# SPECTRAL ANNOUNCES SECOND QUARTER RESULTS AND PROVIDES CORPORATE UPDATE

**TORONTO, Canada – August 12, 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 second quarter ended June 30, 2022 and provided a corporate update.

Chris Seto, CEO of Spectral Medical, stated, "We continue to advance our Tigris trial, evaluating PMX for endotoxemia and septic shock. To date, we have randomized 40 patients out of the total 150 patients required and we have 14 active trial sites enrolling patients. We are also working with the FDA in order to potentially permit an increase in the maximum number of participating sites from 15 to 25 in order to accelerate patient enrollment. Based on the encouraging data received thus far, we believe PMX has the potential to address a significant unmet medical need that is currently estimated at $1.6 billion in the United States alone, as well as provide hope for the approximately 120,000 patients each year who suffer from endotoxemic septic shock with an estimated 50% mortality rate. Importantly, the FDA recently granted PMX Breakthrough Device Designation, which is expected to help expedite the regulatory review process. We are also working closely with Baxter, our exclusive commercial partner in the U.S. and Canada, in order to prepare for commercialization."

"During the quarter, we appointed Sam Amory as Dialco President. Sam brings decades of experience in the medical device and dialysis fields. Sam has overseen a number of new product launches and built out successful sales teams, all of which we believe will positively impact the development of our pipeline. Following his appointment, our SAMI device was selected by ARC Dialysis, the largest inpatient dialysis provider in South Florida, for inpatient dialysis services. More recently, our 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. Our selection is strong validation of SAMI's safety, efficacy, and ease of use. Overall, we are making significant progress, and we intend to build upon these accomplishments throughout the remainder of the year," concluded, Mr. Seto.

**Financial Review**

Revenue for the three-months ended June 30, 2022 was $286,000 compared to $559,000 for the same three-month period in the prior year. For the six-months ended June 30, 2022, revenue was $770,000 compared to $1,305,000 for the same period in 2021, representing a decrease of $535,000, or 41%. 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.

Operating costs for the three-months ended June 30, 2022, were $3,241,000, compared to $3,080,000 for the same period in the preceding year, an increase of $161,000, or 5%. For the six-months ended June 30, 2022, operating costs were $6,413,000 compared to $5,471,000 for the same period in 2021, an increase of $942,000.
While the Company continues to maintain a low cost operating structure for its base business operations, it anticipates its operating costs to increase throughout 2022 as Spectral's Tigris trial enrolment is expected to increase, combined with incremental costs associated with Dialco's upcoming usability trial for DIMI and the increase in field resources for the marketing and commercialization activities of its RRT devices.

Loss for the three-months ended June 30, 2022 was $2,955,000 ($0.011 per share) compared to a loss of$2,521,000 ($0.010 per share) for the same quarter last year. The loss for the six-months ended June 30, 2022 was $5,643,000 ($0.021 loss per share) compared to a loss of $4,166,000 ($0.017 loss per share) for the first six months of 2021.

The Company concluded the second quarter of 2022 with cash of $3,466,000 compared to $8,890,000 cash on hand as of December 31, 2021.

The total number of common shares outstanding for the Company was 268,154,992 at June 30, 2022.

**Corporate Highlights During & Subsequent to the Second Quarter Ended June 30, 2022**

The Company's primary focus continues to be working towards obtaining FDA approval of the PMX treatment; developing the SAMI market; and obtaining regulatory clearance and commercialization of the DIMI platform for home and peritoneal dialysis use.

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

  Recently, University of Michigan randomized their first patient and the clinical staff at U of M witnessed immediate improvement in the patient's status following administration of PMX and was transferred out of the intensive care unit sooner than expected with full discharge from the hospital in under two weeks from admission.

- **Tigris Sites**

  There are currently 14 Tigris sites onboarded and actively enrolling patients. The Company is continuing to consider additional clinical trial sites to allow for the replacement of low performing sites. This would provide maximum potential from fifteen active sites to be screening and enrolling. In addition, we are seeking FDA approval to increase the maximum number of sites from 15 to 25. If permitted we believe this would further accelerate patient enrollment.

