

November 8, 2023

MANAGEMENT'S DISCUSSION & ANALYSIS
(All figures are expressed in thousands of Canadian dollars)

This Management's Discussion & Analysis ("MD&A") for the nine-months ended September 30, 2023 has been prepared to help investors understand the financial performance of Spectral Medical Inc. ("Spectral" or the "Company") in the broader context of the Company's strategic direction, the risks and opportunities as understood by management, and the key success factors that are relevant to the Company's performance. Management has prepared this document in conjunction with its broader responsibilities for the accuracy and reliability of the condensed interim consolidated financial statements and accompanying notes, which have been prepared in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board (IFRS), including IAS 34, "Interim Financial Reporting", as well as the development and maintenance of appropriate information systems and internal controls to ensure that the financial information is complete and reliable. The Finance and Audit Committee of the Board of Directors has reviewed this document and all other publicly reported financial information for integrity, usefulness, reliability and consistency.

This MD&A is dated November 8, 2023 and should be read in conjunction with the condensed interim consolidated financial statements for the nine-months ended September 30, 2023, and the audited annual consolidated financial statements of the Company for the years ended December 31, 2022 and December 31, 2021 ("Annual Financial Statements"), as well as management's discussion and analysis for the year ended December 31, 2022.

FORWARD LOOKING STATEMENTS

Certain statements contained in this MD&A constitute forward-looking information within the meaning of securities law. Forward-looking information may relate to our future outlook and anticipated events or results and may include statements regarding our future financial position, business strategy, budgets, litigation, projected costs, capital expenditures, financial results, taxes and plans and objectives. In some cases, forward-looking information can be identified by terms such as "may", "will", "should", "expect", "plan", "anticipate", "believe", "intend", "estimate", "predict", "potential", "continue" or other similar expressions concerning matters that are not historical facts. These statements are based on certain factors and assumptions regarding, among other things, expected growth, results of operations, performance and business prospects and opportunities. While we consider these assumptions to be reasonable based on information currently available to us, they may prove to be incorrect. Forward looking-information is also subject to certain factors, including risks and uncertainties that could cause actual results to differ materially from what we currently expect. These factors include, among other things, the availability of funds and resources to pursue development projects, the successful and timely completion of clinical studies, and the ability of the Company to take advantage of business opportunities, the granting of necessary approvals by regulatory authorities as well as general economic, market and business conditions. For more exhaustive information on these risks and uncertainties you should refer to our most recently filed Annual Information Form which is available at www.sedar.com. Forward-looking information contained in this MD&A is based on our current estimates, expectations and projections, which we believe are reasonable as of the current date. You should not place undue importance on forward-looking information and should not rely upon this information as of any other date. While we may elect to, we are under no obligation and do not undertake to update this information at any particular time.

This document and the related consolidated financial statements can also be viewed on the Company's website at www.spectraldx.com and at www.sedar.com. The Company's Annual Information Form and Management Information Circular are also available on these websites.

INTRODUCTION

The Company's primary strategic focus is on the regulatory development and commercialization of its products in the area of septic shock. The Company's products for the treatment of septic shock include its EAA™ diagnostic and PMX therapeutic device. If approved, this will be the first targeted therapy guided by a specific diagnostic in the area of sepsis. Furthermore, the Company is continuing its legacy business of manufacturing and selling certain proprietary reagents.

ENDOTOXIN ACTIVITY ASSAY (“EAA™”)

Spectral has pioneered the development of biochemical markers for the clinical syndrome known as “septic shock”. In 2003, the Company achieved U.S. Food and Drug Administration (“FDA”), Health Canada (“HC”) and European CE clearance of the EAA™ for the first recognized rapid test for the risk of developing sepsis in the Intensive Care Unit (“ICU”). In North America alone over 1,700,000¹ patients are diagnosed with the clinical syndrome of sepsis annually. Approximately 425,000² patients develop septic shock in the ICU, with a mortality rate at approximately 50%³. The Company's addressable market, which is comprised of patients suffering from endotoxemic septic shock, represents an estimated 140,000 patients per year. Earlier identification and treatment of patients at risk for sepsis reduces mortality and saves significant cost by reducing the length of stay in the ICU and by helping to guide therapeutic interventions. Spectral's EAA™ endotoxin activity measurement is the only FDA cleared diagnostic for this indication currently on the market.

POLYMYXIN B-HEMOPERFUSION (“PMX”)

PMX is a therapeutic hemoperfusion device that removes endotoxin from the bloodstream. PMX has been on the market in many countries outside the U.S. and has been used in more than 340,000⁴ patients to date, and has demonstrated in clinical trials that it safely (fewer than 0.01% adverse events) and effectively removes endotoxin and reduces mortality in patients with septic shock.

