

## **MANAGEMENT'S DISCUSSION & ANALYSIS**

**(All figures are expressed in thousands of Canadian dollars)**

This Management's Discussion & Analysis ("MD&A") for the three and nine-months ended September 30, 2020 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 10, 2020 and should be read in conjunction with the condensed interim consolidated financial statements for the three and nine-months ended September 30, 2020, and the audited annual consolidated financial statements of the Company for the years ended December 31, 2019 and 2018 ("the Annual Financial Statements"), as well as the MD&A for the year ended December 31, 2019.

### **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](http://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 condensed interim consolidated financial statements can also be viewed on the Company's website at [www.spectraldx.com](http://www.spectraldx.com) and at [www.sedar.com](http://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 to develop and commercialize a treatment for septic shock utilizing 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. In addition, the Company is taking steps to co-develop a complimentary platform initially targeting the renal replacement therapy ("RRT") segment of the market and is continuing its legacy business of manufacturing and selling certain proprietary reagents.

### 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 1,700,000<sup>1</sup> patients are diagnosed with the clinical syndrome of sepsis annually. Approximately 330,000<sup>2</sup> patients develop severe sepsis and septic shock in the ICU, with a mortality rate between 30% and 50%<sup>2</sup>. 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 measurement is the only FDA cleared diagnostic for this indication currently on the market.

### PMX

PMX is a therapeutic hemoperfusion device that removes endotoxin from the bloodstream. PMX has been used in approximately 200,000<sup>3</sup> patients to date globally and has demonstrated in clinical trials that it safely and effectively removes endotoxin and reduces mortality in patients with severe sepsis and 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.

### RRT

The Company entered into the RRT business by acquiring the rights to SAMI, an easy-to-use dialysis machine on which to use its PMX cartridges, from Infomed S.A. ("Infomed"). The Company entered into a manufacturing and supply agreement with Infomed on December 1, 2018. The agreement expires on December 31, 2026, with a provision to extend it for additional two-year terms.

SAMI complements the PMX/EAA™ development, as it can be used to deliver the Company's therapy in the ICU and reduces reliance on third party instrumentation. This state-of-the-art equipment will enable the Company to provide a fully integrated and user-friendly septic shock treatment system to the ICU. In addition, SAMI is also designed to provide an open platform for other hemoperfusion cartridges and to deliver continuous renal replacement therapy ("CRRT") when indicated.

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<sup>1</sup> 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.

<sup>2</sup> National (Nationwide) Inpatient Sample ("NIS") database, 2013.

<sup>3</sup> Report of Prior Investigations ("ROPI") is a report that is part of the Code of Federal Regulations, from September 1994 to January 2020.

On December 13, 2017, the Company received 510(k) clearance from the FDA for SAMI for use in CRRT and therapeutic plasma exchange (“TPE”). Since it has also been designed as an open platform hemoperfusion delivery device, the Company intends to seek further 510(k) clearance for this purpose when there is an FDA approved hemoperfusion cartridge available for use in the U.S. market, including potentially the Company’s PMX treatment.

On February 18, 2018, the Company announced that HC approved SAMI, under License No. 100541 for use in CRRT, TPE, as well as for Hemoperfusion (“HP”), a modality specifically designed to facilitate patient treatment with the PMX cartridge.

On March 8, 2018, SAMI received a CE mark in Europe for the same applications.

The Company decided to test SAMI in the broader CRRT market and entered into its first exclusive distribution agreement on January 1, 2019. The agreement was amended on November 1, 2019 and will expire on December 31, 2021.

The Company has exclusive license rights for SAMI in North America for all CRRT applications and has worldwide exclusivity for any hemoperfusion applications.

On March 18, 2019, Dialco entered into a development, licence and exclusive distribution agreement with Infomed to extend its license to include the North American exclusive rights to an easy-to-use home hemodialysis machine (“DIMI”), built on the same platform as SAMI. The Company is seeking to obtain regulatory approval for DIMI in Canada and the United States for in-home use. DIMI is already CE marked for hemodialysis in Europe by Infomed. The initial license term expires on March 18, 2021, with some conditional provisions to extend it for four successive five-year terms, including achieving certain regulatory milestones and raising funds for commercialization.

As part of this transition, Spectral transferred its RRT business to its wholly owned subsidiary, Dialco Medical Inc. (“Dialco”) in 2019.

