



**AMENDED AND RESTATED ANNUAL INFORMATION FORM**

*Year ended December 31, 2014*

May 4, 2015

**TABLE OF CONTENTS****AMENDED AND RESTATED ANNUAL INFORMATION FORM**

Year ended December 31, 2014

FORWARD-LOOKING INFORMATION	1
CURRENCY	1
CORPORATE STRUCTURE	1
NARRATIVE DESCRIPTION OF THE BUSINESS OF SPECTRAL	2
PRODUCTS	7
EAA™	7
Competition	9
PMX	9
Competition	10
BIOLOGICAL REAGENTS	11
TRENDS	12
MANUFACTURING	12
GOVERNMENT REGULATION	12
REGULATION - U.S.	13
REGULATION - CANADA	14
REGULATION – EUROPE	14
PATENTS AND TRADEMARKS	14
PROPERTIES	15
EMPLOYEES	15
LEGAL PROCEEDINGS	15
RISK FACTORS	15
DIVIDENDS	25
DESCRIPTION OF CAPITAL STRUCTURE	25
MARKET FOR SECURITIES	26
Trading Price and Volume	26
DIRECTORS AND OFFICERS	27
FINANCE AND AUDIT COMMITTEE	29
INTEREST OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS	30
TRANSFER AGENT	30
MATERIAL CONTRACTS	30

INTEREST OF EXPERTS	31
ADDITIONAL INFORMATION	32

**SPECTRAL MEDICAL INC.**  
*(formerly Spectral Diagnostics Inc.)*  
**(“SPECTRAL” OR THE “COMPANY”)**  
**AMENDED AND RESTATED ANNUAL INFORMATION FORM**  
**FOR THE YEAR ENDED DECEMBER 31, 2014**

**FORWARD-LOOKING INFORMATION**

Certain statements contained or incorporated by reference in this Amended and Restated Annual Information Form (“AIF”) constitute “forward-looking statements” (within the meaning of applicable securities laws). Forward-looking statements include those relating to, but not limited to, the submission of the modular Premarket Approach in the first half of 2015, the results of our statistical analysis plan being available in Q4 2015, the successful development of our hemoperfusion/RRT (renal replacement therapies) pump, including securing CE mark, FDA 510K licensing and clearances in 2015 for such pump, the successful designation of PMX in the recently announced Expedited Access Program for medical devices, initiatives to upgrade our Toronto manufacturing operations for EAA™, the successful completion of our EUPHRATES trial and obtaining regulatory approval in the United States for a treatment for septic shock that combines EAA™ with PMX, our plans for the commercialization of PMX and EAA™ and our expectations, intentions, plans and beliefs, including information as to the future financial or operating performance of Spectral and anticipated events or results. In certain cases, forward-looking statements can be identified by the use of words such as “plans”, “expects”, “intends”, “believes” or variations of such words, or statements that certain actions, events or results “may”, “could”, “would”, “might” or “will” be taken, occur or be achieved. Such forward-looking statements or forward looking information reflect management’s beliefs, estimates and opinions regarding Spectral’s future growth, results of operations, performance, and business prospects and opportunities at the time such statements are made. Forward-looking statements are necessarily based upon a number of estimates and assumptions that, while considered reasonable by Spectral, are inherently subject to significant business, economic, competitive, political and social uncertainties and contingencies. Forward-looking statements are not guarantees of future performance. By their nature, forward-looking statements involve known and unknown risks, uncertainties and other factors that are in many cases beyond the Company’s control. Such risks and uncertainties include those factors referred to in the section “Risk Factors” in this AIF. Although Spectral has attempted to identify important factors that could cause actual actions, events or results to differ materially from those expressed or implied in the forward-looking statements, there may be other factors that cause actions, events or results not to be as anticipated, estimated or intended. There can be no assurance that forward-looking statements will prove to be accurate. Accordingly, readers should not place undue reliance on forward-looking statements. Spectral expressly disclaims any intention or obligation to update or revise any forward-looking statements, or to update the reasons why actual results could differ from those reflected in the forward-looking statements, whether as a result of new information, events or otherwise, except in accordance with applicable securities laws.

**CURRENCY**

Unless otherwise noted, all dollar references in this AIF are expressed in Canadian dollars.

**CORPORATE STRUCTURE**

The Company was incorporated as Spectral Diagnostics Inc. pursuant to the *Business Corporations Act* (Ontario) (the “OBCA”) on July 29, 1991. Pursuant to Articles of Amendment, effective March 16, 1992,

Spectral (i) re-designated, reclassified and changed its authorized capital to provide that the authorized capital consists of an unlimited number of one class of shares designated as "Common Shares" ("Shares"); and (ii) deleted the private company provisions from its Articles.

On April 1, 2005, Spectral amalgamated with its wholly owned subsidiary, Sepsis Inc. ("Sepsis"), under the OBCA and continued as Spectral Diagnostics Inc.

The Company's year end was changed to December 31, effective as at the end of the 2006 calendar year.

Effective December 31, 2014, the Company changed its name to "Spectral Medical Inc."

The Company has one wholly owned U.S. subsidiary, Spectral Diagnostics (US) Inc., which was incorporated on September 14, 2009 under Section 102 of the General Law of the State of Delaware. Spectral Diagnostics (New Brunswick) Inc., which was incorporated on June 28, 2010 under the *Business Corporations Act* (New Brunswick), was dissolved December 9, 2014. The Company also has a 49% ownership interest in Altercyte Inc., incorporated July 9, 2012 under the General Law of the State of Delaware. The remaining 51% is held by individuals in the U.S. Neither of the remaining two subsidiaries have active operations.

The head and registered office of the Company is located at 135 The West Mall, Unit 2, Toronto, Ontario M9C 1C2.

## **NARRATIVE DESCRIPTION OF THE BUSINESS OF SPECTRAL**

The Company's strategic focus is on the development and commercialization, in North America, of the first theranostic treatment for septic shock utilizing its Endotoxin Activity Assay (EAA™) diagnostic and the Toraymyxin™ ("PMX") therapeutic. This unique approach first identifies patients with high endotoxin levels that would most benefit from a targeted therapy and then applies a treatment that removes endotoxin from the blood stream. The Company also manufactures and sells certain proprietary reagents.

## **CLINICAL AND COMMERCIALIZATION MILESTONES**

The Company's sole 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. ("Toray") of Japan, granting Spectral the exclusive development and commercial rights in the U.S. for PMX. Under the terms of the agreement, Spectral is seeking U.S. Food & Drug Administration ("FDA") approval for PMX. The Company intends to commercialize the product together with its EAA™, which is the only FDA cleared diagnostic for the measurement of endotoxin.

The Company received final approval of its Investigation Device Exemption ("IDE") from the FDA on February 26, 2010. This 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.

The Company signed a long-term, exclusive distribution agreement in November 2010 with Toray and Toray Medical Co., Ltd. of Japan to market and sell PMX in Canada. Both the PMX product and Spectral's EAA™ diagnostic are already approved for sale by Health Canada. The Company is developing

commercial plans for the Canadian market so that it is in position to commence sales activities pending FDA approval.

In the fourth quarter of 2011, "Xigris", an Eli Lilly product, was withdrawn from the market globally, following the 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 ("Aggenix 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 Company's request to add up to an additional 30 clinical trial sites. This provided 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 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. 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 Company's Vice President, Sales & Marketing. Dr. Guadagni will primarily be 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 the Company's Endotoxin Activity Assay (EAA™) 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  $\leq 9$  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 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 trial's 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 of 2014. 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 Company's overall path to commercialization, whereby the FDA approved the Company's 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 ("PMA"), which is expected to 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 pending FDA approval.

The composite mortality rate of randomized patients in the trial since the implementation of the additional exclusion criterion in early April 2014 has increased significantly, which 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 reduction in mortality from 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 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.

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 additional exclusion criterion. The Company will 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 of 2015. Results are anticipated to be available late in the fourth quarter of 2015. 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 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 pending FDA approval.

The Company's focus is on the successful completion of the EUPHRATES trial and obtaining regulatory approval in the United States for a treatment for septic shock that combines Spectral's EAA™ diagnostic with PMX, a targeted therapy. This theranostics approach is the first in the area of sepsis.

The FDA has accepted the Company's plan for a rolling Pre Market Approval (PMA) submission. The submission consists of four separate modules. The first three modules will include physical, chemical and safety testing data, as well as requisite manufacturing information. The fourth and final module provides clinical data.

Spectral has completed the first three modules and plans to submit them beginning in May 2015, in accordance with an agreed timeframe with the FDA over the next four to six months. The final module will be submitted upon availability of clinical data from the EUPHRATES trial. This process allows for timely review of the various modules so that the timeframe to commercialization, after completion of clinical data analysis, can be reduced significantly.

In addition to its rolling PMA submission, the Company is evaluating the potential benefits of the recently announced Expedited Access Program (EAP) for medical devices by the FDA. An EAP designation could result in an early conditional approval of PMX for sale in the United States and shift some of the focus for gathering confirmatory clinical data to post market approval.

Toray, in accordance with the exclusive license agreement with the Company, has built a new manufacturing facility in Japan dedicated to PMX and is in the process of ensuring that the new plant will meet FDA regulatory requirements. The Company is also in the process of updating its own manufacturing operations in Toronto for EAA™. These initiatives should ensure a sufficient and reliable supply of product for the North American market upon FDA market approval of PMX.

Other steps in the Company's commercialization program include the development of an effective sales force and a targeted market launch of the PMX product in the United States. These initiatives could be undertaken by the Company on its own, or through an alliance with a third party that already has such capabilities. The Company will evaluate the most appropriate direction as it moves forward with its clinical and regulatory pathway. The costs of these programs cannot be reasonably estimated at this time. It is likely, however, that additional capital would be required to implement these initiatives. The Company expects to determine its commercialization path over the next twelve to eighteen months.

## **FINANCINGS**

The Company has completed a number of private placement financings to raise funds in order to support the Company's EUPHRATES clinical trial and for general corporate purposes. The financings are detailed as follows:

### ***March 2, 2010***

The Company completed a private placement financing for aggregate gross proceeds of \$19,500,000. Net proceeds from the financing, after related costs, were approximately \$17,500,000.

### ***September 9, 2011***

The Company completed a private placement of 33,333,333 Shares pursuant to an arrangement agreement dated June 28, 2011 (as amended, the "Arrangement Agreement") entered into with Medwell Capital Corp. ("Medwell") for aggregate gross consideration of \$10,000,000. In accordance with the plan of arrangement pursuant to the Arrangement Agreement, Medwell distributed 54,282,834 Shares to its shareholders and retained a 13.4% residual ownership position in Spectral at that time.

