SPECTRAL Medical INC

REVISED ANNUAL INFORMATION FORM
Year ended December 31, 2024

This Revised Annual Information Form has been prepared and filed to incorporate updates regarding the release of topline results from the Tigris clinical trial, and to disclose a director's prior role as an executive officer and director of a corporation which was involved in bankruptcy proceedings. This Revised Annual Information amends and restates the Annual Information Form of Spectral Medical Inc. dated March 26, 2025.

September 26, 2025

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SPECTRAL MEDICAL INC.
(“SPECTRAL” OR THE “COMPANY”)
REVISED ANNUAL INFORMATION FORM
FOR THE YEAR ENDED DECEMBER 31, 2024

FORWARD-LOOKING INFORMATION

Certain statements contained or incorporated by reference in this Revised 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 Pre-Market Application (“PMA”) for Toraymyxin™ (“PMX”) which commenced in 2015 and was completed in 2017; obtaining regulatory approval in the United States for PMX; our plans for the commercialization of PMX, Endotoxin Activity Assay (“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 thousands of Canadian dollars, except for Share and per Share data.

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 at the end of the 2006 calendar year.

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

The Company has two wholly owned U.S. subsidiaries: i) Spectral Diagnostics (US) Inc. incorporated on September 14, 2009 under Section 102 of the General Law of the State of Delaware and holds the Investigational Device Exemption ("IDE") on behalf of Spectral Medical Inc.; ii) Spectral Medical (US) Inc., incorporated on February 4, 2021 under Section 102 of the General Law of the State of Delaware. These subsidiaries do not have active operations.

The Company has one wholly owned Canadian subsidiary, Dialco Medical Inc. (Dialco) which was incorporated pursuant to the OBCA on March 15, 2019. On September 1, 2021, Dialco incorporated one wholly-owned U.S. subsidiary, Dialco Medical (US) Inc., under the laws of the state of Delaware. This subsidiary also does not have any active operations. Dialco Medical Inc. operations have been declared as discontinued operation post December 12, 2022.

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 primary strategic focus is on the regulatory development and commercialization of its products in the areas of septic shock. The Company's products for the treatment of septic shock include its EAA™ diagnostic and PMX therapeutic device. If approved, this will be the first targeted therapy guided by a specific diagnostic in the area of sepsis. Furthermore, the Company is continuing its legacy business of manufacturing and selling certain proprietary reagents.

CLINICAL DEVELOPMENT AND REGULATORY PROGRAM

The Company's clinical development program continues to focus on obtaining U.S. Food & Drug Administration ("FDA") approval for PMX.

On March 6, 2009, Spectral signed a license agreement with Toray Industries, Inc. of Japan granting Spectral the exclusive development and commercial rights in the U.S. for PMX. Under the terms of the agreement, Spectral is seeking FDA approval for PMX, and if successful, intends to commercialize the product, together with its EAA™. On May 29, 2019, an amendment to the agreement was made to amend the expiry date of the license agreement from December 31, 2029 to December 31, 2034.

On February 26, 2010, the Company received final approval of its Investigational Device Exemption ("IDE") from the FDA, which permitted the Company to conduct a pivotal trial for PMX (the "EUPHRATES" trial) in the U.S., and later, Canada.

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 U.S. comparing standard of care versus PMX plus standard of care.

In November 2010, the Company announced that it entered into a long-term, exclusive distribution agreement with Toray Industries, Inc. and Toray Medical Co., Ltd. to market and sell Toraymyxin™ in Canada.

Top line results for the Company's pivotal Phase III EUPHRATES trial were announced on October 3, 2016. Although the trial did not statistically achieve its primary endpoint, there were two important observations that are supportive of endotoxin removal in septic shock.

The EUPHRATES study also showed that endotoxemia remains a major cause of the unacceptably high mortality of patients in septic shock. It is the only trial designed to show the relationship between endotoxemia (based on a reliable method of measurement) and its removal with a cartridge specifically designed to remove endotoxin.

In addition, detailed analysis of the EUPHRATES trial database showed that there appears to be an upper limit to a patient's pre-treatment burden of endotoxin as measured by the EAA, above which the trial could not demonstrate benefit for the PMX cartridge. Based on that information we were able to demonstrate a significant reduction in 28-day mortality (adjusted for APACHE II and baseline MAP) for patients with baseline EAA intervals from 0.6 to 0.89 [23/88 (26.1%) vs. 39/106 (36.8%) (difference − 10.7, OR 0.52 95% CI (0.27, 0.99)), P = 0.047].[1] At 28 days, the relative reduction in mortality was 30%. Survival over time analysis showed a statistically significant and sustained increase in survival at all three time points: 52% risk reduction at 14 days (Hazard Ratio ["HR"] 0.48, p=0.019), 42% risk reduction at 28 days (HR 0.59, p= 0.043) and 41% risk reduction at 90 days (HR 0.59, p=0.037).

In this patient population, an improvement in organ function was seen in the PMX treated group compared to the sham group. There was a statistically significant increase in mean arterial blood pressure 72 hours post treatment for the PMX group (p=0.0462) and a substantial increase in days alive and free from mechanical ventilator support [median difference of 14 days, (p=0.0043)].

Furthermore, the trial results indicates that for patients where no bacteria could be identified by culture yet were highly endotoxemic (approximately one third of the n=194 group), treatment with the PMX cartridge had a 28-day mortality of 21% versus 42% for the sham group (p=0.046), a relative risk reduction of 50%. These patients appear to be at higher risk for mortality, with endotoxemia likely due to translocation of endotoxin from the gastro-intestinal system. With no microbiology targets to treat there are fewer options left to help these patients.

On March 16, 2018, the FDA notified the Company that it had determined that more evidence is required to make a final determination to approve the PMX cartridge. The FDA acknowledged the unmet need for therapies in septic shock patients who face a high risk of death, and the challenges in performing clinical studies in this vulnerable patient population.

On February 19, 2019, the Company, with interaction from the FDA, received IDE approval for a follow-on trial (the "Tigris Study"). The Tigris Study will utilize a Bayesian approach to analyze the primary endpoint of 28-day mortality by leveraging data already obtained in EUPHRATES. The study is open label and patients are randomized 2:1 for treatment vs. control, with a targeted enrollment of 150 patients at 10 sites in the U.S.

In October 2019, the Company obtained FDA approval for a sub-study of the Tigris Study whereby SAMI will be used to deliver hemoperfusion in a selected number of sites.On April 14, 2020, the Company announced that the FDA approved an IDE for PMX to treat COVID-19 patients suffering from septic shock. Increased levels of endotoxin activity have been identified in COVID-19 patients in Asia, Italy and the U.S. The COVID-19 Protocol for PMX was subsequently closed in 2021.

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[1] *ICM publication Klein DJ, et al. Polymyxin B hemoperfusion in endotoxemic septic shock patients without extreme endotoxemia: a post hoc analysis of the EUPHRATES trial. (2018) Intensive Care Medicine.*

Similarly, the Company announced on April 20, 2020, that Health Canada issued an Interim Order expanding the already approved indication for use of PMX to include patients with COVID-19. The expanded use of PMX in relation to COVID-19 was subsequently closed in March 2024.

In August 2020, the Company announced FDA approval to add up to 5 additional Tigris clinical trial sites. This approval allowed for an increase to 15 trial sites.

