



## SPECTRAL ANNOUNCES FIRST QUARTER RESULTS AND PROVIDES CORPORATE UPDATE

**TORONTO, Canada – May 13, 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 first quarter ended March 31, 2022 and provided a corporate update.

Chris Seto, CEO of Spectral Medical, commented, “We are pleased to report continued progress on our Tigris trial. Specifically, enrollment activity ramped up following our February investigator meeting along with the recent protocol amendment acceptance by the FDA allowing for the use of SOFA scoring as inclusion criteria into the study. We have now randomized a total of 34 patients out of the 150 total patients to be enrolled. Additionally, we believe the launch of the EDEN sub-study will provide another tool to support enrollment, as these patients will be considered for the Tigris study. We remain encouraged by the early results from the Tigris trial, as the mortality outcome data to date has been ahead of expectations. Moreover, we continue to target completion of the Tigris trial enrollment in mid-2023.”

Dr. John Kellum, Chief Medical Officer of Spectral, further noted, “We continue to advance the development and commercialization of our SAMI and DIMI devices through our Dialco Medical subsidiary. We remain focused on the start of our DIMI usability trial for home use and we expect first patient enrollment in the third quarter of 2022 with a study duration of approximately 18 months. We appreciate the support of our potential clinical site trial partners who have been working hard to address staffing shortages across the dialysis clinic industry. With the FDA approved protocol amendment to the DIMI home hemodialysis study that simplifies the protocol and allows for extended use for patients, we are now progressing to the site contracting phase.

### Financial Review

Revenue for the three-months ended March 31, 2022 was \$484,000 compared to \$746,000 for the same three month period last year. The majority of the decrease is due to the timing of orders for products.

Operating costs for the quarter ended March 31, 2022, were \$3,172,000 compared to \$2,391,000 for the corresponding period in 2021, representing an increase of \$781,000.

An increase of \$533,000 over the same period in the prior year related to salaries and benefits. In 2021, the Company received funds from the Canada Emergency Wage Subsidy program for \$250,000. This program expired at the end of 2021 and there were no additional funds received in 2022. In addition, the Company expanded its sales/technical specialists in the U.S., in the second quarter of 2021, which resulted in an expense of \$157,000 in the first quarter of 2022 compared to the first quarter of 2021, where there was no expense. In addition, the increase reflects a full quarters expense for the Chief Medical Officer, hired on March 1, 2021 in the prior year. Consulting and professional fees also increased \$134,000 in the first quarter of 2022 compared to the same period a year ago due to increased clinical activity as well as DIMI product development fees.

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 significantly, 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 quarter ended March 31, 2022 was \$2,688,000 (\$0.010 per share) compared a loss of \$1,645,000 (\$0.007 per share) for the same quarter last year.

The Company concluded the first quarter of 2022 with cash of \$6,472,000 compared to \$8,890,000 cash on hand as of December 31, 2021.

The total number of common shares outstanding for the Company was 268,146,781 as at March 31, 2022.

## **CORPORATE HIGHLIGHTS DURING & SUBSEQUENT TO FIRST QUARTER ENDED MARCH 31, 2022**

### **Tigris Trial and Regulatory Program**

- **Patient Enrollment**

Total of 34 patients randomized to-date out of the 150 total to be enrolled in Tigris, with preliminary mortality outcome data continuing to exceed expectations. Of the seven patients enrolled in 2022, four were enrolled as a result of the recent FDA approved protocol amendment allowing for the use of SOFA scoring as inclusion criteria into the study.

An investigator meeting was held in February 2022. This meeting along with the recent protocol amendment acceptance by the FDA has resulted in trial sites responding by reporting renewed patient screening activities – leading to increased enrollment activity in April, with four patients randomized.

- **Tigris Sites**

There are currently 14 Tigris sites onboarded. One site was recently closed out of the Tigris study, as the clinical team concluded there was no path to rehabilitating productive performance at this site. The Company is taking steps to provide maximum potential from fifteen active sites, from a screening and enrolling perspective. The clinical team is continuing to consider additional clinical trial sites to allow for the replacement of low performing sites, and is in the final steps of opening West Virginia University for 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 the Tigris site ICUs, the Company continues to target interim enrollment in Q4 2022, and 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 the Tigris study, which provides another tool to support enrollment.

