

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

This Management's Discussion & Analysis ("MD&A") for the nine-months ended September 30, 2021 has been prepared to help investors understand the financial performance of Spectral Medical Inc. ("Spectral" or the "Company") in the broader context of the Company's strategic direction, the risks and opportunities as understood by management, and the key success factors that are relevant to the Company's performance. Management has prepared this document in conjunction with its broader responsibilities for the accuracy and reliability of the condensed interim consolidated financial statements and accompanying notes, which have been prepared in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board (IFRS), including IAS 34, "Interim Financial Reporting", as well as the development and maintenance of appropriate information systems and internal controls to ensure that the financial information is complete and reliable. The Finance and Audit Committee of the Board of Directors has reviewed this document and all other publicly reported financial information for integrity, usefulness, reliability and consistency.

This MD&A is dated November 11, 2021 and should be read in conjunction with the condensed interim consolidated financial statements for the nine-months ended September 30, 2021 and the audited annual consolidated financial statements of the Company for the years ended December 31, 2020 and December 31, 2019 ("Annual Financial Statements"), as well as management's discussion and analysis for the year ended December 31, 2020.

**FORWARD LOOKING STATEMENTS**

Certain statements contained in this MD&A constitute forward-looking information within the meaning of securities law. Forward-looking information may relate to our future outlook and anticipated events or results and may include statements regarding our future financial position, business strategy, budgets, litigation, projected costs, capital expenditures, financial results, taxes and plans and objectives. In some cases, forward-looking information can be identified by terms such as "may", "will", "should", "expect", "plan", "anticipate", "believe", "intend", "estimate", "predict", "potential", "continue" or other similar expressions concerning matters that are not historical facts. These statements are based on certain factors and assumptions regarding, among other things, expected growth, results of operations, performance and business prospects and opportunities. While we consider these assumptions to be reasonable based on information currently available to us, they may prove to be incorrect. Forward looking-information is also subject to certain factors, including risks and uncertainties that could cause actual results to differ materially from what we currently expect. These factors include, among other things, the availability of funds and resources to pursue development projects, the successful and timely completion of clinical studies, and the ability of the Company to take advantage of business opportunities, the granting of necessary approvals by regulatory authorities as well as general economic, market and business conditions. For more exhaustive information on these risks and uncertainties you should refer to our most recently filed Annual Information Form which is available at [www.sedar.com](http://www.sedar.com). Forward-looking information contained in this MD&A is based on our current estimates, expectations and projections, which we believe are reasonable as of the current date. You should not place undue importance on forward-looking information and should not rely upon this information as of any other date. While we may elect to, we are under no obligation and do not undertake to update this information at any particular time.

This document and the related consolidated financial statements can also be viewed on the Company's website at [www.spectraldx.com](http://www.spectraldx.com) and at [www.sedar.com](http://www.sedar.com). The Company's Annual Information Form and Management Information Circular are also available on these websites.

## INTRODUCTION

The Company's primary strategic focus is on the regulatory development and commercialization of its products in the areas of septic shock and renal disease. 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. In the area of renal disease, the Company has developed a platform to perform renal replacement therapy ("RRT") initially targeting the acute kidney injury segment of the market and continuing to the chronic dialysis dependent population including those on home hemodialysis. The platform is also able to deliver hemoperfusion including PMX. Furthermore, the Company is continuing its legacy business of manufacturing and selling certain proprietary reagents.

### ENDOTOXIN ACTIVITY ASSAY ("EAA™")

Spectral has pioneered the development of biochemical markers for the clinical syndrome known as "septic shock". In 2003, the Company achieved U.S. Food and Drug Administration ("FDA"), Health Canada ("HC") and European CE clearance of the EAA™ for the first recognized rapid test for the risk of developing sepsis in the Intensive Care Unit ("ICU"). In North America alone over 1,700,000<sup>1</sup> patients are diagnosed with the clinical syndrome of sepsis annually. Approximately 330,000<sup>2</sup> patients develop septic shock in the ICU, with a mortality rate at approximately 50%<sup>2</sup>. The Company's addressable market, which is comprised of patients suffering from endotoxemic septic shock, represents an estimated 120,000 patients per year. Earlier identification and treatment of patients at risk for sepsis reduces mortality and saves significant cost by reducing the length of stay in the ICU and by helping to guide therapeutic interventions. Spectral's EAA™ endotoxin activity measurement is the only FDA cleared diagnostic for this indication currently on the market.