On June 11, 2021, the Company held a virtual Tigris Study investigator meeting with existing study sites. The agenda of the meeting, which was attended by the principal investigators, study site staff, and the Company's clinical team, was to re-engage and reinvigorate Tigris Study sites in anticipation of COVID-19 receding and the diminished strain on trial site intensive care units ("ICUs").

On November 29, 2021, the Company announced that the FDA approved a protocol amendment to its Tigris Study allowing for the use of sequential organ failure assessment ("SOFA") scoring as inclusion criteria into the study. Adding SOFA as an alternative to capture cardiovascular dysfunction when it is already being treated by vasopressor drugs removes a critical barrier to enrollment using MODS and harmonizes the study protocol with current sepsis guidelines and practice patterns across most hospitals. Management believes the addition of SOFA into the study should have a significantly positive impact on enrollment.

On July 11, 2022, the Company announced that the FDA granted Breakthrough Device designation for the Company's PMX device. The goal of the Breakthrough Device Program (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program) is to provide patients and health care providers with timely access to medical devices by speeding up their development, assessment, and review, while preserving the statutory standards for premarket approval, 510(k) clearance, and De Novo marketing authorization, consistent with the Agency's mission to protect and promote public health.

On August 18, 2022, the Company announced FDA approval to add up to 10 additional Tigris clinical trial sites. This approval allowed for an increase to 25 trial sites.

On March 23, 2023, the Company engaged a new contract research organization ("CRO"), Beaufort. Beaufort has extensive experience with ICU clinical trials and brings a strong regulatory group, experienced biostats personnel, and additional clinical field resources. During the third quarter, full transition from the incumbent CRO was completed. As part of its engagement, Beaufort is reviewing and evaluating recruitment and enrollment processes on a site-by-site basis of Tigris Study sites.

On April 6, 2023, the Company announced positive results from the EUPHAS-2 clinical trial. This study included 50 critically ill Endotoxic Septic Shock patients assessed with Spectral's EAA diagnostic and treatment with PMX. The study reported a 28-day mortality of just 36% with the treated patients versus a predicted 75% mortality utilizing the widely accepted SAPS II mortality estimation tool. This represents more than a 50% estimated relative mortality reduction with the use of PMX. The patient population of the EUPHAS-2 study aligns with the patient population of the Tigris Study.

On May 17-18, 2023, the Company held a Tigris Study Investigator Meeting in Charlotte, North Carolina. The in-person meeting was attended by principal investigators and clinical research coordinators from all existing and new trial sites, as well as the Company's new CRO, Beaufort. Also in attendance were representatives from the Company's strategic partner Baxter International Inc. ("Baxter"). It was believed that the Investigator Meeting will help bolster ongoing enrollment activities related to the Tigris Study.

On August 22, 2023, the Company executed an agreement with Baxter on a sub-study to obtain FDA clearance for hemoperfusion for Baxter's Prismax device; the Prismax with its leading installed base, is anticipated to be the primary device utilized for PMX treatments upon commercial launch.

On November 14, 2023, the Company announced the publication of its Tigris Study methods paper in Critical Care, which discusses the use of Bayesian methods in clinical trial design. Simulation studies incorporating historical data from a 179-patient subgroup of Spectral's EUPHRATES trial combined with data from the Tigris Study demonstrated an increase in power across a range of observed hypothetical results.

On March 12-13, 2024, the Company held a Tigris Study Investigator Meeting in conjunction with the *29th International Conference on Advances in Critical Care Nephrology* in San Diego, California. The in-person meeting was attended by multiple stakeholders, including: principal investigators and clinical research coordinators from existing and new trial sites; its CRO, Beaufort; and representatives from the Company's strategic partner Baxter. The focus of the meeting was on the practical aspects of diagnosing endotoxic septic shock and treating with PMX, as well as featuring several talks from trial sites on how EAA and PMX could be implemented into routine clinical practice after potential regulatory approval of PMX.

In April 2025, full enrollment for the Tigris Study was completed with 157 total patients enrolled, 151 evaluable patients and 100 treated with PMX.
Data lock was completed by the end of July 2025 and on August 12, 2025, Spectral together with Vantive US Healthcare LLC ("Vantive") announced topline results from Spectral's Tigris Study. The Tigris Study was a U.S.-based, multicenter, randomized, controlled Phase 3 study evaluating PMX in adults with endotoxic septic shock, defined by an EAA level between 0.60 and 0.90. Eligible patients also had to meet criteria for multiple organ dysfunction, including a Multiple Organ Dysfunction Score (MODS) >9 or a Sequential Organ Failure Assessment (SOFA) score of >11. A total of 157 patients were randomized in a 2:1 ratio to receive either PMX plus standard care (n=106) or standard care alone (n=51). The primary endpoint – 28-day all-cause mortality – was evaluated using a prespecified Bayesian statistical model, which evaluates results in the context of prior probability. The model incorporated data from 179 patients in the previously conducted EUPHRATES trial alongside the data from the Tigris Study.

The goal of the Tigris Study was to confirm the benefit of PMX hemoadsorption in patients with endotoxic septic shock, defined by EAA 0.60 but < 0.90. The Tigris trial's design and analysis plan were aligned with published FDA's *Guidance for the Use of Bayesian Statistics in Medical Device Clinical Trials*.[2] The purpose of Bayesian analysis is to update prior evidence with new trial data, producing a 'posterior probability' that reflects the most current and complete picture of the treatment effect. Results are presented for adjusted and unadjusted analyses. Consistent with expert recommendations and the FDA's guidance on clinical trials, the adjusted analysis is used to account for baseline prognostic covariates such as severity of illness and comorbidities – which provides a more precise estimate of the true treatment effect. Unadjusted analyses do not account for these important differences.

Primary Endpoint (28-Day Mortality). In the intention-to-treat cohort, the adjusted posterior probability of benefit at 28 days was 95.3%, exceeding the prespecified 95% threshold and therefore meeting the primary endpoint. The observed 28-day mortality in Tigris was 38.7% with PMX versus 45.1% with standard of care, a 6.4% absolute difference. From the unadjusted posterior distribution, the absolute risk reduction was 8.3%, representing an 18% relative risk reduction with a posterior probability of 92.3%. In the modified intention-to-treat population (patients receiving any assigned treatment; 100 PMX and 51 control), the observed 28-day mortality was 37.0% with PMX versus 45.1% with standard of care, an 8.1% absolute difference.

Key Secondary Endpoint (90-Day Mortality). The key secondary endpoint demonstrated a >99% posterior probability of benefit for PMX at 90 days; the adjusted posterior probability was 99.4%. The observed 90-day mortality (Tigris alone) was 43.4% with PMX versus 60.8% with standard of care, a 17.4%

[2] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-use-bayesian-statistics-medical-device-clinical-trials

absolute difference. From the unadjusted posterior distribution, the absolute risk reduction was 12.3%, representing a 20.2% relative risk reduction with a posterior probability of 98.3%. The resultant number needed to treat (NNT) to save one life at 90 days was 8.1.

Overall, the results of the Tigris Study met or exceeded the prespecified targets as further detailed in the material change report discussing the topline results from the Tigris Study filed on SEDAR+ dated August 14, 2025.

