**

The Company will reevaluate the timing of patient enrollment and ultimately timing to last patient enrollment when it has assessed the impacts of the various patient enrollment

initiatives that are being executed. Management expects it will communicate the updated estimated timeline by the end of the second quarter of 2023.

- **PMX: FDA Breakthrough Device Designation**

On July 11, 2022, the Company announced that the FDA granted Breakthrough Device designation for the Company's PMX device. The goal of the Breakthrough Device Program is to provide patients and health care providers with timely access to medical devices by speeding up their development, assessment, and review, while preserving the statutory standards for premarket approval, 510(k) clearance, and De Novo marketing authorization, consistent with the Agency's mission to protect and promote public health.

- **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 also working with Baxter on a sub-study to obtain FDA approval for hemoperfusion for Baxter's Prismax device. The parameters for the Prismax sub-study have been finalized, and the sub-study will be initiated in the near term. The end result of the sub-study is to gain hemoperfusion approval for the Prismax. 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.

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

The Company has 4 active EDEN sites and enrolled 42 patients into the observational study. To date, 3 Tigris patient enrollments are attributed to an initial enrollment in the EDEN study.

i-Dialco Inc.

On December 12, 2022, Spectral entered into a joint arrangement with Infomed SA ("Infomed"), a Swiss company dedicated to the development and manufacturing of blood purification devices. The new joint venture company, i-Dialco Inc. ("i-Dialco"), exclusively focuses on advancing commercialization of the SAMI and DIMI dialysis devices in the North American markets.

Under the Joint Venture, Spectral contributed SAMI and DIMI regulatory approvals, as well as

transfer its Medical Device Single Audit Program (MDSAP) certification to i-Dialco. Infomed, an established medical device manufacturer and original developer of the SAMI and DIMI devices, contributed all hardware, software and certain other intellectual property to further develop the SAMI and DIMI platforms. All prior license fees and minimum purchase requirements for Spectral have been replaced by a zero-cost license to the technology, granted by Infomed to the Joint Venture. In addition, Infomed has agreed to fund all future development of the i-Dialco business, including working capital and commercialization costs, as well as planned development activities. The goal of the Joint Venture is to establish SAMI and DIMI as leading dialysis systems in the market, while capitalizing on Infomed's technology, expertise and resources. Spectral owns 30% of the Joint Venture and Infomed owns 70% of the Joint Venture.

With the establishment of i-Dialco, the previous Dialco operations were considered discontinued as at December 31, 2022.

Investor Day Information

The Company will host a conference call at 4:00 PM Eastern Time on Thursday, April 6, 2023, to provide an update on the Tigris trial and other recent developments.

Conference Call Details:

DATE: Thursday, April 6, 2023

TIME: 4:00 p.m. (ET)

DIAL IN NUMBER: 1-877-407-0789 or 1-201-689-8562

*CallMe

<https://callme.viavid.com/viavid/?callme=true&passcode=13737450&h=true&info=Name&r=true&B=6>

Participants can use Guest dial-in #s above and be answered by an operator OR click the Call me link for instant telephone access to the event. *Available 15 minutes prior to scheduled start time.

Replay:

1-844-512-2921 or 1-412-317-6671

Available April 6, 2023 7:00 p.m. ET, until April 13, 2023 11:59 p.m. ET

CONFERENCE ID: 13737450

ONLINE ACCESS: https://viavid.webcasts.com/starthere.jsp?ei=1606504&tp_key=16415c0765

The Spectral presentation can be viewed on the Company's website through the following link: <https://spectraldx.com/investors/#investor-updates>

Financial Review

Revenue for the three-months ended December 31, 2022 was \$553,000 compared to \$512,000 for the same three-month period last year. Total revenue for the year ended December 31, 2022 was \$1,667,000 compared to \$1,996,000 for prior year, representing a decrease of \$329,000, or 16%. The decrease in product revenue was mainly due to the timing of orders in addition to certain supply chain constraints.

Operating costs for the quarter ended December 31, 2022 were \$1,711,000 compared to \$2,538,000 for the same period in 2021. When excluding the impact of the \$998,000 gain on investment in i-Dialco, operating costs for the quarter ended December 31, 2022 were \$2,709,000 compared to \$2,538,000 for the same period in the prior year. For the year ended December 31, 2022, operating costs were \$9,264,000 compared to \$8,955,000 for the same period in 2021, an increase of \$309,000. When excluding the impact of the \$998,000 gain on investment in i-Dialco, operating costs for the year ended December 31, 2022 was \$10,262,000 compared to \$8,955,000 for the same period in the prior year. The increase was due primarily to severance costs and increased professional services.

Loss for the three-months ended December 31, 2022 was \$2,472,000, or \$0.007 per share, compared to a loss of \$2,552,000, or \$0.01 per share, for the same quarter last year. The loss for the year ended December 31, 2022 was \$11,250,000, or \$0.04 per share, compared to a loss of \$8,785,000 or \$0.003 per share, for 2021.

The Company concluded the 2022 year with cash of \$8,414,00 compared to \$8,890,000 cash on hand as of December 31, 2021.

The total number of common shares outstanding for the Company was 278,547,804 at December 31, 2022.

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.

For further information, please contact:

Ali Mahdavi
Capital Markets & Investor
Relations

Spinnaker Capital Markets Inc.
416-962-3300
am@spinnakercmi.com

David Waldman/Natalya
Rudman

US Investor Relations
Crescendo Communications,
LLC
212-671-1020
edt@crescendo-ir.com

Blair McInnis
CFO
Spectral Medical Inc.
416-626-3233
bmcinnis@spectraldx.com

Spectral Medical Inc.