### ***April 2, 2013***

The Company completed a private placement financing, whereby the Company issued 18,666,667 Shares, at a price of \$0.30 per Share, to three investors for aggregate gross proceeds of \$5,600,000 ("the 2013



Private Placement"). The Company received net proceeds of \$5,480,000. As part of the 2013 Private Placement, Spectral issued 16,666,667 Shares to Toray at a price of \$0.30 per Share, for \$5,000,000 representing approximately 12.6% of the then issued and outstanding Shares, calculated on a non-diluted basis and 2,000,000 Shares to two other investors at a price of \$0.30 per Share, for gross proceeds of \$600,000, bringing the aggregate gross proceeds of the Private Placement to \$5,600,000.

***July 25, 2014 and April 1, 2015***

On June 10, 2014, the Company entered into agreements for a non-brokered private placement of up to \$18,200,000 (the "2014 Private Placement"), comprised of a Tranche "A" component and a Tranche "B" component.

The Tranche "A" component of the 2014 Private Placement was completed on July 25, 2014. The Tranche "A" component was comprised of 45,051,186 Shares issued at a subscription price of \$0.293 per Share for aggregate gross proceeds of \$13,200,000, of which (a) 17,064,846 Shares, for aggregate proceeds of \$5,000,000, were sold to Toray; (b) 15,358,360 Shares, for aggregate gross proceeds of \$4,500,000 were sold to Birch Hill Equity Partners Management Inc. ("Birch Hill"); (c) 9,726,958 Shares for aggregate proceeds of \$2,850,000, were sold to other investors; and (d) 2,901,022 Shares, for aggregate proceeds of \$850,000 were sold to other related parties at the date of the transaction.

The Tranche "B" component of the 2014 Private Placement was comprised of additional Shares to be sold to Toray by the Company of up to \$5,000,000, if, as and when the Company exercises the right (the "Call Right"), granted by Toray to the Company. The Call Right was 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 was determined by dividing the Call Right amount exercised (up to the \$5,000,000), as applicable, by the volume weighted average trading price of the Shares on the Toronto Stock Exchange ("TSX") for the 20 trading days ending on the business day prior to the day the Call Right is exercised. On March 14, 2015, the Company provided written notice to Toray to exercise the Call Right. Therefore, on April 1, 2015, Toray purchased 9,041,592 Shares from the Company 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 trading period ending March 13, 2015) for aggregate gross proceeds of \$5,000,000.

Following the exercise by the Company of the Call Right, and in connection with the exercise by Birch Hill of their pre-emptive rights, on April 1, 2015 Birch Hill acquired a further 2,007,872 Shares at a subscription price of \$0.553 per Share, for net proceeds of \$1.1 million.

The net proceeds of the 2014 Private Placement will be used to fund the Company's EUPHRATES clinical development program for PMX and for working capital and general corporate purposes.

***Share Purchase Warrant Exercise***

In addition to the private placements described above, the Company received \$585,000 in October 2013 on the exercise of 1,462,500 share purchase warrants, at an exercise price of \$0.40 per Share, which funds are also being used primarily for the EUPHRATES trial.

## **SUBSEQUENT EVENT**

### **Normal Course Issuer Bid**

On December 15, 2014, the Company announced that the TSX approved its notice of intention to make a normal course issuer bid ("NCIB") for its outstanding Shares through the facilities of the TSX. 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 on December 17, 2014 and ending on 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 NCIB will be cancelled.

Since December 31, 2014, the Company has repurchased 90,000 Shares pursuant to the NCIB for \$55,000.

## **PRODUCTS**

### **EAA™**

#### **Description and Clinical Development**

The Company has developed a rapid diagnostic test for detection of components of gram negative bacterial cell wall (endotoxin). Increased blood levels of endotoxin are indicative of invasive infection or severe leakage of endotoxin from the gut. Endotoxin initiates a systemic response which can rapidly lead to organ dysfunction, septic shock and ultimately death.

The incidence of sepsis is approximately 1,000,000 cases reported per year in the United States, with over 2 million cases worldwide. Rapid diagnostic tests to rule in or rule out sepsis have previously not been available. The current state of the art in microbiology for one case of sepsis requires a minimum of 24 hours to confirm the presence of a potentially infectious micro-organism and frequently up to 72 hours to definitively rule out the presence of an infectious micro-organism.

The intensive care unit of a hospital ("ICU") has the highest attributable mortality and cost due to infection and its sequelae. ICUs in North America consume significant financial and health care resources and ICU patients with sepsis have mortality rates which generally range between 30% and 50%. Inappropriate antibiotic use and lack of rapid diagnostics for sepsis detection compound the high cost of patient management and the impact of lost productivity due to mortality and morbidity.

A significant increase in sepsis can be expected in the next decade due to a number of factors, such as:

- advances in medical technologies, such as increasingly aggressive cancer therapies;
- improvements in the life expectancy rates of patients predisposed to sepsis, such as premature neonates, patients with co-morbid conditions, and immune suppressed patients;
- the aging of the population, which significantly increases the demographic segment predisposed to sepsis; and

- the widespread use of broad-spectrum antibiotics has increased the rates of both antibiotic resistance and infections contracted as a result of being hospitalized, which have a direct impact on the incidence of sepsis.

In 1995, the Company entered into a strategic alliance with two researchers, Dr. Alex Romaschin from The University of Toronto and Dr. Paul Walker from The Toronto General Hospital, to further the development of rapid diagnostic tests for the detection of infections in patients in critical care settings. The alliance was incorporated as Sepsis Inc. and carried out research and development on infection diagnostic tests under a joint venture agreement with the Company. In August 1998, the Company and Sepsis had advanced the development of infection diagnostic tests and entered into a strategic development and marketing alliance with Elan Diagnostic ("Elan"), a business unit of Elan Pharmaceutical plc., now Alkermes Pharma Ireland Ltd. ("Alkermes").

Alkermes made an initial purchase of 7% in Sepsis for US\$ 2 million and committed to funding up to US\$6 million on the successful attainment of regulatory submissions and approvals. Under the terms of the agreements with Alkermes, Sepsis was entitled to receive funding for the development of certain infection diagnostic products, milestone payments on the achievement of regulatory submissions and the receipt of approvals for certain infection diagnostic tests, royalties based on "in-market" sales of these tests and on manufacturing profits. The Company received US\$ 3 million in funding and earned US\$ 2.5 million in milestone revenue from Alkermes.

The first Sepsis infection diagnostic test, an endotoxin activity assay measuring gram-negative infection, identifies patients who are at risk for developing severe sepsis on admission to intensive care settings. This assay is used to risk stratify patients for developing sepsis.

In February 2001, Spectral reached an agreement to acquire 29.4% of the issued shares in the capital of Sepsis from Dr. Paul Walker and Dr. Alex Romaschin, the co-inventors of Sepsis proprietary infection diagnostic products, in exchange for 1.5 million Shares on the satisfactory submission to the FDA for marketing approval of the gram-negative infection test. The acquisition increased Spectral's ownership to approximately 93% of the issued and outstanding shares of Sepsis, effective June 18, 2001. The Company received Health Canada approval for the EAA™ in December 2002 and FDA clearance in June 2003.

On June 18, 2001, the Company reported the acceptance for filing by Sepsis of its Premarket Approval ("PMA") application to the FDA for its first gram negative EAA™. The EAA™ is a rapid in-vitro diagnostic test that measures endotoxin activity in a whole blood sample.

In October 2001, the EAA™ test was presented to the FDA Microbiology Advisory Panel. The test was not recommended for approval for ruling out gram negative infection. While the EAA™ assay was considered novel and a significant improvement over existing technology, the premise that endotoxin could rule out gram-negative infection in these complex critical patients was challenged.

In December 2001, Spectral submitted an application to Health Canada for approval for marketing of the EAA™ test in Canada and received approval in March 2002 for the manufacture and marketing of the EAA™ test. European approval was received in 2002.

In April 2002, agreement was reached with the FDA for a re-submission path of the EAA™ as a 510K – de novo classification. This submission described the use of the EAA™ to risk stratify patients in the ICU for the development of severe sepsis. On June 18, 2003, Spectral announced receipt of final notification of market clearance in the U.S. for its EAA™. The uniqueness of the assay is demonstrated by the approval

process, which first determined that the EAA™ was both safe and effective, and then directed it to be listed with U.S. Federal Registry as the standard method for endotoxin analysis. Any other assays for endotoxin will require pre-market notification and will be assessed against the Special Controls Guidance Document identifying the EAA™ as the standard.

On July 17, 2003, the Company reached an agreement with Alkermes and its affiliates to terminate their joint venture relationship and all related agreements. Pursuant to such termination, Spectral acquired all rights to the EAA™ including all related intellectual property and marketing rights. On August 20, 2003, the Company paid \$1.2 million (received from the proceeds of a private placement to Elan) as consideration for the termination of all previous obligations owing to Alkermes. Following the termination of the joint venture agreements with Alkermes, the Company obtained full rights and control over commercialization of the EAA™ effective August 20, 2003. The acquisition increased Spectral's ownership in Sepsis to 100%. On April 1, 2005, the Company amalgamated with Sepsis and continued as Spectral Diagnostics Inc. Effective December 31, 2014, the Company changed its name to "Spectral Medical Inc."

The EAA™ assay is currently under evaluation by a number of major health care institutions worldwide and distribution arrangements are in place in Europe and Japan.

### **Competition**

Currently, the EAA™ is the first FDA cleared test for risk stratification of patients for developing severe sepsis and one of two products, the other being a procalcitonin test, on the market. There are other products in development that may undergo clinical testing trials in the future and perhaps result in further competition to Spectral's assay. The assays will provide information that is different from the EAA™, but may also be useful in the management of sepsis. It is difficult to predict when any of these new assays may be available for the market.

### **PMX**

#### **Description and Clinical Development**

PMX is a therapeutic hemoperfusion device that removes endotoxin from the bloodstream and is manufactured by Toray. PMX has been used in more than 100,000 patients globally and has demonstrated in clinical trials that it safely and effectively removes endotoxin and reduces mortality in patients with severe sepsis.

Spectral has obtained from Toray certain exclusive rights to commercialize, develop and exploit PMX. On March 6, 2009, Spectral entered into a License and Material Supply Agreement with Toray, which was subsequently amended and restated in June 2014. This agreement will expire on December 31, 2029, but is subject to a five year renewal option upon mutual agreement of the parties. Under this agreement, Toray granted Spectral an exclusive license in the United States and Puerto Rico to Toray's intellectual property rights in and to PMX, and Spectral took responsibility for seeking (at Spectral's own expense) appropriate regulatory authorizations of the PMX product in the United States and Puerto Rico. Consideration payable by Spectral to Toray for the grant of rights includes certain milestone payments related to obtaining appropriate regulatory authorization to commence sales of PMX in the United States and Puerto Rico, as well as an obligation on Spectral to pay royalties to Toray once commercial sales begin in the United States and Puerto Rico. The agreement also includes obligations on Toray in respect of supply of the PMX.

In addition, on November 10, 2010, Spectral entered into an Exclusive Distribution Agreement with Toray, which gives Spectral the exclusive right to distribute PMX in Canada. This distribution agreement will terminate on March 31, 2021, but may be automatically renewed on a year-to-year basis unless either party

gives the other party written notice not to renew at least 6 months prior to the expiration date of the original term or the extended term of the agreement. There is a guaranteed minimum purchase quantity provided for in the agreement, which can be reviewed after April 1, 2015, and revised upon mutual agreement of the parties.