FINANCINGS

The Company has completed a number of private placement financings and public offerings to raise funds in order to support the Company's clinical development and regulatory program and for general corporate purposes. The financings completed in the last three years are detailed as follows:

June 18, 2020

On June 18, 2020, the Company closed a public offering resulting in the issuance of 8,500,000 units ("Units") for aggregate gross proceeds of $5,100. The Company received net cash proceeds of $4,316. Each Unit consisted of one Share priced at $0.60 per Share and one-half of a share purchase warrant ("Warrant"), resulting in the issue of 4,250,000 share purchase warrants to the subscribers. Each whole Warrant entitles the holder to acquire one additional Share at an exercise price of $0.75 per Share for a two-year period expiring June 18, 2022. In addition, 510,000 broker warrants were issued, which entitles the broker to acquire one additional Share at an exercise price of $0.60 per Share, expiring June 18, 2022.

On July 6, 2020, the Company announced that it filed a final short form base shelf prospectus with the securities regulatory authorities in each of the provinces of Canada, except Québec, effective July 3, 2020 (the "Effective Date"). This allows the Company to qualify the distribution by way of a prospectus of up to $50,000 of Shares, debt securities, subscription receipts, warrants and units or any combination thereof, from time to time, during the 25-month period from the Effective Date.

July 27, 2021

On July 27, 2021, the Company closed a bought deal offering (the "Offering") resulting in the issuance of 23,530,000 units (the "Units"), at a price of $0.425 per Unit. Aggregate gross proceeds of the Offering were approximately $10,000. Each Unit consists of one Share of the Company and one-half of one Sharepurchase warrant (each whole share purchase warrant a "Warrant"), with each Warrant entitling the holder to acquire one Share at a price of $0.50, with an expiry date of July 27, 2024.

The Company also issued a number of compensation options to the underwriters representing 6.5% of the total number of Units issued under the Offering. Each Compensation Option entitles the holder to acquire one Share at an exercise price of $0.486 per Share for a 2-year period expiring July 27, 2023.

November 2, 2022

On November 2, 2022, the Company closed its prospectus offering of units (the "Unit Offering") of the Company and concurrent private placement and together with the Unit Offering, of USD$5,000 of convertible senior notes (the "Notes"). Aggregate gross proceeds raised pursuant to the Unit Offering and private placement were approximately $10,800. The Unit Offering consisted of the sale of 10,061,250 Units at a price of $0.40 per Unit and 5,000 Notes at a price of USD$1,000 per Note. Each Unit consisted of one common share of the Company and one-half ($^1/_2$) of one Common Share purchase warrant of the Company, with each Warrant entitling the holder thereof to acquire one Common Share at a price of $0.48 for a period of 36 months, expiring November 2, 2025.

The Company also issued a number of compensation warrants to the underwriters representing 9.9% of the total number of units issued under the Unit Offering, with each Warrant entitling the holder thereof to acquire one Common Share at a price of $0.40 for a period of 36 months, expiring November 2, 2025.

September 7, 2023

On September 7, 2023, Spectral completed its private placement of USD$4,553 in convertible senior notes (the “Notes”). The private placement consisted of the sale of 4,553 Notes at a price of USD$1,000 per Note, bearing interest of 9% and are due November 1, 2026 (the “2026 Maturity Date”). Holders of the Notes may convert all or any portion of the Notes into Shares of the company in integral multiples of USD$1,000 principal amount at any time prior to the 2026 Maturity Date. The notes are convertible into approximately 15,475,647 Shares representing a conversion price of approximately CAD$0.40 per share subject to certain anti-dilution and make-whole fundamental change adjustments.

The Company also issued a number of compensation warrants to the underwriter representing 6% of the total number of units issued under the Unit Offering, with each Warrant entitling the holder thereof to acquire one Common Share at a price of CAD$0.40 for a period of 36 months, expiring September 6, 2026.

May 30, 2024

On May 30, 2024 Spectral completed its private placement of USD$6,232 in convertible senior notes (the “Notes”). The private placement consisted of the sale of 6,232 Notes at a price of USD$1,000 per Note, bearing interest of 9% and are due May 1, 2028 (the “2028 Maturity Date”). Holders of the Notes may convert all or any portion of the Notes into common shares of the Company in integral multiples of USD$1,000 principal amount at any time prior to the 2028 Maturity Date. The notes are convertible into approximately 16,359,000 Common Shares representing a conversion price of approximately CAD$0.52 per share subject to certain anti-dilution and make whole fundamental change adjustments.

The Company also issued a number of compensation warrants to the underwriter for the issue on May 30, 2024 representing 6% of the total number of units issued under the Unit Offering, with each Warrant entitling the holder thereof to acquire one Common Share at a price of CAD$0.45 for a period of 48 months, expiring May 30, 2028.

July 19, 2024

On July 19th, 2024 Spectral completed its private placement of USD$1,000 in convertible senior notes (the “Notes”) of an additional non-brokered offering sold to Birch Hill pursuant to the exercise of its anti-dilution pre-emptive rights relating to the closing of the offering of Notes that was completed on May 30, 2024. The private placement consisted of the sale of 1,000 Notes at a price of USD$1,000 per Note, bearing interest of 9% and are due May 1, 2028. Holders of the Notes may convert all or any portion of the Notes into common shares of the Company in integral multiples of USD$1,000 principal amount at any time prior to the 2028 Maturity Date. The notes are convertible into approximately 2,644,231 Common Shares representing a conversion price of approximately CAD$0.52 per share subject to certain anti-dilution and make whole fundamental change adjustments.

PRODUCTS

ENDOTOXIN ACTIVITY ASSAY

Description and Clinical Development

The Company has developed a rapid in-vitro diagnostic test for the detection of components the gram-negative bacterial cell wall (Lipopolysaccharides or Endotoxins). Increased blood-levels of endotoxin are indicative of an invasive infection or severe leakage of endotoxin from the gut. Circulating endotoxin is capable of initiating a systemic inflammatory response which can rapidly lead to organ dysfunction, septic shock and ultimately death.

According to the Centers for Disease Control and Prevention, the incidence of sepsis is approximately 1,700,000[3] cases annually in the United States, of which 425,000[4] patients are expected to develop septic shock. Of those patients with septic shock, the Company's management estimates, based on EUPHRATES trial data, that 140,000 patients could develop endotoxic septic shock.

Rapid diagnostic tests to rule in or rule out sepsis have previously not been available. The current standard of care for the microbiological diagnosis of sepsis requires a minimum of 24 hours for confirmation and frequently up to 72 hours to definitively rule out the presence of an infectious microorganism.

The ICU of a hospital has the highest attributable mortality and cost due to bacterial infections and the consequences. ICUs in North America consume significant financial and healthcare resources. Furthermore, North American ICU patients with septic shock have mortality rates which generally range between 30% and 50%.[5] The inappropriate use of antibiotics and the 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 comorbid conditions, and immunocompromised patients;
- Compounded with an aging of the population, which significantly increases the demographic segment predisposed to sepsis; and
- The widespread use of broad-spectrum antibiotics, which 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

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[3] *Centers for Disease Control and Prevention, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Healthcare Quality Promotion (DHQP) August 9, 2022*

[4] *Critical Care Medicine 46(12):p 1889-1897, December 2018*

[5] *National Centre for Emerging and Zoonotic Infectious Disease (NCEZID); Centers for Disease Control and Prevention, Division of Health Care Quality Promotion (DHCQP) data reports, 2016.*

incorporated as Sepsis and carried out research and development on diagnostic tests for infection 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, a business unit of Elan Pharmaceutical plc, now Alkermes Pharma Ireland Ltd. ("Alkermes").

Alkermes made an initial purchase of 7% in Sepsis for USD$2,000 and committed to funding up to USD$6,000 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 first Sepsis produced diagnostic test for infection, the EAA™, aids in the diagnosis of gram-negative infection by identifying patients who are at risk for developing severe sepsis on admission to intensive care settings.