PROPRIETARY REAGENTS

Spectral develops, produces and markets recombinant proteins, antibodies and calibrators. These materials are sold for use in research and development as well as in products manufactured by other diagnostic companies.

¹ Centers for Disease Control and Prevention, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Healthcare Quality Promotion (DHQP) August 9, 2022

² *Critical Care Medicine* 46(12): p 1889-1897, December 2018

³ National Centre for Emerging and Zoonotic Infectious Disease (NCEZID); Centers for Disease Control and Prevention, Division of Health Care Quality Promotion (DHCQP) data reports, 2016.

⁴ Report of Prior Investigations (“ROPI”) is a report that is part of the Code of Federal Regulations, from September 1994 to January 2022.

DIALCO AND INVESTMENT IN iDIALCO JOINT ARRANGEMENT

Dialco Medical Inc. (“Dialco”) was incorporated in 2019 as a medical device start-up as a subsidiary of Spectral. Dialco was formed with the objective to commercially develop the SAMI and DIMI dialysis machines. SAMI is a proprietary Continuous Renal Replacement Therapy (“CRRT”) device focused on the acute market (ICU dialysis) and sub-acute markets. Dialco commenced procurement and development of SAMI units in 2017 but has had limited sales activity, with the first commercial sales occurring in 2020.

DIMI is a hemodialysis (HD) device focused on the chronic market (skilled nursing facilities and in-home). The DIMI device is not FDA approved for in-home use, and requires a home usability trial (“DIMI Trial”) prior to commercialization activities.

The DIMI Trial experienced challenges in securing participating sites to enroll patients in addition to complexity in running a trial where patients would have to be monitored while in-home. It was difficult to accurately budget for the cost of completing the DIMI Trial, but Spectral expected costs to exceed \$10,000. In order to pursue and complete the DIMI Trial, external funds would have been required. In 2022 Spectral engaged an investment bank and initiated a broad funding campaign reaching out to over 100 potential investors. The targeted audience of potential investors were predominantly healthcare and medical device-focused investors, which included private equity, venture capital, family offices, institutional investors of varying sizes, as well as potential strategic partners operating in the dialysis sector. The capital raise process was unsuccessful and Spectral was unable to find investors that were interested in investing in Dialco. With Spectral being unable to secure financing to support the DIMI Trial, on December 12, 2022, Spectral negotiated and entered into the joint arrangement with Infomed SA (“Infomed”), obtaining 30% interest in iDialco joint venture (the “iDialco”), whereby Infomed would fund operating expenditures of iDialco in addition to seeking to fund the DIMI Trial. iDialco will development and manufacture blood purification devices, exclusively focused on commercializing the SAMI and DIMI dialysis devices in the North American markets.

Summary of key benefits of the iDialco joint venture:

- While holding a minority 30% ownership, Spectral maintains a strong governance position with certain key majority approval requirements including but not limited to debt financing arrangements, issuance of new shares, corporate changes and various fundamental changes;
- The iDialco operations are fully funded by Infomed in addition to future development costs of both the SAMI and DIMI units. Spectral no longer has the financial obligation to fund operations, SAMI and DIMI development costs or the DIMI Trial, which is estimated to cost in excess of \$10,000 USD to complete;
- Spectral maintains access to procure SAMI units, with removal of any minimum order quantities, should they be required to support PMX commercialization strategies, use in the Tigris Trial or sub studies it may undertake from time to time;
- Spectral can focus existing financial and human capital resources on the Tigris Trial and ultimately the commercialization of PMX.

As at September 30, 2023, Spectral’s investment in iDialco was \$794 (\$998 – as of December 31, 2022). With the investment in iDialco, Spectral is no longer focused on the dialysis device market, and therefore the Dialco operations were considered discontinued as at December 31, 2022.

CLINICAL DEVELOPMENT

The Company's clinical development program continues to focus on obtaining FDA approval for PMX. Below is a summary of key clinical development updates during 2022 and 2023;

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 (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/breakthrough-devices-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.

On August 18, 2022, the Company announced FDA approval to add up to 10 additional Tigris clinical trial sites. This approval allows for an increase to 25 trial sites. The Company believes the addition of sites will have a positive impact on patient enrollment rates into the Tigris trial.

On March 23, 2023, the Company engaged a new contract research organization ("CRO"), Beaufort. Beaufort has extensive experience with ICU clinical trials and brings a strong regulatory group, experienced biostats personnel, and additional clinical field resources. Full transition from the incumbent CRO was completed in September 2023. As part of its engagement, Beaufort is reviewing and evaluating recruitment and enrollment processes on a site-by-site basis of Tigris sites.

