



## SPECTRAL MEDICAL ANNOUNCES THIRD QUARTER RESULTS AND PROVIDES CORPORATE UPDATE

**TORONTO, Canada – November 10, 2022 – Spectral Medical Inc. (“Spectral” or the “Company”) (TSX: EDT)**, a late stage theranostic company advancing therapeutic options for sepsis and septic shock, as well as commercializing a new proprietary platform targeting the renal replacement therapy market through its wholly-owned subsidiary Dialco Medical Inc. (“Dialco”), today announced its financial results for the third quarter ended September 30, 2022 and provided a corporate update.

Chris Seto, CEO of Spectral Medical, commented, “We are making steady headway with our Tigris trial, a Phase III clinical trial evaluating PMX for endotoxemia and septic shock. We are witnessing stable recruitment levels across our Tigris clinical trial sites with 48 patients now enrolled out of the 150 total patients to be enrolled in the trial. We are also nearing completion of the onboarding process of two additional sites and expect another two sites to be onboarded and enrolling by the first quarter of 2023. We remain confident in the outlook for PMX and the Tigris trial given the encouraging data received thus far. Our goal, assuming Tigris is successful, is to quickly move towards FDA submission and bring hope to the approximately 120,000 patients each year that suffer from endotoxemic septic shock and face an estimated mortality rate in excess of 50%.”

Dr. John Kellum, Chief Medical Officer of Spectral Medical, stated, “As COVID-19 intensive care unit (ICU) cases diminish and the fall season surge of influenza takes hold, we have witnessed an approximate 50% increase in ICU sepsis cases. This influx of sepsis cases combined with the additional clinical trial sites has improved screening activities as well as accelerated enrollment. Notably, the preliminary mortality data we have received to date continues to exceed our expectations and strengthens our confidence in PMX and the outcome of the Tigris trial. We continue to believe that PMX has the potential to address the large unmet medical need that is currently estimated at \$1.6 billion in the United States alone with no FDA approved sepsis solutions on the market.”

Mr. Seto added, “Additionally, we continue to work closely with our strategic commercial partner, Baxter, and have conducted a pre-launch workshop with the Baxter team to further accelerate our commercial penetration, assuming FDA approval. Baxter also participated in our recent offering and agreed to purchase certain of the Notes in connection with an amendment to a portion of the interim milestone payment (at 90 patient enrollment), which we believe demonstrates their confidence in PMX and the Tigris trial. Furthermore, our recent offering, which generated gross proceeds of \$10.8 million, provides us substantial runway towards reaching significant clinical milestones. Overall, we have a strong balance sheet and believe we are well positioned to swiftly progress PMX towards commercialization, as well as penetrate this large U.S. market assuming FDA approval.”

## **Corporate Highlights During & Subsequent to the Third Quarter Ended September 30, 2022**

### **Tigris**

- **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.

- **Patient Enrollment**

Total of 48 patients randomized to date out of the 150 total patients to be enrolled in the Tigris trial. Patient screening activities and patient enrollment at the sites are increasing and results to date of those enrolled in the study continue to exceed expectations.

- **Tigris Sites**

There are currently 14 Tigris sites onboarded and actively enrolling patients. The Company is nearing completion of onboarding an additional two sites with two more expected to be onboarded by the end of 2022.

- **Timing**

The Company continues to focus on finalizing the Tigris trial within the reasonably shortest timelines. Assuming there is no significant recurrence of COVID-19 cases in the Tigris site ICUs, the Company targets reaching interim enrollment of 90 patients in Q1 2023, and finalizing its Tigris trial enrollment during the second half of 2023.

- **PMX Commercialization**

In anticipation of a positive Tigris trial outcome, the Company has been working closely over the last six months 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.

- **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 onboarded 5 EDEN sites and enrolled 28 patients into the observational study.

## **Dialco**

The Company is actively exploring strategic alternatives for the Dialco business.

- **DIMI Usability Trial**

The Dialco team continues to evaluate the timing of the DIMI usability trial as the dialysis clinic industry continues to experience labor shortages, high staffing turnover and wage pressure. These headwinds continue to adversely impact trial site commitment, dialysis clinic trial infrastructure, and trial budget costs. The Company's potential trial site partners have communicated that these challenges will continue into the foreseeable future.

- **SAMI Commercialization**

SAMI continues to be launched in Canada and the U.S. with successful clinical evaluations ongoing in key hemodialysis centers, as well as expansion of the commercial sales pipeline. In June 2022, ARC Dialysis, the largest inpatient dialysis provider in South Florida, selected the SAMI device for inpatient dialysis services following an extensive clinical evaluation of the technology. In addition, the SAMI device was selected and added to the approved products list for the United States Department of Veterans Affairs (VA), which provides healthcare services to veterans.