Dialco continues its commercialization efforts for SAMI both in the U.S. and in Canada. The regulatory submission to the FDA for DIMI was completed on October 25, 2019. On August 31, 2020, the Company received FDA 510(k) clearance for DIMI to treat patients with acute and/or chronic renal failure with or without fluid overload using hemodialysis (“HD”), hemodiafiltration (“HDF”), hemofiltration (“HF”) and/or ultrafiltration (“UF”) in hospital or clinical settings. This is the first major step of the full regulatory development of DIMI. Further advances will be clearance for home and peritoneal dialysis use. Dialco also submitted an application to HC to add DIMI as a new product under the SAMI family of products.

## **CLINICAL DEVELOPMENT**

The Company’s clinical development program continues to focus on obtaining FDA approval for PMX.

On March 6, 2009, Spectral signed a license agreement with Toray Industries, Inc. of Japan granting Spectral the exclusive development and commercial rights in the U.S. for PMX, a therapeutic device for the treatment of septic shock that removes endotoxin from the bloodstream. Under the terms of the agreement, Spectral is seeking FDA approval for PMX and, if successful intends to commercialize the product, together with its EAA™, the only FDA cleared diagnostic for the measurement of endotoxin. On May 29, 2019, an amendment to the

agreement was made to amend the expiry date of the licence agreement from December 31, 2029 to December 31, 2034.

On February 26, 2010, the Company received final approval of its Investigational Device Exemption (“IDE”) from the FDA, which permitted the Company to conduct a pivotal trial for PMX (the “EUPHRATES” trial) in the U.S., and later, Canada.

In October 2010, the Company announced the initiation of its EUPHRATES trial (Evaluating the Use of Polymyxin B Hemoperfusion in a Randomized controlled trial of Adults Treated for Endotoxemia and Septic shock) in the U.S. comparing standard of care versus PMX plus standard of care.

In November 2010, the Company announced that it entered into a long-term, exclusive distribution agreement with Toray Industries, Inc. and Toray Medical Co., Ltd. to market and sell Toraymyxin™ in Canada.

Top line results for the Company’s pivotal Phase III EUPHRATES trial were announced on October 3, 2016. Although the trial did not statistically achieve its primary endpoint, the trial results did show that use of the PMX cartridge is safe and demonstrated a five (5) percent reduction in mortality at 28 days in the sickest group of patients (MODS>9) who were treated with two PMX cartridges. This was a pre-specified population which, in addition to a mortality benefit, showed beneficial treatment effects across multiple secondary endpoints and that the mortality benefit increased as a function of the amount of endotoxin removed.

The EUPHRATES study also showed that endotoxemia remains a major cause of the unacceptably high mortality of patients in septic shock. It is the only trial to have been designed to show the relationship between endotoxemia (based on a reliable method of measurement) and its removal with a cartridge specifically designed to remove endotoxin.

The database for the EUPHRATES trial contains detailed data on the clinical characteristics of 450 randomized subjects with high levels of endotoxin. These subjects were followed closely over 28 days for changes in endotoxin levels, as well as for other details of the clinical course of their septic shock episode.

The detailed analysis of the EUPHRATES trial database showed that there appears to be an upper limit to a patient’s pre-treatment burden of endotoxin as measured by the EAA, above which the trial could not demonstrate benefit for the PMX cartridge.

In patients with septic shock, MODS>9 and a baseline EAA  $\geq 0.6$  and  $< 0.9$  (n=194) the PMX treatment group demonstrated an absolute reduction in mortality of 14% at 14 days (p=0.0103), 10.7% at 28 days (p =0.0474) and 11% at 90 days (p=0.0383), when baseline APACHE and mean arterial pressure were controlled in each arm. At 28 days, the relative reduction in mortality was 30%. Survival over time analysis showed a statistically significant and sustained increase in survival at all three time points: 52% risk reduction at 14 days (Hazard Ratio [“HR”] 0.48, p=0.0189), 42% risk reduction at 28 days (HR 0.585, p= 0.0429) and 41% risk reduction at 90 days (HR 0.594, p=0.0373).

In this patient population, an improvement in organ function was seen in the PMX treated group compared to the sham group. There was a statistically significant increase in mean arterial blood pressure 72 hours post treatment for the PMX group (p=0.0462) and a substantial increase in days alive and free from mechanical ventilator support [median difference of 14 days, (p=0.0043)].

Furthermore, the trial data indicates that for patients where no bacteria could be identified by culture yet were highly endotoxemic (approximately one third of the n=194 group), treatment with the PMX cartridge had a 28-

day mortality of 21% versus 42% for the sham group ( $p=0.046$ ), a relative risk reduction of 50%. These patients appear to be at higher risk for baseline mortality, with endotoxemia likely due to translocation of endotoxin from the gastro-intestinal system. With no microbiology targets to treat there are fewer options left to help these patients.

