

March 28, 2018

**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, 2017 has been prepared to help investors understand the financial performance of 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 financial statements, 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 28, 2018 and should be read in conjunction with the consolidated financial statements for the years ended December 31, 2017, and December 31, 2016.

**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**

Spectral Medical Inc. (“Spectral” or the Company”) is strategically focused on the development and commercialization of a treatment for septic shock utilizing its Endotoxin Activity Assay (EAA™) and the Toraymyxin™ (“PMX”) therapeutic. If approved, this will be the first targeted therapy guided by a specific diagnostic in the area of sepsis. The Company also manufactures and sells 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. Federal Drug Administration (“FDA”), Health Canada and European CE clearance of the Endotoxin Activity Assay (“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 through non-exclusive license and supply agreements. Royalty revenues are earned from these license arrangements based on a percentage of end user sales of Troponin I.

## **CLINICAL DEVELOPMENT**

The Company’s only clinical development program continues to be focused on obtaining U.S. Food and Drug Administration (“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 Endotoxin Activity Assay (EAA™), the only FDA cleared diagnostic for the measurement of endotoxin.

On February 26, 2010, the Company received final approval of its Investigation Device Exemption (“IDE”) from the FDA, which permitted the Company to conduct a pivotal trial for PMX (the EUPHRATES trial) in the United States.

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 United States comparing standard of care versus PMX plus standard of care.

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

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 statistically 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 means 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 US 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 this time, considers its US 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 0.6 and 0.9, 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, and expects to schedule a meeting with the FDA in the near future to develop a plan that generates additional data under a “least burdensome” approach. The Company anticipates this plan to be substantially limited in cost and time lines compared to the EUPHRATES trial.

Once the Company has determined its regulatory path forward with the FDA it will be in a position to further announce those plans, and provide updates on financial and other strategic matters.

The Company presented the trial results at the 35<sup>th</sup> Vincenza Course on AKI and CRRT and at the Canadian Critical Care Forum (CCCF 2017). The Company also held discussions with Canadian clinicians focused on the utilization of Toraymyxin™ in anticipation of the launch of this treatment in Canada.

On December 13, 2017, the Company announced that it entered into its first distribution agreement with Caster Medical Systems (“CMS”) to launch PMX and EAA™ in Canada, commencing in the first quarter of 2018.

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.

These measures include the development of a proprietary stand-alone pump (the “Spectral Apheresis Machine or “SAM”) dedicated to the Company’s therapy that enables treatment delivery in the ICU and reduces reliance on third party instrumentation. The addition of 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. SAM 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 SAM for use in CRRT and therapeutic plasma exchange (“TPE”). Since SAM 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 US market, including potentially the Company’s PMX treatment.

On February 18, 2018, the Company announced that Health Canada (“HC”) has approved, 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, SAM received a CE mark in Europe for the same applications.

As SAM was designed to be user friendly and is built on a small footprint, the Company believes that there is an opportunity to pursue use of SAM in the broader CRRT market. The global CRRT market is projected to reach USD \$1.5 billion in 2022, from approximately USD \$1.1 billion in 2017.

The Company has exclusive license right for SAM in North America for all CRRT applications and has worldwide exclusivity for any hemoperfusion applications. The Company is in the process of developing a commercial strategy for this product.

## OPERATIONS

In 2017, the Company continued to focus its activities on its regulatory program to achieve potential 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.

## OPERATING RESULTS

### SELECTED ANNUAL INFORMATION

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

	December 31 2017 \$	December 31 2016 \$	December 31 2015 \$
Revenue	3,806	3,545	3,089
Loss and comprehensive loss	(3,939)	(10,149)	(9,524)
Basic and diluted loss per common share	(0.02)	(0.05)	(0.05)
Weighted average number of common shares outstanding	207,329,193	204,679,282	188,064,621
Total assets	3,473	7,100	8,459

The total number of common shares (“Shares”) outstanding as of the date of this Management’s Discussion & Analysis is 207,796,522.

## REVENUE

Total revenues for the year ended December 31, 2017 were \$3,806 compared to \$3,545 for the prior year, representing an increase of approximately 7%.

Royalty revenue of \$2,497 (2016 - \$2,290) is earned in US dollars and has remained consistent with prior year levels.

Sales of proprietary biochemicals of \$403 (2016 - \$462) decreased by \$59, or 13%, over the prior year due mainly to timing of orders.

EAA™ product and instrumentation revenues increased by 13%, from \$793 in 2016 to \$899 in this fiscal year and are expected to remain relatively consistent in 2018.

## FINANCE INCOME

Finance income in 2017 was \$nil compared to \$68 in 2016. The decrease is due to lower average cash balances during the year in non-interest bearing accounts.

## EXPENSES

Operating costs in 2017 were \$7,745, compared to \$13,762 in the prior year; representing an decrease of \$6,017. 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.

EUPHRATES trial and regulatory program costs (as disclosed in Note 17 of the consolidated financial statements) were \$1,813 in 2017 compared to \$6,864 for the year ended December 31, 2016. A significant portion of EUPHRATES trial costs is comprised of consulting and professional fees paid to the trial's 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. Cumulative trial and regulatory program costs total \$41,536 as of December 31, 2017.

Product development costs in 2017 of \$238 and 2016 of \$67 are related to the development of the Company's proprietary hemoperfusion/RRT (renal replacement therapies) instrument.

Regulatory and investor relations costs in 2017 amounted to \$479, compared to \$866 in 2016. The decrease was attributable to a curtailing of certain investor relations initiatives, pending potential FDA approval of the Company's PMA application.

### Loss

For the year ended December 31, 2017, the Company reported a loss of \$3,939 compared to a loss of \$10,149 for the year ended December 31, 2016.

