



SPECTRAL ANNOUNCES FOURTH QUARTER AND FISCAL 2021 RESULTS AND CORPORATE UPDATE

TORONTO, Canada – March 24, 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 fourth quarter and for the year ended December 31, 2021 and provided a corporate update.

Chris Seto, CEO of Spectral Medical, commented, “2021 was a foundational year for Spectral and Dialco as we reported key achievements, both clinically and operationally, despite the headwinds presented by several waves of COVID variants. While clinical enrollment activity continued to be negatively impacted, the Company responded quickly and implemented key tools and changes to aide in advancing our clinical programs. On the Tigris front, we recently implemented the FDA protocol amendment allowing sequential organ failure assessment (SOFA) scoring as an inclusion criteria into the study, in conjunction with a full complement of Tigris sites engaged. Along with other sub-study activity, Tigris is well positioned for an expedient and positive outcome. Tigris enrollment now stands at 30 patients randomized out of the 150 total patients to be enrolled. While the sample size is small, we remain highly encouraged by the preliminary mortality outcome data, which continues to exceed expectations. Assuming there is no significant recurrence of COVID-19 variants, we remain committed to completing Tigris trial enrollment in mid-2023.”

“In terms of our Dialco subsidiary, we have experienced site initiation challenges related to staffing shortages across the dialysis clinic industry. Nevertheless, we have taken a number of steps to help us advance the DIMI trial. In January 2022, the FDA approved an amendment to the DIMI home hemodialysis study that simplifies the protocol and allows for extended use for patients, which should improve enrollment by addressing both patient and clinical logistics flow issues experienced throughout the industry. We have progressed to the site contracting phase and anticipate initial patient enrolment into our DIMI usability trial for home use in the third quarter of 2022.”

Dr. John Kellum, Chief Medical Officer of Spectral, further noted, “We are witnessing the positive impact, including robust use, of the new SOFA scoring as an inclusion criteria for screening in the Tigris trial, especially in the first quarter of 2022. Additionally, the initiation of the EDEN sub-study could have a positive impact on recruitment as these patients will be considered for the Tigris study. Moreover, our recent FDA-approved amendment to our DIMI study simplifies the protocol and allows for extended use for patients, which could have a positive impact on enrollment.”

Mr. Seto concluded, “Overall, we remain very encouraged by the outlook for the business. We believe our clinical programs are on solid footing, backed by great technologies. Our relationship with our exclusive distribution partner for PMX in North America continues to strengthen, as we work closely on pre-launch activities including 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. At the same time, we continue to strengthen our leadership and advisory resources, with the recent appointment of Blair McInnis as CFO of Spectral, and the formation of our Dialco Medical Advisory Board comprised of world-class home hemodialysis experts. We will continue to add key personnel – specifically executive leadership at Dialco in the coming months, which will help accelerate both our clinical and commercial activities around both the DIMI and SAMI devices. In terms of the SAMI device, we are focused on deploying devices in the field and gaining clinical awareness, and we are seeing a robust pipeline of SAMI activities, which we look to capitalize on in 2022. In the meantime, we continue to carefully manage expenses and have maintained a solid balance sheet. As a result, we believe Spectral is well positioned in both the sepsis and home hemodialysis markets, both of which represent multi-billion-dollar addressable markets.”

Financial Review

Revenue for the three months ended December 31, 2021 was \$517,000 compared to \$535,000 for the same three month period last year. Revenue for the year ended December 31, 2021 was \$2,052,000 compared to \$2,101,000 for the prior year, representing a decrease of \$49,000, or 2%. The majority of the decrease is due to the decrease in royalty revenue. This was mitigated by an increase in product revenue, and revenue from the exclusive

distribution agreement with Baxter International Inc. ("Baxter").

For the quarter ended December 31, 2021, the Company reported operating costs of \$3,069,000 compared to \$2,682,000 for the corresponding period in 2020. Operating costs for the year ended December 31, 2021 amounted to \$10,837,000 compared to \$11,199,000 in 2020. The decrease relates to non-recurring fees payable to a financial advisory services firm incurred in the first quarter of 2020, relating to a legacy financial advisory agreement. In addition, it incurred approximately \$275,000 in professional fees in connection with a withdrawn prospectus offering in early March 2020. The decrease was partially offset by increased clinical trial activity for Tigris, EDEN and the DIMI usability trials, as well as the fees from a professional employment organization that manages Dialco's field force in the United States.

The Company continues to maintain a low cost operating structure for its base business operations. The Company 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 December 31, 2021 was \$2,552,000 (\$0.010 per share) compared a loss of \$2,147,000 (\$0.009 per share) for the same quarter last year. For the year ended December 31, 2021, the Company reported a loss of \$8,785,000, (\$0.03 per share), compared to a loss of \$9,098,000 (\$0.04 per share), for the year ended December 31, 2020.

The Company concluded the 2021 year with cash of \$8,890,000 compared to \$5,807,000 cash on hand as of December 31, 2020.

The total number of common shares outstanding for the Company was 267,886,408 as at December 31, 2021.

CORPORATE HIGHLIGHTS DURING & SUBSEQUENT TO FOURTH QUARTER AND FISCAL YEAR ENDED DECEMBER 31, 2021

Tigris Trial and Regulatory Program

- **SOFA Score Amendment**

On November 29, 2021, the Company announced that the United States Federal Food and Drug Agency ("FDA") approved a protocol amendment to its Tigris trial allowing for the use of sequential organ failure assessment ("SOFA") scoring as inclusion criteria into the study, which should have a significantly positive impact on enrollment.

