

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

This Management's Discussion & Analysis ("MD&A") for the six-months ended June 30, 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 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 August 13, 2018 and should be read in conjunction with the condensed interim consolidated financial statements for the six-months ended June 30, 2018, and the audited annual consolidated financial statements of the Company for the years ended December 31, 2017 and 2016 ("the Annual Financial Statements"), as well as the MD&A for the year ended December 31, 2017. The condensed interim consolidated financial statements of Spectral and related notes were prepared in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board ("IFRS") applicable to the preparation of interim financial statements including International Accounting Standard 34, Interim Financial Reporting. In this MD&A, unless the context requires otherwise, references to "we" or "our" are references to Spectral.

**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 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.

## **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 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 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 timelines 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 continues to dialogue with the FDA concerning the pathway forward for its targeted therapy for septic shock.

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, which commenced 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 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. The pump 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 the pump 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 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, the pump received a CE mark in Europe for the same applications.

As it 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 the pump 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 rights for the pump 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**

The Company continues 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, the PMX therapeutic, and its proprietary reagents under the terms of existing commercial arrangements.

## **OPERATING RESULTS**

### **REVENUE**

Revenue for the three-months ended June 30, 2018 was \$234 compared to \$1,055 for the same period in the prior year. For the six-months ended June 30, 2018 revenue was \$1,397 compared to \$1,965 for the same period in 2017. Royalty revenue from one customer has decreased from \$880 (US\$659) to \$117 (US\$91) for the first six-months of 2018, due to the expiry of certain patents. All royalty revenue contracts will expire by the end of 2019. The Company is currently in the process of discussing potential technology transfers and other commercial options in respect of the underlying reagents to partially mitigate the short term revenue loss.

The prior year's revenue has been restated to comply with the changes in accounting policy as described below. Revenues are also subject to the timing of customer orders and shipments.

### **EXPENSES**

Operating costs for the three-months ended June 30, 2018 were \$1,744, compared to \$2,205 for the same period in the preceding year, a decrease of \$461. For the six-months ended June 30, 2018, operating expenses were \$3,621 compared to \$4,108 for the same period in 2017, a decrease of \$487. The decrease is directly related to the reduction of activities related to the clinical trial. Enrolment in the trial was completed in June 2016, and final patient follow up was completed in the third quarter of 2017. The Company continues to maintain a low cost operating structure for its base business operations.

Clinical trial and regulatory program costs (as disclosed in Note 12 of the condensed interim consolidated financial statements) were \$511 for the six-months ended June 30, 2018 compared to \$1,197 for the six-months ended June 30, 2017. A significant portion of clinical trial and regulatory 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 Company continues to plan for the regulatory path forward so that once determined, it will be able to execute the plan within a short time frame. Cumulative trial and regulatory program costs total \$42,047 as of June 30, 2018.

Product development costs for the six-months ended June 30, 2018 and 2017, of \$66 and \$50 respectively are related to the development of the Company's pump, and are incurred when certain milestones have been met.

Regulatory and investor relations costs in the first half of 2018 were \$279, compared to \$161 for the same period in 2017. The increase is attributable to increased share compensation expense for share options granted to certain consultants.

### **LOSS**

For the three-months ended June 30, 2018, the Company reported a loss of \$1,510 compared to a loss of \$1,150 for the three-months ended June 30, 2017. The loss for the six-months ended June 30, 2018 was \$2,224, which is comparable to the loss of \$2,143 for the six-months ended June 30, 2017.

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

## SHARES OUTSTANDING

The total number of Shares outstanding for the Company was 225,591,183 as at June 30, 2018.

## ACCOUNTING STANDARDS ADOPTED IN THE CURRENT PERIOD

A number of new standards and amendments to standards and interpretations have been applied in preparing the condensed interim consolidated financial statements as described in Note 5. The Company has elected to use the full retrospective method upon adoption of these standards which requires retrospective adjustments to the condensed interim consolidated financial statements for the earliest year presented. The impact on adoption of the new standards are described within Note 7.

### 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 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 the new standard, IFRS 9, *Financial Instruments* as of January 1, 2018. The new standard replaces the guidance in IAS 39 that relates to the classification and measurement of financial instruments.

## BALANCE SHEET, FINANCIAL CONDITION AND GOING CONCERN

Cash of \$5,222 at June 30, 2018, increased by \$3,773, from \$1,449 at December 31, 2017. This increase was attributable to the following:

Cash operating losses, including changes in working capital	\$(1,474)
Net proceeds from the private placement	5,197
Proceeds from share options exercised	91
Purchases of property and equipment	(41)
	<u>\$3,773</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 June 30, 2018 condensed interim consolidated financial statements do not reflect the adjustments to the carrying amounts of assets and liabilities and the reported expenses and balance sheet classifications that would be necessary if the Company were unable to realize its assets and settle its liabilities as a going concern in the normal course of operations. Such adjustments could be material.

## **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 and 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 Note 15 to the condensed interim consolidated financial statements for the six-months ended June 30, 2018 and 2017.

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

Toray holds 45,630,105 Shares of the Company as at June 30, 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.

### **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 June 30, 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 2018 pursuant to its existing commercial arrangements for EAA™, PMX, 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 effects on the Company's financial performance.

#### **a. Credit Risk**

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

- i. Cash: The Company places its cash with Canadian Schedule I banks.
- ii. Trade and other receivables: The Company sells its products to distribution partners in major markets. The credit risk associated with the accounts receivable pursuant to these agreements is evaluated during initial negotiations and on an ongoing basis. There have been no events of default under these agreements. As at June 30, 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 \$611 as at June 30, 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. At June 30, 2018, cash included US\$109. Trade and other receivables included a total of US\$256 and €54. Trade and other payables included a total of US\$169. 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 exchange rates on the June 30, 2018 amounts would impact losses by \$34.
- 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 Company has identified the accounting policies and estimates that are critical to the understanding of the Company's operation and financial results in the Annual 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 Annual 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 Annual 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 9 of the condensed interim consolidated financial statements for the six-months ended June 30, 2018 and 2017. 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 June 30, 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 Note 9 of the condensed interim consolidated financial statements for the six-months ended June 30, 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 and trade and other receivables are classified as loans and receivables with a total carrying value of \$5,777 at June 30, 2018 and \$3,865 at June 30, 2017.

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 \$611 at June 30, 2018, and \$1,043 at June 30, 2017.

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 June 30, 2018, management has designed disclosure controls and procedures ("DC&P") that provide reasonable assurance that information required to be disclosed by the Company in its filings under Canadian securities legislation is recorded, processed, summarized and reported in a timely manner. The system of DC&P includes, among other things, the Company's Corporate Disclosure and Whistleblower policies and Code of Conduct, the review and approval procedures of the Disclosure Committee and continuous review and monitoring procedures by senior management.

As at June 30, 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 six-months ended June 30, 2018 that have materially affected, or are reasonably likely to materially affect, its ICFR.

An evaluation of the design and effectiveness of the Company's DC&P and the design of the ICFR has been conducted by management, under the supervision of the Chief Executive Officer (CEO) and Interim Chief Financial Officer (CFO). Based on this evaluation, the CEO and CFO have concluded that, as of June 30, 2018, the Company's DC&P, as defined by National Instrument 52-109 – Certification of Disclosure in Issuers' Annual and Interim Filings, are designed and operating effectively and the ICFR is designed effectively.