## **Financial Review**

Revenue for the three-months ended September 30, 2022 was \$374,000 compared to \$230,000 for the same three-month period in the prior year. For the nine-months ended September 30, 2022, revenue was \$1,144,000 compared to \$1,535,000 for the same period in 2021, representing a decrease of \$391,000 or 25%. The decrease in product revenue was mainly due to the timing of orders in addition to supply chain constraints related to sourcing materials for the EAA diagnostic device. The Company has now secured alternative sources of supply.

Operating costs for the three-months ended September 30, 2022, were \$3,509,000 compared to \$2,297,000 for the same period in the preceding year, an increase of \$1,212,000 or 53%. For the nine-months ended September 30, 2022, operating costs were \$9,922,000 compared to \$7,768,000 for the same period in 2021, an increase of \$2,154,000, or 28%. The change in costs were primarily due to an increase in salaries and benefits, consulting, and professional fees, including hiring a Chief Financial Officer and President of Dialco, increased consulting and professional fees related to clinical trial activity for Tigris, EDEN and the DIMI usability trials, and

product development fees for the DIMI product.

Loss for the three-months ended September 30, 2022 was \$3,135,000, or \$0.012 per share, compared to a loss of \$2,067,000, or \$0.008 per share, for the same quarter last year. The loss for the nine-months ended September 30, 2022 was \$8,778,000, or \$0.033 per share, compared to a loss of \$6,233,000 or \$0.025 per share, for the first nine months of 2021.

The Company concluded the third quarter of 2022 with cash of \$1,191,000 compared to \$8,890,000 cash on hand as of December 31, 2021. Subsequently, the Company closed an offering on November 2, 2022 resulting in gross proceeds of \$10,800,000.

The total number of common shares outstanding for the Company was 268,439,277 at September 30, 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, through its wholly owned subsidiary, Dialco Medical Inc., is also commercializing a new set of proprietary platforms addressing renal replacement therapy (RRT) across the dialysis spectrum. SAMI is targeting the acute RRT market, while DIMI is targeting the chronic RRT market. Dialco is currently pursuing regulatory approval for U.S. in-home use of DIMI, which is based on the same RRT platform as SAMI, but will be intended for home hemodialysis use. DIMI recently received its FDA 510k clearance for use in hospital and clinical settings, and obtained its Health Canada license for use within Canadian hospitals, clinics and in home.

Spectral is listed on the Toronto Stock Exchange under the symbol EDT. For more information please visit [www.spectraldx.com](http://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)

(Unaudited)

	September 30, 2022	December 31, 2021
	\$	\$
<b>Assets</b>		
<b>Current assets</b>		
Cash	1,191	8,890
Trade and other receivables	76	205
Inventories	660	293
Prepayments and other assets	798	875
	2,725	10,263
<b>Non-current assets</b>		
Right-of-use-asset	461	532
Property and equipment	408	532
Intangible asset	215	228
<b>Total assets</b>	<b>3,809</b>	<b>11,555</b>
<b>Liabilities</b>		
Current liabilities		
Trade and other payables	2,015	1,522
Current portion of contract liabilities	705	689
Current portion of lease liability	95	92
	2,815	2,303
Non-current liability		
Lease liability	418	490
Non-current portion of contract liabilities	4,178	4,679
<b>Total liabilities</b>	<b>7,411</b>	<b>7,472</b>
<b>Shareholders' (deficiency) equity</b>		
Share capital	84,688	84,357
Contributed surplus	8,773	7,985
Share-based compensation	8,746	7,984
Warrants	1,463	2,251
Deficit	(107,272)	(98,494)
<b>Total shareholders' (deficiency) equity</b>	<b>(3,602)</b>	<b>4,083</b>
<b>Total liabilities and shareholders' equity</b>	<b>3,809</b>	<b>11,555</b>