### POLYMYXIN B-HEMOPERFUSION ("PMX")

PMX is a therapeutic hemoperfusion device that removes endotoxin from the bloodstream. PMX has been on the market in many countries outside the U.S. and has been used in more than 300,000<sup>3</sup> patients to date, and has demonstrated in clinical trials that it safely and effectively removes endotoxin and reduces mortality in patients with septic shock.

### PROPRIETARY REAGENTS

Spectral develops, produces and markets recombinant proteins, antibodies and calibrators. These materials are sold for use in research and development as well as in products manufactured by other diagnostic companies.

### RENAL REPLACEMENT THERAPY ("RRT")

The Company entered into the RRT business by acquiring the rights to SAMI, an easy-to-use dialysis machine on which to use its PMX cartridges, from Infomed S.A. ("Infomed"). The Company entered into a

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<sup>1</sup> *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.*

<sup>2</sup> *National (Nationwide) Inpatient Sample ("NIS") database, 2013.*

<sup>3</sup> *Report of Prior Investigations ("ROPI") is a report that is part of the Code of Federal Regulations, from September 1994 to January 2021.*

manufacturing and supply agreement with Infomed on December 1, 2018. The agreement expires on December 31, 2026, with a provision to extend it for additional two-year terms.

SAMI complements the PMX/EAA™ development as it can be used to deliver the Company's therapy in the ICU and reduces reliance on third party instrumentation. This state-of-the-art equipment will enable the Company to provide a fully integrated and user-friendly septic shock treatment system to the ICU. In addition, SAMI is also designed to provide an open platform for other hemoperfusion cartridges and to deliver continuous renal replacement therapy ("CRRT") when indicated for patients with kidney failure.

On December 13, 2017, the Company received 510(k) clearance from the FDA for SAMI for use in CRRT and therapeutic plasma exchange ("TPE"). Since it is also designed as an open platform hemoperfusion delivery device, the Company intends to seek further 510(k) clearance for this purpose when there is an FDA approved hemoperfusion cartridge available for use in the U.S. market, including the Company's planned PMX treatment.

On February 18, 2018, the Company announced that HC approved SAMI, under License No. 100541 for use in CRRT, TPE, as well as for Hemoperfusion ("HP"), a modality specifically designed to facilitate patient treatment with the PMX cartridge.

On March 8, 2018, SAMI received a CE mark in Europe for the same applications.

The Company has exclusive license rights for SAMI in North America for all CRRT applications and has worldwide exclusivity for any hemoperfusion applications.

Spectral transferred its RRT business to its wholly owned subsidiary, Dialco Medical Inc. ("Dialco") in 2019.

On March 18, 2019, Dialco entered into a development, licence and exclusive distribution agreement with Infomed to extend its license to include the North American exclusive rights to an easy-to-use home hemodialysis machine ("DIMI"), built on the same platform as SAMI. The Company is seeking to obtain regulatory approval for DIMI in the United States for in-home use. DIMI is already CE marked for hemodialysis in Europe by Infomed.

On August 31, 2020, the Company received FDA 510(k) clearance for DIMI to treat patients with acute and/or chronic renal failure with or without fluid overload using hemodialysis ("HD"), hemofiltration ("HF") and/or ultrafiltration ("UF") in hospital or clinical settings. This is the first major step of the full regulatory development of DIMI. Further advances will be clearance for home and peritoneal dialysis use. Dialco also submitted an application to HC to add DIMI as a new product under the SAMI family of products.