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's proprietary infection diagnostic products, in exchange for 1,500 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.

On June 18, 2001, the Company reported the acceptance for filing by Sepsis of its 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, an agreement was reached with the FDA for a resubmission path of the EAA™ as a 510(k) – 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 premarket 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 $1,200 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%.

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.

***POLYMYXIN B-HEMOPERFUSION* ("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 361,945[6] patients globally and has demonstrated in clinical trials that it safely and effectively removes endotoxin and reduces mortality in patients with severe sepsis, with a rate of SAEs of 0.01%.

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 and amended in May, 2019. This agreement expires on December 31, 2034, with one five-year renewal term, upon mutual written agreement at least six months prior to the expiry of the extended term of the agreement. Under the terms of this agreement, Toray granted Spectral an exclusive license to Toray's intellectual property rights in and to PMX in the United States and Puerto Rico, and Spectral took responsibility for seeking (at Spectral's 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.

In addition, on November 10, 2010, Spectral entered into an Exclusive Distribution Agreement with Toray, which initially provided Spectral with the exclusive right to distribute PMX in Canada. On April 1, 2019, the Exclusive Distribution Agreement was amended to remove any minimum purchase quantity obligations of PMX by Spectral and to extend the term to expire on June 30, 2036. This distribution agreement may be automatically renewed on a year-to-year basis unless either party gives the other party written notice that it does not wish to renew at least six months prior to the expiration date of the original term or the extended term of the agreement.

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

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[6] *Report of Prior Investigations ("ROPI") is a report that is part of the Code of Federal Regulations, from September 1994 to February 2025*

organ function. PMX reduced 28-day mortality in patients with severe sepsis and septic shock by 21% as compared to those patients in the conventional therapy group.

The Company announced in November 2014, at 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 Company obtained final approval of its IDE from the FDA to conduct the EUPHRATES trial, a randomized double blinded prospective trial, comparing standard of care versus standard of care plus PMX in patients with proven endotoxemia. 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 was configured to enroll 446 evaluable patients with the primary endpoint of 28-day mortality. It was completed in June 2016 and top results were announced on October 3, 2017 (see “Clinical Development” section).

The Tigris trial commenced in 2019 as an amendment to the original EUPHRATES IDE, to collect additional data that will be incorporated into the original data collected using the Bayesian statistical approach. Approximately 425,000 patients develop severe sepsis and septic shock in the ICU, annually in the U.S with a mortality rate between 30% and 50%. The Company believes that out of the number of patients expected to develop septic shock, approximately 140,000 would fit within the Company’s Tigris trial patient population ranges established using the Company’s EUPHRATES trial and data available from the National Inpatient Sample database.

The most recent sales and marketing data (from December 2024) for PMX indicates that there have been 361,945 PMX cartridges sold to hospitals around the world.

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 the Company’s 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.

- CytoSorbents is currently selling a hemoperfusion cartridge outside of the U.S. for the removal of cytokines in patients with acute inflammatory diseases. They have recently announced a trial in Europe for reversal of refractory shock due to sepsis in patients receiving continuous hemodialysis. The endpoint is shock reversal and not mortality; and therefore, will not be acceptable to the FDA.

- Jafron Biomedical, based in China, has a sorbent technology with similar claims to Cytosorbents and markets outside of the U.S.

- Oxiris™ (Baxter), is a modified dialysis membrane that is functionalized to absorb various molecules including endotoxin. It has a small surface are compared to the PMX cartridge. Oxiris is sold outside the U.S. for patients with sepsis and acute renal failure.

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.

PROPRIETARY 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. Currently, customers for these products include Abbott Laboratories. Beckman Coulter was also a customer until the Company successfully negotiated a technology transfer in 2018. All performance obligations under that technology transfer were fulfilled at the end of 2019. Royalty revenue was earned to the end of 2018 from these license arrangements based on a percentage of end-user sales of Troponin I, except for Abbott Laboratories, which pays a fixed access fee annually. The agreement pursuant to which the Company earns the fixed access fee from Abbott expired in 2021. The Company executed a new contract with Abbott Laboratories at the end of 2021. Also, the Company added Bio-Rad as a new customer for reagent products in 2022.

COMMERCIALIZATION INITIATIVES

The Company has taken a number of other operational and strategic measures to prepare itself for commercialization.

On February 4, 2020, the Company announced that it had completed an exclusive distribution agreement with Baxter, for PMX and EAA™ in the U.S. and Canada. As part of this agreement, Baxter has the right to pay the Company a series of milestone payments including a nonrefundable USD$5,000 upfront rights payment, which was received in February 2020. Under the terms of the agreement, Baxter will be the Company's exclusive distributor of the PMX filter in the U.S. and Canada. Baxter also has non-exclusive rights to distribute EAA™ globally. Under the terms of the agreement, the Company is entitled to access Baxter's market capabilities while retaining control over the PMX regulatory process. Baxter has the option to maintain exclusive rights for PMX distribution through future milestone payments and maintaining minimum purchase requirements for PMX products.

Pursuant to the November 2, 2022 private placement, Baxter International Inc. agreed to purchase certain of the Notes in connection with an amendment to a portion of the initial milestone payment due to the Company under the Distribution Agreement.

On January 6, 2023, Baxter announced a corporate re-organization, in which it will spin-off its Renal and Acute Therapies business, into an independent entity Vantive which was completed around July 2024.

Pursuant to the September 7, 2023 private placement, Baxter International Inc. agreed to purchase certain of the Notes in connection with an amendment to a portion of the Second Milestone Exclusive Rights Payment due to the Company under the Distribution Agreement.

On February 15, 2024, the Company notified Baxter that it had enrolled patient number 90. Subsequently, Baxter exercised its right to maintain its exclusive distribution rights for PMX and paid a non-dilutive USD$1,500 payment to the Spectral.

On February 21, 2024, the Company and Baxter also announced an amendment to the initial term of the distribution agreement to 10 years post PMA approval.

On August 13, 2024, Baxter International announced that it had reached a definitive agreement with The Carlyle Group to divest its Vantive business ("Vantive-Carlyle transaction"). The Vantive-Carlyle transaction closed on February 3, 2025, at which time Spectral Medical's PMX distribution agreement with Baxter was assigned to Vantive.

TRENDS

The Company's diagnostic product, EAA™, was approved in 2003 and was 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 potential approval of the PMX treatment, are difficult to predict.

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 425,000 patients that suffer from severe sepsis or septic shock each year in the U.S.

MANUFACTURING

Spectral has established a strong foundation in manufacturing, product development, and intellectual property protection. The Company's focus on innovation, quality, and strategic partnerships positions it well for continued growth and diversification in the medical diagnostics and treatment field.

EAA™ (Endotoxin Activity Assay)

The EAA™ is a pioneering diagnostic tool for measuring endotoxin activity in human whole blood. Spectral Medical Inc. manufactures this product at its Canadian facility in Toronto, Ontario, which adheres to Current Good Manufacturing Practices ("cGMP") and meets regulatory requirements set by the FDA and Health Canada. The Company actively maintains ISO:13485:2016 certification. In 2007, the Company upgraded its manufacturing facilities – enabling self-sufficiency in EAA™ production and the manufacture of proprietary biological reagents.