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) in June 2010. The results demonstrated that, when PMX is added to conventional therapy, the result is significantly improved hemodynamics and organ function. PMX reduced 28-day mortality in patients with severe sepsis and septic shock by 21% in comparison to those patients in the conventional therapy group.

The Company obtained final approval of its IDE from the FDA to conduct a pivotal U.S. trial – a randomized double blinded prospective trial, comparing standard of care versus standard of care plus PMX in patients with proven endotoxemia (“the EUPHRATES trial”). The use of a specific diagnostic test, the EAA™, to identify endotoxin, a substance that is known to be harmful to the body, and to then proceed to remove it with the PMX column makes this study unique in the history of sepsis clinical trials. The study is currently configured, to enrol 605 evaluable patients with the primary end point of 28 day mortality.

The Company announced in November, 2014 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. They also noted 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.

Of the 350,000 patients in the U.S. who are diagnosed with the clinical syndrome of severe sepsis and septic shock each year, there are over half of them who develop high levels of endotoxin and who currently face a high risk of mortality with limited treatment options.

PMX is sold in Japan and Europe and has been used safely and effectively in over 100,000 patients worldwide. The product is approved for sale in many jurisdictions worldwide, including Canada.

### **Competition**

To date, there has been no other major direct therapeutic competitor identified in this particular market segment, although there are a number of companies that either are, or were, engaged in clinical research and development related to other sepsis therapies.

There are a number of technologies either currently marketed or at a different stage of development as compared to our PMX program in the U.S., including:

- Xigris™ (Eli Lilly), which is activated protein C and targets factors responsible for coagulation, fibrinolysis, and inflammation such as TNF-alpha. This product had been sold in various major markets around the world but was pulled from the market after an unsuccessful confirmatory pivotal trial in October 2011.

- Talactoferrin alfa (Agennix AG), which is also thought to target TNF and may possibly have an antibacterial effect as well as a significant effect in cancer. The first of two anticipated pivotal Phase III trials was halted in February 2012 for safety reasons.
- CytoFab™ (AstraZeneca), which is similarly thought to neutralize the effects of TNF in a sepsis patient. In 2005, Protherics was suggesting that TNF had a more profound effect on sepsis syndrome than IL-1. Timing of the initiation of a pivotal trial is uncertain.
- Eritoran (Eisai), which targets the TLR-4 pathway in an attempt to down-regulate its negative effect in critically ill patients. Eisai announced in Q1 2011 that a pivotal trial with Eritoran failed to meet its primary endpoint.
- Gambro, Fresenius and CytoSorbents are exploring the hypothesis that the removal of “middle weight molecular peptides” such as cytokines via extracorporeal purification will have a statistically significant treatment effect on sepsis patients. None of these programs has made an announcement in respect of conducting late stage clinical trials in the U.S.
- Inflammagen™ Therapeutics has initiated a 200-patient Phase II pilot study to examine the efficacy and safety of Inflammagen Shok-Pak as a potential treatment for critically ill patients in the ICU. Shok-Pak is believed to block auto digestion, a condition in which digestive enzymes not only break down food inside the intestine, but also the intestine itself, causing these enzymes to be carried into the bloodstream and lymphatic system where they digest and destroy healthy tissue. Conditions expected to qualify for the study include new-onset sepsis and septic shock, post-operative complications and new-onset gastrointestinal bleeding. The primary endpoint is to provide preliminary efficacy and safety data on the gastrointestinal administration of Inflammagen Shok-Pak in the reduction of morbidity at discharge or at day 28.
- There are a number of compounds targeting sepsis in preclinical development. These are very early stage and there is no clinical evidence available to date.

## **BIOLOGICAL REAGENTS**

Since 1997, the Company's scientific expertise has provided the forum for new products and technologies, positioning the Company for a larger and diversified base of business. Spectral has leveraged its diagnostic expertise in molecular biology, assay development and production into other revenue producing activities. The Company develops, produces and markets recombinant cardiac proteins, antibodies and calibrators. These are sold for use in research and development as well as in products manufactured by other diagnostic companies.

The Company has actively marketed its capability to develop and manufacture monoclonal and polyclonal antibodies and recombinant proteins. In 1999, the Company engaged non-exclusive distributors to broaden its in-house sales and marketing activities in this area resulting in broader offerings of these products.

The Company has entered into license and supply agreements with diagnostic product manufacturers for the use of its proprietary Troponin I recombinant protein molecules for the calibration of commercial Troponin I assays. Customers for these products include Beckman Coulter, Abbott Laboratories and BioMerieux. Royalty revenue is earned from these license arrangements based on a percentage of end user sales of Troponin I.

## **TRENDS**

The Company's diagnostic product, EAA™, was approved in 2003 and is now being used in a clinical trial to guide a specific therapy for the removal of endotoxin in patients with septic shock. Future revenue trends, after the approval of this combination theranostic treatment, are difficult to predict.

The Company believes that it will experience consistent sales of its EAA™ product but that the market for the diagnostic as a stand-alone product is limited. Sales of this product are currently under \$1 million per annum.

Royalty and reagent revenues are expected to continue at similar levels to 2014 for the next year under existing contracts and will help fund day-to-day operations.

Management has determined that the successful commercialization of PMX, a therapeutic for the absorption of endotoxin, in combination with the EAA™ diagnostic will be its key strategic focus. This therapeutic device, if approved, could fill a large unmet need for the approximately 350,000 patients that suffer from severe sepsis or septic shock each year in the U.S. Commercialization could commence as early as the first half of 2016, provided the FDA approves the PMA submission.

## **MANUFACTURING**

Spectral manufactures the EAA™ at its Canadian facility at 135 The West Mall, Toronto, Ontario. This facility complies with the requirements of Current Good Manufacturing Practices ("CGMPs") and regulating authorities including the FDA and Health Canada's Therapeutic Product Programme. The Company upgraded its manufacturing facilities in 2007 and is self-sufficient for the manufacture of its EAA™ product and the manufacture of its proprietary biological reagents. At Spectral, antigens are recombinantly-engineered and produced in bacteria using leading edge technology and know-how. Several recombinantly-derived, patented molecules have shown superior performance and stability over their native counterpart. The Company's patented recombinant single-chain Troponin I-C polypeptide has gained worldwide recognition as a superior reagent for calibration of cardiac Troponin I assays. Certain non-proprietary assembly processes are currently subcontracted to third party suppliers.

The PMX device is manufactured by Toray. Construction of Toray's new plant facilities has been completed. The new plant complies with FDA regulatory requirements and is expected to be fully operational before the U.S. market launch of PMX.

## **GOVERNMENT REGULATION**

The Company is subject to various government regulations with respect to the sales and marketing of products in the U.S. and Canada and by comparable laws in other countries. For example, all medical devices sold in the U.S. must be manufactured under U.S. Quality System Regulation for Medical Devices, 21 CFR Part 820 (cGMP compliance). In Canada, such medical devices must be in compliance with Canadian Medical Device Regulations ("CMDR") and ISO 13485:2003 Quality Management Systems Requirements for Regulatory Purposes.

The Company began to introduce Quality Program under ISO 9001: 1994 and under U.S. FDA 21 CFR 820 Quality System regulations as early as 1994. Spectral received its first ISO 9001:1994 Quality Standards certifications in May 1996 with Lloyd's Registrar Quality Assurance (LRQA) and successfully obtained re-certification in 2003.

Health Canada introduced requirements for ISO 13485 Quality Management System for all medical devices manufactured and sold in Canada and made this requirement mandatory commencing January 1, 2003.

ISO 13485 Quality Management System compliance is also a pre-requisite for products sold in the European Community. On April 16, 2002, 2004 and 2007 Spectral earned CAN/CSA-ISO 13485-98 Quality Management System certification under Canadian Medical Device Conformity Assessment System ("CMDCAS") that meets the Health Canada requirements of section 32(2) (f), 32(3) (j) and 32(4) (p) of the CMDR and European Medical device regulations. In 2002, 2004, 2007, and 2010, Spectral also successfully defended FDA foreign facility inspections under 21 CFR QS regulations. In May 2005, Spectral updated its quality programs with the latest ISO Quality Management Systems (ISO 9001:2000 and ISO 13485:2003) and acquired certification by TÜV SÜD America Inc. The following are the current medical devices cleared for marketing by the FDA and the corresponding date of 510(k) and Health Canada approval:

- Endotoxin Activity Assay Kit – Health Canada, March 2002;
- Endotoxin Activity Assay Kit – FDA, June 16, 2003; and
- Endotoxin Activity Assay Kit – CE Mark, September 8, 2003.

PMX, for which Toray has all regulatory compliance responsibility, is also approved for sale in Canada.

#### **REGULATION - U.S.**

The testing, production and sale of products are subject to regulation by numerous state and federal governmental authorities, principally the FDA.

Pursuant to the U.S. Federal Food, Drug, and Cosmetic Act ("FD&C Act"), the FDA regulates the pre-clinical and clinical testing, manufacture, labeling, distribution and promotion of medical devices.

Medical devices are segregated into one of three classes (Class I, II or III). The classification of a device is based on the level of control necessary to assure the safety and effectiveness of the device. The complexity of the submission and generally the approval times are based on the regulatory class of the device. Device classification depends on the intended use and also the indications for use of the device. In addition, classification is risk based, that is, the risk the device poses to the patient and/or the user is a major factor in the class it is assigned. Class I devices include devices with the lowest risk and Class III devices include those with the greatest risk. Class I devices are subject to general controls, Class II devices are subject to general controls and special controls and Class III devices are subject to general controls and must receive Pre Market Approval ("PMA") from the FDA.

Before some Class I and most Class II devices can be introduced in the market, either the manufacturer or distributor of the device is required to follow the pre-market notification process described in section 510(k) of the FD&C Act. A 510(k) is a pre-marketing submission made to the FDA to demonstrate that the device to be marketed is as safe and effective as (that is, substantially equivalent to) a legally marketed device that is not subject to a PMA. Applicants must compare their 510(k) device to one or more similar devices currently on the U.S. market and make and support their substantial equivalency claims. Recently, the FDA has been requiring more rigorous demonstration of substantial equivalence than in the past, in some cases requiring submission of extensive clinical data. It generally takes from three to six months from submission to obtain 510(k) clearance but in some cases may take longer. For any devices that are cleared through the 510(k) process, modifications or enhancements that could significantly affect safety or effectiveness, or that constitute a major change in the intended use of the device, require a new 510(k) submission.



