

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

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

This Management's Discussion & Analysis ("MD&A") for the nine months ended September 30, 2015 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.

The following discussion should be read in conjunction with the condensed interim financial statements for the nine months ended September 30, 2015, and the audited annual financial statements of the Company for the years ended December 31, 2014 and 2013 (the "Annual Financial Statements"), as well as management's discussion and analysis for the year ended December 31, 2014.

### **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.

### **DISCLOSURE CONTROLS AND INTERNAL CONTROLS**

The Company's 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 ("IFRS").

The accounting policies applied in these financial statements are based on IFRS effective for the nine months ended September 30, 2015, as issued and outstanding as of November 12, 2015, the date the Board of Directors approved the statements.

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

- They have reviewed the condensed interim financial statements and this MD&A (“the 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

This document and the related 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) 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 (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.

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 Company's 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 (EAA™), the only FDA cleared diagnostic for the measurement of endotoxin.

\* 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 (“IDE”) 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 January, 2013, an 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 were 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. This recommendation was consistent with data from previous PMX trials, which demonstrated that the PMX column is most effective in reducing mortality rates of sicker patients.

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 end point of 28-day mortality had been achieved.

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 Toraymyxin™. 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.

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. The first three modules include physical, chemical and safety testing data, as well as requisite manufacturing information. All three modules have now been filed with the FDA. The Company expects to file the fourth, and final, module providing clinical data by the fourth quarter of 2016 as an anticipated final step in the PMA approval process.

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 remains powered at 80 percent and the alpha remains at  $<0.05$  for its primary end

point. 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.

In order to determine the appropriate sample size, statistical analysis was performed based on the actual composite mortality rate of patients randomized in the trial (approximately 50 percent) and the actual mortality rate of similar patients who were treated with the PMX medical device in Europe using the same protocol as the EUPHRATES trial (approximately 40 percent). The mortality data for these treated patients was drawn from a validated patient registry which has been tracking such information for over three years. The sample size recalculation is further supported by independent published data showing a predicted mortality rate in the range of 60 to 65 percent for patients in septic shock with a multiple organ dysfunction score ("MODS") similar to those being randomized in the Company's trial.

The Company is now on track to recruit the last 65 of the required 446 evaluable trial patients. Based on current enrolment rates, it is expected that the trial should be completed by June, 2016.

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 150,000 sepsis patients safely and effectively. Spectral's EAA™ can identify patients that will 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 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.

## **COMMERCIALIZATION PROGRESS**

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 Intensive Care Unit ("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 stand-alone pump is also designed to provide an open platform for other hemoperfusion cartridges and to deliver continuous renal replacement therapy ("CRRT") when indicated. Approval of the instrument by Health Canada is anticipated during the fourth quarter of 2015 ,or in early 2016, with 510K approval in the United States targeted for the first quarter of 2016.

Other commercialization initiatives include new packaging for the EAA™ diagnostic to simplify usage and reduce lab technician time in hospitals; the automation and scale up of the manufacturing process at Spectral's plant in Toronto, Canada to increase production capacity; and lastly, the Company is planning for a sales and distribution infrastructure capable of servicing a large potential market in anticipation of timely FDA approval and subsequent commercialization of its unique treatment for septic shock.

## **OPERATIONS**

During the first nine months of 2015, the Company's activities focused on implementation of the EUPHRATES trial and commercialization readiness programs.

The Company also continued to sell its EAA™ diagnostic and its proprietary reagents under the terms of existing commercial arrangements.

In October 2015, the Company expanded its business alliance with the Toray Medical Co., Ltd. through an exclusive agreement to distribute Spectral's EAA™ diagnostic across fifteen countries in the Middle and Far East: India, South Korea, Taiwan, Singapore, Thailand, Malaysia, Indonesia, Philippines, Vietnam, Cambodia, Myanmar, Brunei, Laos, the Kingdom of Saudi Arabia, and the Republic of Turkey. Revenues from this agreement are expected starting in the first quarter of 2016.

On November 10, 2015, the Company announced a non exclusive European distribution agreement for its EAA™ diagnostic with Fresenius Medical Care in eight countries – Germany, Denmark, Sweden, Finland, Norway, Poland, Hungary and the Czech Republic.

## **OPERATING RESULTS**

### **REVENUE**

Revenue for the three months ended September 30, 2015 was \$679, compared to \$643 for the same period in the preceding year. For the nine months ended September 30, 2015 revenue was \$2,374 compared to \$2,265 for the same period in 2014. Revenues for the first nine months of the year were consistent with prior year levels and this trend is expected to continue for the remainder of the year.

### **EXPENSES**

Operating costs for the three months ended September 30, 2015 were \$3,192, compared to \$2,668 for the same period in the preceding year, an increase of \$524. For the nine months ended September 30, 2015 operating expenses were \$9,566 compared to \$9,930 for the same period in 2014, a decrease of \$364.