On November 11, 2020, the Company announced that a paper from the University of Michigan Medical Center ("UMMC") reporting on the deployment and use of its SAMI unit during the COVID-19 pandemic was published in the Journal of Blood Purification, titled, "Deployment of a new CRRT/PIRRT device during the COVID-19 pandemic emergency: organizational challenges an implementation results". The paper describes the first month of using SAMI as part of UMMC's PIRRT (Prolonged Intermittent Renal Replacement Therapy) program throughout April 2020. The installation and training were successfully managed remotely with SAMI utilized to treat 23 patients in the first 4 weeks. The paper goes on to state, "The results from the nurse questionnaire, as well as the successful deployment of the SAMI in our institution during the pandemic with only 3-hour virtual training support that operating the SAMI is simple and safe. The setup of the SAMI has been refined to be as simple as possible, and interactions that normally cause issues (connecting the bloodline to the various safety sensors and pumps) have been refined to almost a

single gesture of inserting the disposable cassette into the machine. This approach together with a comprehensive self-testing procedure allows the unit to eliminate as many potential user errors as reasonably possible.”

Also in November 2020, the Company announced that Dialco received its Medical Device Single Audit Program (“MDSAP”) certification for “the design, manufacture, installation and service of equipment for extracorporeal blood purification and its related disposable”. MDSAP allows the conduct of a single regulatory audit of a medical device manufacturer’s quality management system to satisfy the requirement of multiple regulatory jurisdictions or authorities to enable appropriate regulatory oversight of medical device manufacturer’s quality management systems while minimizing the regulatory burden on the industry.

On February 23, 2021, the Company announced that Dialco received IDE authorization by the FDA to conduct a usability trial to demonstrate the safety and efficacy of DIMI for performing hemodialysis in the home environment. The trial is expected to enroll 35 patients, and will analyze delivered dialysis dose and potential adverse events happening during six weeks of use at home compared to six weeks of use in the hospital setting on some patients. The DIMI usability trial is registered and posted on the ClinicalTrials.gov website under the identifier of NCT04868643.

On March 31, 2021, the Company announced that Dialco received its license from HC for the DIMI RRT system. The HC license for DIMI is indicated for hemodialysis, hemodiafiltration and ultrafiltration for patients weighing 20 kgs or more, and can be used in hospitals, clinics and at home.

On April 8, 2021, the Company announced that Dialco entered into an expanded, long-term licensing agreement with Infomed for the DIMI hemodialysis system, extending Dialco’s exclusive rights in the United States and Canada through 2041. The initial term of the agreement shall extend to December 31, 2026 (“Initial Term”), and the agreement will automatically extend for three additional five-year periods (“Renewal Terms”).

On June 7, 2021, the Company announced that Dialco engaged CROMSOURCE, a full-service Contract Research Organization (“CRO”), for its upcoming DIMI IDE usability clinical trial. CROMSOURCE is a high quality, ISO certified international provider of outsourced clinical trial services that has been a trusted partner to pharmaceutical, medical device, and biotechnology companies for more than 20 years.

## **CLINICAL DEVELOPMENT**

The Company’s clinical development program continues to focus on obtaining 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 licence 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 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]<sup>4</sup>. 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=0.046) and a substantial increase in days alive and free from mechanical ventilator support [median difference of 14 days, (p=0.004)].

Furthermore, the trial results indicate 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

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<sup>4</sup> 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,

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, "Tigris". This trial will utilize a Bayesian approach to analyse the primary endpoint of 28-day mortality by leveraging data already obtained in EUPHRATES.

The Tigris trial is open label and patients are randomized 2:1 for treatment vs. control. It is expected to enrol 150 patients in 15 sites in the U.S.

In October 2019, the Company obtained FDA approval for a sub-study of Tigris 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.

Similarly, the Company announced on April 20, 2020, that HC issued an Interim Order expanding the already approved indication for use of PMX to include patients with COVID-19.

