

March 27, 2019

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

This Management's Discussion & Analysis ("MD&A") for the year ended December 31, 2018 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 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), 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 March 27, 2019 and should be read in conjunction with the consolidated financial statements for the years ended December 31, 2018 and December 31, 2017.

### **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 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 1,000,000\* patients are diagnosed with the clinical syndrome of sepsis annually. Between 30% and 50% of patients with severe sepsis and septic shock die in the ICU. 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 more than 150,000 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 is taking steps to enter into the RRT business. Spectral first acquired the rights to SAMI from Infomed S.A., as an easy-to-use dialysis machine on which to use its PMX cartridges.

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.

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.

*\* Ref: Martin. G., Expert Rev Anti Infect Ther. 2012 June; 10(6): 701-706*

On February 18, 2018, the Company announced that HC has 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 recently announced the first commercial sales contract for SAMI in early 2019. The CRRT market in the U.S. is projected to reach USD \$1.5 billion in 2022, from approximately USD \$1.1 billion in 2017.

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 20, 2019 Spectral announced it had extended 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. Spectral is seeking to obtain regulatory approval for DIMI in Canada and the United States. DIMI is already CE marked for hemodialysis in Europe by Infomed.

As part of this transition, Spectral transferred its RRT business to a newly created wholly owned subsidiary, Dialco Medical Inc. (“Dialco”), to be managed by Dr. Gualtiero Guadagni. Dialco will focus on the commercial development of SAMI as well as the regulatory development of DIMI.

## **CLINICAL DEVELOPMENT**

The Company’s clinical development program continues to be focused 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 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 January 2013, the first interim analysis was conducted on the 76 randomized patients who were followed for 28 days. The Data Safety and Monitoring Board (“DSMB”), consisting of experts in the fields of critical care medicine, infectious disease, nephrology, biostatistics and regulatory affairs, reviewed the totality of the data set for evidence of safety concerns, such as adverse events and/or adverse device effects, related to the use of the PMX cartridge. The results from the first interim safety analysis by the DSMB stated that there are no safety issues to date concerning the application of the PMX cartridge to patients in the EUPHRATES trial.

On January 27, 2014, the DSMB met to review the results of the second interim analysis after 184 patients had been randomized and followed for 28 days in accordance with the Statistical Analysis Plan agreed to

with the FDA. On that date, the DSMB reported that stopping rules for safety, efficacy and futility were not met and that the trial should continue. The DSMB did not, however, provide the planned sample size recalculation at that time. The DSMB requested that additional analysis be performed by the Contract Research Organization on the original 184 patients prior to the recalculation.

The Company received the recommendations of the DSMB pursuant to its analysis on April 10, 2014, which recommendations included an additional exclusion criterion. The DSMB recommended that patients with a Multiple Organ Dysfunction Score (MODS) score of  $\leq 9$  no longer be eligible for randomization in the trial. The MODS score is a recognized scoring system used to evaluate the degree of organ dysfunction which exists in patients with sepsis.

In late September 2014, pursuant to the protocol change in April 2014 to effect the exclusion criterion that further refined patient selection to sicker patients, the FDA recommended that only data for those patients randomized after the change be considered in the determination of whether a statistical significant outcome related to the primary endpoint of 28-day mortality had been achieved.

In April 2015, the FDA accepted the Company's formal plan, and related content, for a rolling Pre-Market Approval ("PMA") submission consisting of four separate modules.

On September 14, 2015, the Company announced that the sample size for its EUPHRATES trial had been reset to 446 evaluable patients, of which 176 patients randomized after the protocol change on April 10, 2014 will be considered for determination of the primary endpoint of 28-day mortality as recommended by the FDA. The trial remained powered at 80 percent and the alpha remained at  $<0.05$  for its primary endpoint. The methodology for the sample size recalculation was recommended by the trial's Steering Committee and accepted by the DSMB without further comment. The Company submitted a revised statistical plan to the FDA related to the sample size change and it was formally accepted.