Consolidated Statements of Financial Position

(in thousands of Canadian dollars)

	December 31 2022 \$	December 31 2021 \$
Assets		
Current assets		
Cash	8,414	8,890
Trade and other receivables	1,056	205
Inventories	340	293
Prepayments and other assets	276	875
	10,086	10,263
Non-current assets		
Right-of-use-asset	464	532
Property and equipment	237	532
Intangible asset	211	228
Investment in i-Dialco	998	-
Total assets	11,996	11,555
Liabilities		
Current liabilities		
Trade and other payables	3,167	1,522
Current portion of contract liabilities	696	689
Current portion of lease liability	96	92
	3,959	2,303
Non-current liability		
Lease liability	420	490
Non-current portion of contract liabilities	4,011	4,679
Notes payable	6,129	-
Total liabilities	14,519	7,472
Shareholders' (deficiency) equity		
Share capital	87,050	84,357
Contributed surplus	8,773	7,985
Share-based compensation	8,908	7,984
Warrants	2,490	2,251
Deficit	(109,744)	(98,494)
Total shareholders' (deficiency) equity	(2,523)	4,083
Total liabilities and shareholders' (deficiency) equity	11,996	11,555

Spectral Medical Inc.

Consolidated Statements of Loss and Comprehensive Loss
For the years ended December 31, 2022 and 2021

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

	2022 \$	2021 \$
Revenue	1,667	1,996
Expenses		
Changes in inventories of finished goods and work-in-process	-	286
Raw materials and consumables used	684	503
Salaries and benefits	3,767	3,009
Consulting and professional fees	2,653	2,016
Regulatory and investor relations	567	604
Travel and entertainment	247	193
Facilities and communication	297	148
Insurance	477	389
Depreciation and amortization	225	246
Interest expense	104	28
Foreign exchange loss	49	51
Share-based compensation	1,197	1,259
Other expense	(5)	92
Write down of property and equipment	-	162
Gain on disposal of property and equipment	-	(31)
Net gain on joint arrangement	(998)	-
	9,264	8,955
Loss and comprehensive loss for the year from continuing operations	(7,597)	(6,959)
Loss from discontinued operations	(3,653)	(1,826)
Loss and comprehensive loss for the year	(11,250)	(8,785)
Basic and diluted loss from continuing operations per common share	(0.03)	(0.03)
Basic and diluted loss from discontinued operations per common share	(0.01)	(0.00)
Basic and diluted loss per common share	(0.04)	(0.03)
Weighted average number of common shares outstanding – basic and diluted	269,843,447	252,464,462

Spectral Medical Inc.

Consolidated Statements of Changes in Shareholders' (Deficiency) Equity
For the years ended December 31, 2022 and 2021

(in thousands of Canadian dollars)

	Issued capital		Contributed surplus	Share-based compensation	Warrants	Deficit	Total Shareholders' (deficiency) equity
	Number	\$	\$	\$	\$	\$	\$
Balance, December 31, 2020	236,755,745	71,870	7,981	6,771	2,418	(89,709)	(669)
Bought deal offering	23,530,000	7,406	-	-	1,464	-	8,870
Share options exercised	143,333	98	-	(46)	-	-	52
Warrants exercised	7,457,330	4,983	-	-	(1,627)	-	3,356
Warrants expired	-	-	4	-	(4)	-	-
Loss and comprehensive loss for the year	-	-	-	-	-	(8,785)	(8,785)
Share-based compensation	-	-	-	1,259	-	-	1,259
Balance, December 31, 2021	267,886,408	84,357	7,985	7,984	2,251	(98,494)	4,083
Bought deal offering	10,061,250	2,313	-	-	1,027	-	3,340
Share options exercised	268,797	157	-	(69)	-	-	88
RSU released	331,349	223	-	(204)	-	-	19
Warrants expired	-	-	788	-	(788)	-	-
Loss and comprehensive loss for the year	-	-	-	-	-	(11,250)	(11,250)
Share-based compensation	-	-	-	1,197	-	-	1,197
Balance, December 31, 2022	278,547,804	87,050	8,773	8,908	2,490	(109,744)	(2,523)

Spectral Medical Inc.

Consolidated Statements of Cash Flows
For the years ended December 31, 2022 and 2021

(in thousands of Canadian dollars)

	2022 \$	2021 \$
Cash flow provided by (used in)		
Operating activities		
Loss for the year	(11,250)	(8,785)
Adjustments for:		
Depreciation on right-of-use asset	94	93
Depreciation on property and equipment	161	183
Amortization of intangible asset	17	18
Interest expense on lease liability	25	28
Unrealized foreign exchange loss on cash	-	56
Share-based compensation	1,197	1,259
Write down of expired consumables	-	106
Write down of property and equipment	-	181
Disposal of property and equipment	167	-
Gain on investment in i-Dialco	(998)	-
Gain on disposal of property and equipment	-	(83)
Changes in items of working capital:		
Trade and other receivables	(851)	55
Inventories	(47)	(51)
Prepayments and other assets	599	(486)
Right-of-use-asset	(26)	-
Trade and other payables	1,645	(619)
Contract liabilities	(661)	(656)
Net cash used in operating activities	(9,928)	(8,701)
Investing activities		
Proceeds on disposal of property and equipment	-	158
Purchases of property and equipment	(33)	(483)
Net cash used in investing activities	(33)	(325)
Financing activities		
Proceeds from bought deal offering	4,025	10,000
Transaction costs paid	(1,335)	(1,130)
Note payable	6,798	-
Lease liability payments	(91)	(113)
Share options exercised	88	52
Warrants exercised	-	3,356
Net cash provided by financing activities	9,485	12,165
Increase (decrease) in cash	(476)	3,139
Effects of exchange rate changes on cash	-	(56)
Cash, beginning of year	8,890	5,807
Cash, end of year	8,414	8,890