On June 11, 2021, the Company held a Tigris 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 sites in anticipation of COVID-19 receding and the diminished strain on trial site ICUs,

The COVID-19 pandemic has had significantly negative impacts on non-COVID research in the ICU. The fourth wave of COVID-19 infections, spurred by the delta variant of the virus, had many ICUs in hard hit regions of the U.S. at full capacity of critically ill patients with COVID-19. Research staff were either drawn into clinical care, or were unable to enter the hospital or were engaged in high-priority studies of COVID therapies. However, as of the date of this MD&A, there are twelve clinical sites that have resumed screening and are open for enrollment. Recruitment has been significantly impacted but should normalize as the proportion of patients in the U.S. develop immunity either from vaccination or infection. A disturbing trend in the U.S. is the relatively low influenza vaccination rates but this could have a beneficial impact on enrollment into Tigris as bacterial sepsis often follows flu and hospitals will be less burdened by critically ill COVID positive patients.

## **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 International Inc. ("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 non-refundable US\$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.

SAMI continues to be launched in Canada and the U.S. for use as an RRT machine. It continues successful clinical evaluation in key hemodialysis centres and building its commercial sales pipeline. As hospitals are experiencing a significant shortage of CRRT machines in COVID-19 affected ICUs, there has been increased activity with respect to the use of SAMI in the treatment of COVID-19 positive patients. The Company has successfully developed remote installation, set-up and high-level on-line training of SAMI.

In order to support commercial expansion, and in anticipation to the start-up of the DIMI usability trial, Dialco is expanding its field force for sales training and technical support. At the time of this MD&A, Dialco has one field force resource in Ontario, and four employees in the U.S. The U.S. field force employees are located in Pennsylvania, Florida, Michigan, and California. Recruitment initiatives continue for further U.S. field force expansion in targeted states.

The Company continues to evaluate other distribution arrangements or channels that would best expand our market presence in the U.S.

## **OPERATIONS**

The Company continues to focus its activities on its regulatory programs to achieve FDA approval of the PMX treatment for endotoxemic septic shock, and FDA clearance and HC approval for DIMI.

The Company also continues to sell its EAA™ diagnostic under the terms of existing commercial arrangements. Previously, the Company anticipated a multi-country launch of EAA™ with an existing distribution partner in mid Q4 2020. The product launch has been delayed.

Proprietary reagents continue to sell under regular purchase orders as issued by customers. The Company is continuing its efforts in the commercialization of SAMI as well as the development and commercialization of DIMI.

On February 1, 2021, the Company announced the appointment of Dr. John Kellum, as Chief Medical Officer, effective March 1, 2021. He is responsible for leading all medical, scientific and clinical activities, as well as the scientific evaluation of partnership opportunities. Dr. Kellum is considered one of the leading critical care researchers and world's foremost experts in sepsis, blood purification and acute kidney injury ("AKI").

On March 8, 2021, the Company announced the appointment of Mr. Chris Seto as CEO, effective April 1, 2021. He will continue to retain his responsibilities as CFO. Dr. Paul Walker will remain committed to the Company and continue to be a member of the Board of Directors.

On June 3, 2021, the Company announced the addition of Ms. Jan D'Alvise as an independent director to the Board of Directors. Ms. D'Alvise has extensive experience in the pharmaceutical, diagnostic, medical device, and drug discovery research segments of the healthcare industry. From 2016 to present, Ms. D'Alvise continues as the President and CEO of Acasti Pharma (ACST), a specialty pharma company, and serves on its board of directors.

On August 9, 2021, the Company announced the resignation of Mr. Gualtiero Guadagni as President of Dialco to pursue other opportunities.

## OPERATING RESULTS

### REVENUE

Revenue for the three-months ended September 30, 2021 was \$230 compared to \$418 for the same period in the prior year. For the nine-months ended September 30, 2021, revenue was \$1,535 compared to \$1,566 for the same period in 2020, representing a decrease of \$31, or 2%.

Royalty revenue for the three-months ended September 30, 2021 was \$29, a decrease of \$122 from \$151 for the same period in the prior year. This is due to a decrease in usage of the Company's IP from one customer. Royalty revenue for the nine-months ended September 30, 2021 of \$254 (2020 - \$547) decreased as well as the decreased in usage of the Company's IP. The customer reported a decline in their manufacturing in the second and third quarters of 2021.