PMX (Toraymyxin PMX-20R)

PMX is a device that removes endotoxin from the blood using Polymyxin-B's electrochemical properties. Manufactured by Toray, the PMX device is produced in a facility that has been audited by the FDA and received necessary regulatory approvals.

Proprietary Reagents

Since 1997, the Company has leveraged its diagnostic expertise to develop, produce, and market recombinant cardiac proteins and calibrators. The Company's infrastructure and technical competency allow for the production of high-quality biological reagents for both R&D and commercial purposes. Spectral's recombinantly-engineered reagents, produced using cutting-edge technology, have shown superior performance and stability compared to their native counterparts.

Spectral's recombinant single-chain Troponin I-C polypeptide has gained worldwide recognition as a superior reagent for calibrating cardiac Troponin I assays. The Company has established license and supply agreements with diagnostic product manufacturers for the use of its proprietary Troponin I recombinant protein molecules.

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 manufactured in compliance with Canadian Medical Device Regulations ("CMDR") and the latest ISO 13485:2016 Quality Management Systems Requirements for Regulatory Purposes.

The Company began to introduce Quality Program under ISO 9001 and under U.S. FDA 21 CFR 820 Quality System regulations as early as 1994.

Health Canada introduced requirements for ISO 13485:2016 Quality Management System for all medical devices manufactured and sold in Canada and made this requirement mandatory commencing January 1, 2003. ISO 13485:2016 Quality Management System compliance is also a prerequisite for products sold in the European community. The first CAN/CSA-ISO 13485:2016 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 was earned by Spectral on April 16, 2002. In January 2021, the Company changed the registrar from TUV SUD America to Intertek. In 2017 Spectral received its first Medical Device Single Audit Program (MDSAP) certification. MDSAP replaces CMDCAS and it is a program that allows registrars to conduct a single audit that covers ISO 13485:2016 and regulatory requirements of multiple jurisdictions. Spectral is currently MDSAP certified in both Canada and the U.S. after completing two annual surveillance audits in 2021 and 2022 and a successful recertification audit in 2023. In 2024, the annual surveillance audit was completed with zero (0) findings. In 2002, 2004, 2007, and 2010, Spectral also successfully defended FDA foreign facility inspections under 21 CFR QS regulations. In 2009, 2014 and 2018 Spectral was inspected by Health Canada and has successfully achieved a compliant rating. The following are the current medical devices cleared for marketing by the FDA and the corresponding date of 510(k) and Health Canada approval:

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 that 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 Authorization ("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 efficacy 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 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 and results of operations.

- Endotoxin Activity Assay Kit – FDA, June 16, 2003; (Class-2)
- Smartline TL Tube Luminometer FDA (Class 1)
- TORAYMYXIN PMX-20R – Pending approval

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

Spectral has concluded a clinical trial (the EUPHRATES trial) in the U.S. and is seeking a PMA for PMX, a Class III medical device, with the Tigris trial.

The EAA™ is cleared as a Class II medical device by the FDA.

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.

PMX and EAA™ in Canada are approved as Class III medical devices.

- Endotoxin Activity Assay Kit – Health Canada, March, 2002 (Class-3)
- Smartline TL Tube Luminometer Health Canada (Class 1)
- TORAYMYXIN PMX-20R – Health Canada December 2003 (licensed by Toray Industries Inc.)

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.

- Endotoxin Activity Assay Kit – CE Mark, September 9, 2003 (Class- Other IVD)
- Smartline TL Tube Luminometer CE Mark (Class A)

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.

With respect to trademarks, the Company has obtained U.S. trademark registrations for the Spectral design logo and EAA™ products. 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 10,500 square feet of office, manufacturing and laboratory space located at 135 The West Mall, Units 2 and 4, Toronto, Ontario. The lease on the facilities at Unit 2 was renewed on September 1, 2017 and expires August 31, 2022. In December 2021, the Company extended its lease term for an additional five years, expiring August 31, 2027.

The lease for Unit 4 was signed on October 1, 2020 and Addendum to the sublease dated October 1, 2020 was signed on September 1, 2023 which reflects a reduction in square footage for a term expiring September 30, 2030.

EMPLOYEES

As at December 31, 2024, Spectral had 29 employees.

FOREIGN OPERATIONS

The Company currently conducts operations in Canada and the United States, and distributes and offers its products globally. As such, it does not anticipate any risks associated with foreign operations.

LEGAL PROCEEDINGS

The Company, from time to time, is involved in various claims and legal proceedings of a nature considered normal to its business. It is not feasible to predict or determine the outcome of any legal proceedings with certainty. Currently, there are no legal proceedings, and therefore, no provision has been made in the Company's consolidated 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 AIF, before deciding to purchase securities of the Company.

The risks and uncertainties described below are those the Company currently believes to be material, but they are not the only ones the Company faces. If any of the following risks, or any other risks and uncertainties that the Company has not yet identified or that the Company currently considers 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 and regulatory program

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 carried similar risks, as did the Tigris trial, including the possibility of clinical failure to show efficacy or safety, 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 diverse populations 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.

The results of the EUPHRATES trial, including its failure to statistically meet its primary endpoint, and the March 16, 2018 FDA notification to the Company that more evidence is required to make a final determination to approve the PMX cartridge, may together have a material negative impact on the Company's ability to obtain FDA approval of PMX. The Tigris Study results may fail to provide the evidence and information required by the FDA, or the Company may not find the resources and support required for its completion, or do so in a cost effective and timely manner.

There is the risk that, should the FDA approve PMX, it could approve it subject to certain conditions such as the Company conducting additional post-approval clinicals or registry trials that the Company may not be able to do to the satisfaction of the FDA, which could lead to an eventual withdrawal of product approval.

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 labeling 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 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 delay 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 and commercialization activities and operations. The Company may attempt to raise additional funds for these purposes through public, private equity, debt financing, and 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. Failure by the Company to raise sufficient funds in a timely manner, to fund its minimum purchase order or development requirements, or to pay license fees, may result in a loss of licenses for its technologies. Furthermore, there can be no assurance that unforeseen developments or circumstances will not alter the Company's requirement for capital. Additional financings that the Company may pursue may involve the sales 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 operation of the Company.

Significant Development and Marketing Required

Spectral's therapeutic products require development, testing and investment prior to any final commercialization, and in support of commercial optimization development. There can be no assurance that such products will be successfully developed and optimized, proven to be safe and effective in clinical trials, receive applicable regulatory approvals, and 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 any of the EAA™ and PMX products in North America and elsewhere will likely require that Spectral find one or more skilled development sales and marketing partners that can provide the substantial expertise, time and costs associated with successfully bringing these new products 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, in the event it is approved, 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 these 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 competitive advantages, 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, the Company 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, operating loss 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 healthcare 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, it may be unsuccessful in extending their protection through patent term extensions. Patent(s) or licenses to patented technologies which expire prior to the completion of clinical trials could render such patent(s) ineligible for patent extension terms. The expiration of, or the failure to maintain or extend its 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 the 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 the Company's patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of the Company's 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. If license terms expire, they will have to be renewed. In addition, license agreements typically subject Spectral to milestone obligations and royalty payments. Some of these obligations are substantial and obligate the Company to obtain certain regulatory approvals by a specified date meet certain financial and other development obligations and exercise diligence in bringing potential products to market. The failure to meet these obligations can result in the termination of the licenses and the loss of rights to any underlying technology. Any failure to renew a development, license or distribution agreement on favourable terms, or termination of any such agreement, 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, third party licenses of technology can 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, 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, international market conditions, and expiry of the Company's relevant patents. 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 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 the Company may sell its 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 healthcare 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 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 device 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 healthcare through various means. For example, in certain foreign markets, pricing of the Company's 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 health care 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, and its contract manufacturers including the manufacturers of PMX must manufacture their 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 or its contract manufacturers attempt to scale-up manufacturing and if such scale-up cannot 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 commercial agreements with third parties. The marketing of a product and 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 Company develops a sales force; the Company will be competing against companies that 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 and medical devices. 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 and plans to enter into 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 has added and may in the future decide to further add or acquire new products, services or businesses or expand internationally. There can be no assurance 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 the growth of its current or future products. 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, manufacturing, marketing 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.