On March 16, 2018, the FDA notified the Company that it had determined that more evidence is required to make a final determination to approve the PMX cartridge. The FDA acknowledged the unmet need for therapies in septic shock patients who face a high risk of death, and the challenges in performing clinical studies in this vulnerable patient population. Therefore, the FDA encouraged the Company to utilize mechanisms other than randomized placebo-controlled trials (such as the EUPHRATES trial) to add to the evidence already submitted, and they provided the Company with several less burdensome examples, including single arm studies, data obtained outside the U.S. and real world registries. In addition, the FDA offered to discuss Spectral's proposal for further data collection in order to develop a mutually agreeable plan.

During the later part of 2018, the Company was engaged with the FDA in an interactive Q-sub process for the design and format for the next trial required to add to the safety and efficacy data from the EUPHRATES trial. This follow-on trial, "Tigris", is expected to focus specifically on the population of patients that showed a benefit in the EUPHRATES trial.

Tigris is using the same primary endpoint of 28-day mortality and is expected to enroll 150 patients with a MODS score  $> 9$  and endotoxin levels between 0.60 and 0.90, as measured by the EAA™ companion diagnostic. Patients will be randomized 2:1 for treatment vs. control arm and it will be open label. The trial will employ a Bayesian statistical approach to combine data from the two trials. The FDA mandated the Tigris trial to use ten clinical sites from the EUPHRATES trial.

On February 19, 2019, the Company announced that the Tigris trial has been approved by the FDA as an amendment to the original EUPHRATES's IDE and, therefore, data collected in the Tigris trial can be incorporated into the data collected from the EUPHRATES trial.

On September 20, 2019, the Company held its first Investigator Meeting for the Tigris trial, where investigators and coordinators demonstrated their enthusiasm and support for the trial at the site level.

In October 2019, the Company obtained FDA approval whereby SAMI will be used to deliver hemoperfusion in the Tigris trial.

On April 14, 2020, the Company announced that the FDA approved an IDE for PMX to treat COVID-19 patients suffering from septic shock, and is a supplement to the Company's current Tigris trial. The IDE supplement approval recognizes that there is sufficient safety and effectiveness data to allow clinicians to use PMX to treat patients that are similar to patients in the Tigris trial, plus are COVID-19 positive. Increased levels of endotoxin activity have been identified in COVID-19 patients in Asia, Italy and the U.S. Several COVID-19 patients have been treated with PMX in the U.S.

Similarly, the Company announced on April 20, 2020, that Health Canada issued an Interim Order expanding the already approved indication for use of PMX for patients with COVID-19.

There is a scientific case for the use of PMX in COVID-19 patients. PMX has been used to treat patients during other analogous viral pandemics including the avian flu (H5N1) and swine flu (H1N1) pandemics, which also resulted in acute respiratory distress syndrome. In previous publications, the use of PMX during these similar

viral pandemics showed improvement in chest x-ray results and lung function, and successful weaning from mechanical ventilation.

Recruitment of patients into the trial is currently being negatively impacted by the COVID-19 pandemic. In the third quarter of 2020, there were nine initiated clinical sites. Of these nine sites, six sites experienced suspended research activities due to the COVID-19 pandemic. By the beginning of September 2020, all Tigris sites had resumed their research activities and were actively screening. All of these sites are experienced in using the PMX cartridge and demonstrated a better than average enrollment rate in the EUPHRATES trial. On August 10, 2020, the FDA approved a protocol amendment to increase the number of Tigris sites to fifteen from ten in the initial protocol. The increase in the number of sites could potentially offset enrollment delays experienced to-date, with access to a potentially much larger population of eligible patients. At the date of this MD&A, there are eleven initiated clinical sites in Tigris.

PMX is marketed in Japan and Europe and has been used to treat more than 200,000<sup>3</sup> sepsis patients safely and effectively. Spectral's EAA™ can identify patients that are most likely to benefit from PMX and monitor the effects of the treatment. This combination of the EAA™ diagnostic and the PMX therapeutic has been utilized by clinicians in Europe since November 2007 and has demonstrated a reduction in mortality.

## **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 Toraymyxin™ PMX-20R 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 on February 21, 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 the 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.

SAMI continues to be launched in Canada and the U.S. for use as a RRT machine. It continues successful clinical evaluation in key hemodialysis centres and building its commercial sales pipeline. As hospitals are experiencing a significant shortage of CRRT machines in COVID-19 affected ICU's, 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, set-up and high-level on-line training of SAMI.

## **OPERATIONS**

The Company continues to focus its activities on its regulatory program 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. Previously, the Company anticipated a multi country launch of EAA™ with an existing distribution partner in mid Q4 2020, which now has been delayed. Proprietary reagents continue to sell under regular purchase orders as issued by customers. The Company is continuing its efforts in the commercialization of SAMI as well as the development and commercialization of DIMI.