In 2020, the Company began to recognize the revenue relating to the exclusive distribution agreement with Baxter, as described above. The Company is recognizing revenue from the US\$5,000 (CA\$6,629) non-refundable upfront payment on a straight-line basis over the initial nine-year and eleven-month term of the agreement. This amounted to revenue of \$167 and \$501 for the three and nine-months ended September 30, 2021 compared to \$167 and \$445 for the same three and nine-month period in the prior year.

Changes in product revenue for the three and nine-months ended September 30, 2021 are detailed below:

|                              | Three-months ended September 30, 2021 |            |              |         | Nine-months ended September 30, 2021 |            |              |         |
|------------------------------|---------------------------------------|------------|--------------|---------|--------------------------------------|------------|--------------|---------|
|                              | 2021<br>\$                            | 2020<br>\$ | Change<br>\$ | %Change | 2021<br>\$                           | 2020<br>\$ | Change<br>\$ | %Change |
| <b>Product revenue</b>       |                                       |            |              |         |                                      |            |              |         |
| Proprietary                  |                                       |            |              |         |                                      |            |              |         |
| biochemicals                 | 5                                     | 87         | (82)         | (94%)   | 329                                  | 356        | (27)         | (8%)    |
| EAA™ diagnostic              | 29                                    | -          | 29           | 100%    | 364                                  | 140        | 224          | 160%    |
| Instrumentation              | -                                     | -          | -            | -       | 66                                   | 20         | 46           | 230%    |
| RRT                          | -                                     | 13         | (13)         | (100%)  | 21                                   | 58         | (37)         | (64%)   |
| <b>Total Product revenue</b> | <b>34</b>                             | <b>100</b> | <b>(66)</b>  |         | <b>780</b>                           | <b>574</b> | <b>206</b>   |         |

### EXPENSES

Operating costs for the three-months ended September 30, 2021, were \$2,297, compared to \$1,995 for the same period in the preceding year, an increase of \$302, or 15%. For the nine-months ended September 30, 2021, operating costs were \$7,768 compared to \$8,517 for the same period in 2020, a decrease of \$749.

The change in costs were primarily due to a decrease in consulting and professional fees and foreign exchange, offset by an increase in salaries and benefits, as described in more detail below.

Consulting and professional fees are \$913 and \$2,075 for the three and nine-months ended September 30, 2021, compared to \$418 and \$3,612 for the three and nine-months ended September 30, 2020, an increase of \$495 and a decrease of \$1,537, respectively.

The increase of \$495 for the three-months ended September 30, 2021, is primarily due to the initiation of three additional clinical trial sites for Tigris and the commencement of an observational study, "EDEN". In

addition, initial expenses were incurred for the DIMI usability trial, as well as expenses associated with the design and development of pre-filled dialysate bags for the purpose of completing the DIMI dialysis portfolio of product offerings.

The decrease for the nine-months ended September 30, 2021, is primarily due to a US\$1,343 (\$1,782) fee payable to a financial advisory services firm incurred in the first quarter of 2020, relating to a legacy financial advisory agreement. In addition, the Company incurred approximately \$275 in professional fees in connection with a withdrawn prospectus offering in early March 2020.

Salaries and benefits are \$1,204 and \$4,268 for the three and nine-month periods ended September 30, 2021, prior to the receipt of government assistance of \$378 and \$628 for the same period. This resulted in a net expense of \$826 and \$3,640, respectively. Salaries and benefits were \$1,014 and \$3,505 for the same periods in the prior year, an increase of \$190 and \$763 respectively. The Company did not receive any government assistance for the three and nine-month periods ended September 30, 2020.

The increase is due to the number of Awards that were granted in the second quarter of 2021. In addition, the increase reflects the addition of Dr. Kellum, effective March 1, 2021, as well as a number of sale/technical specialists in the U.S. to support Dialco activities. The government assistance received was primarily from the Canada Emergency Wage Subsidy program established to support businesses during the COVID-19 pandemic.

