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

This Managements Discussion & Analysis (%MD&A+) for the year ended December 31, 2014 has been prepared to help investors understand the financial performance of the Company in the broader context of the Companys strategic direction, the risks and opportunities as understood by management, and the key success factors that are relevant to the Companys 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.

The following discussion should be read in conjunction with the financial statements for the years ended December 31, 2014, and December 31, 2013.

#### 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+, \mathbf{w}ill+, \mathbf{k}hould+, \maxpect+, % Man+, % Anticipate+, % Delieve+, \*Matend+, \*Mastimate+, \*Maredict+, \*Matendict+, factors and assumptions regarding, among other things, expected growth, results of operations, performance and business prospects and opportunities. While we consider these assumptions to be reasonable based on information currently available to us, they may prove to be incorrect. Forward looking-information is also subject to certain factors, including risks and uncertainties that could cause actual results to differ materially from what we currently expect. These factors include, among other things, the availability of funds and resources to pursue development projects, the successful and timely completion of clinical studies, and the ability of the Company to take advantage of business opportunities, the granting of necessary approvals by regulatory authorities as well as general economic, market and business conditions. For more exhaustive information on these risks and uncertainties you should refer to our most recently filed annual information form which is available at www.sedar.com. Forward-looking information contained in this MD&A is based on our current estimates, expectations and projections, which we believe are reasonable as of the current date. You should not place undue importance on forward-looking information and should not rely upon this information as of any other date. While we may elect to, we are under no obligation and do not undertake to update this information at any particular time.

# **DISCLOSURE CONTROLS AND INTERNAL CONTROLS**

The Companys management maintains a system of disclosure controls and procedures to provide reasonable assurance that material information is made known, and has designed internal controls over financial reporting to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board (%FRS+).

The accounting policies applied in these financial statements are based on IFRS effective for the year ended December 31, 2014, as issued and outstanding as of March 24, 2015, the date the Board of Directors approved the statements.

As at December 31, 2014, management has evaluated the effectiveness of its disclosure controls and procedures, and of its internal controls over financial reporting, and has concluded that such processes

are operating effectively. There has been no change during the Companys most recent interim period in the internal controls over financial reporting.

Dr. Paul M. Walker, Chief Executive Officer, and Mr. Anthony Businskas, Chief Financial Officer, in accordance with Multilateral Instrument NI 52-109, have also both certified that:

- They have reviewed the financial statements and this MD&A (% Filings+);
- Based on their knowledge, these Filings do not contain any untrue fact or omit a material fact;
- The Filings present fairly the financial position, statements of loss and comprehensive loss, changes in equity, and cash flows of the Company;
- They have designed such disclosure controls and procedures, or caused them to be designed under their supervision, to provide reasonable assurance that material information relating to the Company is made known to them by others within the Company, particularly during the period in which the annual filings are being prepared;
- They have designed such internal controls over financial reporting, or caused them to be designed under their supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with IFRS; and
- They have evaluated effectiveness of disclosure controls and procedures as of the end of the period covered by the annual filings and have caused the Company to disclose in the annual MD&A their conclusions about the effectiveness of the disclosure controls and procedures as of the end of the period covered by the annual filings based on such evaluation.

This document and the related financial statements can also be viewed on the Companys website at <a href="https://www.spectraldx.com">www.spectraldx.com</a> and at <a href="https://www.sedar.com">www.sedar.com</a>. The Companys Annual Information Form and Management Information Circular are also available on these websites.

# INTRODUCTION

Spectral Medical Inc. (%Spectral+or the Company+) was formerly known as Spectral Diagnostics Inc. Its name was changed effective December 31, 2014 to reflect the Company¢s continuing transition into a therapeutic development company. Spectral is strategically focused on the development and commercialization of a treatment for severe sepsis and septic shock utilizing its Endotoxin Activity Assay (EAAï) and the Toraymyxinï (%MX+) 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.

#### $EAA^{TM}$

Spectral has pioneered the development of biochemical markers for the clinical syndrome known as <code>%eptic</code> shock+ In 2003, the Company achieved U.S. Federal Drug Administration (%DA+), Health Canada and European CE clearance of the Endotoxin Activity Assay (%AAï +) for the first recognized rapid test for the risk of developing sepsis in the Intensive Care Unit (%CU+). 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. Spectrals EAAï 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 100,000 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.