On April 6, 2023, the Company announced positive results from the EUPHAS-2 clinical trial. This study included 50 critically ill Endotoxemic Septic Shock patients assessed with Spectral's EAA diagnostic and treatment with PMX. The study reported a 28-day mortality of just 36% with the treated patients versus a predicted 75% mortality utilizing the widely accepted SAPS II mortality estimation tool. This represents more than a 50% estimated relative mortality reduction with the use of PMX. The patient population of the EUPHAS-2 study aligns with the patient population of the Tigris Trial.

On May 17-18, 2023, the Company held a Tigris trial investigator meeting in Charlotte, North Carolina. The in-person meeting was attended by principal investigators and clinical research coordinators from all existing and new trial sites, as well as the Company's new CRO, Beaufort. Also in attendance were representatives from the Company's strategic partner Baxter.

COMMERCIALIZATION INITIATIVES

The Company has taken a number of other operational and strategic measures to prepare itself for commercialization.

On February 4, 2020, the Company announced that it had completed an exclusive distribution agreement with Baxter International Inc. ("Baxter"), for PMX and EAA™ in the U.S. and Canada. As part of this agreement, Baxter has the right to pay the Company a series of milestone payments including a non-refundable US\$5,000 upfront rights payment, which was received in February 2020. Under the terms of the agreement, Baxter will be the Company's exclusive distributor of the PMX filter in the U.S. and Canada. Baxter also has non-exclusive rights to distribute EAA™ globally. Under the terms of the agreement, the Company is entitled to access Baxter's market capabilities while retaining control over the PMX regulatory process. Baxter has the option to maintain exclusive rights for PMX distribution through future milestone payments and maintaining minimum purchase requirements for PMX products.

Pursuant to the November 2, 2022 private placement, Baxter International Inc. (NYSE: BAX) (“**Baxter**”) agreed to purchase certain of the Notes in connection with an amendment to a portion of the initial milestone payment due to the Company under the Distribution Agreement.

On January 6, 2023, Baxter announced a corporate re-organization, in which it will spin-off its Renal and Acute Therapies business, into an independent, publicly traded entity (“Vantive”) expected to take 12-18 months to complete. With respect to Spectral’s partnership with Baxter, the Company has been dealing with the Acute Therapies business unit; as such, we anticipate our exclusive distribution agreement will be transferred to Vantive at the time of the spin-off.

May 5, 2023, Baxter announced a new CEO of the proposed Vantive business.

On Aug 22, 2023, Spectral executed a collaborative research agreement with Baxter Healthcare Corporation whereby it will provide certain clinical research services for the Prismax sub study. Specifically, the sub study aims to obtain approval for hemoperfusion for Baxter’s Prismax device, which could be utilized in the commercial phase to administer the PMX therapy upon FDA approval of PMX.

Pursuant to the September 7, 2023 private placement, Baxter agreed to purchase certain of the Notes in connection with an amendment to a portion of the second milestone payment due to the Company under the Distribution Agreement.

OPERATIONS

The Company continues to focus its activities on its regulatory programs to achieve FDA approval of the PMX treatment for endotoxemic septic shock. The Company also continues to sell its EAA™ diagnostic under the terms of existing commercial arrangements. Proprietary reagents continue to sell under regular purchase orders as issued by customers. Below is a summary of key Operational updates during 2022 and 2023;

On March 21, 2022, the Company announced the appointment of Blair McInnis as CFO, who assumes the role from Chris Seto who continues in his role as CEO. 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.

On December 12, 2022, the Company entered into a joint arrangement with Infomed SA (“Infomed”), obtaining 30% interest in iDialco joint venture (the “iDialco”), whereby Infomed would fund operating expenditures of iDialco in addition to seeking to fund the DIMI Trial. iDialco will develop and manufacture blood purification devices, exclusively focused on commercializing the SAMI and DIMI dialysis devices in the North American markets. With the establishment of iDialco, the previous Dialco operations were considered discontinued as at December 31, 2022.

On May 4, 2023, Mr. Jim Funk tendered his resignation from the Board of Directors of the Company, Mr. Funk served as a member of the Board of Directors since June 20, 2022.

On June 27, 2023, the Company announced that it had appointed Dr. David W. Feigal to its Board of Directors. Dr. Feigal brings over four decades of experience in regulatory affairs and clinical research of medical devices, biologics, and products in multiple therapeutic areas. Currently, Dr. Feigal is a Partner at NDA Partners LLC, a ProPharma Company, which is a life sciences management consulting and contract

development organization (CDO) focused on providing product development and regulatory services to the pharmaceutical, biotechnology, and medical device industries worldwide. He has also worked for major U.S. and international life science corporations such as Amgen, Inc. serving as Vice President of Global Regulatory Affairs, and Elan Pharmaceuticals, Inc., serving as Senior Vice President of Global Regulatory Affairs and Global Safety Surveillance and Biostatistics. He has an extensive track record of international regulatory success with the approval/clearance of medical products in numerous therapeutic areas.