On June 4, 2020, Mr. Chris Seto, was appointed as the Company's COO, where he will oversee the daily operations of the Company, in addition to his responsibilities as the Company's CFO.

On August 4, 2020, the Company announced the appointment of Mr. John Nosenzo as an independent director to the Board of Directors.

## OPERATING RESULTS

### REVENUE

Revenue for the three-months ended September 30, 2020 was \$418 compared to \$534 for the same period in the prior year. For the nine-months ended, September 30, 2020, revenue was \$1,566 compared to \$2,122 for the same period in 2019, representing a decrease of \$556, or 26%.

Royalty revenue for the three-months ended September 30, 2020 was \$151, an increase of \$121 from \$30 for the same period in the prior year. This is due to an increase in usage of the Company's IP from one customer. Royalty revenue for the nine-months ended September 30, 2020 of \$547 (2019: \$100) increased due to the timing and recognition of revenue from a technology access fee, as well as the increase in usage of the Company's IP.

Technology transfer revenue decreased by \$534 for both the three and nine-months ended September 30, 2020 as the Company completed its performance obligations in connection with the technology transfer and manufacturing support agreement in 2019.

The Company also began to recognize the revenue relating to the exclusive distribution agreement with Baxter, as described above. The Company is recognizing revenue from the US\$5,000 (CA\$6,629) non-refundable upfront payment on a straight-line basis over the initial nine-year and eleven-month term of the agreement. This amounted to revenue of \$167 and \$445 for the three and nine-months ended September 30, 2020, respectively.

Changes in product revenue for the three and nine-months ended September 30, 2020 are detailed below:

	Three-months ended September 30, 2020				Nine-months ended September 30, 2020			
	2020 \$	2019 \$	Change \$	% Change	2020 \$	2019 \$	Change \$	% Change
<b>Product revenue</b>								
Proprietary biochemicals	87	221	(134)	(61%)	356	595	(239)	(40%)
EAA™ diagnostic	-	96	(96)	(100%)	140	333	(193)	(58%)
Instrumentation	-	-	-		20	39	(19)	(49%)
RRT	13	187	(174)	(93%)	58	521	(463)	(89%)
<b>Total Product revenue</b>	<b>100</b>	<b>504</b>	<b>(404)</b>		<b>574</b>	<b>1,488</b>	<b>(914)</b>	

The decrease in product revenue has decreased mainly due to the timing of orders. In addition, RRT revenue of \$187 and \$521 for the three and nine-months ended September 30, 2019 represents the Company's first completed shipments as part of an exclusive distribution agreement signed in 2019. In late 2019, the customer shifted its business model to an asset light CRRT service provider and amended the exclusive distribution agreement. As such, future sales under this agreement are not expected. RRT revenue is expected to increase as SAMI is launched in Canada and the United States.

## EXPENSES

Operating costs for the three-months ended September 30, 2020, were \$1,995, compared to \$1,935 for the same period in the preceding year, an increase of \$60, or 3%. For the nine-months ended, September 30, 2020, operating costs are \$8,517 compared to \$5,568 for the same period in 2019, an increase of \$2,949, or 53%.

The change in costs are primarily due to an increase in salaries and benefits, consulting and professional fees, and the impact of foreign exchange movements.

Salaries and benefits are \$1,014 and \$3,505 for the three and nine-month periods ended September 30, 2020 respectively, compared to \$954 and \$2,614 for the same periods in the prior year, an increase of \$60 and \$891 respectively. This is due to: i) the addition of the Company's CFO, who joined in August 2019, and ii) the weighted average of the fair value of share options granted in 2020, is \$0.531, compared to \$0.324 for share options granted in 2019, resulting in increased share compensation expense.

Consulting and professional fees are \$418 and \$3,612 for the three and nine-months ended, September 30, 2020, compared to \$423 and \$1,064 for the three and nine-months ended September 30, 2019. This represents a decrease of \$5 for the three-months ended September 30, 2020 and an increase of \$2,548, respectively. The increase is largely comprised of a US\$1,343 (CA\$1,830) fee payable to a financial advisory services firm incurred in the first quarter of 2020, relating to a legacy financial advisory agreement as described in Note 8 of the condensed interim consolidated financial statements. In addition, the Company continues to ramp up activity for its clinical development and regulatory program; and it incurred approximately \$275 in professional fees in connection with the withdrawn prospectus offering in early March 2020.