The Company has onboarded four EDEN sites and enrolled seven patients into the observational study.

- **Commercialization Pre-Launch Activity**

Our relationship with our exclusive distribution partner for PMX in North America continues to strengthen, as our joint committee meetings have advanced further than simply monitoring progress on the Tigris Trial. Our exclusive distribution partner remains committed with a tactical focus on the development of the North American launch of PMX, along with the already commercialized companion diagnostic EAA. These pre-launch activities include developing a broad campaign to bring endotoxins to the forefront and more broadly explain their role as it relates to the pathology of certain septic shock.

### **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 Q3 2022 with study duration of approximately 18 months. The timing of the start of the DIMI usability trial for home hemodialysis has also been impacted by the COVID pandemic. Dialysis clinics are experiencing severe staffing shortages as they work to accommodate current patients as well as respond to an increase in patients with COVID related kidney injury requiring dialysis. On January 31, 2022, the FDA approved an amendment to the DIMI home hemodialysis study that simplifies the protocol and allows for extended use for patients. Management believes that the revised protocol increases study feasibility and should improve enrollment.

- **Medical Advisory Board**

Dialco formed a Medical Advisory Board comprised of leading home hemodialysis experts, with significant experience in clinical research, patient care and patient-centered outcomes related to dialysis in the home. The medical advisory board's focus will be to support in guiding the DIMI usability trial and continued clinical

development of the DIMI device.

- **DIMI Commercialization**

Management believes the 35-patient usability trial represents a prime commercialization opportunity to demonstrate positive real-world experience and the versatility of DIMI amongst Dialco's clinical trial partners, who are also potential DIMI customers. In order to support commercial expansion, and in anticipation to the start-up of the DIMI usability trial, Dialco is expanding its field force for sales training and technical support. Dialco currently has field representatives in Ontario, as well as Pennsylvania, Florida and Michigan, with recruitment initiatives underway for further expansion.

- **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. As hospitals are experiencing a significant shortage of CRRT machines in COVID-19 affected ICUs, there has been increased activity with respect to the use of SAMI in the treatment of COVID-19 positive patients. The Company has successfully developed remote installation, and set-up on-line training for SAMI. The Company expects to continue to generate revenue in 2022 pursuant to its existing commercial arrangements for SAMI machines and disposables.

### **Addition to Spectral Senior Leadership Team**

On March 21, 2022, the Company announced the appointment of Blair McInnis as CFO. He is responsible for overseeing the financial management of the Company, including finance, accounting, treasury, business planning and investor relations. Mr. McInnis has over fifteen years of corporate finance and reporting experience, most recently as Vice President of Finance at SMTC Corporation, a Nasdaq-listed issuer prior to being taken private by HIG in 2021.

### **U.S. Listing Update**

Management and the Board believe a senior U.S. listing aligns with the goals of the business and its stakeholders, and the Company continues to prepare for a potential listing on a senior U.S. exchange.

### **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. Approximately 330,000 patients are diagnosed with severe sepsis and 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)

	March 31, 2022	December 31, 2021
	\$	\$
<b>Assets</b>		
<b>Current assets</b>		
Cash	6,472	8,890
Trade and other receivables	286	205
Inventories	519	293
Prepayments and other assets	1,137	875
	8,414	10,263
<b>Non-current assets</b>		
Right-of-use-asset	508	532
Property and equipment	489	532
Intangible asset	224	228
<b>Total assets</b>	<b>9,635</b>	<b>11,555</b>
<b>Liabilities</b>		
Current liabilities		
Trade and other payables	1,670	1,522
Current portion of contract liabilities	742	689
Current portion of lease liability	93	92
	2,505	2,303
<b>Non-current liability</b>		
Lease liability	467	490
Non-current portion of contract liabilities	4,512	4,679
<b>Total liabilities</b>	<b>7,484</b>	<b>7,472</b>
<b>Shareholders' equity</b>		
Share capital	84,502	84,357
Contributed surplus	7,985	7,985
Share-based compensation	8,595	7,984
Warrants	2,251	2,251
Deficit	(101,182)	(98,494)
<b>Total shareholders' equity</b>	<b>2,151</b>	<b>4,083</b>
<b>Total liabilities and shareholders' equity</b>	<b>9,635</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 March 31, 2022	Three-months ended March 31, 2021
	\$	\$
<b>Revenue</b>	<b>484</b>	<b>746</b>
<b>Expenses</b>		
Changes in inventories of finished goods and work-in-process	36	66
Raw materials and consumables used	112	75
Salaries and benefits	1,793	1,260
Consulting and professional fees	678	544
Regulatory and investor relations	180	136
Travel and entertainment	85	26
Facilities and communication	90	70
Insurance	119	97
Depreciation and amortization	73	80
Interest expense on lease liability	7	7
Foreign exchange loss	2	41
Other (income) expense	(3)	24
Gain on disposal of property and equipment	-	(35)
	3,172	2,391
<b>Loss and comprehensive loss for the period</b>	<b>(2,688)</b>	<b>(1,645)</b>
<b>Basic and diluted loss per common share</b>	<b>(0.010)</b>	<b>(0.007)</b>
<b>Weighted average number of common shares outstanding – basic and diluted</b>	<b>267,980,359</b>	<b>237,067,764</b>