Reliance on Third Party Suppliers

Some of the Company's products are currently manufactured by third party suppliers, including PMX by Toray International. There is no assurance that such suppliers will continue to reliably supply products to us at the level of quality the Company requires. If any of these third parties suffer liquidity or operational problems, the supply of the Company's products could be affected. If any of the suppliers becomes insolvent or is forced to lay off employees assisting with the production of the Company's products, the Company's business could be adversely affected. In the event any of the Company's suppliers become unable or unwilling to continue to provide the products in required volumes and quality levels at acceptable prices, the Company will be required to identify and obtain acceptable replacement manufacturing or supply sources. There is no assurance that reliable manufacturers or suppliers could be located and retained on a timely basis. An extended interruption in the supply of the Company's products would result in a substantial loss of sales. In addition, any actual or perceived degradation of product quality. As a result of the Company's reliance on third party suppliers may have an adverse effect on sales or result in increased product returns and buybacks.

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, 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 the Company's 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 has been able or will in the future 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, 2024 is $140,839. 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.

Global Events

Natural disasters, such as earthquakes, tsunamis, floods or wildfires, public health crises, such as epidemics and pandemics, political instability, acts of terrorism, war or other conflicts, general market conditions, interest rates, availability of credit, interest rates, economic uncertainty, changes in laws and other events outside of the Company's control, may adversely impact the Company's business, financial condition and operating results, including the Company's ability to provide services.

Cybersecurity

Cyber-attacks have the potential to impact the Company both operationally and financially. Despite the implementation of security measures, internal computer systems, and those of third parties on which the Company relies, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions (including ransomware attacks). No network or system can ever be completely secure, and the risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur it could cause interruptions in operations and result in material legal claims and liability and damage to reputation. If a security breach results in the exposure or unauthorized disclosure of personal information, additional costs could be incurred including those associated with data breach notification and remediation expenses, investigation costs, regulatory penalties and fines, and legal proceedings.

Going Concern

The ability of the Company, to realize its assets and meet its obligations as they come due is dependent on obtaining regulatory approval from the FDA of PMX, and the successful commercialization of PMX, and achieving future profitable operations, the outcome of which cannot be predicted at this time. Furthermore, the Company will require additional funding from commercial transactions or investors to continue the development and commercialization of products. These circumstances cast substantial doubt as to the ability of the Company to meet its obligations as they come due and, accordingly, the ultimate appropriateness of the use of accounting principles applicable to a going concern.

Management has assessed the Company's ability to continue as a going concern and concluded that it is dependent on the successful execution of management's operating and strategic plan, which includes among other things, securing additional financing, the commercialization of its products, the continued financial support of its shareholders and, ultimately, the attainment of future profitable operations. There are no assurances that any of these initiatives will be successful which indicates the existence of a material uncertainty that may cast substantial doubt about the Company's ability to continue as a going concern. Factors within and outside the Company's control could have a significant bearing on its ability to obtain additional financing.

DIVIDENDS

The Company has not paid dividends since its incorporation and it 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 26, 2025, there were 285,117,225 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 (the "Board") 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 March 26, 2025, the following securities were outstanding:

- 12,212,831 options to acquire Shares were issued and outstanding. Such options were granted to the directors, officers, employees, consultants and underwriters of the Company. Each option is exercisable for one Share. The weighted average exercise price of the outstanding options is $0.41 with the weighted average remaining contractual life being 2.62 years.
- 7,711,840 warrants were issued and outstanding. Each warrant is exercisable for one Share. Such warrants were issued with a weighted average exercise price of $0.49.
- 7,007,805 RSUs were issued and outstanding. Such RSUs were granted to the officers and employees of the Company. Each RSU is exercisable for one Share.
- 4,039,218 DSUs were issued and outstanding. 100% of the grant amount of DSUs vest on the grant date. DSUs are awarded to the Board of Directors and are settled in equity.

MARKET FOR SECURITIES

Trading Price and Volume

The Shares are listed and posted for trading on the TSX under the symbol "EDT".

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

Month	High ($ per Share)	Low ($ per Share)	Volume of Shares Traded
January 2024	0.54	0.435	2,890,352
February 2024	0.67	0.485	3,225,268
March 2024	0.59	0.385	1,349,064
April 2024	0.49	0.405	807,199
May 2024	0.57	0.425	1,626,951
June 2024	0.55	0.46	721,596
July 2024	0.53	0.475	892,377
August 2024	0.75	0.54	2,380,124
September 2024	0.7	0.57	1,698,857
October 2024	0.62	0.55	1,411,322
November 2024	0.62	0.5	1,658,847
December 2024	0.57	0.455	1,381,207

Securities Issued

During the financial year ended December 31, 2024, the Corporation issued the following securities that are outstanding but not listed or quoted on a market place:

Date of Issuance	Number of Securities	Security	Exercise Price per Security ($)	Issue Price per Security ($)
03-Jan-24	131,722	Deferred Share Units	N/A	0.47
03-Jan-24	4,500	Common Share Options	0.365	0.365
03-Jan-24	4,500	Share Units (RSU)	N/A	0.365
01-Apr-24	152,456	Deferred Share Units	N/A	0.47
05-Apr-24	682,928	Deferred Share Units	N/A	0.41
05-Apr-24	1,695,065	Common Share Options	0.41	0.41
05-Apr-24	1,592,543	Share Units (RSU)	N/A	0.41
30-May-24	981,540	Warrants	0.45	0.45
02-Jul-24	106,332	Deferred Share Units	N/A	0.47
16-Aug-24	104,478	Deferred Share Units	N/A	0.67
16-Aug-24	22,000	Options	0.67	0.67
16-Aug-24	22,000	Share Units (RSU)	N/A	0.67
01-Oct-24	66,649	Deferred Share Units	N/A	$0.61

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 as at March 26, 2025. Each director holds office until the next annual meeting of shareholders of Spectral.