The Company recorded a foreign exchange gain of \$57 for the three-month period ended September 30, 2021, compared to a foreign exchange loss of \$37 for the same period in 2020. For the nine-months ended, the Company incurred a foreign exchange loss of \$110, compared to a foreign exchange gain of \$144 for the nine-months ended September 30, 2020.

The CAD/USD foreign exchange rate has decreased from 1.3339 to 1.2741 on September 30, 2020 to September 30, 2021 respectively. The impact of the exchange fluctuation relates to the US\$5,000 upfront cash payment from Baxter received in February 2020, and the US dollar cash balances from that point forward.

Clinical development and regulatory program costs (as disclosed in Note 9 of the condensed interim consolidated financial statements) were \$761 for the three-months ended September 30, 2021 compared to \$393 for the same period in the prior year. For the nine-months ended September 30, 2021, clinical development costs were \$1,404 compared to \$1,435 for the corresponding period in the prior year. A significant portion of clinical trial and regulatory costs consists of consulting and professional fees paid to contract research organizations, clinical sites, and other clinical and regulatory consultants. These costs are expected to increase as the Company completes the initialization of clinical sites and the randomization of patients into the Tigris clinical trial, the EDEN observational study, and DIMI usability trial. Cumulative trial and regulatory program costs total \$47,130 as of September 30, 2021.

## **Loss**

For the three-months ended September 30, 2021, the Company reported a loss of \$2,067 (\$0.008 loss per share) compared to a loss of \$1,577 (\$0.007 loss per share) for the three-months ended September 30, 2020. The loss for the nine-months ended September 30, 2021 was \$6,233 (\$0.025 loss per share) compared to a loss of \$6,951 (\$0.030 loss per share) for the first nine months of 2020.

**SEGMENT PERFORMANCE****Three-months ended September 30, 2021**

|                             | <b>Spectral<br/>Medical Inc.</b> | <b>Dialco<br/>Medical Inc.</b> | <b>Corporate</b> | <b>Total</b> |
|-----------------------------|----------------------------------|--------------------------------|------------------|--------------|
| Revenue                     | 230                              | -                              | -                | 230          |
| Expenses                    | 811                              | 657                            | 829              | 2,297        |
| Segment loss for the period | (581)                            | (657)                          |                  |              |

**Three-months ended September 30, 2020**

|                             | <b>Spectral Medical<br/>Inc.</b> | <b>Dialco<br/>Medical Inc.</b> | <b>Corporate</b> | <b>Total</b> |
|-----------------------------|----------------------------------|--------------------------------|------------------|--------------|
| Revenue                     | 405                              | 13                             | -                | 418          |
| Expenses                    | 1,002                            | 223                            | 770              | 1,995        |
| Segment loss for the period | (597)                            | (210)                          |                  |              |

**Nine-months ended September 30, 2021**

|                             | <b>Spectral<br/>Medical Inc.</b> | <b>Dialco<br/>Medical Inc.</b> | <b>Corporate</b> | <b>Total</b> |
|-----------------------------|----------------------------------|--------------------------------|------------------|--------------|
| Revenue                     | 1,514                            | 21                             | -                | 1,535        |
| Expenses                    | 3,083                            | 1,287                          | 3,255            | 7,625        |
| Segment loss for the period | (1,569)                          | (1,266)                        |                  |              |
| Intercompany due from/(to)  | 3,461                            | (3,461)                        |                  |              |

**Nine-months ended September 30, 2020**

|                             | <b>Spectral Medical<br/>Inc.</b> | <b>Dialco<br/>Medical Inc.</b> | <b>Corporate</b> | <b>Total</b> |
|-----------------------------|----------------------------------|--------------------------------|------------------|--------------|
| Revenue                     | 1,508                            | 58                             | -                | 1,566        |
| Expenses                    | 4,831                            | 704                            | 2,982            | 8,517        |
| Segment loss for the period | (3,323)                          | (646)                          |                  |              |
| Intercompany due from/(to)  | 1,647                            | (1,647)                        |                  |              |