On October 2, 2023, Mr. Nosenzo tendered his resignation from the Board of Directors of the Company due to health reasons. Mr. Nosenzo served as a member of the Board of Directors since August 2020

OPERATING RESULTS

REVENUE

Revenue for three-months ended September 30, 2023, was \$397 compared to \$362 for the same period last year, representing an increase of \$35, or 9.7%. Revenue for nine-months ended September 30, 2023, was \$1,233 and \$1,114 for the same period last year, representing an increase of \$119, or 10.7%. This increase was mainly due to an increase in proprietary biochemicals product revenue.

Royalty revenue for nine-months ended September 30, 2023 was \$126 compared to \$164 for the same nine-month period in 2022. The underlying patent associated with royalty revenue expired in February, 2022. There will be no further revenue from this customer in the future.

Changes in product revenue for the three and nine-months September 30, 2023 are detailed below:

Three-months ended September 30				
	2023	2022	Change	Change
	\$	\$	\$	%
Product revenue				
Proprietary biochemicals	116	75	41	55%
EAA™ diagnostic	70	52	18	35%
Instrumentation	0	68	(68)	100%
Total Product revenue	186	195	(9)	(4.61%)

Nine-months ended September 30				
	2023	2022	Change	Change
	\$	\$	\$	%
Product revenue				
Proprietary biochemicals	349	161	188	117%
EAA™ diagnostic	150	200	(50)	(25%)
Instrumentation	63	88	(25)	(28)%
Total Product revenue	562	449	113	25%

EXPENSES

Operating expenses for the three-months ended September 30, 2023, were \$3,658, compared to \$2,705 for the same period in the prior year, an increase of \$953, or 35.2%. The change is primarily due to an increase of \$265 in consulting and professional fees primarily due to increased site and patient fees related to the Tigris trial and Eden observational study. Interest expense increased \$167 primarily related to the Notes Payable, which was not outstanding in the same period in the prior year. Foreign exchange loss increased by \$127 over the same period in the prior year, primarily related to foreign exchange loss on USD cash balances.

Operating expenses for the nine-months ended September 30, 2023, were \$10,215, compared to \$7,552 for the same period in the preceding year, an increase of \$2,663, or 35.2%. The change is due to an increase in share-based compensation of \$295. In addition, consulting and professional fees increased by \$1,240 primarily due to increased site and patient fees related to the Tigris trial and Eden observational study. Interest expense increased \$410 primarily related to the Notes Payable, which was not outstanding in the same period in the prior year. Lastly, loss incurred on joint arrangement was \$205 which was not incurred for the same period in the prior year.

Clinical development and regulatory program costs (as disclosed in Note 11 of the condensed interim consolidated financial statements) are \$1,263 for the three-months ended September 30, 2023 compared to \$1,177 for the same period in the prior year. For the nine-months ended September 30, 2022, clinical development costs are \$3,258 compared to \$2,362 for the corresponding period in the prior year. A significant portion of clinical trial and regulatory costs consists of consulting and professional fees paid to contract research organizations, clinical sites, and other clinical and regulatory consultants. The increase in costs reflects increased activity with respect to the initialization of clinical sites and the randomization of patients into the Tigris clinical trial and the EDEN observational study.

Loss

Loss for the three-months ended September 30, 2023 was \$3,391, or \$0.01 per share, compared to a loss of \$3,135, or \$0.01 per share, for the same quarter last year. The increased loss of \$256 was due to increased operating expenses, partially offset by a reduction in loss from discontinued operations of \$662 related to the reduction in Dialco operating expenses.

Loss for the nine-months ended September 30, 2023 was \$9,107, or \$0.02 per share, compared to a loss of \$8,778, or \$0.01 per share, for the same quarter last year. The increased loss of \$329 was due to increased operating expenses, partially offset by a reduction in loss from discontinued operations of \$2,215 related to the prior Dialco operating expenses.

SECURITIES OUTSTANDING

The total number of securities outstanding for the Company as at September 30, 2023 is as follows:

	Number
Common shares	278,576,261
Share options	12,366,158
RSUs	4,118,240
DSUs	2,712,847
PSUs	3,000,000
Warrants	18,714,014

ACCOUNTING STANDARDS ADOPTED IN THE CURRENT YEAR

There were no new standards or amendments to standards and interpretations that have been applied in preparing the condensed interim consolidated financial statements with the exception of the following:

a. IAS 1, 'Presentation of Financial Statements'

In February 2021, the IASB issued an amendment to IAS 1 to improve accounting policy disclosures and to help users of the financial statements to distinguish between changes in accounting estimates and changes in accounting policies. The amendment was adopted on January 1, 2023. The amendment did not have a material impact on its consolidated financial statements.