A PMA application must be filed for Class III devices. A PMA application must be supported by valid scientific evidence to demonstrate the safety and effectiveness of the device, typically including the results of clinical investigations, bench tests and laboratory studies. The PMA application must also contain a complete description of the device and its components and a detailed description of the methods, facilities and controls used to manufacture the device. In addition, the submission must include the proposed labeling, advertising literature and any training materials. Before the manufacturer of a device can submit the device for FDA approval, it generally must conduct a clinical investigation of the device. Although clinical investigations of most devices are subject to the investigational device exemption ("IDE") requirement, clinical investigations of in-vitro diagnostic tests are exempt from the IDE requirement. In addition, the in-vitro diagnostic device must be labeled for research use only ("RUO") or investigational use only ("IUO"), and distribution controls must be established to assure that in-vitro diagnostic devices distributed for research or clinical investigation are used only for those purposes.

Products are also subject to the Clinical Laboratories Improvement Act ("CLIA") and related federal and state regulations that provide for regulation of laboratory testing. The scope of these regulations includes quality control, proficiency testing, personnel standards and federal inspections. CLIA categorizes tests as "waived", "moderately complex" or "highly complex" on the basis of specific criteria. Future amendments of CLIA or the promulgation of additional regulations impacting laboratory testing may have a material adverse effect on Spectral's ability to market products and may have a material adverse effect upon the Company's business, financial condition or results of operations.

Spectral is currently conducting a clinical trial (the EUPHRATES trial) in the U.S. and is seeking a PMA for PMX, a Class III medical device.

Toray, under the terms of its license agreement with Spectral, is responsible for all manufacturing regulatory compliance with FDA standards.

#### **REGULATION - CANADA**

Health Canada sets out the requirements governing the sale, importation and advertisement of medical devices. These regulations are intended to ensure that medical devices distributed in Canada are both safe and effective.

The Company is also required to comply with certain procedures for the disposal of its waste products under the Canadian Code of Practice for the Management of Biological Waste (the "Code"). The Company believes it is in compliance with all required Code provisions.

#### **REGULATION – EUROPE**

The Company's products are subject to registration under the EU Medical Device Directives for general medical devices and in-vitro diagnostic products. All of Spectral's diagnostic tests have acquired CE mark certifications in Europe.

The products of the Company have been submitted in other countries, when appropriate, for registration and approval on a country-by-country basis.

#### **PATENTS AND TRADEMARKS**

Since incorporation, the Company has invested in a patent program to protect its proprietary research and intellectual property. All employees and consultants of the Company are required to assign their rights and inventions to the Company as a term of their employment with Spectral. The patent program of the

Company has resulted in the filing of patent applications and the subsequent issue of several patents throughout the world in connection with its EAA™ product, reagents, antibodies and calibrators.

Many patent applications have been filed by the Company in North America and other countries throughout the world in respect of recombinant proteins, genetically engineered molecules, purified proteins and specific antibodies or combinations of antibodies employed in the commercial products of the Company. Several of these applications have resulted in the issue of patents in various jurisdictions. Other patent applications have been filed describing and claiming a patent in relation to the devices on which the reactions take place.

With respect to trademarks, the Company has obtained U.S. trademark registrations for the Spectral design logo and EAA™ products. Spectral trademarks are either registered or have applications pending in numerous other countries. The Company intends to market its diagnostic tests and control products under these trademarks in selected markets.

Patents for PMX have also been issued worldwide and are the responsibility of Toray. The product has been trademarked outside of North America and trademarks for North America are pending.

## **PROPERTIES**

The Company currently leases approximately 9,000 square feet of office, manufacturing and laboratory space located at 135 The West Mall, Unit 2, Toronto, Ontario. Leases on these facilities expire in July 2017 and are renewable for a further five-year term thereafter.

## **EMPLOYEES**

As at December 31, 2014, Spectral had nineteen employees.

## **LEGAL PROCEEDINGS**

The Company, from time to time, is involved in various claims and legal proceedings of a nature considered normal to its business. While it is not feasible to predict or determine the outcome of these proceedings with certainty, management believes any current actions to be without merit and no provision in respect of these matters has been made in the Company's financial statements.

## **RISK FACTORS**

This AIF includes forward-looking statements about the Company's business and results of operations that are subject to certain risks and uncertainties, including those outlined below. Investors should consider the following risk factors, which are inherent to the Company and its operations, and other information contained in this Annual Information Form, before deciding to purchase securities of the Company.

The risks and uncertainties described below are those we currently believe to be material, but they are not the only ones we face. If any of the following risks, or any other risks and uncertainties that the Company has not yet identified or that we currently consider not to be material, actually occur or become material risks, the Company's business, prospects, financial condition and results of operations and, consequently the price of the Shares, could be materially and adversely affected. There is no assurance that risk management steps taken by the Company will avoid future losses due to the uncertainties described below or other unforeseen risks.

The following factors should be considered carefully in evaluating Spectral and its business:

## **Clinical Development**

The outcome of any clinical trial is uncertain and subject to various risks, including the rate of patient enrolment, trial costs, time to trial completion, quality of clinical data, regulatory issues, efficacy and safety concerns. The Company's EUPHRATES trial carries similar risks, including the possibility of clinical failure to show efficacy or safety, a potential requirement to increase the number of patients enrolled in the trial and the possibility that the product may not be approved. A material change in any of these items could have a significant adverse impact on the operations of the Company.

Positive results from pre-clinical studies and early clinical trials should not be relied upon as evidence that later stage or large scale clinical trials will succeed. The Company will be required to demonstrate with substantial evidence through well-controlled clinical trials that its products are safe and effective for use in a diverse population before the Company can obtain regulatory approvals for their commercial sale. Success in early clinical trials does not mean that future clinical trials will be successful.

## **Product Failure**

The Company's products could cause undesirable and potentially serious side effects during clinical trials that could delay or prevent their regulatory approval or commercialization. Undesirable side effects caused by any of our products could cause the Company or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by regulatory authorities. This, in turn, could prevent the Company from commercializing its products and generating revenues from their sale. In addition, if our products receive marketing approval and the Company or others later identify undesirable side effects caused by the product:

- regulatory authorities may withdraw their approval for the product;
- the Company may be required to recall the product, change the way the product is administered, conduct additional clinical trials or change the labelling of the product;
- a product may become less competitive and product sales may decrease; or
- Spectral's reputation may suffer.

Any one or a combination of these events could prevent the Company from achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing the product, which in turn could delay or prevent the Company from generating revenues from the sale of the product.

## **High Degree of Regulation**

Spectral operates in a highly regulated industry and is subject to the authority and approvals of certain regulatory agencies, including Health Canada, the FDA, the European Union and applicable health authorities in other countries, with regard to the development, testing, manufacturing, marketing and sale of its products. The commercialization of the Company's products first requires the approval of the regulatory agencies in each of the countries where it intends to sell its products. In order to obtain the required approvals, the Company must demonstrate, following preclinical and clinical studies, the safety, efficacy and quality of a product. If the results of the clinical studies of the Company's products are not positive, the Company may not be in a position to make any filing to obtain the mandatory regulatory approval or it may have to perform additional clinical studies on any of its products until the results support the safety and efficacy of such product, therefore incurring additional delays and costs.

Furthermore, the obtaining of regulatory approval is subject to the discretion of regulatory agencies. Even if the Company obtains positive results relating to the safety and efficacy of a product, a regulatory agency may not accept such results as being conclusive and allow the Company to sell its products in its country. A regulatory agency may require that additional tests on the safety and efficacy of a product be conducted prior to granting approval, if any. In addition, regulatory agencies have the power to limit the indicated use of a product, even if the Company obtains regulatory approval for such product.

The process of obtaining such approvals can be costly and time-consuming, and there can be no assurance that regulatory approvals will be obtained or maintained. Any failure to obtain (or significant delay in obtaining) or maintain Health Canada and FDA approvals (or, to a lesser extent, approval of applicable health authorities in other countries) for Spectral's new or existing products could materially affect Spectral's ability to market its products successfully and could therefore have a material adverse effect on the business of Spectral.

In addition, the manufacture, marketing and sale of the products will be subject to ongoing and extensive governmental regulation in the country in which the Company intends to market its products. For instance, if the Company obtains marketing approval for its product in the United States, the marketing of this product will be subject to extensive regulatory requirements administered by the FDA and other regulatory bodies, such as adverse event reporting requirements in compliance with all of the FDA's marketing and promotional requirements. The manufacturing facilities for the Company's product will also be subject to continual review and periodic inspection and approval of manufacturing modifications. Failure to comply with any of these post-approval requirements can result in a series of sanctions, including withdrawal of the right to market a product.

### **Need for Additional Financing**

Spectral's future liquidity and funding requirements could be impacted by a number of factors, including:

- the extent to which new or existing products are successfully developed, gain market acceptance and are competitive;
- the requirement to finance existing or new projects;
- the costs, timing, potential expansion and results of clinical studies and regulatory actions regarding potential products; and
- the costs and timing associated with business development activities, including potential licensing of technologies patented by others.

The Company may be required, from time to time, to raise additional funds for its clinical development activities and operations. The Company may attempt to raise additional funds for these purposes through public or private equity or debt financing, collaborations with other life sciences companies and/or from other sources. There can be no assurance that additional funding or partnerships will be available on terms acceptable to the Company and which would foster successful commercialization of Spectral's products. Furthermore, there can be no assurance that unforeseen developments or circumstances will not alter our requirements for capital. Additional financings that we may pursue may involve the sale of Shares or financial instruments that are exchangeable for, or convertible into, Shares, which could result in dilution to our shareholders. The inability to raise capital on a timely basis, or under appropriate terms, could have a material adverse impact on the operations of the Company.

### **Significant Development and Marketing Required**

Diagnostics, medical devices and other therapeutic products require additional development, testing and investment prior to any final commercialization. There can be no assurance that such products will be successfully developed, prove to be safe and effective in clinical trials, receive applicable regulatory approvals, be capable of being produced in commercial quantities at reasonable costs or be successfully marketed. The long-term success of Spectral must be considered in light of the expenses, difficulties and delays frequently encountered in connection with the development of new technology and the competitive and highly regulated environment in which Spectral operates.

In addition, the successful commercialization of the PMX product in North America will likely require that Spectral finds an appropriate sales and marketing partner that can address the substantial time and costs associated with bringing this new product to market. Failure to find such a partner could adversely affect the financial condition and future prospects of the Company.

### **Market Acceptance of Current and New Products**

Spectral's EAA™ and PMX are relatively new to the market and are subject to all the difficulties new products encounter in development and on introduction. Levels of market acceptance for the Company's products could be impacted by several factors, some of which are not within Spectral's control, including but are not limited to: its or its partners' ability to convince physicians and administrators that these products represent viable and efficacious diagnostic tests and related treatments; the safety, efficacy and cost-effectiveness of the Company's products; the effectiveness of the Company's sales and marketing efforts (or those of its commercial partners); prevalence and severity of side effects; and availability of alternative products from competitors.