**SECURITIES OUTSTANDING**

The total number of securities outstanding for the Company as at September 30, 2021 is as follows:

|               | <b>Number</b> |
|---------------|---------------|
| Common shares | 267,886,408   |
| Share options | 9,580,554     |
| RSUs          | 717,348       |
| Warrants      | 18,054,450    |

On June 3, 2021, the shareholders' approved a special resolution (the "Share Consolidation Resolution"), authorizing an amendment to the Company's articles to consolidate the issued and outstanding Shares

(“the Consolidation”), based on a consolidation ratio in the range of one post-Consolidation Share for ten pre-Consolidation Shares to one post-Consolidation Share for twenty pre-Consolidation Shares, as determined by the Board of Directors in their sole discretion.

#### **ACCOUNTING STANDARDS ADOPTED IN THE CURRENT YEAR**

There were no new standards or amendments to standards and interpretations that have been applied in preparing the condensed interim consolidated financial statements with the exception of the following:

##### **Government grants**

In accordance with IAS 20, Accounting for Government Grants and Disclosure of Government Assistance, a government grant is recognized only when there is reasonable assurance that the Company will comply with any conditions attached to the grant and the grant will be received. Government grants are recognized in loss and comprehensive loss on a systematic basis over the periods in which the Company recognizes as expenses the related costs for which the grants are intended to compensate.

#### **ACCOUNTING STANDARDS ISSUED BUT NOT YET APPLIED**

Accounting standards or amendments to existing accounting standards that have been issued, but have future effective dates are as follows:

*a. IAS 1, ‘Presentation of Financial Statements’*

The amendment to IAS 1 clarifies how to classify debt and other liabilities as either current or non-current. The amendment will be effective for periods beginning on or after January 1, 2022. The Company is currently evaluating the new guidance and impacts on its consolidated financial statements.

*b. IFRS 3, ‘Reference to Conceptual Framework’*

In May 2020, the IASB issued an amendment to IFRS 3 to (i) clarify references to the 2018 Conceptual Framework in order to determine what constitutes an asset or liability in a business combination, (ii) add an exception for certain liabilities and contingent liabilities to refer to IAS 37 or IFRIC 21 and (iii) clarify that an acquirer should not recognize contingent assets at the acquisition date. The mandatory effective date would be annual periods beginning on or after January 1, 2022, with early adoption permitted. The amended standard is not expected to have an impact on the consolidated financial statements.

*c. IAS 37, ‘Onerous Contracts – Cost of Fulfilling a Contract’*

In May 2020, the IASB issued an amendment to IAS 37 to clarify which costs to include in estimating the cost of fulfilling a contract for the purpose of assessing whether that contract is onerous. The mandatory effective date would be annual periods beginning on or after January 1, 2022, with early adoption permitted. The amended standard is not expected to have an impact on the consolidated financial statements.

Other accounting standards or amendments to existing accounting standards that have been issued, but have future effective dates, are either not applicable or are not expected to have a significant impact on the Company’s consolidated financial statements.

## SELECTED QUARTERLY FINANCIAL DATA

(in thousands of Canadian dollars, except for Share and per Share data)

The following table summarizes the quarterly financial information for the nine-months ended September 30, 2021.

| <b>Nine-months ended<br/>September 30, 2021</b>  | <b>First<br/>Quarter</b> | <b>Second<br/>Quarter</b> | <b>Third<br/>Quarter</b> | <b>Total</b> |
|--|--------------------------|---------------------------|--------------------------|--------------|
| Revenue  | 746                      | 559                       | 230                      | 1,535        |
| Loss and comprehensive loss                      | (1,645)                  | (2,521)                   | (2,067)                  | (6,233)      |
| Basic and diluted loss per<br>Share              | (0.007)                  | (0.010)                   | (0.008)                  | (0.025)      |
| Weighted average number of<br>Shares outstanding | 237,067,764              | 243,543,981               | 260,928,039              | 247,267,326  |