IAS 12, 'Income Tax'

In May 2021, the IASB issued an amendment to IAS 12 requiring companies to recognize deferred tax on transactions that, on initial recognition, give rise to equal amounts of taxable and deductible temporary differences. The amendment was adopted on January 1, 2023. The amendment did not have a material impact on its consolidated financial statements.

Other accounting standards or amendments to existing accounting standards that have been issued, but have future effective dates, are either not applicable or are not expected to have a significant impact on the Company's consolidated financial statements.

SELECTED QUARTERLY FINANCIAL DATA

(In CAD (000s), except for Share and per Share data)

The following table summarizes the quarterly financial information for the Nine-months ended September 30, 2023:

Nine-months ended September 30, 2023	First Quarter	Second Quarter	Third Quarter
	\$	\$	\$
Revenue	530	306	397
Loss and comprehensive loss for the year from continuing operations	(1,734)	(3,988)	(3,261)
Income (Loss) from discontinued operations	(43)	49	(130)
Loss and comprehensive loss for the year	(1,777)	(3,939)	(3,391)
Basic and diluted loss from continuing operations per common share	(0.01)	(0.01)	(0.01)
Basic and diluted loss from discontinued operations per common share	(0.00)	(0.00)	(0.00)
Basic and diluted loss per common share	(0.01)	(0.01)	(0.01)
Weighted average number of common shares outstanding – basic and diluted	278,547,804	278,552,182	278,604,718

The following table summarizes the quarterly financial information for the year ended December 31, 2022 and the comparative year ended December 31, 2021

Year ended December 31, 2022	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
Revenue	477	276	362	552	1,667
Loss and comprehensive loss from continuing operations	(2,039)	(2,056)	(2,343)	(1,158)	(7,597)
Loss and comprehensive loss from discontinued operations	(649)	(899)	(792)	(1,314)	(3,653)
Loss and comprehensive loss	(2,688)	(2,955)	(3,135)	(2,472)	(11,250)
Basic and diluted loss per Share	(0.01)	(0.011)	(0.012)	(0.009)	(0.04)
Weighted average number of Shares outstanding	267,980,359	268,147,683	268,283,387	274,903,419	269,843,447

Year ended December 31, 2021	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
Revenue	700	553	230	512	1,995
Loss and comprehensive loss from continuing operations	(1,451)	(2,073)	(1,410)	(2,026)	(6,960)
Loss and comprehensive loss from discontinued operations	(194)	(448)	(657)	(526)	(1,825)
Loss and comprehensive loss	(1,645)	(2,521)	(2,067)	(2,552)	(8,785)
Basic and diluted loss per Share	(0.007)	(0.01)	(0.008)	(0.01)	(0.003)
Weighted average number of Shares outstanding	237,067,764	243,543,981	260,928,039	267,886,408	2,524,643,462

BALANCE SHEET, FINANCIAL CONDITION AND GOING CONCERN

Cash of \$5,031 as at September 30, 2023, decreased by \$3,383 from \$8,414 as at December 31, 2022. The decrease in cash in the third quarter of 2023 was primarily due to the funding of operating and working capital requirements. Cash is primarily used for the Company's Tigris clinical trial for its PMX treatment for endotoxemic septic shock including data analysis and submission of documentation to the FDA, the EDEN observational study, and for general corporate and working capital purposes.

	September 30, 2023	September 30, 2022
	\$	\$
Net cash used in operating activities	(9,065)	(7,642)
Net cash used in investing activities	-	(90)
Net cash provided by financing activities	5,683	
Change in cash	(3,383)	(7,732)
Effects of Exchange rate of changes on cash	-	33
Cash, beginning of the period	8,414	8,890
Cash, end of the period	5,031	1,191

As described in Note 1 of the condensed interim consolidated financial statements, management has assessed the Company's ability to continue as a going concern and concluded that it is dependent on the successful execution of management's operating and strategic plan, which includes among other things, securing additional financing, the commercialization of its products, the continued financial support of its shareholders and, ultimately, the attainment of future profitable operations. There are no assurances that any of these initiatives will be successful. Factors within and outside the Company's control could have a significant bearing on its ability to obtain additional financing.

The Company's September 30, 2023 condensed interim consolidated financial statements do not reflect the adjustments to the carrying amounts of assets and liabilities and the reported expenses and balance sheet classifications that would be necessary if the Company were unable to realize its assets and settle its liabilities as a going concern in the normal course of operations. Such adjustments could be material.

RELATED PARTIES

All related parties and the respective transactions have been disclosed in Note 13 of the condensed interim consolidated financial statements for the nine-months ended September 30, 2023 and 2022.