### **Ability to Retain and Attract Key Management and Other Experienced Personnel**

Since its inception, the Company has been and continues to be dependent on its ability to attract and retain key scientific, engineering, technical and commercial personnel upon whom the Company relies for its product innovations and commercialization programs. The Company is dependent upon the efforts, skill and business contacts of key members of management and other employees for both the information they generate during the normal course of their activities and the synergies which exist amongst their various fields of expertise and knowledge. Accordingly, the Company's continued success will depend upon the ongoing service of these individuals, who are not obligated to remain employed with the Company. Furthermore, because of a relative scarcity of individuals with the high degree of education and business experience required for the Company's business, competition among companies for qualified employees is intense and, as a result, we may not be able to attract and retain such individuals on acceptable terms, or at all. The loss of the services of any of these individuals could have a material adverse effect on revenues, net income and cash flows and could harm the Company's ability to maintain or grow existing assets and raise additional funds in the future.

In addition, the Company's ability to manage growth effectively will require it to continue to implement and improve its management systems and to recruit and train new employees. There can be no assurance that Spectral will be able to successfully attract and retain skilled and experienced personnel.

### **Competition**

The Company competes with other entities that develop and produce products aimed at diagnosing and treating similar conditions to those addressed by the Company's products, including early-stage

companies, established pharmaceutical companies, universities, research institutions, governmental agencies and health care providers.

In addition, new or prospective products of the Company may be required to compete with existing or future diagnostics, medical devices or other treatments for sepsis. Many of the Company's competitors have more financial and other resources, larger numbers of research and development staff, and more experience and capabilities in researching, developing and testing products in clinical trials, in obtaining FDA and other regulatory approvals, and in manufacturing, marketing and distribution, than the Company. The Company's competitors may succeed in developing, obtaining patent protection for, receiving FDA and other regulatory approvals for, or commercializing, products more rapidly than the Company. In addition, competitive products may be manufactured and marketed more successfully than the Company's new and prospective products.

### **Rapidly Changing Technology**

The field of sepsis is characterized by rapidly changing and developing technologies that include new diagnostics, medical devices and other treatments which could render Spectral's products obsolete at any time and thereby adversely affect the financial condition and future prospects of the Company. There can be no assurance that Spectral will keep pace with technological developments. Competitors have developed or are developing technologies that could be the basis for competitive products. Some of these products have an entirely different approach or means of accomplishing the desired diagnostic or therapeutic effect as compared with the Company's products, and could be more effective and less costly than the Company's products. In addition, alternative forms of medical treatment may be competitive with the Company's products.

### **Patent Protection and Infringement**

The biotechnology industry is heavily reliant on patented technology, and it is not always clear to industry participants which patents cover which types of products, processes or methods of use. The coverage of patents is subject to interpretation by the courts, and this interpretation is not always uniform. As a result, the industry is litigious by nature as products and processes may be subject to patent infringement and to claims of infringement upon the patents of others. Although the Company follows a patent program to protect its technology and takes precautions to avoid infringement against the technology of others, the Company cannot guarantee that the protective steps it has taken are adequate to protect its intellectual property rights. In addition, as the Company's patents expire, we may be unsuccessful in extending their protection through patent term extensions. The expiration of, or the failure to maintain or extend our patents, could have a material adverse effect on the Company's operations.

If the Company is sued for patent infringement, the Company would need to demonstrate that its products or methods of use either do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid, and the Company may not be able to do this. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

The technologies, products and processes of Spectral may be subject to claims of infringement upon the patents of others and, if such claims are successful, could result in the requirement to access such technology by license agreement. There can be no assurance that such licenses would be available on commercially acceptable terms or at all. If Spectral is required to acquire rights to valid and enforceable patents but cannot do so at a reasonable cost, Spectral's ability to manufacture or market its products would

be materially adversely affected. The cost of Spectral's defense against infringement claims by other patent holders may be significant and could negatively impact Spectral's operations.

Spectral has filed patent applications in North America and other countries relating to, *inter alia*, its EAA™ product, reagents, antibodies and calibrators. Several of these applications have resulted in the issue of patents in various jurisdictions. Although Spectral believes that the outstanding patents applied for may be issued, there can be no such assurance, nor can Spectral assure that competitors will not develop functionally similar or superior diagnostic testing devices. Moreover, there is a question as to the extent to which biotechnology discoveries and related products and processes can effectively be protected by patents. The law regarding the breadth or scope of biotechnology patents is new and evolving. No assurance can be given that, if a patent issued to Spectral is challenged, it will be held to be valid and enforceable or will be found to have a scope sufficiently broad to cover competitors' products or processes. The cost of enforcing Spectral's patent rights in lawsuits that it may bring against infringers may be significant and could negatively impact Spectral's operations.

### **Protection of Intellectual Property Rights in Foreign Jurisdictions**

The Company may not be able to protect its intellectual property rights throughout the world. Filing, prosecuting and defending patents on our products in every jurisdiction would be prohibitively expensive. Competitors may use our technologies in jurisdictions where the Company has not obtained patent protection to develop products similar to our own. These products may compete with our products and may not be covered by any of the Company's patent claims or other intellectual property rights.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of Canada and United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favour the enforcement of patents and other intellectual property protection, particularly those relating to life sciences, which could make it difficult for the Company to stop the infringement of our patents. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

### **Licensed Technology**

Certain aspects of Spectral's business are predicated on licensed technology and intellectual property, for example, the technology and intellectual property rights that are licensed from Toray. This subjects Spectral to certain risks that would not be present had Spectral developed the technology and intellectual property independently. Specifically, license agreements typically subject Spectral to milestone obligations and royalty payments. Some of these obligations may be substantial and may obligate the Company to obtain certain regulatory approvals by a specified date or exercise diligence in bringing potential products to market. The failure to meet these obligations typically results in the termination of the license and the loss of rights to the technology. Any such termination could adversely affect the Company's business and financial condition.

In addition, in many third party licenses, Spectral has no control over the prosecution of patents and other intellectual property rights underlying such licenses. As a result, Spectral is dependent on the licensor to diligently pursue and prosecute these intellectual property rights. In such a circumstance, the licensor may not have sufficient incentive to diligently pursue such protection. The failure of the licensor to diligently pursue such protection could adversely affect the Company's business and financial condition.

Additionally, Spectral typically only receives the benefit of intellectual property protection under licenses in those jurisdictions where applications for protection are filed. As a result, the failure of a licensor to file applications for protection in all jurisdictions where the Company intends to conduct business could undercut the ability of the Company to successfully carry on business in these jurisdictions. This could adversely affect the Company's business and financial condition.

Finally, many third party licenses of technology expire when the patents underlying the technology expire or at some period of time after expiration. As a result, the ability of Spectral to exploit and fully commercialize the technology over time may be limited. This may adversely affect the Company's business and financial condition.

### **Fluctuations in Revenue**

The Company's quarterly and annual revenues may fluctuate due to several factors, including seasonal variations in demand, competitive pressure on selling prices, customer order patterns, the rate of acceptance of the Company's products, product delays or production inefficiencies, regulatory uncertainties or delays, clinical trial timing and costs, and timing associated with business development activities, including potential licensing of technologies and international market conditions. The impact of one, or a combination of several, of these factors could have a significant adverse effect on the operations of the Company. In addition, changes in existing collaborative and joint venture relationships, as well as the establishment of new relationships, product licensing and other financing relationships, could materially impact the Company's financial position and results from operations.

### **Changes in Laws and Regulations**

The government and regulatory authorities in Canada, the United States, Europe and other markets in which we may sell our products may propose and adopt new legislation and regulatory requirements relating to medical products approval criteria and manufacturing requirements. In addition, new legislation or changes to existing legislation affecting the Company and its potential customers could decrease demand for the Company's products and affect its results of operation and financial condition. For example, the implementation of health care reform legislation that regulates diagnostic devices could limit the profits that could be made from the development of new diagnostic products. Such legislation or regulatory requirements, or the failure to comply with such, could adversely impact our operations and could have a material adverse effect on the Company's business, financial condition and results of operations.

### **Uncertainties Regarding Health Care Reimbursement and Reform**

The future revenues and profitability of diagnostic companies, as well as the availability of capital, may be affected by the continuing efforts of government and third party payers to contain or reduce costs of health care through various means. For example, in certain foreign markets, pricing of our products is subject to government control. In the U.S., there have been a number of federal and state proposals to implement similar government controls. Spectral's ability to successfully market its products may depend in part on the extent to which reimbursement for the cost of such products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Significant uncertainty exists as to whether newly approved healthcare products will qualify for reimbursement. Furthermore, challenges to the price of medical products and services are becoming more frequent. There can be no assurance that adequate third-party coverage will be available to establish price levels, which would allow Spectral to realize an acceptable return on its investment in product development. While the Company cannot predict whether any such legislative or regulatory proposals will be adopted, the



announcement or adoption of such proposals could have a material adverse effect on the Company's operations.

### **Effects of Inflation and Foreign Currency Fluctuations**

A significant portion of the Company's revenues are denominated in U.S. and European currency, and, therefore, are subject to fluctuations in exchange rates. There is a risk that significant fluctuations in exchange rates may impact the Company's operating margins and may therefore have an adverse impact on the Company's results of operations.

### **Manufacturing Capability**

The Company, or its contract manufacturers (if applicable), must manufacture products in compliance with regulatory requirements, in sufficient quantities and on a timely basis, while maintaining product quality and acceptable manufacturing costs. If the Company is unable to manufacture or contract for such capabilities on acceptable terms, Spectral's plans for commercialization could be materially adversely affected.

Spectral's manufacturing facilities and those of its contract manufacturers are, or will be, subject to periodic regulatory inspections by the FDA and other regulatory agencies and these facilities are subject to Quality System Regulations requirements of the FDA and other standards organizations. Spectral, or its contractors, may not satisfy such regulatory or standards requirements, and any failure to do so may have a material adverse effect on the Company.

In addition, production and scale-up of manufacturing for new products may require the development of new manufacturing technologies and expertise. Manufacturing and quality control problems may arise as the Company attempts to scale-up manufacturing and such scale-up may not be achieved in a timely manner, at a commercially reasonable cost, or at all.

### **Marketing Capability**

The Company currently has limited marketing capabilities and a minimal sales force. In addition, the Company has limited experience in developing, training or managing a marketing or sales force. In order to commercialize its products, the Company must either develop its own sales force or enter into a commercial agreement with a third party. The development of a sales force is costly and will be time-consuming given the limited experience the Company has in that respect. To the extent the Corporation develops a sales force, the Company will be competing against companies who have more experience managing a sales force than the Company and access to more funds than the Company with which to manage a sales force. Consequently, there can be no guarantee that the sales force that the Company would develop would be efficient and would maximize the revenues derived from the sale of the Company's products.

### **Product Liability**

A risk of product liability claims is inherent in the development and commercialization of human therapeutic products. The occurrence of unanticipated serious adverse events or other safety problems could cause regulatory agencies to impose significant restrictions on the indicated uses for which the Company's products may be marketed or impose other restrictions on the distribution or sale of its products. In addition, post-market discovery of previously unknown safety problems could result in withdrawal of the product from the market, product recalls or other material adverse effects on the Company's operations.