Results of a randomized controlled trial (the EUPHAS trial) were published in the *Journal of the American Medical Association* (JAMA, 2009; Vol. 301 No. 23, 2445-2452). The results demonstrated that when PMX is added to conventional therapy, there is significantly improved hemodynamics and organ function, and reduced 28-day mortality in patients with severe sepsis and septic shock in comparison to those patients in the conventional therapy group.

#### 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 Companys only clinical development program is focused on obtaining U.S. 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 U.S. FDA approval for PMX and intends to commercialize the product, together with its Endotoxin Activity Assay (EAAï), the only FDA cleared diagnostic for the measurement of endotoxin.

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

On February 26, 2010, the Company received final approval of its Investigation Device Exemption (%DE+) from the U.S. FDA, which permits 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.

In November, 2010, the Company signed a long-term, exclusive distribution agreement with Toray Industries, Inc. and Toray Medical Co., Ltd. of Japan (collectively ‰oray+) to market and sell PMX in Canada. The Company is developing commercial plans for the Canadian market so that it is ready to commence sales activities upon FDA approval.

In the fourth quarter of 2011, %igris+, an Eli Lilly product, was withdrawn from the market globally, following results of a European clinical study which showed that the trial did not meet the primary endpoint of a statistically significant reduction in 28-day all cause mortality in patients with septic shock. In February, 2012, the first of two anticipated pivotal Phase III sepsis studies for Tolactoferrin alfa (%ggenix AG+) was halted for safety reasons. While unfortunate for sepsis patients and clinicians, the opportunity to find an effective treatment remains.

On June 20, 2012, the FDA approved the Companys request to add up to an additional 30 clinical trial sites. This provides the Company with the capability to expand the trial to a total of 60 clinical sites in North America and internationally.

On September 26, 2012, the FDA approved an amended protocol for the EUPHRATES trial, which included two planned interim analyses instead of one.

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 safely 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. In addition, the results stated that the EUPHRATES clinical protocol appeared to be defining the correct target patient population for this study.

On May 1, 2013, the Company announced the appointment of Dr. Gualtiero Guadagni as the Companys Vice President, Sales and Marketing. Dr. Guadagni is primarily responsible for the development of sales and marketing programs, the expansion of commercial opportunities and the execution of sales and marketing initiatives for PMX and EAAï in Canada, the United States and Europe.

On September 26, 2013, the Company announced that the 184 patients required for the planned, second interim analysis had been randomized into its 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 11, 2014, which recommendations included an additional exclusion criterion. The DSMB recommended that patients with a Multiple Organ Dysfunction Score (MODS) score of m 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. This recommendation is consistent with data from previous PMX trials, which demonstrated that the PMX column is most effective in reducing mortality rates of sicker patients. Based on these recommendations, the trials sample size was recalculated and increased from 360 to 605 evaluable patients. The increase in the sample size enhanced the likelihood of demonstrating, with sufficient power, a statistically and clinically significant effect. The Company submitted a protocol amendment to the FDA for the recommended additional exclusion criterion, which amendment was approved in the second quarter. The EUPHRATES trial has been using the new exclusion criterion since receiving the recommendation from the DSMB on April 11, 2014. The additional criterion has further positively refined the target patient population for the trial.

In late September, 2014 the Company received notice from the FDA concerning the Companys overall path to commercialization, whereby the FDA approved the Companys Statistical plan subsequent to the second interim analysis of the EUPHRATES trial, and also agreed to a clear regulatory pathway. In that regard, the FDA has agreed to accept a modular Premarket Approach (%MA+), which should be submitted in the first half of 2015. The modular submission provides the opportunity to meaningfully accelerate the commercialization period to as early as the first half of 2016 upon FDA approval.

The composite mortality rate of randomized patients in the trial since the implementation of an additional exclusion criterion on early April, 2014 has increased significantly, which trend suggests a strong clinical indication and that those patients most likely to benefit from the treatment are being properly identified and randomized into the trial. This composite mortality rate is similar to that seen in the prior European EUPHAS study, which demonstrated a significant mortality reduction in septic shock.