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 Company completed its review of this extensive database in the first quarter of 2017, determined that the data was sufficient to proceed with filing the fourth and final module of its PMA submission to the FDA and submitted the fourth module on May 30, 2017.

The detailed analysis of the EUPHRATES trial data base 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 July 20, 2017, the FDA accepted the Company's rolling PMA application for PMX for review. The acceptance of the filing meant that the FDA made a threshold determination that the application was sufficiently complete to permit a substantive review.

On October 27, 2017, the Company met with the FDA concerning the status of its PMA application. The meeting consisted of a general discussion of issues identified by the FDA after the first 100 days of regulatory review and suggestions for clarification of those issues. The Company completed its response to those questions in the latter part of 2017. A further round of questions was received and all responses were submitted to the FDA early in 2018.

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 Spectral to utilize mechanisms other than randomized placebo-controlled trials (such as the EUPHRATES trial) to add to the evidence already submitted, and they provided Spectral 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.

The Company, at that time, considered its U.S. clinical development program to be as follows:

- i. The EUPHRATES trial identified a clearly defined per protocol sub-group where PMX provides a 42% relative risk reduction in 28-day mortality, with improvement in several secondary endpoints. This treatment benefit was seen in the 194 patients with pre-treatment EAA between 0.60 and 0.90, and multiple failing organ systems (MODS>9).

- ii. As set out in its guidance documents, any sub-group analysis presents certain “non-approvable” challenges for the FDA to overcome, with the FDA preferring to see prospective hypothesis-confirming data coming from an entire study patient group.
- iii. The Company is satisfied that the FDA undertook such a thorough review of the data and considers its response to be supportive for a path forward.

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 will use the same primary endpoint of 28-day mortality, 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. Tigris will operate exclusively at U.S. hospital sites that are experienced in using the PMX cartridge, and who had demonstrated a better than average enrollment rate in 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.

PMX is marketed in Japan and Europe and has been used to treat more than 150,000 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 clear reduction in mortality.

## **COMMERCIALIZATION INITIATIVES**

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

The Company completed its first distribution agreement for SAMI with a private U.S. company in January, 2019. The Company is to provide SAMI for use in a specific therapeutic niche where an open platform CRRT machine is preferred. In addition, SAMI is being launched in Canada and the U.S. for use as a renal replacement therapy machine giving priority to customers that have followed its development and have expressed an interest in its technology.

The first order of machines was shipped in February 2019 for a value of \$120. A second order is expected to ship in the second quarter of 2019 for a value of approximately \$500.

## **OPERATIONS**

In 2018, the Company continued 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 and its proprietary reagents under the terms of existing commercial arrangements. It has also continued to develop and commenced commercialization of SAMI.

## OPERATING RESULTS

### SELECTED ANNUAL INFORMATION

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

	December 31 2018	December 31 2017 Restated*	December 31 2016 Restated*
	\$	\$	\$
Revenue	3,840	3,669	3,705
Loss and comprehensive loss	(2,489)	(4,076)	(9,989)
Basic and diluted loss per common share	(0.01)	(0.02)	(0.05)
Weighted average number of common shares outstanding	220,172,675	207,329,193	204,679,282
Total assets	6,977	3,473	7,100

\*The Company implemented IFRS 15, *Revenue from Contracts with Customers* and IFRS 9, *Financial Instruments* as described in Note 3(xxv) and Note 4 of the consolidated financial statements.

The total number of common shares (“Shares”) outstanding as of the date of this MD&A is 225,591,183.

### REVENUE

The prior year’s revenue has been restated to comply with the changes in accounting policy as described below.

Revenue for the three months ended December 31, 2018 was \$1,864 compared to \$884 for the same three-month period last year. Total revenue for the year ended December 31, 2018 were \$3,840 compared to \$3,669 for the prior year, representing an increase of approximately 4%.