In addition, Spectral may be subject to claims of personal injury and could become liable to clinical laboratories, hospitals and patients for injuries resulting from use of its products. Spectral could suffer financial loss due to defects in its products and such financial loss as well as potential litigation expenses could have a material adverse effect on its operations. Spectral has obtained product liability insurance to protect against possible losses of this nature; however, such insurance is expensive and offers limited protection. No assurance can be given that such insurance will be adequate to cover all claims or that Spectral will be able to maintain such insurance at a reasonable cost. A product liability claim against the Company could potentially be greater than the coverage offered and, therefore, have a material adverse effect upon the Company and its financial position. Furthermore, a product liability claim could tarnish the Company's reputation, whether or not such claims are covered by insurance or are with or without merit.

### **Reliance on Key Distributors to Market the Company's Products**

The Company has a number of arrangements with other companies for the marketing, distribution and sale of its products. Revenues are dependent on the sales and marketing efforts of such third parties and there can be no assurance that their efforts will be successful. Failure to establish sustainable and successful sales and marketing programs may have a material adverse effect on the Company's operations.

If any of the Company's distribution agreements are terminated and the Company is unable to enter into alternative agreements or, if the Company elects to distribute new products directly, additional investment in sales and marketing resources would be required. The Company has limited experience in direct sales, marketing and distribution of its products. A failure of the Company to successfully market its products would have a material and adverse effect on the Company.

### **Growth Management**

The Company may decide to add or acquire new products, services or businesses or expand internationally. There can be no assurances that the addition of new products, services or business or expansion internationally, if any, will prove successful. Future growth may cause a strain on the Company's management and its operational and financial resources. There can be no assurance that the Company will be able to effectively manage such growth. The Company's failure to do so could have a material adverse effect upon its business, prospects, results of operation and financial condition. Such demands may require the hiring of additional management personnel and the possible development of additional expertise by management. The performance of any potential new products or businesses or international expansion would be uncertain.

### **Dependence on Contractors**

The Company contracts certain services to outside vendors and consultants in order to implement its clinical programs and operations. These services are key to the Company's success. If any of these vendors or services becomes unavailable, the Company would be required to find appropriate alternatives on a timely basis. Any significant delay could have a material adverse impact on the Company's operations.

### **No Key Man Insurance**

The Company does not have key man insurance in place in respect of any of its senior officers or personnel. Therefore, there is a risk that the unexpected loss of the services of any of its senior officers or key personnel (through serious injury, death or resignation) could have a material adverse effect on the Company's operations.

## **Shareholder Control**

If certain of the Company's shareholders act together, they may be able to exert a significant degree of influence over the Company's management and affairs and over matters requiring shareholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may facilitate or delay or prevent a change in control of the Company and might affect the market price of the Shares. The interests of controlling shareholders may not always coincide with the Company's interests or the interests of other shareholders. In addition, if such a shareholder holds its shares for the purpose of investment, and if it were to sell those shares in the market in the future, it could have significant influences on the market price of the Shares, depending on the market environment at the time of such sale.

## **Legal Proceedings**

As the Company is a therapeutic development entity, the Company may become, in the ordinary course of its business, a party to litigation including, among others, claims in respect of indemnifications the Company has extended to third parties (such as clinical sites) in the normal course of business; matters alleging employment discrimination, product liability, patent or other intellectual property rights infringement, patent invalidity or breach of commercial contract. In general, litigation claims can be expensive and time consuming to bring and to defend against and could result in settlements for damages that could significantly impact the Company's results of operations and financial condition.

Insurance coverage may not be sufficient and the Company may be exposed to lawsuits and other claims related to products used in clinical studies and other product liability, which could increase expenses, harm our reputation and keep management from growing the business.

The use of human therapeutic products, including PMX, involves an inherent risk of product liability claims and adverse publicity. Clinical studies involve trials on humans. These studies create a risk of liability for side effects to participants resulting from an adverse reaction to the products being tested or resulting from negligence or misconduct. While the Company currently maintains insurance related to its completed clinical trials, there is no assurance that this insurance will continue to be available on commercially reasonable terms. Any claims might also exceed the amounts of this coverage. If the Company is unable to obtain insurance at reasonable rates or to otherwise protect itself against potential liability proceedings, it may be required to slow down any future development or investment. The obligation to pay indemnities from clinical trials following complaints could have a material adverse effect on the Company's business, financial condition and results of operations. Claims against the Company, regardless of their merit or potential outcome, may also result in severe public relations problems that could seriously damage the Company's reputation and business viability.

In addition, certain drug retailers require minimum product liability insurance coverage as a condition of purchasing or accepting products for distribution. If any of the Company's products are approved for sale through a compassionate use program, it is the Company's intention to obtain adequate product liability insurance before such products are made available. Failure to satisfy these insurance requirements could impede the Company's ability, or that of any potential distributors of the products, to achieve distribution of these products, which could have a material adverse effect on the Company's business, financial condition and results of operations.

### **Limited Number of Products**

The success of the Company's operations will depend upon: (i) the availability of appropriate product opportunities; (ii) the Company's ability to identify, select, acquire, grow and market those products; and (iii) the Company's ability to generate funds for future products. The Company can expect to encounter competition from other entities having product objectives similar to the Company's. These groups may compete for the same products as the Company, may be better capitalized, have more personnel, and have a longer operating history.

There can be no assurance that there will be a sufficient number of suitable product opportunities available to the Company or that the Company will be able to identify suitable product opportunities. Identifying attractive opportunities is difficult, highly competitive and involves a high degree of uncertainty.

### **Volatility of Share Price**

The stock market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of the Company. In addition, the market price of the Shares, like the share prices of many publicly traded biotechnology companies, has been highly volatile. Announcement of technological innovations or new commercial products by the Company or its competitors, developments or disputes concerning patent or proprietary rights, publicity regarding actual or potential medical results relating to products under development by the Company or its competitors, regulatory developments in both the U.S. and foreign countries, public concern as to the safety of biotechnology products and economic and other external factors, as well as period-to-period fluctuations in financial results, may have a significant impact on the market price of the Shares. The Shares have been subject to significant price and volume fluctuations and may continue to be subject to significant price and volume fluctuations in the future.

In addition, the Shares have, so far, experienced relatively low trading volumes. Significant trades could adversely affect the market price of the Shares.

### **History of Operating Losses**

Since inception, the Company has incurred losses each year. The accumulated deficit from inception to December 31, 2014 is approximately \$49 million. The Company expects to incur additional losses during the periods of research and development, clinical testing, and application for regulatory approval of its products. Unless and until such time as payments from corporate collaborations, product sales and/or royalty payments generate sufficient revenues to fund its continuing operations, the Company expects it will continue to incur losses from operations.

### **DIVIDENDS**

The Company has not paid dividends since its incorporation and Spectral currently has no intention to change its dividend policy in the near future.

### **DESCRIPTION OF CAPITAL STRUCTURE**

Spectral is authorized to issue an unlimited number of Shares. As at March 24, 2015, there were 179,755,741 Shares issued and outstanding. Holders of Shares are entitled to one vote per Share at all meetings of the Company's shareholders, are entitled to dividends if, as and when declared by the board of directors of the Company, and are entitled to participate ratably with respect to the distribution of assets in the event of liquidation, dissolution or winding up of the Company, whether voluntary or involuntary, or any

other distribution of assets for the purpose of winding up the Company's affairs. There are no restrictions on the issue, transfer or ownership of the Shares.

As at December 31, 2014, 5,566,000 options to acquire Shares were issued and outstanding. Each option is exercisable for one Share at a price ranging between \$0.20 and \$0.61 per Share. Such options were granted to the directors, officers, key employees, and others of the Company and have expiry dates ranging from March 2, 2015 to October 15, 2019.

On January 22, 2015, a further 1,250,000 options to acquire Shares were issued to directors, officers, employees, and others of the Company. Each such option is exercisable for one Share at an exercise price of \$0.375 per Share and has an expiry date of January 22, 2020.

All outstanding Share purchase warrants expired on September 2, 2014.

## MARKET FOR SECURITIES

### Trading Price and Volume

The Shares are listed and posted for trading on the Toronto Stock Exchange (the "TSX") under the symbol "EDT" and on the OTCQX exchange in the U.S. under the symbol "EDTXF".

The following table sets forth the price ranges and volume traded on the TSX of the Shares for the periods indicated:

Month	High (\$)	Low (\$)	Volume of Common Shares Traded
January 2014	0.68	0.34	9,123,289
February 2014	0.44	0.30	2,150,080
March 2014	0.38	0.22	3,883,508
April 2014	0.52	0.27	5,093,338
May 2014	0.32	0.26	838,334
June 2014	0.425	0.29	1,689,870
July 2014	0.44	0.37	1,583,365
August 2014	0.40	0.345	1,253,224
September 2014	0.39	0.295	990,935
October 2014	0.35	0.28	957,636
November 2014	0.42	0.32	4,845,305
December 2014	0.395	0.30	1,802,991

## DIRECTORS AND OFFICERS

The following table sets out the names, province or state and country of residence for each of the directors and executive officers of Spectral, their respective positions held with the Company and their principal occupations during the five preceding years, the periods during which each director has served as a director and the number of Shares and options of Spectral beneficially owned, or controlled or directed, directly or indirectly, by that person. Each director holds office until the next annual meeting of shareholders of Spectral.

<b>Name Province/State and Country of Residence Position with the Company and Principal Occupation</b>	<b>Director Since</b>	<b>Number of Shares Beneficially Owned <sup>(1)</sup></b>	<b>Options to Acquire Shares Held <sup>(2)</sup></b>
MR. ANTHONY P. BIHL III <sup>(3)(5)</sup> Connecticut, USA Director CEO of Bioventus LLC	2008	300,000	250,000
MR. ANTHONY BUSINSKAS Ontario, Canada Executive Vice President, CFO & Corporate Secretary	-	125,000	710,000
MS. DEBRA FOSTER Ontario, Canada Vice President Clinical Development	-	54,855	412,500
Dr. GUALTIERO GUADAGNI Ontario, Canada Vice President Sales & Marketing	-	71,361	266,000
MR. KEVIN GIESE <sup>(4)(11)</sup> Alberta, Canada Director Director, President & CEO, Medwell Capital Corp.	2010	3,047,350 <sup>(8)</sup>	250,000
MR. GUILLERMO HERRERA <sup>(6)(7)(9)</sup> Illinois, USA Director Independent Business Consultant	2006	75,000	250,000
MR. WILLIAM STEVENS <sup>(4)(7)(12)</sup> Ontario, Canada Director Independent Consultant	2014	100,000	125,000
Mr. KOICHIRO TAKESHITA Kanagawa, Japan Director, Medical Device Division, Toray Industries, Inc.	2013	-	-
DR. PAUL M. WALKER Ontario, Canada Director, President & CEO	2001	1,456,950 <sup>(10)</sup>	1,900,000

Notes:

- (1) Information as to Shares beneficially owned is based on information provided by the respective directors and officers and has not been verified by the Company.
- (2) Each option is exercisable on its terms for one Share
- (3) Chairman of the Board of Directors
- (4) Member of the Finance and Audit Committee
- (5) Chairman of the Human Resources and Compensation Committee
- (6) Member of the Nomination and Governance Committee
- (7) Member of the Human Resources and Compensation Committee
- (8) These Shares are held by Queensbury Ventures Inc., a company controlled by Mr. Giese and by Mr. Giese directly
- (9) Chairman of the Finance and Audit Committee
- (10) These Shares are held by 1464672 Ontario Inc., a company controlled by Dr. Walker and by Dr. Walker directly.
- (11) Chairman of the Nomination and Governance Committee
- (12) Mr. Stevens became director on September 24, 2014

All of the directors and officers have been engaged for five years in their present principal occupation or in other capacities with the companies or organizations with which they currently hold positions, with exception of (i) Mr. Guillermo Herrera, who was previously Chairman and founder of Pinnacle Biologics Inc. and was with Abbott Laboratories for 24 years prior to that; and (ii) Mr. Anthony P. Bihl III, who is CEO of Bioventus LLC and was Group President of American Medical Systems from 2011 to 2012, President & CEO of American Medical Systems from 2008 to 2011 and, previously, CEO of Siemens DX.