- **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 our Tigris site ICUs, the Company targets finalizing its Tigris trial enrollment in mid-2023.

- **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 on boarded 4 EDEN sites and enrolled 17 patients into the observational study.

**Dialco**

- **DIMI Usability Trial**

  The Dialco team is focused on the DIMI usability trial to obtain FDA clearance for in home use and expects first patient enrollment in Q422 with study duration of approximately 18 - 24 months. We continue to work towards formalizing participating trial sites, however our progress continues to experience delays due in part to staffing in dialysis clinics still lagging in the wake of COVID-19, and availability of eligible clinics and hospitals with home dialysis programs

- **SAMI Commercialization**

  SAMI continues to be launched in Canada and the U.S. with successful clinical evaluations ongoing in key hemodialysis centres, as well as expansion of the commercial sales pipeline. Recently, 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. The Company expects to continue to generate revenue in 2022 pursuant to its existing commercial arrangements for SAMI machines and disposables.

**Management Team**

On May 16, 2022, the Company announced the appointment of Samuel Amory as President of Dialco. Mr. Amory is responsible for the operations of Dialco, including the commercialization of its SAMI and DIMI devices. Mr. Amory brings decades of experience in the medical device and dialysis fields. Since 2005, he served as Vice President of the US Renal Therapies division at B. Braun Medical, a leader in fluid therapy and pain management.

**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.

**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)**

| | June 30, 2022 | December 31, 2021 |
|---|---|---|
| | $ | $ |
| | | |
| **Assets** | | |
| **Current assets** | | |
| Cash | 3,466 | 8,890 |
| Trade and other receivables | 100 | 205 |
| Inventories | 463 | 293 |
| Prepayments and other assets | 1,141 | 875 |
| | 5,170 | 10,263 |
| **Non-current assets** | | |
| Right-of-use-asset | 485 | 532 |
| Property and equipment | 382 | 532 |
| Intangible asset | 219 | 228 |
| **Total assets** | **6,256** | **11,555** |
| | | |
| **Liabilities** | | |
| **Current liabilities** | | |
| Trade and other payables | 1,410 | 1,522 |
| Current portion of contract liabilities | 668 | 689 |
| Current portion of lease liability | 94 | 92 |
| | 2,172 | 2,303 |
| **Non-current liability** | | |
| Lease liability | 443 | 490 |
| Non-current portion of contract liabilities | 4,345 | 4,679 |
| **Total liabilities** | **6,960** | **7,472** |
| | | |
| **Shareholders' (deficiency) equity** | | |
| Share capital | 84,509 | 84,357 |
| Contributed surplus | 8,773 | 7,985 |
| Share-based compensation | 8,688 | 7,984 |
| Warrants | 1,463 | 2,251 |
| Deficit | (104,137) | (98,494) |
| Total shareholders' (deficiency) equity | **(704)** | **4,083** |
| **Total liabilities and shareholders' equity** | **6,256** | **11,555** |

# 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, 2022 | Three-months ended June 30, 2021 | Six-months ended June 30, 2022 | Six-months ended June 30, 2021 |
|---|---|---|---|---|
| | $ | $ | $ | $ |
| **Revenue** | **286** | **559** | **770** | **1,305** |
| **Expenses** | | | | |
| Changes in inventories of finished goods and work-in-process | 47 | 106 | 83 | 172 |
| Raw materials and consumables used | 177 | 90 | 289 | 165 |
| Salaries and benefits | 1,303 | 1,554 | 3,096 | 2,814 |
| Consulting and professional fees | 1,018 | 618 | 1,696 | 1,162 |
| Regulatory and investor relations | 140 | 138 | 320 | 274 |
| Travel and entertainment | 118 | 34 | 203 | 60 |
| Facilities and communication | 155 | 76 | 245 | 146 |
| Insurance | 119 | 97 | 238 | 194 |
| Depreciation and amortization | 71 | 72 | 144 | 152 |
| Interest expense on lease liability | 6 | 7 | 13 | 14 |
| Foreign exchange loss | 10 | 53 | 12 | 94 |
| Other (income) expense | (6) | 66 | (9) | 90 |
| Write down of property and equipment to fair value | 83 | 174 | 83 | 174 |
| Gain on disposal of property and equipment | - | (5) | - | (40) |
| | 3,241 | 3,080 | 6,413 | 5,471 |
| **Loss and comprehensive loss for the period** | **(2,955)** | **(2,521)** | **(5,643)** | **(4,166)** |
| **Basic and diluted loss per common share** | **(0.011)** | **(0.010)** | **(0.021)** | **(0.017)** |
| **Weighted average number of common shares outstanding – basic and diluted** | **268,147,683** | **243,543,981** | **268,064,079** | **240,323,764** |