Name, Province/State and Country of Residence, Position with the Company and Principal Occupation	Director Since	Number of Shares Beneficially Owned (1)(2)	Options to Acquire Shares Held (2)(3)	Warrants(2)(3)	RSUs to Acquire Shares Held (2)(3)	DSUs to Acquire Shares Held (2)(3)	PSUs to Acquire Shares Held (2)(3)
MR. CRISTIANO FRANZI (7) (13) Herrliberg, Switzerland Director	2024	-	-	-	-	265,131	-
MS. JANELLE D'ALVISE (6)(9) California, USA CEO, Radio Eye Inc.	2021	-	300,952	-	-	870,633	-
MR. JUN HAYAKAWA (7) Tokyo, Japan Director General Manager, Pharmaceutical & Medical Products Business Planning Division, Toray Industries, Inc.	2018	-	-	-	-	-	-
DR. JOHN KELLUM Pennsylvania, USA Chief Medical Officer	-	108,824	2,600,936	54,412	1,762,928	-	-
Mr. DAVID WILLIAM Jr. FEIGAL (6) (8) (12) California, USA Director	2023	-	-	-	-	661,262	-
MR. CHRIS SETO Ontario, Canada Director CEO & CFO	2021	1,164,870	5,217,292	167,435	3,389,805	-	-
MR. WILLIAM STEVENS (10) (9) Ontario, Canada Director President of GS Investment Corp.	2014	895,432	505,702	208,432	-	972,640	-
DR. PAUL M. WALKER (4) (5) (7) (8) (11) Ontario, Canada	2001	1,878,855 (11)	2,327,292	-	85,445	455,297	-
Mrs. MEDHA GUPTA Ontario, Canada VP Finance	2023	-	80, 0 0 0	-	80,000	-	-

Notes:

(1) Information as to Shares beneficially owned is based on information provided by the respective directors and officers and has not been independently verified by the Company.

(2) Information is reported as of the date of this AIF.

(3) Each option/warrant/RSU/DSU/PSU is exercisable on its terms for one Share.

(4) Chairman of the Board.

(5) Chairman of the Human Resources and Compensation Committee.

(6) Member of the Finance and Audit Committee.

(7) Member of the Nomination and Governance Committee.

(8) Chairman of the Nomination and Governance Committee.

(9) Member of the Human Resources and Compensation Committee.

(10) Chairman of the Finance and Audit Committee.

(11) These Shares are held directly by Dr. Walker and by entities over which he has control or direction.

(12) Mr. Feigal was appointed as the member of the board and Finance and Audit committee on June 22, 2023.

(13) Mr. Franzi was appointed as the member of the board and Nomination and Governance Committee on June 7, 2024.

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) Dr. Kellum who was a Director of the Center for Critical Care Nephrology and Vice-Chair for Research in the Department of Critical Care Medicine at the University of Pittsburgh. Dr. Kellum is a Distinguished Professor of Critical Care Medicine, Medicine, Bioengineering, and Clinical and Translational Science at the University of Pittsburgh; and (ii) Mrs. Medha Gupta who was Controller of Pfaff Automotive partners from 2022-2023 and Corporate Controller of Timken Canada from 2018 to 2022.

The directors and executive officers of Spectral, as a group, beneficially own or exercise control or direction over, directly or indirectly 4,047,981 Shares representing approximately 1.4% of the issued and outstanding Shares as of March 26, 2025.

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, (i) 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 (ii) 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 (i) 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 (ii) has within the last ten years, become bankrupt, 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.

Ms. D'Alvise, was the Chief Executive Officer and a board member of Pediatric Bioscience, Inc. a private company that, due to a failed pivotal clinical trial, filed a motion for bankruptcy under Chapter 7 of the U.S. Bankruptcy Code, in the United States Bankruptcy Court, Southern District of California (San Diego), on March 2, 2016. The trustee issued a final report on the matter in April 2017.

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 on the Finance and Audit Committee: Mr. Stevens, Ms. D'Alvise and Mr. Feigal. Mr. Stevens is the independent Chair of the Finance and Audit Committee. Ms. D'Alvise and Mr. Feigal are also independent members. All three members are financially literate. A brief biography of such members follows:

David Feigal: Mr. Feigal was appointed on the Board on June 2023. Mr. Feigal brings over four decades of experience in regulatory affairs and clinical research of medical devices, biologics, and products in multiple therapeutic areas. He is currently a Partner in NDA Partners. He spent 12 years with the US FDA where he was Director, Center for Devices & Radiological Health (CDRH), Director, Division of Anti-infective & Antiviral Drug Products, Center for Drug Evaluation & Research (CDER), and Deputy Director, Center for Biologics Evaluation & Research (CBER). He is the former Vice President of Global Regulatory Strategy, Amgen, and former Senior Vice President, Head of Global Regulatory and Global Safety Surveillance at Elan Corporation. Before joining the FDA, he worked for 10 years within the academic and hospital settings of the University of California in San Diego, San Francisco, and Davis. Mr. Feigal has contributed to global government programs conducted by the World Health Organization, the European Medicines Evaluation Agency (EMEA), the National Institutes of Health, and others. He has served on numerous committees within the U.S. Department of Health and Human Services, has served on boards of both companies and funds, is a renowned speaker, and has published over 50 papers. He holds a BA from University of Minnesota, an MD from Stanford University and a Master of Public Health from the University of California, Berkeley.

Janelle D'Alvise: Janelle D'Alvise: Ms. D'Alvise is a serial CEO/entrepreneur with extensive experience in the pharmaceutical, diagnostic, medical device, Health IT/AI, and drug discovery research segments of the healthcare industry. She joined the board of Spectral Medical, Inc. (EDT:TO) in 2021 as an independent director, and currently serves on their Finance & Audit and Human Resources & Compensation Committees. She previously served on the boards of numerous medical device and pharmaceutical companies and research non-profits. Ms. D'Alvise is currently the Managing Partner at HealthPath Strategies, an executive management consulting firm that advises numerous start-up companies in the life-science sector. She is also an entrepreneur-in-residence at San Diego CONNECT and the Cedars-Sinai Accelerator. From 2016 to 2023, Ms. D'Alvise served as the President and CEO of Acasti Pharma, Inc. (ACST:Nasdaq and TSXV), a specialty pharma company from 2016 through 2023, and served on their board of directors. Prior to Acasti, Ms. D'Alvise was the President and Chairman of Pediatric Bioscience, a private company developing a diagnostic test for autism. Before that, she was the CEO of Gish Biomedical, a cardiopulmonary medical device company that she sold to the Sorin Group. Prior to Gish, Ms. D'Alvise was the CEO and member of the board of trustees for the Sidney Kimmel Cancer Center, a drug discovery research institute developing oncology medicines that she sold to the Sanford Burnham Prebys Institute. Prior to SKCC, Ms. D'Alvise was the Co-Founder/President & CEO/Chairman of NuGEN, Inc., and the Co-Founder, Executive VP/COO and a board member of Metrika, Inc. Ms. D'Alvise built both companies from a technology concept through to successful regulatory approvals, product introduction, and sustainable revenue growth. Ms. D'Alvise was also a VP of Drug Development at Syntex/Roche, and Business Unit Director of their Pain and Inflammation business, and VP of Commercial Operations at SYVA, (Syntex's clinical diagnostics division). Ms. D'Alvise received a B.S. in Biochemistry from Michigan Technological

University, and she completed post-graduate studies at the University of Michigan, Stanford University, and the Wharton Business Schools.

William Stevens: Mr. Stevens is the President of GS Investment Corp., a private investment management company. Prior to this, Mr. Stevens was Managing Director of Westerkirk Capital Inc., a private investment management company. 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.

External Auditor Service Fees (By Category)

The aggregate fees billed by the Company's auditor, MNP LLP, in the last two fiscal years are as follows:

Description of Fees	December 31, 2024	December 31, 2023
Audit Fees(1)	270,728	262,440
Audit Related Fees (2)	13,500	85,000
Tax Fees (3)	-	-
All Other Fees (4)	-	-
Total	**284,228**	**347,440**

Notes:

(1) "Audit Fees" include fees necessary to perform the annual audit and quarterly reviews of the Company's consolidated financial statements. Audit Fees include fees for review of tax provisions and for accounting consultations on matters reflected in the financial statements. Audit Fees also include audit or other attest services required by legislation or regulation, such as comfort letters, consents, reviews of securities filings and statutory audits.