Royalty revenue of \$1,295 (2017 - \$2,358) is earned in U.S. dollars. Royalty revenue from one customer decreased from \$1,719 (USD\$1,124) due to the expiry of certain patents.

The Company entered into a technology transfer agreement (the “Agreement”) whereby the Company has transferred certain technology and related materials to an undisclosed third party. The Agreement generated \$1,158 of additional revenue in 2018 and is expected to generate approximately a further \$1,100 of revenue in 2019.

Sales of proprietary biochemicals of \$571 (2017 - \$403) increased by \$168, or 42%, over the prior year due mainly to timing of orders and an increase in the unit price to customers to offset the loss in royalty revenue.

EAA™ product and instrumentation revenue decreased by 15%, from \$901 in 2017 to \$782 in 2018 and is expected to remain relatively consistent in 2019.

## EXPENSES

For the quarter ended December 31, 2018, the Company reported operating costs of \$1,420 compared to \$1,960 for the corresponding period in 2017. Operating costs in 2018 were \$6,329, compared to \$7,745 in the prior year; representing an decrease of \$1,416, or 18.3%. The decrease is directly related to the reduction of activities related to the EUPHRATES trial. Enrolment in the trial was completed in June 2016, and final patient follow up finished in the third quarter of 2017. The Company continues to maintain a low cost operating structure for its base business operations.

Clinical development and regulatory program costs (as disclosed in Note 18 of the consolidated financial statements) were \$882 in 2018 compared to \$1,813 for the year ended December 31, 2017. A significant portion of clinical trial and regulatory costs is comprised of consulting and professional fees paid to the contract research organization, product distribution centre, co-ordinating centre, and other clinical and regulatory consultants. The decrease is a direct result of the reduction in trial activities and the delay in determining the Company's regulatory path forward. Cumulative trial and regulatory program costs total \$42,418 as of December 31, 2018.

Product development costs in 2018 of \$110 and 2017 of \$238 are related to the development of SAMI.

Salary and benefits costs in 2018 amounted to \$3,095, compared to \$3,534 in 2017. The decrease was attributable to the retirement of the Company's CFO in January 2018. The Company's current interim CFO is a consultant whose fees are included under "consulting and professional fees".

## Loss

Income for the quarter ended December 31, 2018 was \$444 (\$0.002 per share) compared to a loss of \$1,076 (\$0.005 per share) for the same quarter last year. For the year ended December 31, 2018, the Company reported a loss of \$2,489 compared to a loss of \$4,076 for the year ended December 31, 2017.

## SHARES OUTSTANDING

The total number of Shares outstanding for the Company was 225,591,183 as at December 31, 2018.

## 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, 2018 and have been applied in preparing the consolidated financial statements as described below). The impact on adoption of the new standards are described in Note 4 of the consolidated financial statements.

### a. IFRS 15, *Revenue from Contracts with Customers*

The Company implemented the new standard, IFRS 15, *Revenue from Contracts with Customers* as of January 1, 2018. The Company has elected to use the full retrospective method upon adoption of this standard which requires retrospective adjustments to the consolidated financial statements for the earliest year presented. The new standard amends revenue recognition requirements and establishes principles for recording information about the nature, timing and uncertainty of revenue and cash flows arising from contracts with customers. The standard replaces IAS 18, *Revenue* and IAS 11, *Construction contracts* and related interpretations.

The new standard also introduces expanded disclosure requirements.

b. IFRS 9, *Financial Instruments*

The Company implemented IFRS 9, *Financial Instruments* retrospectively as of January 1, 2018. This Standard was not applied to items that had already been derecognised at the date of initial application. The new standard includes revised guidance on the classification and measurement of financial assets, including impairment and a new general hedge accounting model. The standard replaces IAS 39, *Financial Instruments: Recognition and Measurement* and related interpretations. The Company also applied related amendments to IFRS 7, *Financial Instruments: Disclosures*.