On November 25, 2014, the Company announced the presentation at the American Society of Nephrology of the largest ever analysis of Japanese registry data on the significant mortality rate reduction in patients with septic shock treated with Toraymyxini. The mortality rate of patients treated with two PMX cartridges was 34.5% compared to 47.0% in the untreated group, representing an approximate 25% relative reduction in mortality at 28 days. It was noted that PMX therapy is most effective in patients at the highest risk of death and that those patients who were treated with two PMX cartridges demonstrated a more meaningful benefit versus those treated with only one cartridge. This is the same treatment methodology used in the EUPHRATES trial.

On March 10, 2015, the Company announced the results of the most recent DSMB meeting. The key recommendations of the DSMB were that the EUPHRATES trial proceed as planned and that an interim analysis be performed on the patients randomized since the last protocol amendment with the amended exclusion criterion. The Company will now submit its statistical analysis plan to the FDA for approval. The analysis will be performed on patients randomized into the trial for the period from the date of the implementation of the additional exclusion criterion in April, 2014 until approximately the end of the third quarter. Results should be available late in the fourth quarter. The analysis plan will include stopping rules for safety, efficacy and futility, as well as a sample size recalculation if necessary.

As another important step towards commercialization, the Company has developed a working prototype of its proprietary hemoperfusion/RRT (renal replacement therapies) pump. This pump is specifically designed to simplify its treatment for patients with septic shock and is intended for use in acute care settings under the direction of doctors and nurses. The pump was introduced to a select group of critical care clinicians and nephrologists at the CRRT conference held in San Diego in February, 2015. The Company expects to secure CE mark, FDA 510K licensing and clearances in 2015 in preparation for the potential commercial launch of its septic shock treatment device, PMX, as early as the first half of 2016.

As of March 24, 2015, 335 patients have been randomized into the EUPHRATES trial, 64 of whom have been randomized since implementation of the additional exclusion criterion in April, 2014.

The EUPHRATES trial is currently the only active Phase III study in the area of septic shock.

PMX is marketed in Japan and Europe and has been used to treat more than 100,000 sepsis patients safely and effectively. Spectrals EAAï can identify patients that will benefit from PMX and monitor the

effects of the treatment. This combination of the EAAï diagnostic and the PMX therapeutic has been utilized by clinicians in Europe since November 2007 and has demonstrated a significant reduction in mortality. The market opportunity for Spectral is large, as the combined diagnostic and therapeutic product is expected to fulfill a major unmet need for the approximately 350,000 patients who develop severe sepsis or septic shock in the U.S. each year. Over half of these patients potentially have highly elevated levels of endotoxin. The U.S. market potential for this treatment is estimated at over \$ 3 billion.

#### **OPERATIONS**

In 2014 the Companys activities focused on implementation of the EUPHRATES trial.

The Company also continued to sell its EAAï 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 2014 \$	December 31 2013 \$	December 31 2012 \$
Revenue	2,964	2,672	2,589
Loss and comprehensive loss	(9,492)	(11,307)	(8,543)
Basic and diluted loss per common share	(0.06)	(0.09)	(80.0)
Weighted average number of commons shares outstanding	154,540,951	128,265,141	113,883,394
Total assets	11,862	9,438	12,586

The total number of shares outstanding as of the date of this Managements Discussion & Analysis is 179,755,741.

# REVENUE

Total revenues for the year ended December 31, 2014 were \$2,964 compared to \$2,672 for the prior year, representing an increase of approximately 11 %.

Royalty revenue of \$1,890 (2013 - \$1,602) is earned in US dollars and has remained consistent with prior year levels. Recorded royalty revenue in 2014 was positively impacted by a strengthening US dollar against the Canadian currency.

Sales of proprietary biochemicals of \$282 increased by \$30, or 12%, over the prior year due primarily to the timing of orders by one of the Companys major customers.