(2) "Audit-Related Fees" include fees for services that are traditionally performed by the auditor. These audit-related services include employee benefit audits, due diligence assistance, accounting consultations on proposed transactions, internal control reviews and audit or attest services not required by legislation or regulation.

(3) "Tax Fees" include fees for all tax services other than those included in "Audit Fees" and "Audit-Related Fees". This category includes fees for tax compliance, tax planning and tax advice. Tax planning and tax advice includes assistance with tax audits and appeals, tax advice related to mergers and acquisitions, and requests for rulings or technical advice from tax authorities.

(4) "All Other Fees" include fees for all other non-audit services.

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. Jun Hayakawa is the Toray nominee to the Board. Mr. Hayakawa is the General Manager, Pharmaceutical and Medical Products Business Planning Dept. of Toray. As at March 26, 2025, Toray owns and controls 45,630,105 Shares, or 16%, of the currently issued and outstanding Shares, calculated on a non-diluted basis.

Mr. William Stevens is the nominee of the Birch Hill LPs to the Board. Mr. William Stevens is the President of GS Investment Corp. As at March 26, 2025, the Birch Hill LPs own and 36,210,017 Shares, representing approximately 13% of the issued and outstanding Shares, calculated on a non-diluted basis.

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, 2020 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, as amended.

- A long-term, exclusive distribution agreement with Toray to market and sell PMX in Canada, as amended.

- A private placement agreement dated March 7, 2013 with Toray (the "**2013 Private Placement**"). Pursuant to the 2013 Private Placement, the Company sold and Toray subscribed for 16,666,667 Shares in its capital for a subscription price of $0.30 per Share for aggregate subscription proceeds of $5,000. The 2013 Private Placement gave Toray certain pre-emptive rights, including pre-emptive rights upon issuance of additional Shares. The Company must give Toray notice of any issuance of 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 (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 the Company, to subscribe for and purchase from the Company, 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 shall be extinguished.

- A private placement agreement dated June 10, 2014 with the Birch Hill LPs (the "2014 Private Placement") whereby the Company sold and the Birch Hill LPs subscribed for 15,358,360 Shares for aggregate proceeds of $4,500. Under the 2014 Private Placement, the Birch Hill LPs were granted certain pre-emptive rights, including pre-emptive rights upon issuance of additional Shares. The Company must give the Birch Hill LPs 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 the Birch Hill LPs sell, assign or transfer any of the Shares under the private placement agreement, other than to an affiliate. Upon receipt of notice, the Birch Hill LPs shall have the right, exercisable for a period of thirty days by written notice to the Company, to subscribe for and purchase from the Company, 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 the Birch Hill LPs fail to deliver any such notice within such period, then the preemptive rights shall be extinguished.

- A master services agreement, dated May 7, 2018, with Amarex Clinical Research, LLC to set up and conduct the Tigris Study to collect additional data regarding the safety and efficacy of Toraymyxin™ treatment for patients with endotoxemic septic shock. This agreement was terminated in 2023.

- A manufacturing and supply agreement, dated December 1, 2018, with Infomed S.A. to manufacture and supply SAMI and give the Company exclusive license rights for SAMI in North America for all CRRT applications and worldwide exclusivity for any hemoperfusion applications.

- An exclusive distribution agreement, dated February 3, 2020 with Baxter International Inc. for PMX and EAA™ in the U.S. and Canada. Baxter will be the Company's exclusive distributor of the PMX filter in the U.S. and Canada. Baxter also has non-exclusive rights to distribute the EAA™ globally. Baxter has the option to maintain exclusive rights for PMX through future milestone payments and maintaining certain performance obligations. The exclusive distribution agreement was assigned to Vantive.

- On March 23, 2023, the Company engaged a new CRO, Beaufort. Beaufort has extensive experience with ICU clinical trials and brings a strong regulatory group, experienced biostats personnel, and additional clinical field resources. During the third quarter, full transition from the incumbent CRO was completed. As part of its engagement, Beaufort is reviewing and evaluating recruitment and enrollment processes on a site-by-site basis of Tigris sites;

Copies of these contracts may be found under the Company's profile on SEDAR+ at www.sedarplus.com.

INTEREST OF EXPERTS

The Company's auditors are MNP LLP, Chartered Professional Accountants, who have prepared an independent auditor's report dated March 26, 2025 in respect of the Company's consolidated financial statements as at December 31, 2024 and for the year then ended. The consolidated financial statements for the year ended December 31, 2023 were audited by the Company's previous auditor, PricewaterhouseCoopers LLP, who prepared an independent auditor's report dated March 28, 2024. MNP LLP has advised that they are independent with respect to the Company within the meaning of the Chartered Professional Accountants of Ontario CPA Code of Professional Conduct. PricewaterhouseCoopers LLP has also confirmed that they were independent with respect to the Company within the meaning of the Chartered Professional Accountants of Ontario CPA Code of Professional Conduct.

ADDITIONAL INFORMATION

Additional information relating to Spectral may be found under the Company's profile on SEDAR+ at www.sedarplus.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 consolidated financial statements as at December 31, 2024 and December 31, 2023 and for the years then ended, 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. For further information, please contact: Mrs. Medha Gupta, VP of Finance of Spectral Medical Inc., at the corporate head office at (416) 626-3233 ext. 2100.

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 Company. 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 Company'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 Company's consolidated financial statements are complete, accurate, and in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standard Board.

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 VP of Finance of the Company, representatives of the external auditors and such other officers or support staff as may be deemed appropriate.

C. DUTIES AND RESPONSIBILITIES

i. Consolidated financial statements and Disclosures

a) Review, and recommend to the Board for approval, the annual audited consolidated 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 Company.

c) Review and, if appropriate, to **approve and** authorize the release of the quarterly unaudited consolidated financial statements including management's discussion and analysis, the quarterly interim report to shareholders and the quarterly press release on earnings of the Company. 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 consolidated financial statements, reports of a financial nature, (other than quarterly unaudited consolidated 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 Company'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 consolidated 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 Company, 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 Company;
  - any new or pending developments in accounting and reporting standards that may affect or impact on the Company;
  - the impact of the Company'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 Company.

h) At least annually, request the external auditor to provide their views on the quality (not just the acceptability) of the Company'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 Company, and the manner in which these matters have been disclosed in the consolidated 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 Company'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 Company'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.

j) Meet with the external auditor annually 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;

k) 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.

l) Review and approve the Company's hiring policies regarding employees and former employees of the present and former external auditors of the Company.

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 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 Company, including the use of the Company'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 Company.

v. Compliance/Risk/Fraud

a) Discuss with management the Company's major risk exposures and the steps management has taken to monitor and control such exposures, including the Company's risk assessment and risk management policies;

b) Discuss with management the Company's policies and procedures designed to prevent, identify and detect fraud;

c) Discuss with management the Company’s policies and procedures designed to ensure an effective compliance and ethics program, including the Company’s code of ethics;

d) Discuss with management and the general counsel any legal matters that may have a material impact on the consolidated financial statements or the Company’s compliance requirements;

e) On an annual basis, review the adequacy of the Company’s insurance rogram.

vi. Other

a) Review, as required, any claims of indemnification pursuant to the by-laws of the Company;

b) On a quarterly basis, review all related party transactions as defined by the CPA Handbook and report thereon to the Board;

c) In accordance with the Company’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 Company 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.