- **Patient Enrollment**

Total of 30 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 three patients enrolled in early 2022, two 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

- **Tigris Sites**

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. 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.

- **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 the first half of 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.

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 California, 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 Chief Financial Officer (effective April 4, 2022). Mr. McInnis brings over 15 years of corporate finance and financial reporting experience. Most recently, he served as Vice President Finance at SMTC Corporation, a provider of global electronics manufacturing services with annualized revenues in excess of \$450 million, where he managed financial reporting, budgeting, treasury management and forecasting for the organization. During his tenure, he helped oversee the financial aspects of the acquisition and privatization of the Company by H.I.G. Capital, a leading global private equity firm, prior to which, SMTC was listed on Nasdaq.

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.

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)

	December 31, 2021 \$	December 31, 2020 \$
Assets		
Current assets		
Cash	8,890	5,807
Trade and other receivables	205	260
Inventories	293	348
Prepayments and other assets	875	389
	10,263	6,804
Non-current assets		
Right-of-use-asset	532	625
Property and equipment	532	488
Intangible asset	228	246
Total assets	11,555	8,163
Liabilities		
Current liabilities		
Trade and other payables	1,522	2,141
Current portion of contract liabilities	689	676
Current portion of lease liability	92	85
	2,303	2,902
Non-current liability		
Lease liability	490	582
Non-current portion of contract liabilities	4,679	5,348
Total liabilities	7,472	8,832
Shareholders' equity (deficiency)		
Share capital	84,357	71,870
Contributed surplus	7,985	7,981
Share-based compensation	7,984	6,771
Warrants	2,251	2,418
Deficit	(98,494)	(89,709)
Total shareholders' equity (deficiency)	4,083	(669)
Total liabilities and shareholders' equity (deficiency)	11,555	8,163

Spectral Medical Inc.

Consolidated Statements of Loss and Comprehensive Loss
For the years ended December 31, 2021 and 2020

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

	2021 \$	2020 \$
Revenue	2,052	2,101
Expenses		
Changes in inventories of finished goods and work-in-process	286	127
Raw materials and consumables used	546	501
Salaries and benefits	5,163	4,750
Consulting and professional fees	2,707	4,064
Regulatory and investor relations	612	541
Travel and entertainment	270	146
Facilities and communication	293	361
Insurance	389	248
Depreciation and amortization	294	304
Interest expense on lease liability	28	32
Foreign exchange loss (gain)	58	(7)
Other expense	93	148
Write down of property and equipment	181	-
Gain on disposal of property and equipment	(83)	(16)
	10,837	11,199
Loss and comprehensive loss for the year	(8,785)	(9,098)
Basic and diluted loss per common share	(0.03)	(0.04)
Weighted average number of common shares outstanding – basic and diluted	252,464,462	232,502,463

Spectral Medical Inc.

Consolidated Statements of Changes in Shareholders' (Deficiency) Equity
For the years ended December 31, 2021 and 2020

(in thousands of Canadian dollars)

	Issued capital		Contributed surplus	Share-based compensation	Warrants	Deficit	Total Shareholders' (deficiency) equity
	Number	\$	\$	\$	\$	\$	\$
Balance, January 1, 2020	225,876,683	66,837	7,981	6,183	1,870	(80,611)	2,260
Public offering	8,500,000	3,526	-	-	788	-	4,314
Share options exercised	1,279,062	772	-	(292)	-	-	480
Warrants exercised	1,100,000	735	-	-	(240)	-	495
Loss and comprehensive loss for the year	-	-	-	-	-	(9,098)	(9,098)
Share-based compensation	-	-	-	880	-	-	880
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

Spectral Medical Inc.

Consolidated Statements of Cash Flows
For the years ended December 31, 2021 and 2020

(in thousands of Canadian dollars)

	2021 \$	2020 \$
Cash flow provided by (used in)		
Operating activities		
Loss for the year	(8,785)	(9,098)
Adjustments for:		
Depreciation on right-of-use asset	93	94
Depreciation on property and equipment	183	193
Amortization of intangible asset	18	17
Interest expense on lease liability	28	32
Unrealized foreign exchange loss on cash	56	187
Share-based compensation	1,259	880
Write down of expired consumables	106	-
Write down of property and equipment	181	-
Gain on disposal of property and equipment	(83)	(16)
Changes in items of working capital:		
Trade and other receivables	55	11
Inventories	(51)	(72)
Prepayments and other assets	(486)	(234)
Contract asset	-	519
Trade and other payables	(619)	1,139
Contract liabilities	(656)	6,024
Net cash used in operating activities	(8,701)	(324)
Investing activities		
Proceeds on disposal of property and equipment	158	18
Property and equipment expenditures	(483)	(315)
Net cash used in investing activities	(325)	(297)
Financing activities		
Proceeds from financing	10,000	5,100
Transaction costs paid	(1,130)	(786)
Lease liability payments	(113)	(109)
Share options exercised	52	480
Warrants exercised	3,356	495
Net cash provided by financing activities	12,165	5,180
Increase in cash	3,139	4,559
Effects of exchange rate changes on cash	(56)	(187)
Cash, beginning of year	5,807	1,435
Cash, end of year	8,890	5,807