1. Toray Industries, Inc. (“Toray”)

Toray holds 45,630,105 Shares of the Company as at September 30, 2023, representing approximately 16.40% (December 31, 2022 – 16.90%) of Spectral’s issued and outstanding Shares, calculated on a non-diluted basis.

Toray is entitled to certain pre-emptive rights, including pre-emptive rights upon issuance of additional Shares.

Toray is entitled to nominate one director (the “Toray Representative”) to the Board of Directors as long as it owns in the aggregate not less than 10% of the Shares issued and outstanding calculated on a non-diluted basis.

The principal transactions with Toray which were carried out in the ordinary course of business are:

	<i>Three- months ended September 30, 2023</i>	<i>Three- months ended September 30, 2022</i>	<i>Nine- months ended September 30, 2023</i>	<i>Nine- months ended September 30, 2022</i>
	\$	\$	\$	\$
Revenue				
Toray Medical Co., Ltd.	-	-	-	68
Purchases				
Toray International America Inc.	-	-	-	40
Due (to)				
Toray Medical Co., Ltd.	-	-	-	-
Toray International America Inc.	-	-	-	-

2. Birch Hill Equity Partners Management Inc. (“Birch Hill”)

Birch Hill, through a number of its funds and an investee company, holds 36,210,017 Shares of the Company as at September 30, 2023 representing approximately a 13% (December 31, 2022 – 13%) ownership interest, calculated on a non-diluted basis.

Birch Hill is entitled to certain pre-emptive rights, including pre-emptive rights upon issuance of additional Shares.

Birch Hill is entitled to nominate one director to the Company’s Board of Directors so long as it owns in aggregate not less than 5% of the issued and outstanding Shares of the Company calculated on a non-diluted basis.

3. iDialco Inc. (“iDialco”)

On December 12, 2022, Spectral entered into a joint arrangement with Infomed SA, obtaining 30% interest in iDialco. iDialco develops and manufactures blood purification devices, exclusively focused on commercializing the SAMI and DIMI dialysis devices in the North American markets.

For the period ended September 30, 2023, the Company invoiced iDialco \$711, of which pertained to passthrough costs, primarily related to employee services rendered, which are expected to fully transfer by the end of 2023.

4. Key management consists of the Company's executive officers and its Board of Directors.

There are no other related party transactions.

OUTLOOK

The Company's primary focus continues to be working towards obtaining FDA approval of the PMX treatment; and progressing pre-commercialization launch activities for PMX.

TIGRIS

During and subsequent to the third quarter of 2023, we continued to make progress with our initiatives to increase the pace of enrollment in the Tigris Trial in addition to productivity at each site. The Tigris study has 76 patients enrolled and 20 active sites at the time of this MD&A.

Below is a summary of key updates to these initiatives:

- During and subsequent to the third quarter the Company enrolled an additional eleven patients, of which nine or approximately 80% came from new sites opened for enrollment in 2023;
- 76 patients enrolled to date and the Company continues to close in on its interim target of 90 patients, an important milestone as Spectral's strategic commercial partner, Baxter (BAX:NYSE), will have the opportunity to view the data as well as provide a second milestone payment to Spectral;
- Addition of two new trial sites, the Mayo Clinic and Emory Healthcare, subsequent to the third quarter bringing current total trial sites to 20;
- During the third quarter, full transition from the incumbent CRO, Beaufort was completed;
- Spectral Medical was featured in an episode of the 'The Balancing Act' airing on Lifetime TV (Advancing Therapeutic Options for Sepsis and Endotoxic Septic Shock - The Balancing Act) focused on advancing therapeutic options for sepsis and endotoxic septic shock, which was aired during the quarter; and
- On September 7, 2023, Spectral completed a private placement of convertible notes for gross proceeds of USD\$4,553,000 led by the Company's strategic investors Baxter and Pinnacle Island LP.
- On September 7, 2023, Spectral completed its private placement and received USD\$4,553,000 in convertible notes payable (the "Notes"). 4,553 Notes were issued and have a face value of USD \$ 1,000 per Note, bearing interest of 9% and are due November 1, 2026 (the "maturity date"). Holders of the Notes may convert all or any portion of the Notes into common shares of the company in integral multiples of US\$ 1,000 principal amount at any time prior to the Maturity Date. The notes are convertible into approximately 15,475,647 Common Shares representing a conversion price of approximately CAD\$0.40 per share subject to certain anti-dilution and make-whole fundamental change adjustments. Paradigm Capital Inc. was the Underwriter for the bought deal private placement

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 executed an agreement with Baxter during the quarter for a sub-study to obtain FDA approval for hemoperfusion for Baxter's Prismax device; the Prismax with its leading installed base, is anticipated to be the primary device utilized for PMX treatments on commercial launch.