Clinical development and regulatory program costs (as disclosed in Note 13 of the condensed interim consolidated financial statements) were \$393 for the three-months ended September 30, 2020 compared to \$427 for the same period in the prior year. For the nine-months ended September 30, 2020, clinical development costs were \$1,435 compared to \$868 for the corresponding period in the prior year. A significant portion of clinical trial and regulatory costs is comprised of consulting and professional fees paid to the contract research organization, clinical sites, and other clinical and regulatory consultants. These costs are expected to increase as the Company continues to randomize patients into the trial. Cumulative trial and regulatory program costs total \$45,149 as of September 30, 2020.

The Company recorded a foreign exchange loss of \$110 for the three-month period ended September 30, 2020, compared to a foreign exchange gain of \$35 for the same period in 2019. For the nine-months ended, the Company incurred a foreign exchange gain of \$144, compared to a foreign exchange loss of \$70 for the nine-months ended September 20, 2019. The CAD/USD foreign exchange rate decreased from 1.4187 to 1.3339 on March 31, 2020 to September 30, 2020 respectively, effectively reversing a portion of the unrealized foreign exchange gain of \$464 at March 31, 2020 on the Baxter upfront payment, which has been retained in a US dollar bank account.

## Loss

For the three-months ended September 30, 2020, the Company reported a loss of \$1,577 (\$0.007 loss per Share) compared to a loss of \$1,401 (\$0.006 loss per Share) for the three-months ended September 30, 2019. The loss for the nine-months ended September 30, 2020 was \$6,951 (\$0.030 loss per Share) compared to a loss of \$3,446 (\$0.015 loss per Share) for the first nine months of 2019.

**SEGMENT PERFORMANCE****Three-months ended September 30, 2020**

	<b>Spectral Medical Inc.</b>	<b>Dialco Medical Inc.</b>	<b>Corporate</b>	<b>Total</b>
Revenue	405	13	-	418
Expenses	1,002	223	770	1,995
Segment loss for the period	(597)	(210)		

**Nine-months ended September 30, 2020**

	<b>Spectral Medical Inc.</b>	<b>Dialco Medical Inc.</b>	<b>Corporate</b>	<b>Total</b>
Revenue	1,508	58	-	1,566
Expenses	4,831	704	2,982	8,517
Segment loss for the period	(3,323)	(646)		
Intercompany due from/(to)	1,647	(1,647)		

**Three-months ended September 30, 2019**

	<b>Spectral Medical Inc.</b>	<b>Dialco Medical Inc.</b>	<b>Corporate</b>	<b>Total</b>
Revenue	534	-	-	534
Expenses	1,019	176	740	1,935
Segment loss for the period	(485)	(176)		

**Nine-months ended September 30, 2019**

	<b>Spectral Medical Inc.</b>	<b>Dialco Medical Inc.</b>	<b>Corporate</b>	<b>Total</b>
Revenue	2,122	-	-	2,122
Expenses	3,649	338	1,581	5,568
Segment loss for the period	(1,527)	(338)		
Intercompany due from/(to)	431	(431)		

**SECURITIES OUTSTANDING**

The total number of securities outstanding for the Company as at September 30, 2020 is as follows:

	<b>Number</b>
Common shares	236,605,745
Share options	9,016,825
Warrants	12,232,331

On June 4, 2020, the shareholders' approved a special resolution (the "Share Consolidation Resolution"), authorizing an amendment to the Company's articles to consolidate the issued and outstanding Shares ("the Consolidation"), based on a consolidation ratio in the range of one post-Consolidation Share for ten pre-Consolidation Shares to one post-Consolidation Share for twenty pre-Consolidation Shares, as determined by the Board of Directors in their sole discretion.

## ACCOUNTING STANDARDS ADOPTED IN THE CURRENT PERIOD

A number of new standards and amendments to standards and interpretations were effective for annual periods beginning on or after January 1, 2020 and have been applied in preparing these condensed interim consolidated financial statements.

a. *IAS 1, 'Presentation of Financial Statements', and IAS 8, 'Accounting Policies, Changes in Accounting Estimates and Errors (Amendment)'*

In October 2018 the IASB issued '*Definition of Material (Amendments to IAS 1 and IAS 8)*' to clarify the definition of 'material' and to align the definition used in the Conceptual Framework and the standards themselves. The amendments are effective for annual reporting periods beginning on or after January 1, 2020. The Company adopted these amendments to IAS 1 and IAS 8 effective January 1, 2020 and determined that there was no impact on the Company's condensed interim consolidated financial statements.

b. *Conceptual Framework for Financial Reporting*

Together with the revised '*Conceptual Framework*' published in March 2018, the IASB also issued '*Amendments to References to the Conceptual Framework in IFRS Standards*'. The amendments are effective for annual periods beginning on or after January 1, 2020. The Company adopted these amendments to IAS 1 effective January 1, 2020 and determined that there was no impact on the Company's condensed interim consolidated financial statements.

c. *IFRS 3, 'Definition of a Business'*

In October 2018, the IASB issued an amendment that revises the definition of a business. The amendment aims to resolve the difficulties that arise when an entity determines whether it has acquired a business or a group of assets. The mandatory effective date was for annual periods beginning on or after January 1, 2020. The Company adopted this amendment effective January 1, 2020 and determined that there was no impact on the Company's condensed interim consolidated financial statements.