The directors and executive officers of Spectral, as a group, beneficially own or exercise control or direction over, directly or indirectly 5,230,696 Shares representing approximately 2.91% of the issued and outstanding Shares as of the date of this AIF.

Other than as set forth in this AIF:

(a) to the knowledge of the Company, no director or executive officer of the Company is, or has been in the last ten years, a director, chief executive officer or chief financial officer of any company that, while that person was acting in that capacity, (a) was the subject of a cease trade order or similar order, or an order that denied the relevant company access to any exemptions under securities legislation, for a period of more than 30 consecutive days; or (b) was subject to an event that resulted, after that person ceased to be a director or executive officer, in the relevant company being the subject of a cease trade or similar order, or an order that denied the relevant company access to any exemption under securities legislation, for a period of more than 30 consecutive days; and

(b) to the knowledge of the Company, no director, executive officer or shareholder holding a sufficient number of securities to materially affect control of the Company (a) is or has been in the last ten years a director or executive officer of any company that, while that person was acting in that capacity, or within a year of that person ceasing to act in that capacity, became bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency or was subject to or instituted any proceedings, arrangement or compromise with creditors or had a receiver, receiver manager or trustee appointed to hold its assets or (b) has within the last ten years made a proposal under any legislation relating to bankruptcy or insolvency, or become subject to or instituted any proceedings, arrangement or compromise with creditors, or had a receiver, receiver manager or trustee appointed to hold the assets of the director, executive officer or shareholder.

## FINANCE AND AUDIT COMMITTEE

The full text of the Finance and Audit Committee's charter is attached hereto as Schedule "A".

There are three members of the Finance and Audit Committee, Mr. Herrera, Mr. Bihl and Mr. Stevens. Mr. Herrera is the independent Chair of the Finance and Audit Committee. Mr. Bihl and Mr. Stevens are also independent members. All three members are financially literate. A brief biography of such members follows:

**Guillermo Herrera:** Mr. Herrera is a seasoned global healthcare executive with more than 30 years of experience. Currently, Mr. Herrera is an independent business consultant. Previously, Mr. Herrera was the Chairman and founder of Pinnacle Biologics Inc. Prior to that, Mr. Herrera spent 24 years at Abbott Laboratories, most recently serving as Senior Vice President, International Operations and President of Abbott International. In this role, Mr. Herrera was accountable for international commercial operations including sales and marketing of pharmaceutical, nutritional and hospital products in markets outside the U.S.. In 2004, Mr. Herrera joined Rosetta Partners LLC as the Partner and Principal in charge of the private equity division. Mr. Herrera received a B.A. in industrial economics from the Universidad del Valle, Colombia and a M.B.A. from the Kellogg Graduate School of Management at Northwestern University.

**Anthony Bihl:** Mr. Bihl is an experienced executive with more than 30 years in leadership of global healthcare businesses, including a broad base of operational, financial, and senior executive positions. Mr. Bihl is currently the CEO of Bioventus LLC, a global provider of ortho biologic products, effective December 2, 2013. From 2011 to 2012, Mr. Bihl was the Group President of American Medical Systems ("AMS"), a subsidiary of Endo Pharmaceuticals, in Minneapolis, Minnesota. From 2008 to 2011, Mr. Bihl was the President & Chief Executive Officer of AMS. From 2000 to 2007, Mr. Bihl served in various senior leadership positions at Bayer Healthcare, Diagnostics Division including Vice President of Finance, Senior Vice President of Business Planning and Administration and President, Diagnostics Division. Most recently, he was CEO of Siemens DX, upon the acquisition of Bayer's Diagnostics Division by Siemens AG.

**Will Stevens:** Mr. Stevens is an independent business consultant. Mr. Stevens brings over 20 years of experience in the capital markets and the investment industry to Spectral. He has held senior roles in investment banking and private equity and has a successful track record of value creation for shareholders. Mr. Stevens' educational background includes an M.B.A from Harvard University Graduate School of Business Administration.

The charter of the Finance and Audit Committee requires the Finance and Audit Committee to approve the engagement of the external auditor for all non-audit services and the fees for such services, and consider the impact on the independence of the external audit work of fees for such non-audit services.

For the years ended December 31, 2014 and December 31, 2013, the Company's auditor, PricewaterhouseCoopers LLP, was paid as set out below:



**Aggregate Fees Billed for the Years Ended  
(\$)**

<b>Description of Fees</b>	<b>December 31, 2014</b>	<b>December 31, 2013</b>
Audit Fees	63,500	60,000
Audit-Related Fees <sup>(1)</sup>	1,200	1,320
Tax Fees	Nil	Nil
All Other Fees	Nil	Nil
<b>Total</b>	<b>64,700</b>	<b>61,320</b>

<sup>(1)</sup> Administrative expenses

### **INTEREST OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS**

Except as set out below, no director or executive officer of Spectral or any person that beneficially owns, or controls or directs, directly or indirectly, more than 10% of the Shares, or any associate or affiliate of any such person, has had any material interest in any transaction of the Company within the three most recently completed financial years, which has materially affected or is reasonably expected to materially affect the Company.

Mr. Koichiro Takeshita is the Toray nominee to the board of directors. Mr. Takeshita is the Director, Medical Device Division of Toray Industries.

Mr. Will Stevens is the Birch Hill nominee to the board of directors. Mr. Will Stevens is an independent business consultant.

### **TRANSFER AGENT**

The transfer agent and registrar for the Shares is Computershare Trust Company of Canada at its principal office in the city of Toronto.

### **MATERIAL CONTRACTS**

The following is a list of the material contracts of the Company that were either entered into during the most recent financial year or were entered into prior to January 1, 2014 but are still in effect:

- a license agreement with Toray granting the Company the exclusive development and commercial rights in the U.S. for PMX. See “Products – PMX – Description and Clinical Development”.
- a long-term, exclusive distribution agreement with Toray Medical Inc. to market and sell PMX in Canada. See “Products – PMX – Description and Clinical Development”.
- a private placement agreement dated March 7, 2013 with Toray. Pursuant to the 2013 Private Placement, we sold and Toray subscribed for 16,666,667 Shares in our capital for a subscription price of \$0.30 per Share for aggregate subscription proceeds of \$5,000,000.10. The 2013 Private Placement gave Toray certain pre-emptive rights, including pre-emptive rights upon issuance of additional Shares (including Shares issued pursuant to this offering). We must give Toray notice of any issuance of Shares during the pre-emptive rights period that is not related to the exercise of warrants or options, specifying the total number of Shares issued or to be issued and the issue price of such additional Shares. The pre-emptive rights period is defined as the period of time from the effective date of the private placement agreement (March 7, 2013) until the date Toray sells, assigns or transfers any of the Shares under the private placement agreement, other than to an affiliate. Upon receipt of notice,

Toray shall have the right, exercisable for a period of thirty days by written notice to us, to subscribe for and purchase from us, for a price per Share equal to the issue price, up to its proportionate interest of the additional Shares, subject to compliance with applicable laws. If Toray fails to deliver any such notice within such period, then the pre-emptive rights will be extinguished.

- a private placement agreement dated June 10, 2014 with Toray. Pursuant to the 2014 Private Placement, we sold and Toray subscribed for 17,064,846 Shares in our capital for a subscription price of \$0.293 per Share for aggregate subscription proceeds of \$5,000,000. Toray also granted the Company the right but not the obligation, 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 (April 1, 2015), up to that number of Shares as is determined by dividing \$5,000,000 by the 20 day volume weighted average price of the Shares on the TSX immediately before written notice is given. On March 14, 2015, the Company provided written notice to Toray to exercise the Call Right. On April 1, 2015 Toray purchased 9,041,592 Shares from the Company 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 trading period ending March 13, 2015) for aggregate gross proceeds of \$5,000,000. Following the exercise by the Company of the Call Right, and in connection with the exercise by Birch Hill of their pre-emptive rights described below, on April 1, 2015 Birch Hill acquired a further 2,007,872 Shares at a subscription price of \$0.553 per Share, for net proceeds of \$1.1 million.
- A private placement agreement dated June 10, 2014 with Birch Hill, whereby, we sold and Birch Hill subscribed for 15,358,360 Shares for aggregate proceeds of \$4,500,000. Under the 2014 Private Placement, Birch Hill was granted certain pre-emptive rights, including pre-emptive rights upon issuance of additional Shares. We must give Birch Hill notice of any issuance Shares during the pre-emptive rights period, specifying the total number of Shares issued or to be issued and the issue price of such additional Shares. The pre-emptive rights period is defined as the period of time from the effective date of the private placement agreement (June 10, 2014) until the date Birch Hill sells, assigns or transfers any of the Shares under the private placement agreement, other than to an affiliate. Upon receipt of notice, Birch Hill shall have the right, exercisable for a period of thirty days by written notice to us, to subscribe for and purchase from us, for a price per Share equal to the issue price, up to its proportionate interest of the additional Shares, subject to compliance with applicable laws. If Birch Hill fails to deliver any such notice within such period, then the pre-emptive rights will be extinguished.
- An agreement with Medwell Capital Corp. ("Medwell") as of June 11, 2014, whereby Medwell agrees that so long as Medwell owns in the aggregate not less than 5% of the Shares issued and outstanding from time to time, calculated on a non-diluted basis, Medwell is entitled (but not obliged), at any time and from time to time, to nominate one director to the board of directors.

Copies of these contracts may be found under the Company's profile on SEDAR at [www.sedar.com](http://www.sedar.com).

## **INTEREST OF EXPERTS**

PricewaterhouseCoopers LLP is the auditor of the Company and has advised that it is independent with respect to the Company in accordance with the Rules of Professional Conduct of the Institute of Chartered Professional Accountants of Ontario.