**ACCOUNTING STANDARDS ISSUED BUT NOT YET APPLIED**

A number of new standards and amendments to standards and interpretations have not been applied in preparing these consolidated financial statements. None of these standards are expected to have a significant effect on the consolidated financial statements of the Company, except the following set out below:

a. IFRS 16, *Leases*

On January 13, 2016, the International Accounting Standards Board published a new standard, IFRS 16, *Leases*. The new standard will eliminate the distinction between operating and finance leases and will bring most leases on the consolidated statements of financial position for lessees.

This standard is effective for annual reporting periods beginning on or after January 1, 2019. The impact of the adoption of the standard is expected to result in the recognition of all operating leases with the corresponding assets and liabilities recorded in the consolidated financial statements. The Company expects to adopt IFRS 16 using the modified retrospective transition method. Further, the Company currently expects to apply the following practical expedients: (i) grandfather the assessment of which transactions are leases; (ii) recognition exemption of short-term leases; and (iii) recognition exemption leases of low value items. The Company will recognize assets and liabilities for its leased premises on the consolidated statement of financial position upon adoption.

b. *International Financial Reporting Interpretations Committee (IFRIC), Uncertainty over Income Tax Treatments (IFRIC 23)*

In June 2017, the IASB issued IFRIC 23, *Uncertainty over Income Tax Treatments*, with a mandatory effective date of January 1, 2019. The interpretations provide guidance on how to value uncertain income tax positions based on the probability of whether the relevant tax authorities will accept the Company's tax treatments. A company is to assume that a taxation authority with the right to examine any amounts reported to it will examine those amounts and will have full knowledge of all relevant information when doing so. IFRIC 23 is to be applied by recognizing the cumulative effect of initially applying these guidelines in opening retained earnings without adjusting comparative information. The Company has assessed that there will be no financial statement impact upon adoption on January 1, 2019.

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

The following tables summarize quarterly financial information for the year ended December 31, 2018 and the comparative year ended December 31, 2017, as restated:

<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	(714)	(1,510)	(709)	444	(2,489)
Basic and diluted loss 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

<b>Year ended December 31, 2017 (Restated)</b>	<b>First Quarter</b>	<b>Second Quarter</b>	<b>Third Quarter</b>	<b>Fourth Quarter</b>	<b>Total</b>
Revenue	910	1,055	820	884	3,669
Loss and comprehensive loss	(993)	(1,150)	(857)	(1,076)	(4,076)
Basic and diluted loss per Share	(0.005)	(0.006)	(0.004)	(0.005)	(0.02)
Weighted average number of shares outstanding	207,165,587	207,249,708	207,446,674	207,450,379	207,329,193

## BALANCE SHEET, FINANCIAL CONDITION AND GOING CONCERN

Cash of \$4,368 at December 31, 2018, increased by \$2,919, from \$1,449 at December 31, 2017. This increase was attributable to the following:

Cash operating losses, including changes in working capital	\$(2,322)
Net proceeds from private placement	5,197
Proceeds from share options exercised	91
Purchases of property and equipment	(47)
	<u>\$2,919</u>

The ability of the Company to realize its assets and meet its obligations as they come due is dependent on obtaining FDA approval of PMX, and the successful commercialization of PMX, SAMI, DIMI and achieving future profitable operations, the outcome of which cannot be predicted at this time. Furthermore, the Company will require additional funding from commercial transactions or investors to continue the development and commercialization of products. These circumstances lend significant doubt as to the ability of the Company to meet its obligations as they come due and, accordingly, the ultimate appropriateness of the use of accounting principles applicable to a going concern.

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 2018 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.

## **PRIVATE PLACEMENT**

On April 20, 2018, the Company closed a private placement financing resulting in the issuance of 17,694,661 units ("Units") for gross proceeds of \$5,308. Each Unit is comprised of one Share priced at \$0.30 per Share and one-half of a share purchase warrant ("Warrant"). Each whole Warrant entitles the holder to acquire one additional Share at an exercise price of \$0.45 per Share for a three-year period expiring April 20, 2021.