Overall EAAï product revenues (diagnostics and instrumentation) decreased slightly from \$818 in 2013 to \$792 in this fiscal year. Diagnostic test revenues increased by \$146, or 25%, due mainly to increased usage in Europe. Lower instrumentation sales offset the higher revenues from the diagnostic. The Company expects to see a further increase in both diagnostic test revenues and instrumentation sales in 2015.

## **FINANCE INCOME**

Finance income in 2014 was \$60 compared to \$83 in 2013. The decrease is due to lower cash balances throughout the year.

## **EXPENSES**

Operating costs in 2014 were \$13,125, compared to \$14,062 in the prior year. Of this decrease, \$851 is directly attributable to the EUPHRATES trial activities. During 2014, the Company initiated 5 additional clinical sites and enrolled 93 patients. Comparatively, the Company initiated 19 sites and enrolled 142 patients in the trial in 2013. Apart from the activities of the EUPHRATES trial, the Company continues to maintain a low cost operating structure for its base business operations.

Employee benefit costs in 2014 were \$3,460, compared to \$3,332 for the prior year, representing a \$128 increase. The increase is attributed primarily to an increase in the share based compensation.

EUPHRATES trial costs (as disclosed in Note 17 of the Financial Statements) were \$7,073 in 2014 compared to \$7,924 for the year ended December 31, 2013. A significant portion of EUPHRATES trial costs is comprised of consulting and professional fees paid to the trials contract research organization, product distribution centre, co-ordinating centre and other clinical and regulatory consultants. The lower costs in 2014 are a result mainly of a reduced number of new sites initiated and a reduced number of randomized patients in the trial after implementation of the additional exclusion criterion in April, 2014. To date, cumulative trial costs total \$25,890.

There is no management services fee in 2014. The \$275 of management services fee in 2013 was paid to Medwell Capital Corp. for the provision of various consulting services related to the operation and management of the EUPHRATES trial and the Companys investor relations program. The agreement for the provision of this service was terminated in 2013.

The \$273 of product development costs in 2014 is related to the development of the Companys proprietary hemoperfusion/RRT (renal replacement therapies) machine, as described above.

Regulatory and investor relations costs in 2014 amounted to \$300, compared to \$250 in 2013. The increase was attributable to an expansion of investor relations initiatives in the latter part of the year. We expect to continue this program in 2015.

Deferred tax recovery of \$609 in 2014 represents a utilization of capital losses, which were applied to a capital gain that was generated on the expiration of certain warrants on September 2, 2014.

#### Loss

For the year ended December 31, 2014, the Company reported a loss of \$9,492 compared to a loss of \$11,307 for the year ended December 31, 2013 due primarily to lower costs for its EUPHRATES trial and the deferred tax recovery of \$609, described above.

The total number of shares outstanding for the Company was 179,737,241 as at December 31, 2014.

# 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, 2014 and the comparative year ended December 31, 2013:

Year ended December 31, 2014	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
Revenue Loss and comprehensive	844	778	643	699	2,964
loss	(3,175)	(2,451)	(2,012)	(1,854)	(9,492)
Basic and diluted loss per common share	(0.02)	(0.02)	(0.01)	(0.01)	(0.06)
Weighted average number of common shares outstanding	134,462,580	134,462,639	168,846,613	179,737,241	154,540,951

Year ended December 31, 2013	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
Revenue	708	572	679	713	2,672
Loss and comprehensive loss	(2,077)	(3,040)	(2,517)	(3,673)	(11,307)
Basic and diluted loss per common share	(0.02)	(0.02)	(0.02)	(0.03)	(0.09)
Weighted average number of common shares outstanding	113,883,394	132,139,805	132,669,898	134,096,936	128,265,141

# **BALANCE SHEET, FINANCIAL CONDITION AND LIQUIDITY**

Cash and cash equivalents of \$10,054 at December 31, 2014, increased by \$2,825, from \$7,229 at December 31, 2013. This increase was attributable to the following:

Cash operating losses	\$(9,547)
Net proceeds on private placement	12,816
Share options exercised	60
Share purchase warrants exercised	1
Working capital	(461)
Property and equipment, net	(44)
	\$2,825

# **PRIVATE PLACEMENTS**

1. On June 10, 2014, the Company entered into agreements for a non-brokered private placement of up to \$18,200 (the \( \Omega\) ffering+), comprised of a Tranche \( \Omega\)+component and a Tranche \( \Omega\)+component.