Koger Valuation Inc. ("Koger") was retained to assess the fair market value of the Shares and delivered an Advisory Report on the Estimated Fair Market Value as at May 5, 2014. The purpose of the valuation was to

support the Company's determination of an appropriate price per Share in relation to proposed additional financings. To the knowledge of the Company, neither Koger nor any of its "designated professionals", as defined in NI 51-102, beneficially held, directly and indirectly, any of the outstanding Shares of the Company at the time of the preparation of the report.

#### **ADDITIONAL INFORMATION**

Additional information relating to Spectral may be found under the Company's profile on SEDAR at [www.sedar.com](http://www.sedar.com).

Specifically, additional information including directors' and officers' remuneration and indebtedness, principal holders of Spectral's securities and securities authorized for issuance under equity compensation plans, if applicable, is contained in Spectral's Management Information Circular for its most recent annual meeting of shareholders that involved the election of directors. Additional financial information is also provided in Spectral's comparative financial statements for the years ended December 31, 2014 and December 31, 2013, and in the related management's discussion and analysis.

A copy of the above documents may also be obtained upon request to the Corporate Secretary of Spectral at 135 The West Mall, Unit 2, Toronto, Ontario, M9C 1C2 or by contacting Mr. Ali Mahdavi, Spinnaker Capital Markets Inc. at 416-962-3300 or [AM@spinnakercmi.com](mailto:AM@spinnakercmi.com).

For further information, please contact: Mr. Anthony Businskas, Executive Vice President and CFO of Spectral Medical Inc., at the corporate head office at (416) 626-3233 ext. 2200.

(signed) Mr. Anthony Businskas  
Mr. Anthony Businskas,  
Executive Vice President & CFO

## **SCHEDULE “A”**

### **FINANCE & AUDIT COMMITTEE CHARTER**

#### **A. OVERVIEW AND PURPOSE**

The Audit Committee (the “Committee”) is appointed by, and responsible to the Board of Directors (the “Board”). The Committee approves, monitors, evaluates, advises and makes recommendations, in accordance with these terms of reference, on matters affecting the external and internal audits, risk management matters, the integrity of financial reporting and the accounting control policies and practices of the Corporation. The involvement of the Committee in overseeing the financial reporting process, including assessing the reasonableness of management’s accounting judgments and estimates and reviewing key filings with regulatory agencies is an important element of the company’s internal control over financial reporting. The Committee has oversight responsibility for the performance of both the internal auditors (if any) and the external auditors. The Committee also ensures the qualifications and independence of the external auditors. The Committee has oversight of the Corporation’s compliance with legal and regulatory requirements.

It is not the duty of the Committee to plan or conduct audits, or to determine that the Corporation’s financial statements are complete, accurate, and in accordance with generally accepted accounting principles.

#### **B. MEMBERSHIP**

The members of the Committee shall be composed of at least three independent directors, appointed by the Board, all of whom must be financially literate and at least one member shall have accounting or related financial management expertise and be an audit committee financial expert. For greater clarity, the Board has adopted the definitions or attributes of independent director and financial literacy as set out in Multilateral Instrument 52-110 of the Canadian Securities Administrators and the attributes of audit committee financial expert as defined in Item 401(h) of SEC Regulation S-K.

The Chair of the Committee shall be designated by the Board.

Attendance by invitation at all or a portion of Committee meetings is determined by the Committee Chair or its members, and would normally include the Chief Financial Officer of the Corporation, representatives of the external auditors and such other officers or support staff as may be deemed appropriate.

#### **C. DUTIES AND RESPONSIBILITIES**

##### **i. Financial Statements and Disclosures**

- a) Review, and recommend to the Board for approval, the annual audited financial statements;
- b) Review, and recommend to the Board for approval, the following public disclosure documents:
  - the financial content of the annual report;
  - the annual management information circular and proxy materials;
  - the annual information form, including the regulatory requirements for audit committee reporting obligations;
  - the management discussion and analysis section of the annual report; and

- the year-end news release on the earnings of the Corporation.
- c) Review and, if appropriate, to **approve and** authorize the release of the quarterly unaudited financial statements including management's discussion and analysis, the quarterly interim report to shareholders and the quarterly press release on earnings of the Corporation. However, in the event that there is a significant or extraordinary matter that, in the opinion of the Committee, should be reviewed by the Board before the release of such information then the matter shall be referred to the Board for review;
  - d) Review, and recommend to the Board for approval, all annual financial statements, reports of a financial nature, (other than quarterly unaudited financial statements), and the financial content of prospectuses or any other reports which require approval by the Board prior to submission thereof to any regulatory authority;
  - e) Review the CEO and CFO certification of annual and interim disclosure as required by the regulatory authorities;
  - f) Review with management on an annual basis, the Corporation's obligations pursuant to guarantees that have been issued and material obligations that have been entered into, and the manner in which these guarantees and obligations have been, or should be, disclosed in the financial statements.
  - g) Review and assess, in conjunction with management and the external auditor, at least annually or on a quarterly basis where appropriate or required:
    - the appropriateness of accounting policies and financial reporting practices used by the Corporation, including alternative treatments that are available for consideration;
    - any significant proposed changes in financial reporting and accounting policies and practices to be adopted by the Corporation;
    - any new or pending developments in accounting and reporting standards that may affect or impact on the Corporation;
    - the impact of the Corporation's capital structure on current and future profitability, and any off-balance sheet structures; and
    - the key estimates and judgements of management that may be material to the financial reporting of the Corporation.
  - h) At least annually, request the external auditor to provide their views on the quality (not just the acceptability) of the Corporation's annual and interim financial reporting. Such quality assessment should encompass judgements about the appropriateness, aggressiveness or conservatism of estimates and elective accounting principles or methods and judgements about the clarity of disclosures.
  - i) Review any litigation, claim or other contingency, including tax assessments, that could have a material effect upon the financial position or operating results of the Corporation, and the manner in which these matters have been disclosed in the financial statements.

## **ii. External Auditor**

- a) Assess the performance and consider the annual appointment of external auditor for recommendation to the Board for ultimate recommendation for appointment by the shareholders;

- b) Review, approve and execute the annual engagement letter with the external auditor, and ensure there is a clear understanding between the Board, the Committee, the external auditor and management that the external auditor reports directly to the shareholders and the Board through the Committee. The terms of the engagement letter or the annual audit plan should include, but not be limited to, the following:
- staffing;
  - objectives and scope of the external audit work;
  - materiality limits;
  - audit reports required;
  - areas of audit risk;
  - timetable; and,
  - the proposed fees.
- c) Obtain and review a report from the external auditor at least annually regarding the auditor's independence and the profession's or audit firm requirements regarding audit partner rotation;
- d) Approve, before the fact, the engagement of the external auditor for all non-audit services and the fees for such services, and consider the impact on the independence of the external audit work of fees for such non-audit services;
- e) Review all fees paid to the external auditor for audit services and, if appropriate, recommend their approval to the Board;
- f) Receive an annual certification from the external auditor that they participate in the public oversight program established by the Canadian Public Accountability Board (CPAB), and that they are in good standing with the CPAB;
- g) Review a report from the external auditors describing (i) the firm's internal quality control procedures and (ii) any material issues raised by the most recent internal quality control review or peer review of the firm, or by any inquiry or investigation by governmental or professional authorities within the preceding five years regarding the audits carried out by the external auditor together with any steps taken to deal with any such issues;
- h) Receive and resolve any disagreements between management and the external auditor regarding all aspects of the Corporation's financial reporting;
- i) Review with the external auditor the results of the annual audit examination including, but not limited to, the following:
- any difficulties encountered, or restrictions imposed by management, during the annual audit;
  - any significant accounting or financial reporting issues;
  - the auditor's evaluation of the Corporation's internal controls over financial reporting and management's evaluation thereon, including internal control deficiencies identified by the auditor that have not been previously reported to the audit committee;
  - the auditor's evaluation of the selection and application of accounting principles and estimates, and the presentation of disclosures;
  - the post-audit or management letter or other material written communications containing any findings or recommendations of the external auditor including

management's response thereto and the subsequent follow-up to any identified internal accounting control weaknesses; and

- any other matters which the external auditor should bring to the attention of the Committee.
- h) Meet with the external auditor at every meeting of the Committee or as requested by the auditor, without management representatives present; and to meet with management, at least annually or as requested by management, without the external auditor present;
  - i) When there is to be a change in the external auditor, review all issues related to the change, including the information to be included in the notice of change of auditor called for under National Policy 31 and the planned steps for an orderly transition.
  - j) Review and approve the Corporation's hiring policies regarding employees and former employees of the present and former external auditors of the Corporation.

### **iii. Internal Audit**

Review on as periodic basis the need for an internal audit function, and assess the control systems in place that mitigate the need for an internal audit function.

### **iv. Internal Controls**

- a) Obtain reasonable assurance, by discussions with and reports from management and the external auditor that the accounting systems are reliable, the system for preparation of financial data reported to the market is adequate and effective, and that the system of internal controls is effectively designed and implemented;
- b) Review management's annual report on the effectiveness of internal controls and procedures, as well as quarterly and annual CEO and CFO certificates filed pursuant to securities regulations;
- c) Review annually, or as required, the appropriateness of the system of internal controls and approval policies and practices concerning the expenses of the officers of the Corporation, including the use of the Corporation's assets;
- d) Review and approve, on a quarterly after-the-fact basis, the expense accounts of the Board Chair and the Chief Executive Officer of the Corporation.

### **v. Compliance/Risk/Fraud**

- a) Discuss with management the Corporation's major risk exposures and the steps management has taken to monitor and control such exposures, including the Corporation's risk assessment and risk management policies;
- b) Discuss with management the Corporation's policies and procedures designed to prevent, identify and detect fraud;
- c) Discuss with management the Corporation's policies and procedures designed to ensure an effective compliance and ethics program, including the Corporation's code of ethics;

- d) Discuss with management and the general counsel any legal matters that may have a material impact on the financial statements or the Corporation's compliance requirements;
- e) On an annual basis, review the adequacy of the Corporation's insurance program;

**vi. Other**

- a) Review, as required, any claims of indemnification pursuant to the by-laws of the Corporation;
- b) On a quarterly basis, review all related party transactions as defined by the CICA Handbook and report thereon to the Board;
- c) In accordance with the Corporation's Whistleblower Policy, review and determine the disposition of any complaints or correspondence received under the policy;
- d) Review and determine the disposition of any complaints received from shareholders or any regulatory body;
- e) Conduct an assessment, no less than every two years, as to the effectiveness of the Committee and provide a report thereon to the Board;
- f) Receive comments from the external auditor on their assessment of the effectiveness of the Committee's oversight of internal control over financial reporting;
- g) Review annually the terms of reference for the Committee and recommend any required changes to the Board;
- h) Request such information and explanations in regard to the accounts of the Corporation as the Committee may consider necessary and appropriate to carry out its duties and responsibilities;
- i) Consider any other matters which, in the opinion of the Committee or at the request of the Board, would assist the directors to meet their responsibilities;
- j) Provide reports and minutes of meetings to the Board;
- k) Engage independent counsel and other advisors as may be deemed or considered necessary, and determine the fees of such counsel and advisors.