# 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' 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>
Warrants exercised	3,194,732	2,135	-	-	(697)	-	1,438
Loss and comprehensive loss for the period	-	-	-	-	-	(1,645)	(1,645)
Share-based compensation	-	-	-	648	-	-	520
<b>Balance, March 31, 2021</b>	<b>239,950,477</b>	<b>74,005</b>	<b>7,981</b>	<b>7,419</b>	<b>1,721</b>	<b>(91,354)</b>	<b>(228)</b>
Bought deal offering	23,530,000	7,406	-	-	1,464	-	8,870
Share options exercised	143,333	98	-	(46)	-	-	52
Warrants exercised	4,262,598	2,848	-	-	(930)	-	1,918
Warrants expired	-	-	4	-	(4)	-	-
Loss and comprehensive loss for the period	-	-	-	-	-	(7,140)	(7,140)
Share-based compensation	-	-	-	611	-	-	611
<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>267,886,408</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	211,335	114	-	(51)	-	-	63
RSUs released	49,038	31	-	(31)	-	-	-
Loss and comprehensive loss for the period	-	-	-	-	-	(2,688)	(2,688)
Share-based compensation	-	-	-	693	-	-	693
<b>Balance, March 31, 2022</b>	<b>268,146,781</b>	<b>84,502</b>	<b>7,985</b>	<b>8,595</b>	<b>2,251</b>	<b>(101,182)</b>	<b>2,151</b>

# Spectral Medical Inc.

Condensed Interim Consolidated Statements of Cash Flows

In CAD (000s)

(Unaudited)

	Three-months ended March 31, 2022	Three-months ended March 31, 2021
	\$	\$
<b>Cash flow provided by (used in)</b>		
<b>Operating activities</b>		
Loss and comprehensive loss for the period	(2,688)	(1,645)
Adjustments for:		
Depreciation on right-of-use asset	24	23
Depreciation on property and equipment	45	53
Amortization of intangible asset	4	4
Interest expense on lease liability	7	7
Unrealized foreign exchange loss on cash	6	52
Share-based compensation	693	648
Gain on disposal of property and equipment	-	(35)
Changes in items of working capital:		
Trade and other receivables	(81)	(460)
Inventories	(226)	(19)
Prepayments and other assets	(262)	(279)
Trade and other payables	148	(22)
Contract liabilities	(114)	(172)
<b>Net cash used in operating activities</b>	<b>(2,444)</b>	<b>(1,845)</b>
<b>Investing activities</b>		
Proceeds on disposal of property and equipment	-	72
Property and equipment acquisitions	(2)	(189)
<b>Net cash used in investing activities</b>	<b>(2)</b>	<b>(117)</b>
<b>Financing activities</b>		
Lease liability payments	(29)	(28)
Share options exercised	63	-
Warrants exercised	-	1,438
<b>Net cash provided by financing activities</b>	<b>34</b>	<b>1,410</b>
<b>Decrease in cash</b>	<b>(2,412)</b>	<b>(552)</b>
Effects of exchange rate changes on cash	(6)	(52)
Cash, beginning of period	8,890	5,807
<b>Cash, end of period</b>	<b>6,472</b>	<b>5,203</b>