BUSINESS RISKS

The Company's operations are exposed to a variety of risk factors inherent in new product development. The Company's short operating history in its new endeavors makes prediction of future operating results difficult. Actual future results may differ significantly from those projected in any forward-looking statements. Key business risks for the Company are detailed in its most recent Annual Information Form, which is available at www.sedar.com.

RISK MANAGEMENT

1. FINANCIAL RISK MANAGEMENT

In the normal course of business, the Company is exposed to a number of financial risks that can affect its operating performance. These risks are: credit risk, liquidity risk and market risk. The Company's overall risk management program and prudent business practices seek to minimize any potential adverse effects on the Company's financial performance.

a. Credit Risk

Credit risk is the risk of a financial loss to the Company if a customer or counterparty to a financial instrument fails to meet its contractual obligation. Financial instruments that potentially expose the Company to significant credit risk consist of cash, and trade and other receivables.

- i. Cash: The Company places its cash with Canadian Schedule I banks.
- ii. Trade and other receivables: The Company sells its products to distribution partners in major markets. The credit risk associated with the accounts receivable pursuant to these agreements is evaluated during initial negotiations and on an ongoing basis. There have been no events of default under these agreements. As at September 30, 2023 and 2022, no significant accounts receivable balances were considered impaired.

b. Liquidity Risk

Liquidity risk is the risk that the Company will encounter difficulty in meeting obligations associated with its financial liabilities as they become due. The Company is exposed to liquidity risk, as it continues to have net cash outflows to support its operations. The Company's objective for liquidity risk management is to maintain sufficient liquid financial resources to meet commitments and obligations in the most cost-effective manner possible.

The Company achieves this by maintaining sufficient cash and managing working capital. The Company monitors its financial resources on a weekly basis and updates its expected use of cash resources on the latest available data.

The Company will need additional capital to fund its clinical and regulatory programs and commercialization of the Toraymyxin™ therapeutic. Potential sources of capital could include equity and/or debt financings, the collection of revenues resulting from commercialization activities and/or new strategic partnerships.

There can be no assurance that the Company will be able to obtain sufficient capital to meet any or all of the Company's needs. The availability of equity or debt financing will be affected by, among other things, the ability to obtain regulatory approvals, the market acceptance of its products, the state of the capital market generally, strategic alliance agreements and other relevant commercial considerations. In addition, if the Company raised additional funds by issuing equity securities, its existing security holders will likely experience dilution, and any incurrence of additional debt would result in debt service obligations and could require the Company to agree to operating and financial covenants that would restrict its operations. Any failure on the Company's part to raise additional funds on terms favorable to it, or at all, may require it to significantly change or curtail its current or planned operations in order to conserve cash until such time, if ever, that sufficient proceeds from operations are generated, and could result in the Company not taking advantage of business opportunities, the curtailment of its product development programs, the sale or assignment of rights to its technologies and/or products and the inability to file market approval applications at all or in time to competitively market its products.

All of the Company's financial liabilities, except for lease liabilities, contract liabilities and notes payable, are classified as current liabilities. Trade and other payables were \$2,314 as at September 30, 2023 (December 31, 2022 - \$3,167) which have expected settlement dates within one year.

c. Market Risk

- i. **Currency risk:** The majority of the Company's revenue is denominated in U.S. dollars and Euros. As at September 30, 2023, cash included US \$4,251 (September 30, 2022 – US \$100). Trade and other receivables included a total of US \$236 and € 52 (September 30, 2022 - US\$11 and €nil). Trade and other payables included a total of US \$682, €13, (September 30, 2022 - US\$893, €26 and ¥nil). There is no active hedging program currently in place due to the relatively short time frame for settlement of these balances.
- ii. **Interest rate risk:** The Company has no significant exposure to fluctuations in interest rates.

2. CAPITAL RISK MANAGEMENT

The Company's primary objective when managing capital is to safeguard its ability to continue as a going concern and to provide returns for shareholders by ensuring it maintains sufficient levels of cash for working capital and operating purposes, as well as funding to pursue the commercialization efforts of its core products. Capital consists of share capital, contributed surplus, other equity reserves, and deficit. In order to maintain or adjust the capital structure, the Company may issue new Shares from time to time.

CRITICAL ACCOUNTING ESTIMATES

The condensed interim consolidated financial statements of Spectral are prepared in accordance with IFRS as set out in the CPA Canada Handbook. The Company has identified the accounting policies and estimates that are critical to the understanding of the Company's operation and financial results in the consolidated financial statements. Certain policies are selected by management and approved by the Finance and Audit Committee of the Board of Directors. These policies are set out in Note 3 (xxv.) of the consolidated financial statements for the years ended December 31, 2022 and 2021. Certain policies are more significant than others and are, therefore, considered critical accounting estimates. Accounting policies are considered to be critical if they rely on a substantial amount of judgment in their application or if they result from a choice between accounting alternatives and that choice has a material impact on the reported results or financial position.