The Tranche %+component of the private placement, in the amount of \$13,200, was completed on July 25, 2014. The Company received net proceeds of \$12,816 which will be used to fund its EUPHRATES trial and for working capital and general corporate purposes.

The Tranche %+component is comprised of 45,051,186 common shares (%hares+) of the Company at a subscription price of \$0.293 per Share, for aggregate gross proceeds of \$13,200, of which (a) 17,064,846 Shares, for aggregate proceeds of \$5,000, were sold to Toray Industries, Inc.; (b) 15,358,360 Shares, for aggregate gross proceeds of \$4,500 were sold to Birch Hill Equity Partners Management Inc.; (c) 9,726,958 Shares for aggregate proceeds of \$2,850, were sold to other investors; and (d) 2,901,022 Shares, for aggregate proceeds of \$850 were sold to other related parties at the date of the transaction.

The Tranche %+component of the Offering is comprised of additional Shares to be sold to Toray by the Company of up to \$5,000, if, as and when the Company exercises the right (the %all Right+), granted by Toray to the Company. The Call Right is exercisable by written notice given by the Company to Toray at any time on or after March 1, 2015 until March 15, 2015, to require Toray to purchase from the Company, at a subsequent closing to occur on April 1, 2015, up to that number of Shares as is determined by dividing the Call Right amount exercised (up to the \$5,000), as applicable, by the volume weighted average trading price of the Shares on the TSX for the twenty trading days ending on the business day prior to the day the Call Right is exercised. The Shares to be sold to Toray in Tranche %+will only be sold if the Company exercises the Call Right.

2. On April 2, 2013, the Company completed a private placement financing, whereby the Company issued 18,666,667 common shares in the capital of the Company (%Common Shares+), at a price of \$0.30 per Common Share, to three investors for aggregate gross proceeds of \$5,600 (%The Private Placement+). The Company received net proceeds of \$5,480 which was used to continue to support the Company EUPHRATES clinical trial and for general corporate purposes.

As part of the Private Placement, Toray Industries, Inc. (‰oray+) acquired 16,666,667 Common Shares at a price of \$0.30 per Common Share, for \$5,000. Two other investors acquired 2,000,000 Shares at a \$0.30 per Share, for gross proceeds of \$600, bringing the aggregate gross proceeds of the Private Placement to \$5,600.

# **NORMAL COURSE ISSUER BID**

On December 15, 2014 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 common shares (the %hares+). Pursuant to the notice, the Company may purchase up to 3,594,745 of its Shares, representing approximately 2% of its issued and outstanding Shares, during the twelve month period commencing December 17, 2014 and ending December 16, 2015.

At the time of acceptance, there were 179,737,241 Shares issued and outstanding. The Company may purchase up to 22,461 Shares on the TSX during any trading day, which represents approximately 25% of the average daily trading volume on the TSX for the most recently completed six calendar months prior to the TSXs acceptance of the notice of the NCIB. All Shares purchased under the issuer bid will be cancelled.

Subsequent to the year end, the Company repurchased 90,000 Shares for \$56.

#### **RELATED PARTIES**

All related parties and the respective transactions have been disclosed in Note 20 to the Financial Statements for the years ended December 31, 2014 and 2013.

1. Toray Industries, Inc. ( ‰oray+)

Toray holds 33,731,513 Spectral shares, representing approximately 18.8% (2013 . 12.4%) of Spectrals issued and outstanding capital, calculated on a non-diluted basis.

Toray is entitled to nominate one director (the ‰oray Representative+) to the Board of Directors as long as it owns in the aggregate not less than 10% of the common shares issued and outstanding calculated on a non-diluted basis. Mr. Koichiro Takeshita is the Toray representative.

2. Birch Hill Equity Partners Management Inc.(%Birch Hill+)

Birch Hill, through a number of its funds and an investee Company, holds 32,715,345 common shares of the Company representing approximately an 18.2% ownership interest. Birch Hill was not a related party in 2013 since it held less than 10% of the issued and outstanding common shares.