## ACCOUNTING STANDARDS ISSUED BUT NOT YET APPLIED

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 condensed interim consolidated financial statements. These are as follows:

a. *IAS 1, 'Presentation of Financial Statements'*

The amendment to IAS 1 clarifies how to classify debt and other liabilities as either current or non-current. The amendment will be effective for periods beginning on or after January 1, 2022. The Company is currently evaluating the new guidance and impacts on its consolidated financial statements.

b. *IFRS 3, 'Reference to Conceptual Framework'*

In May 2020, the IASB issued an amendment to IFRS 3 to (i) clarify references to the 2018 Conceptual Framework in order to determine what constitutes an asset or liability in a business combination, (ii) add an exception for certain liabilities and contingent liabilities to refer to IAS 37 or IFRIC 21 and (iii) clarify that an acquirer should not recognize contingent assets at the acquisition date. The mandatory effective date would

be annual periods beginning on or after January 1, 2022, with early adoption permitted. The amended standard is not expected to have an impact on the consolidated financial statements.

c. IAS 37, 'Onerous Contracts – Cost of Fulfilling a Contract'

In May 2020, the IASB issued an amendment to IAS 37 to clarify which costs to include in estimating the cost of fulfilling a contract for the purpose of assessing whether that contract is onerous. The mandatory effective date would be annual periods beginning on or after January 1, 2022, with early adoption permitted. The amended standard is not expected to have an impact on the consolidated financial statements.

### SELECTED QUARTERLY FINANCIAL DATA

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

The following tables summarize quarterly financial information for the year ended December 31, 2019 and the comparative year ended December 31, 2018:

<b>Year ended December 31, 2019</b>	<b>First Quarter</b>	<b>Second Quarter</b>	<b>Third Quarter</b>	<b>Fourth Quarter</b>	<b>Total</b>
Revenue	547	1,041	534	746	2,868
Loss and comprehensive loss	(993)	(1,052)	(1,401)	(1,414)	(4,860)
Basic and diluted loss per Share	(0.004)	(0.005)	(0.006)	(0.006)	(0.02)
Weighted average number of Shares outstanding	225,591,183	225,675,249	225,816,183	225,838,590	225,731,215

<b>Year ended December 31, 2018</b>	<b>First Quarter</b>	<b>Second Quarter</b>	<b>Third Quarter</b>	<b>Fourth Quarter</b>	<b>Total</b>
Revenue	1,163	234	579	1,864	3,840
Loss and comprehensive (loss) income	(714)	(1,510)	(709)	444	(2,489)
Basic and diluted (loss) earnings per Share	(0.003)	(0.007)	(0.003)	0.002	(0.01)
Weighted average number of Shares outstanding	207,584,717	221,666,203	225,591,183	225,591,183	220,172,675

The following tables summarize quarterly financial information for the nine-months ended September 30, 2020:

<b>Nine-months ended September 30, 2020</b>	<b>First Quarter</b>	<b>Second Quarter</b>	<b>Third Quarter</b>	<b>Total</b>
Revenue	631	517	418	1,566
Loss and comprehensive loss	(3,425)	(1,949)	(1,577)	(6,951)
Basic and diluted loss per Share	(0.015)	(0.009)	(0.007)	(0.030)
Weighted average number of Shares outstanding	227,434,309	229,226,624	236,605,745	231,109,027

## BALANCE SHEET, FINANCIAL CONDITION AND GOING CONCERN

Cash of \$7,576 at September 30, 2020, increased by \$6,141, from \$1,435 at December 31, 2019. The increase in cash in 2020 was primarily due to the public offering as described below and the US\$5,000 (CA\$6,629) upfront payment from the completion of the exclusive distribution agreement with Baxter. Cash is primarily used for its Phase III registration trial for its PMX treatment for endotoxemic septic shock, including data analysis and submission of documentation to the FDA, and for general corporate and working capital purposes.