Management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reporting period. The most significant estimates are related to the accrual estimates made for clinical trial and regulatory program expenses, recognition and measurement of leases, and the assessment of performance obligations for contracts where technology transfers, licensing, manufacturing support and where one or more other goods or services are bundled into a single contract. Actual results could differ from those estimates.

CONTINGENCIES AND COMMITMENTS

- i. The Company has committed to expenditures for its clinical and regulatory program, which are disclosed in Note 8 of the condensed interim consolidated financial statements for the nine-months ended September 30, 2023 and 2022. In addition, the Company is committed to certain future lease payments primarily in connection with the leased premises.

The contractual undiscounted cash flows of the Company's lease liabilities are as follows:

	September 30, 2023
	\$
Not later than one year	121
Later than one year and not later than five years	535
Total undiscounted lease liability at September 30, 2023	656

In December 2021, the Company extended its Unit #2 lease term for an additional five years, expiring August 31, 2027. In September 1, 2023 Company signed an addendum lease agreement for Unit # 4 for an additional seven year, expiring September 30, 2030

- ii. Directors and officers are indemnified by the Company for various items including, but not limited to, costs to settle lawsuits or actions due to their association with the Company, subject to certain restrictions. The Company has purchased directors' and officers' liability insurance to mitigate the costs of any potential future lawsuits or actions. The term of the indemnification covers the period during which the indemnified party served as a director or officer of the Company.

In the normal course of business, the Company has entered into agreements that include indemnities in favor of third parties, such as purchase and sale agreements, confidentiality agreements, engagement letters with advisors and consultants, leasing contracts and license agreements. These indemnification arrangements may sometimes require such third parties to compensate counterparties for losses as a result of breaches in representations, covenants and warranties provided by the Company or as a result of litigation or other third party claims or statutory sanctions that may be suffered by the counterparties as a consequence of the relevant transaction. In some instances, the terms of these indemnities are not explicitly defined. No accruals have been required to be made as at September 30, 2023 with respect to these agreements.

FINANCIAL INSTRUMENTS AND FAIR VALUES

Financial assets and financial liabilities have been classified into categories that determine their basis of measurement and, for items measured at fair value, whether changes in fair value are recognized within operating loss in the consolidated statement of loss and comprehensive loss.

The Company has designated the following classifications for its financial assets and financial liabilities:

Cash and trade and other receivables are classified as financial assets at amortized cost with a total carrying value of \$5,751 at September 30, 2023 (December 31, 2022 - \$9,470).

Trade and other payables are classified as other financial liabilities, which are measured at amortized cost using the effective interest rate method, with a total carrying value of \$2,314 at September 30, 2023 (December 31, 2022 - \$3,167).

Cash, trade and other receivables, lease liabilities and trade and other payables are reflected in the consolidated financial statements at carrying values that approximate fair values because of the short-term maturities of these financial instruments.

DISCLOSURE CONTROLS AND INTERNAL CONTROLS

Management's responsibility for financial reporting

Disclosure controls and procedures and internal controls over financial reporting

As at September 30, 2023, management has disclosure controls and procedures ("DC&P") that provide reasonable assurance that information required to be disclosed by the Company in its filings under Canadian securities legislation is recorded, processed, summarized and reported in a timely manner. The system of DC&P includes, among other things, the Company's Corporate Disclosure and Whistleblower policies and Code of Conduct, the review and approval procedures of the Disclosure Committee and continuous review and monitoring procedures by senior management.

As at September 30, 2023, management has designed internal controls over financial reporting ("ICFR") within the Company in order to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with IFRS. These controls were designed based on the framework established by Internal Control - Integrated Framework: 2013 issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Due to its inherent limitations, ICFR may not prevent or detect misstatements. In addition, the design of any system of control is based upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all future events, no matter how remote, or that the degree of compliance with the policies or procedures may not deteriorate. Accordingly, even effective ICFR can only provide reasonable, not absolute, assurance of achieving the control objectives for financial reporting.

Changes in internal controls over financial reporting

There have been no changes to the Company's internal controls over financial reporting during the three months ended September 30, 2023 that have materially affected, or are reasonably likely to materially affect, its internal controls over financial reporting.

An evaluation of the design and effectiveness of the Company's DC&P and ICFR has been conducted by management, under the supervision of the Chief Executive Officer (CEO) and Chief Financial Officer (CFO). Based on this evaluation, the CEO and CFO have concluded that, as of December 31, 2022, the Company's disclosure controls and procedures and internal control over financial reporting, as defined by National Instrument 52-109 – Certification of Disclosure in Issuers' Annual and Interim Filings, are operating effectively.