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

3. Key management consists of the Companyos four executive officers and its Board of Directors.

There are no other related party transactions.

# **SUBSEQUENT EVENT**

On March 14, 2015, as described in Note 22, the Company provided written notice to Toray to exercise the Call Right granted by Toray to the Company. Toray is required to purchase from the Company, on April 1, 2015, 9,041,592 common shares (% hares+) at a subscription price of \$0.553 per Share (representing the 20 day volume weighted average trading price of the Shares on the TSX for the 20 day trading period ending March 13, 2015) for aggregate gross proceeds of \$5,000.

#### OUTLOOK

The Company expects to continue to generate sales in 2015 pursuant to its existing and new commercial arrangements for EAAï and its proprietary biological reagents. The strategic focus in 2015 will be on the successful implementation of clinical, regulatory and other operational initiatives targeting commercialization readiness for potential market launch in the U.S. as early as the first half of 2015.

As at December 31, 2014 the Company had \$10,054 available to fund its commercialization activities and operations. An additional \$5,000 is expected upon the closing of Tranche B of our previously announced financing pursuant to exercise of the Call Right in April, 2015.

#### **BUSINESS RISKS**

The Companys operations are exposed to a variety of risk factors inherent in new product development. The Companys 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 <a href="https://www.sedar.com">www.sedar.com</a>.

# **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 cash equivalents and trade and other receivables.

- i. Cash: The Company places its cash with Canadian Schedule I banks.
- ii. Cash equivalent: The cash equivalent consists of a premium money market savings account placed with a Canadian Schedule I bank with an original maturity of 3 months or less. The premium money market savings account can be converted to cash on demand.
- iii. 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, 2014 and 2013, no material 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 cash equivalents 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. All of the Company's financial liabilities are classified as current liabilities. Current liabilities were \$3,042 as at December 31, 2014 with all of them having expected settlement dates within one year. There are uncertainties related to the timing and use of the Company's cash resources.

# c. Market Risk

- i. Currency risk: The majority of the Company's revenue is denominated in U.S. dollars and Euros. At December 31, 2014, cash and cash equivalents included US\$378. Trade and other receivables included a total of US\$393 and "54. Trade and other payables included a total of US\$1,739 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, 2014 amounts would have an impact on losses by \$105.
- ii. Interest rate risk: The Company has no material 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 and cash equivalents 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.

The Company achieves this by maintaining sufficient cash and cash equivalents and 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.

#### CRITICAL ACCOUNTING ESTIMATES

The financial statements of Spectral are prepared in accordance with International Financial Reporting Standards (%FRS+) as issued by the International Accounting Standards Board (%ASB+) 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 Companys operation and financial results in the 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 to the Financial Statements for the years ended December 31, 2014 and 2013. Certain policies are more significant than others and are, therefore, considered critical accounting estimates. Accounting policies are considered to be critical if they rely on a substantial amount of judgment in their application or if they result from a choice between accounting alternatives and that choice has a material impact on the reported results or financial position. The policies identified as critical to Spectral are discussed below.

In addition to accounting policies, 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 Financial Statements and the reported amounts of revenue and expenses during the reporting period. The most significant estimates are related to the recoverability of purchased technology and licences, property and equipment, the valuation assumptions related to share compensation, and accrual estimates made for clinical trial expenses. Actual results could differ from those estimates.

#### **FINANCIAL INSTRUMENTS**

Financial assets and liabilities are recognized when the Company becomes a party to the contractual provision of the instrument. Financial assets are derecognized when the rights to receive cash flows from the assets have expired or have been transferred and the Company has transferred substantially all risks and benefits of ownership.

The classification is determined at initial recognition and depends on the nature and purpose for which the instruments were acquired:

a. Financial assets and financial liabilities at fair value through profit or loss:

A financial asset or financial liability is classified in this category if acquired principally for the purpose of selling or repurchasing in the short term. Derivatives are also included in this category unless they are designated as hedges.