In total, the Company issued 17,694,661 Shares and 8,847,331 Warrants for aggregate gross proceeds of \$5,308. The Company received net proceeds of \$5,197 which will be used for further clinical study of the PMX cartridge, the accompanying regulatory pursuit for FDA approval, and for working capital and general corporate purposes.

## **RELATED PARTIES**

All related parties and the respective transactions have been disclosed in Notes 11 and 21 of the consolidated financial statements for the years ended December 31, 2018 and 2017.

### **1. Toray Industries, Inc. ("Toray")**

Toray holds 45,630,105 Shares of the Company as at December 31, 2018, representing approximately 20.2% (2017 – 22.0%) of Spectral's issued and outstanding Shares, calculated on a non-diluted basis.

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:

	December 31 2018	December 31 2017 Restated (Note 4)
	\$	\$
<b>Revenue</b>		
Toray Medical Co., Ltd.	294	323
<b>Purchases</b>		
Toray International America Inc.	165	99
<b>Reimbursement of expenses</b>		
Toray Industries, Inc.	-	19
<b>Due from/(to)</b>		
Toray Medical Co., Ltd.	84	71
Toray International America Inc.	(34)	-

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 December 31, 2018 representing approximately a 16.0% (2017 – 16.2%) ownership interest, calculated on a non-diluted basis.

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.

There are no other related party transactions.

## OUTLOOK

The Company expects to continue to generate revenue in 2019 pursuant to its existing commercial arrangements for EAA™, its proprietary biological reagents, SAMI, and DIMI. The Company's primary focus continues to be working towards obtaining FDA approval of the PMX treatment.

The outlook for the Company and its ability to continue as a going concern is significantly dependent on the Company's ability to raise adequate capital to continue its regulatory path forward with respect to the Tigris trial and the ultimate approval from the FDA for PMX. It is also dependent on commercialization activities for PMX, SAMI and DIMI. Management cannot reasonably predict the outcome of these activities at this time.

## 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 which is available at [www.sedar.com](http://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 affects 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 December 31, 2018 and 2017, 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. Trade and other payables were \$500 as at December 31, 2018 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 December 31, 2018, cash included US\$717. Trade and other receivables included a total of US\$833 and €87. Trade and other payables included a total of US\$69 and ¥2,750. 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, Euro/Canadian or Yen/Canadian dollar exchange rates on the December 31, 2018 amounts would impact net loss by \$212.
- 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 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 (iv) of the consolidated financial statements for the years ended December 31, 2018 and 2017. 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 valuation assumptions related to share-based compensation, accrual

estimates made for clinical trial and regulatory program expenses, recoverability of deferred income tax assets, intangible asset impairment, 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 13 of the consolidated financial statements for the years ended December 31, 2018 and 2017. In addition, the Company is committed to certain future lease payments primarily in connection with the leased premises.

Future lease payments for the rental of premises are as follows:

	<b>December 31 2018</b>
	<b>\$</b>
Less than 1 year	163
Between 1 and 5 years	459
More than 5 years	-

The lease was renewed for an additional five years commencing in 2017. Lease expense in 2018 was \$141 (2017: \$137).

- 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.
- iii. In the normal course of business, the Company has entered into agreements that include indemnities in favour of third parties, such a 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 December 31, 2018 with respect to these agreements.
- iv. The Company has further commitments related to its exclusive license agreement for PMX with Toray as described in Notes 11 and 13 of the consolidated financial statements for the years ended December 31, 2018 and 2017.

## **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, trade and other receivables, and contract asset are classified as financial assets at amortized cost with a total carrying value of \$5,927 at December 31, 2018 (2017 - \$2,330).

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 \$500 at December 31, 2018 (2017 - \$612).

Cash, trade and other receivables, contract asset, 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 December 31, 2018, 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 DCP 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 December 31, 2018, 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 year ended December 31, 2018 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, 2018, 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.