### SHARES OUTSTANDING

The total number of Shares outstanding for the Company was 207,459,022 as at December 31, 2017.

### 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, 2017 and the comparative year ended December 31, 2016:

<b>Year ended December 31, 2017</b>	<b>First Quarter</b>	<b>Second Quarter</b>	<b>Third Quarter</b>	<b>Fourth Quarter</b>	<b>Total</b>
Revenue	941	1,090	857	918	3,806
Loss and comprehensive loss	(962)	(1,115)	(820)	(1,042)	(3,939)
Basic and diluted loss per Share	(0.005)	(0.005)	(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

<b>Year ended December 31, 2016</b>	<b>First Quarter</b>	<b>Second Quarter</b>	<b>Third Quarter</b>	<b>Fourth Quarter</b>	<b>Total</b>
Revenue	1,062	870	807	806	3,545
Loss and comprehensive loss	(2,994)	(3,498)	(2,633)	(1,024)	(10,149)
Basic and diluted loss per Share	(0.02)	(0.02)	(0.01)	(0.005)	(0.05)
Weighted average number of shares outstanding	198,015,803	206,733,209	206,865,470	207,165,587	204,679,282

## **BALANCE SHEET, FINANCIAL CONDITION AND GOING CONCERN**

Cash of \$1,449 at December 31, 2017, decreased by \$3,631, from \$5,080 at December 31, 2016. This decrease was attributable to the following:

Cash operating losses, including changes in working capital	\$(3,595)
Proceeds from share options exercised	84
Proceeds from disposal of property and equipment	15
Purchases of property and equipment	(135)
	<u>\$(3,631)</u>

The ability of the Company to realize its assets and meet its obligations as they come due is dependent on obtaining regulatory (FDA) approval of the Company's primary product (PMX), successful commercialization of the Company's products (including the PMX product) 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 2017 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.

## **BOUGHT DEAL PROSPECTUS OFFERING**

On February 18, 2016, the Company closed a bought deal prospectus offering ("the Offering") resulting in the issuance of 14,300,000 Shares for gross proceeds of \$10,010.



On February 24, 2016, an additional 806,804 Shares were issued by the Company resulting in gross proceeds of \$565 in connection with the underwriters' exercise of their over-allotment option.

In total, the Company issued 15,106,804 Shares for aggregate gross proceeds of \$10,575. The Company received net cash proceeds of \$9,399 which will be used to fund its EUPHRATES trial and for working capital and general corporate purposes.

The Company also issued 906,408 broker warrants to the underwriters representing 6% of the total number of Shares sold pursuant to the bought deal financing. Each broker warrant entitles the holder thereof to acquire one Share at a price of \$0.70 per Share for a period of 24 months from the closing date. 400,000 broker warrants were exercised in September 2016 for total proceeds of \$280.

### **NORMAL COURSE ISSUER BID**

On July 4, 2016, the Company announced that the Toronto Stock Exchange (the "TSX") approved its notice of intention to make a normal course issuer bid ("NCIB") for its outstanding Shares. Pursuant to the notice, the Company was able to purchase up to 4,134,664 of its Shares, representing approximately 2% of its issued and outstanding Shares, during the twelve-month period commencing July 6, 2016 and ending July 5, 2017.

The Company did not repurchase any Shares under this NCIB in 2017 or 2016.

### **RELATED PARTIES**

All related parties and the respective transactions have been disclosed in Note 20 to the consolidated financial statements for the years ended December 31, 2017 and 2016.

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

Toray holds 45,630,105 Shares of the Company as at December 31, 2017, representing approximately 22.0% (2016 – 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.

#### **2. Birch Hill Equity Partners Management Inc. ("Birch Hill")**

Birch Hill, through a number of its funds and an investee company, holds 33,517,718 Shares of the Company as at December 31, 2017 representing approximately a 16.2% (2016 – 16.2%) ownership interest, calculated on a non-diluted basis as at December 31, 2017.

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 2018 pursuant to its existing commercial arrangements for EAA™ and its proprietary biological reagents. The Company's primary focus continues to be on potentially 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 outcome of the FDA review of its PMA submission for Toraymyxin™ and on its ability to raise adequate capital to complete its regulatory program and potential commercialization activities. 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, 2017 and 2016, 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 \$612 as at December 31, 2017 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. At December 31, 2017, cash included US\$255. Trade and other receivables included a total of US\$742 and €58. Trade and other payables included a total of US\$140 and €1. 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 exchange rates on the December 31, 2017 amounts would impact losses by \$81.
- 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 maintain appropriate levels of cash for working capital and operating purposes, as well as funding commercialization 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 International Financial Reporting Standards (IFRS) as issued by the International Accounting Standard Board 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) to the Consolidated Financial Statements for the years ended December 31, 2017 and 2016. 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 expenses and recoverability of deferred income tax assets. 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 12 of the consolidated financial statements for the years ended December 31, 2017 and 2016. In addition, the Company is committed to certain future lease payments primarily in connection with the leased premises.
- 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, 2017 with respect to these agreements.
- iv. The Company has further commitments related to its exclusive license agreement for PMX with Toray as described in Note 10 of the consolidated financial statements for the years ended December 31, 2017 and 2016.

## **FINANCIAL INSTRUMENTS AND FAIR VALUES**

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

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

Cash and trade and other receivables are classified as loans and receivables with a total carrying value of \$2,330 at December 31, 2017 (2016 - \$5,722).

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 \$612 at December 31, 2017 (2016 - \$1,112).

Cash, trade and other receivables, 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, 2017, 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, 2017, 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, 2017 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, 2017, 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.