Financial instruments in this category are initially and subsequently stated at fair value. Transaction costs are expensed in the statement of loss and comprehensive loss. Gains and losses arising from changes in fair value are presented within operating loss in the statement of loss and comprehensive loss in the year in which they arise. Financial assets and liabilities at fair value through profit or loss are classified as current except for the portion of the expected to be realized or paid beyond twelve months of the balance sheet date, which is classified as non-current.

# b. Loans and receivables:

Loans and receivables are non-derivative financial assets that have fixed or determinable payments that are not quoted in an active market. The Companys cash and cash equivalents and trade and other receivables are classified as loans and receivables.

Loans and receivables are initially recognized at the amount expected to be received, less any discounts to reduce the loans and receivables to fair value. Subsequently, they are carried at amortized cost using the effective interest method less impairment losses. The impairment loss of receivables is based on a review of all outstanding amounts at year end. Bad debts are written off in the period in which they are identified. Interest income is recognized by applying the effective interest rate, except for short-term receivables when the recognition of interest would be immaterial.

#### c. Other financial liabilities at amortized cost:

Other financial liabilities are carried at amortized cost and include accounts payable and accrued liabilities. Other financial liabilities are initially recognized at the amount required to be paid, less, when material, a discount to reduce the payable to fair value. Subsequently, other financial liabilities are measured at amortized cost using the effective interest method. Other financial liabilities are classified as current liabilities if payment is due within twelve months. Otherwise, they are classified as non-current liabilities.

The Company derecognizes financial liabilities when, and only when, the Companys obligations are discharged, cancelled or they expire.

# d. Financial liabilities and equity instruments:

Debt and equity instruments are classified as either financial liabilities, or as equity, in accordance with the substance of the contractual arrangement and the definition of a financial liability and an equity instrument.

An equity instrument is any contract that evidences a residual interest in the assets of an entity after deducting all of its liabilities. Equity instruments issued by the Company are recorded at the proceeds received, net of direct issue costs.

Proceeds received on issuance of units, consisting of common shares and warrants, are allocated to those two instruments based on their relative fair values. Transaction costs are also allocated to the common shares and warrants in proportion to the allocation of proceeds.

Repurchase of the Company's own equity instruments is recognized and deducted directly in equity. No gain or loss is recognized in profit or loss on the purchase, sale, issue or cancellation of the Company's own equity instruments.

Financial liabilities are classified as either financial liabilities at fair value through profit or loss, or other financial liabilities.

# **TRANSACTION COSTS**

Transaction costs directly attributable to financial assets and liabilities that are not classified as fair value through profit or loss are included in the amortized cost of the related asset or liability and recognized in earnings through the effective interest method. Transaction costs related to financial assets and liabilities classified as fair value through profit or loss are expensed as incurred.

The Company does not enter into financial instruments for trading or speculative purposes.

Trade and other payables (excluding advance from a related party) are classified as other financial liabilities and are carried at amortized cost using the effective interest rate method.

## **REVENUE RECOGNITION**

Product sales are recognized as revenue when evidence of a contract exists, the selling price is fixed and determinable, collection is reasonably assured and on shipment to respective customers. Royalty revenue from technology licence agreements is recognized over the term of the agreements based on sales of the underlying products. Technology access fees are recognized as revenue over the term of related licence agreements. The difference between payments received and amounts recognized as revenue is reflected in the balance sheet as deferred revenue.

# **INVENTORIES**

Obsolete, redundant and slow moving inventory is identified and written down to net realizable value.

#### **INCOME TAXES**

As at December 31, 2014, the Company has approximately \$28,000 in deferred income tax assets consisting primarily of operating loss carry forwards and discretionary research development expenditures. Deferred income tax assets are recognised only to the extent that it is probable that future taxable profit will be available against which the temporary differences can be utilised. The Company has not recorded any deferred income tax assets. Approximately \$609 deferred tax asset valuation allowance was released during the year as a result of the expiration of the Share Purchase Warrants that gave rise to a capital gain.

# INTANGIBLE ASSET

On April 21, 2010, the Company paid \$502 to Toray pursuant of the terms of a license agreement granting Spectral the exclusive development and commercial rights in the U.S. for PMX. This amount is being amortized over 20 years, unless there is a permanent impairment in value, in which case it will be written off. The license has a remaining useful life of fifteen years.