# 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 September 30, 2022	Three-months ended September 30, 2021	Nine-months ended September 30, 2022	Nine-months ended September 30, 2021
	\$	\$	\$	\$
Revenue	374	230	1,144	1,535
Expenses				
Changes in inventories of finished goods and work-in-process	78	26	161	198
Raw materials and consumables used	137	108	426	273
Salaries and benefits	1,469	826	4,565	3,640
Consulting and professional fees	1,202	913	2,898	2,075
Regulatory and investor relations	123	128	443	402
Travel and entertainment	123	118	326	178
Facilities and communication	159	50	404	196
Insurance	119	98	357	292
Depreciation and amortization	63	71	207	223
Interest expense on lease liability	6	7	19	21
Foreign exchange loss (gain)	31	(57)	43	37
Other (income) expense	(9)	9	(18)	99
Write down of property and equipment to fair value	8	-	91	174
Gain on disposal of property and equipment	-	-	-	(40)
	3,509	2,297	9,922	7,768
Loss and comprehensive loss for the period	(3,135)	(2,067)	(8,778)	(6,233)
Basic and diluted loss per common share	(0.012)	(0.008)	(0.033)	(0.025)
Weighted average number of common shares outstanding – basic and diluted	268,283,387	260,928,039	268,138,254	247,267,326

## Spectral Medical Inc.

Condensed Interim Consolidated Statements of Changes in Shareholders' (Deficiency)Equity

In CAD (000s)

(Unaudited)

	Number of shares (1)	Share Capital	Contributed surplus	Share-based compensation	Warrants	Deficit	Total Shareholders' (deficiency) equity
		\$	\$	\$	\$	\$	\$
<b>Balance, January 1, 2021</b>	<b>236,755,745</b>	<b>71,870</b>	<b>7,981</b>	<b>6,771</b>	<b>2,418</b>	<b>(89,709)</b>	<b>(669)</b>
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 period	-	-	-	-	-	(6,233)	(6,233)
Share-based compensation	-	-	-	1,117	-	-	1,117
<b>Balance, September 30, 2021</b>	<b>267,886,408</b>	<b>84,357</b>	<b>7,985</b>	<b>7,842</b>	<b>2,251</b>	<b>(95,942)</b>	<b>6,493</b>
Loss and comprehensive loss for the period	-	-	-	-	-	(2,552)	(2,552)
Share-based compensation	-	-	-	142	-	-	142
<b>Balance, December 31, 2021</b>	<b>267,886,408</b>	<b>84,357</b>	<b>7,985</b>	<b>7,984</b>	<b>2,251</b>	<b>(98,494)</b>	<b>4,083</b>
<b>Balance, January 1, 2022</b>	<b>267,886,408</b>	<b>84,357</b>	<b>7,985</b>	<b>7,984</b>	<b>2,251</b>	<b>(98,494)</b>	<b>4,083</b>
Share options exercised	268,797	157	-	(69)	-	-	88
RSUs released	284,072	174	-	(174)	-	-	-
Warrants expired	-	-	788	-	(788)	-	-
Loss and comprehensive loss for the period	-	-	-	-	-	(8,778)	(8,778)
Share-based compensation	-	-	-	1,005	-	-	1,005
<b>Balance, September 30, 2022</b>	<b>268,439,277</b>	<b>84,688</b>	<b>8,773</b>	<b>8,746</b>	<b>1,463</b>	<b>(107,272)</b>	<b>(3,602)</b>



# Spectral Medical Inc.

Condensed Interim Consolidated Statements of Cash Flows

In CAD (000s)

(Unaudited)

	Nine-months ended September 30, 2022	Nine-months ended September 30, 2021
	\$	\$
Cash flow provided by (used in)		
Operating activities		
Loss and comprehensive loss for the period	(8,778)	(6,233)
Adjustments for:		
Depreciation on right-of-use asset	71	70
Depreciation on property and equipment	123	140
Amortization of intangible asset	13	13
Interest expense on lease liability	19	21
Unrealized foreign exchange (gain) loss on cash	(33)	42
Share-based compensation	1,005	1,117
Write down of property and equipment to fair value	91	174
Gain on disposal of property and equipment	-	(40)
Changes in items of working capital:		
Trade and other receivables	129	(307)
Inventories	(367)	(51)
Prepayments and other assets	77	(403)
Trade and other payables	493	(806)
Contract liabilities	(485)	(449)
<b>Net cash used in operating activities</b>	<b>(7,642)</b>	<b>(6,712)</b>
Investing activities		
Proceeds on disposal of property and equipment	-	77
Property and equipment acquisitions	(90)	(401)
<b>Net cash used in investing activities</b>	<b>(90)</b>	<b>(324)</b>
Financing activities		
Proceeds from financing	-	10,000
Transaction costs paid	-	(1,130)
Warrants exercised	-	3,356
Share options exercised	88	52
Lease liability payments	(88)	(84)
<b>Net cash provided by financing activities</b>	<b>-</b>	<b>12,194</b>
(Decrease) increase in cash	(7,732)	5,158
Effects of exchange rate changes on cash	33	(42)
Cash, beginning of period	8,890	5,807
Cash, end of period	<b>1,191</b>	<b>10,923</b>