This fluctuation in operating costs is almost entirely attributable to the EUPHRATES trial activities. The higher costs in the three months ended September 30, 2015 are attributable to costs associated with the PMA submission and investigator meetings held in the third quarter of 2015. The lower costs in the first nine months of 2015 are the result of fewer clinical site initiations and a reduced number of randomized patients in the trial after implementation of the additional exclusion criterion in April, 2014.

Regulatory and investor relations costs for the nine months ended September 30, 2015 amounted to \$505, compared to \$185 for the corresponding period in 2014. The increase is attributable to the expansion of investor relations initiatives which is expected to continue throughout the remainder of the year.

Deferred tax recovery of \$609 for the three and nine months ended September 30, 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.

### **FINANCE INCOME**

Finance income represents interest earned on the Company's premium rate savings account. The amount of interest earned in any given period, is directly dependant on the balance of funds in the account as well as the interest rate at the time.

### **Loss**

For the three months ended September 30, 2015, the Company reported a loss of \$2,493 compared to a loss of \$1,403 for the three months ended September 30, 2014. The same prior year period included a deferred tax loss recovery of \$609. The loss for the nine months ended September 30, 2015 was \$7,124, a small increase from the loss of \$7,029 for the same period in the prior year.

## SHARES OUTSTANDING

The total number of shares outstanding as of the date of this Management's Discussion & Analysis is 190,686,405.

## BALANCE SHEET, FINANCIAL CONDITION AND LIQUIDITY

Cash and cash equivalents of \$8,404, at September 30, 2015, decreased by \$1,650, from \$10,054 at December 31, 2014. This decrease was attributable to the following:

|                                     |                  |
|-------------------------------------|------------------|
| Cash operating losses               | \$(6,811)        |
| Private placement                   | 6,021            |
| Property and equipment expenditures | (235)            |
| Share options exercised             | 139              |
| Shares repurchased under the NCIB   | (355)            |
| Working capital                     | (409)            |
|                                     | <u>\$(1,650)</u> |

## PRIVATE PLACEMENTS

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

The Tranche "A" 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 "A" component was comprised of 45,051,186 common shares ("Shares") 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 "B" component of the Offering was 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 "Call Right"), granted by Toray to the Company.

The Company provided written notice to Toray to exercise the Call Right granted by Toray to the Company on March 14, 2015. On April 1, 2015, Toray purchased 9,041,592 common shares ("Shares") 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 period ended March 13, 2015) for aggregate gross proceeds of \$5,000.

2. In connection with the Toray offering, Birch Hill Equity Partners Management Inc. exercised their anti-dilution rights and acquired 2,007,872 Shares at the subscription price of \$0.553 per Share, for aggregate gross proceeds of \$1,110.

In total, the Company issued 11,049,464 Shares for aggregate gross proceeds of \$6,110. The Company received net proceeds of \$6,021 which will be used to fund its EUPHRATES trial and for working capital and general corporate purposes.

## **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 "Shares"). 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 TSX's acceptance of the notice of the NCIB. All Shares purchased under the issuer bid will be cancelled.

The Company repurchased 480,000 Shares under this NCIB for \$355 as of September 30, 2015.

## **RELATED PARTIES**

All related parties and the respective transactions have been disclosed in Note 12 to the condensed interim financial statements for the nine months ended September 30, 2015 and 2014.

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

Toray holds 42,773,105 Spectral shares, representing approximately 22.4% (2014 – 18.8%) of Spectral's issued and outstanding capital, 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 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 32,984,718 common shares of the Company representing approximately a 17.3% (2014 – 14.1%) ownership interest calculated on a non-diluted basis.

Birch Hill is entitled to nominate one director to the Company's 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 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 sales for the remainder of 2015 pursuant to its existing and new commercial arrangements for EAA™ and its proprietary biological reagents. The strategic focus for the remainder of 2015 will continue to be on the successful implementation of clinical, regulatory and other operational initiatives targeting commercialization readiness for potential market launch in the U.S.

As at September 30, 2015 the Company had \$8,404 available to fund its commercialization activities and operations.

## **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 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 September 30, 2015 and 2014, 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 quarterly 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 \$2,884 as at September 30, 2015 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 September 30, 2015, cash and cash equivalents included US\$32. Trade and other

receivables included a total of US\$411 and €59. Trade and other payables included a total of US\$1,066 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 September 30, 2015 amounts would have an impact on losses by \$86.

- 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 condensed interim financial statements of Spectral for the nine months ended September 30, 2015 are prepared in accordance with IAS 34, "Interim Financial Reporting". The condensed interim financial statements should be read in conjunction with the annual financial statements for the year ended December 31, 2014, which have been prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB") as set out in the CPA Canada Handbook. The Company has identified the accounting policies and estimates that are critical to the understanding of the Company's operation and financial results in the condensed interim financial statements. Certain policies are selected by management and approved by the Finance and Audit Committee of the Board of Directors. These accounting policies are set out in Note 3 of the Annual 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.

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. The condensed interim financial statements of the Company have been prepared using similar estimation methods for the critical accounting estimates as were used for the annual financial statements and they conform to the requirement of IAS 34 "Interim Financial Reporting".