The Company received \$4,316 cash from a public offering related to the issuance of 8,500,000 Units at a price of \$0.60 per Unit, \$495 cash on the exercise of 1,100,000 warrants, at an exercise price of \$0.45 per warrant and \$429 on the exercise of 1,129,062 share options. For the same period in the prior year, the Company received \$101 cash on the exercise of 225,000 warrants, at an exercise price of \$0.45 per warrant.

	September 30 2020 \$	September 30 2019 \$
Cash operating income (loss), including changes in working capital	1,219	(1,283)
Proceeds on disposal of property and equipment	10	-
Purchases of property and equipment	(215)	(93)
Proceeds from public offering	5,100	-
Transaction costs paid	(784)	-
Share options exercised	429	-
Warrants exercised	495	101
Lease liability payments	(81)	(78)
	<b>6,173</b>	<b>(1,353)</b>

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 which indicates the existence of a material uncertainty that may cast significant doubt about the Company's ability to continue as a going concern. 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, 2020, 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.

### PUBLIC OFFERING

On June 18, 2020, the Company closed a public offering resulting in the issuance of 8,500,000 units ("Units") for aggregate gross proceeds of \$5,100. The Company received net cash proceeds of \$4,316. Each Unit consisted of one Share priced at \$0.60 per Share and one-half of a share purchase warrant ("Warrant"), resulting in the issue of 4,250,000 share purchase warrants to the subscribers. Each whole Warrant entitles the holder to acquire one additional Share at an exercise price of \$0.75 per Share for a two-year period expiring June 18, 2022. In addition, 510,000 broker warrants were issued, which entitles the broker to acquire one additional Share at an exercise price of \$0.60 per Share, expiring June 18, 2022.

## BASE SHELF PROSPECTUS

On July 6, 2020, the Company announced that it filed a final short form base shelf prospectus with the securities regulatory authorities in each of the provinces of Canada, except Québec, effective July 3, 2020 (the “Effective Date”). This allows the Company to qualify the distribution by way of a prospectus of up to \$50,000 of common shares, debt securities, subscription receipts, warrants and units or any combination thereof, from time to time, during the 25-month period from the Effective Date.

The base shelf prospectus provides the Company with the flexibility to access the capital markets as potential corporate development opportunities arise.

## RELATED PARTIES

All related parties and the respective transactions are disclosed in Note 16 of the condensed interim consolidated financial statements for the three and nine-months ended September 30, 2020 and 2019.

### 1. Toray Industries, Inc. (“Toray”)

Toray holds 45,630,105 Shares of the Company as at September 30, 2020, representing approximately 19.3% (2019: 20.2%) 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:

	Three-months ended September 30		Nine-months ended September 30	
	2020	2019	2020	2019
		\$		\$
<b>Revenue</b>				
Toray Medical Co., Ltd.	-	-	-	-
<b>Purchases</b>				
Toray International America Inc.	-	-	108	-
Reimbursement of expenses	-	-	-	18
<b>Due from (to)</b>				
Toray International America Inc.			-	-
Toray Industries, Inc.			-	18

Effective April 1, 2019, Toray and the Company amended their respective distribution agreements for the purchase of Toraymyxin and EAA™ and agreed to remove the minimum purchase quantities.

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

Birch Hill, through a number of its funds and an investee company, holds 36,017,718 Shares of the Company as at September 30, 2020 representing approximately a 15.2% (2019: 16.0%) 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. Key management consists of the Company’s four executive officers and its Board of Directors.

### **OUTLOOK**

The Company expects to continue to generate revenue in 2020 pursuant to its existing commercial arrangements for EAA™, its proprietary biological reagents and SAMI. The Company is focused on obtaining FDA approval of the PMX treatment and obtaining regulatory clearance and commercialization of Dialco’s DIMI for home and peritoneal dialysis use.

### **COVID-19 PANDEMIC**

As of the date of this MD&A, there has not been a material adverse impact on the Company’s business due to the COVID-19 pandemic, other than the impacts on the Tigris trial as described below. The Company is in close contact with all of its suppliers, manufacturers and distributors and it has not experienced any material issues such as business interruption, requests for change in terms, supply shortages or similar negative impacts. The ultimate long-term impact of COVID-19 is highly uncertain and cannot be predicted with confidence.