# 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, 2021** | **236,755,745** | **71,870** | **7,981** | **6,771** | **2,418** | **(89,709)** | **(669)** |
| Warrants exercised | 7,457,330 | 4,983 | - | - | (1,627) | - | 3,356 |
| Warrants expired | - | - | 4 | - | (4) | - | - |
| Loss and comprehensive loss for the period | - | - | - | - | - | (4,166) | (4,166) |
| Share-based compensation | - | - | - | 1,007 | - | - | 1,007 |
| **Balance, June 30, 2021** | **244,213,075** | **76,853** | **7,985** | **7,778** | **787** | **(93,875)** | **(472)** |
| Bought deal offering | 23,530,000 | 7,406 | - | - | 1,464 | - | 8,870 |
| Share options exercised | 143,333 | 98 | - | (46) | - | - | 52 |
| Loss and comprehensive loss for the period | - | - | - | - | - | (4,619) | (4,619) |
| Share-based compensation | - | - | - | 252 | - | - | 252 |
| **Balance, December 31, 2021** | **267,886,408** | **84,357** | **7,985** | **7,984** | **2,251** | **(98,494)** | **4,083** |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **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) | - | (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)** |

# Spectral Medical Inc.

Condensed Interim Consolidated Statements of Cash Flows
**In CAD (000s)**
(Unaudited)

| | Six-months ended June 30, 2022 | Six-months ended June 30, 2021 |
|---|---|---|
| | $ | $ |
| **Cash flow provided by (used in)** | | |
| | | |
| **Operating activities** | | |
| Loss and comprehensive loss for the period | (5,643) | (4,166) |
| Adjustments for: | | |
| Depreciation on right-of-use asset | 47 | 47 |
| Depreciation on property and equipment | 88 | 96 |
| Amortization of intangible asset | 9 | 9 |
| Interest expense on lease liability | 13 | 14 |
| Unrealized foreign exchange (gain) loss on cash | (7) | 105 |
| Share-based compensation | 788 | 1,007 |
| Write down of property and equipment to fair value | 83 | 174 |
| Gain on disposal of property and equipment | - | (40) |
| Changes in items of working capital: | | |
| Trade and other receivables | 105 | (31) |
| Inventories | (170) | 52 |
| Prepayments and other assets | (266) | (344) |
| Trade and other payables | (112) | (948) |
| Contract liabilities | (355) | (317) |
| **Net cash used in operating activities** | (5,420) | (4,342) |
| | | |
| **Investing activities** | | |
| Proceeds on disposal of property and equipment | - | 77 |
| Property and equipment acquisitions | (21) | (367) |
| **Net cash used in investing activities** | (21) | (290) |
| | | |
| **Financing activities** | | |
| Lease liability payments | (58) | (56) |
| Share options exercised | 68 | - |
| Warrants exercised | - | 3,356 |
| **Net cash provided by financing activities** | 10 | 1,410 |
| | | |
| **Decrease in cash** | (5,431) | (1,332) |
| Effects of exchange rate changes on cash | 7 | (105) |
| Cash, beginning of period | 8,890 | 5,807 |
| **Cash, end of period** | **3,466** | **4,370** |