Recruitment of patients into the Tigris trial has been negatively impacted by the COVID-19 pandemic. In the third quarter of 2020, there were nine initiated clinical sites. Of these nine sites, six sites experienced suspended research activities due to the COVID-19 pandemic. By the beginning of September 2020, all Tigris sites had resumed their research activities and were actively screening. Currently, there are eleven initiated clinical sites in Tigris. The Company anticipates two additional sites to be initiated, and open for enrolment by November 2020. The Company’s operations could be negatively impacted if the pandemic results in a diversion of intensive care unit (ICU) resources, a change in patient intake patterns and needs or reduced availability of physicians and/or support staff, which in turn could have a negative impact on enrollment in Tigris and timelines for completion of Tigris. Further, the COVID-19 outbreak could result in adverse effects on the Company’s business and operations due to prioritization of clinic resources toward the outbreak or if quarantines and/or restrictions (such as travel restrictions) impede physician, staff or patient movement or interrupt healthcare services.

Should the COVID-19 pandemic in the U.S. prolong limited ICU access at Tigris sites, there is a risk that last patient enrollment could be delayed. The Company has developed mitigation strategies to reduce or eliminate any timing delays, including: (i) COVID-19 supplemental Investigational Device Exemption (“IDE”) protocol keeps existing Tigris clinician skills current for EAA and PMX; (ii) and potentially increasing the number of sites in Tigris. On August 10, 2020, the FDA approved a protocol amendment to increase the number of Tigris sites to fifteen from the ten in the initial protocol. The Company is evaluating potential sites for its FDA supplemental IDE, which could subsequently be added to Tigris; (iii) data collected under the supplemental IDE protocol could be used as

supportive of the PMA for PMX; and (iv) the Company has developed comprehensive on-line training and site support to mitigate any travel restrictions.

## **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 endeavours 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, and the Short Form Prospectus, which are both available at [www.sedar.com](http://www.sedar.com), in addition to the additional risks imposed by COVID-19 described above.

## **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, 2020 and 2019, no significant accounts receivable balances were considered impaired or past due.

#### **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 favourable 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 are classified as current liabilities, except for its long-term portion of its lease liability. Trade and other payables were \$1,778 as at September 30, 2020 with all of them having 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, 2020, cash included US\$3,562. Trade and other receivables included a total of US\$51 and €6. Trade and other payables included a total of US\$909. There is no active hedging program currently in place due to the relatively short time frame for settlement of these balances. A 10% change in the U.S. dollar/Canadian dollar or Euro/Canadian dollar exchange rates on the September 30, 2020 amounts would impact loss by \$362.
- 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 condensed interim 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 (iv.) of the consolidated financial statements for the years ended December 31, 2019 and 2018. 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.

The significant spread of COVID-19 with the U.S., Canada, and elsewhere has resulted in a widespread health crisis and has had adverse effects on local, national and global economies generally and the markets the Company serves.

Uncertain factors, including the duration of the outbreak, the severity of the disease and the actions to contain or treat its impact, could cause interruption of the Company's operations, supply chain and the clinical trial, which could impact the Company's ability to accurately measure the net realizable value of inventory, fair value of trade and other receivables and recoverability of other assets.

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 condensed interim consolidated financial statements and the reported amounts of revenue and expenses during the reporting period. The most significant estimates are related to the valuation assumptions related to share-based compensation and warrants, accrual estimates made for clinical trial and regulatory program expenses, intangible asset impairment, and the assessment of performance obligations and judgment in determining the period over which revenue is recognized for contracts granting exclusive distribution rights. 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, 2020 and 2019. 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:

	<b>September 30 2020</b>
	<b>\$</b>
Not later than one year	112
Later than one year and not later than five years	107
<b>Total undiscounted lease liability at September 30, 2020</b>	<b>219</b>

- 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 favour 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, 2020 with respect to these agreements.

- iii. Trade and other payables include an amount payable to a financial advisory services firm in the amount of US\$742 (CA\$990). The amount payable relates to a legacy financial advisory agreement with the financial advisory firm for any completed strategic transaction or transaction, including any marketing agreements related to Spectral assets. The commercial transaction agreement completed with Baxter as described in Note 9 was captured under the legacy financial advisory agreement.

## **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 condensed interim consolidated statement of loss and comprehensive loss.

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

Cash, trade and other receivables, and contract asset are classified as financial assets at amortized cost with a total carrying value of \$7,906 at September 30, 2020 (December 31, 2019 - \$2,225).

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 \$1,778 at September 30, 2020 (December 31, 2019 - \$1,002).

Cash, trade and other receivables, contract asset, and trade and other payables are reflected in the condensed interim 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, 2020 management has disclosure controls and procedures ("DCP") 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 DCP includes, among other things, the Company's Corporate Disclosure and Whistleblower policies and Code of Conduct, the review and approval procedures of the Company's Finance and Audit Committee and continuous review and monitoring procedures by senior management.

As at September 30, 2020, 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 period ended September 30, 2020, that have materially affected, or are reasonably likely to materially affect, its internal controls over financial reporting.