The following tables summarize quarterly financial information for the year ended December 31, 2020 and the comparative year ended December 31, 2019:

| <b>Year ended December 31,<br/>2020</b>          | <b>First<br/>Quarter</b> | <b>Second<br/>Quarter</b> | <b>Third<br/>Quarter</b> | <b>Fourth<br/>Quarter</b> | <b>Total</b> |
|--|--------------------------|---------------------------|--------------------------|---------------------------|--------------|
| Revenue  | 631                      | 517                       | 418                      | 535                       | 2,101        |
| Loss and comprehensive loss                      | (3,425)                  | (1,949)                   | (1,577)                  | (2,147)                   | (9,098)      |
| Basic and diluted loss per<br>Share              | (0.015)                  | (0.009)                   | (0.007)                  | (0.009)                   | (0.04)       |
| Weighted average number of<br>Shares outstanding | 227,434,309              | 229,226,624               | 236,605,745              | 225,838,590               | 232,502,463  |

| <b>Year ended December 31,<br/>2019</b>          | <b>First<br/>Quarter</b> | <b>Second<br/>Quarter</b> | <b>Third<br/>Quarter</b> | <b>Fourth<br/>Quarter</b> | <b>Total</b> |
|--|--------------------------|---------------------------|--------------------------|---------------------------|--------------|
| Revenue  | 547                      | 1,041                     | 534                      | 746                       | 2,868        |
| Loss and comprehensive loss                      | (993)                    | (1,052)                   | (1,401)                  | (1,414)                   | (4,860)      |
| Basic and diluted loss per<br>Share              | (0.004)                  | (0.005)                   | (0.006)                  | (0.006)                   | (0.02)       |
| Weighted average number of<br>Shares outstanding | 225,591,183              | 225,675,249               | 225,816,183              | 225,838,590               | 225,731,215  |

## BALANCE SHEET, FINANCIAL CONDITION AND GOING CONCERN

Cash of \$10,923 at September 30, 2021, increased by \$5,116 from \$5,807 at December 31, 2020. The increase in cash in the nine-months ended September 30, 2021, was primarily due to the proceeds from the bought deal offering completed in July, 2021, as well as the proceeds from the exercise of warrants. There was an increase in cash of \$6,141 in the nine-month period ended September 30, 2020, primarily due to the public offering as described below and the US\$5,000 (CA\$6,629) upfront payment from the completion of the exclusive distribution agreement with Baxter. Cash is primarily used for the Company's Tigris clinical trial for its PMX treatment for endotoxemic septic shock including data analysis and submission of documentation to the FDA, the EDEN observational study, the DIMI usability trial, DIMI product development, Dialco commercialization efforts, and for general corporate and working capital purposes.

For the nine-months ended September 30, 2021, the Company received \$8,870 on the completion of its bought deal financing (described below) and \$3,356 cash on the exercise of 7,457,330 warrants, at an exercise price of \$0.45 per warrant, \$52 on the exercise of 143,333 Share options, at an exercise price of \$0.36 per Share.

|  | September 30,<br>2021 | September 30,<br>2020 |
|--|-----------------------|-----------------------|
|  | \$                    | \$                    |
| Cash operating (loss) income, including changes in working capital | (6,712)               | 1,219                 |
| Proceeds on disposal of property and equipment                     | 77                    | 10                    |
| Purchases of property and equipment                                | (401)                 | (215)                 |
| Proceeds from financing  | 10,000                | 5,100                 |
| Transaction costs paid   | (1,130)               | (784)                 |
| Share options exercised  | 52                    | 429                   |
| Warrants exercised   | 3,356                 | 495                   |
| Lease liability payments   | (84)                  | (81)                  |
| Effects of exchange rate changes on cash                           | (42)                  | (32)                  |
|  | 5,116                 | 6,141                 |

As described in Note 1 of the condensed interim consolidated financial statements, management has assessed the Company's ability to continue as a going concern and concluded that it is dependent on the successful execution of management's operating and strategic plan, which includes among other things, securing additional financing, the commercialization of its products, the continued financial support of its shareholders and, ultimately, the attainment of future profitable operations. There are no assurances that any of these initiatives will be successful. Factors within and outside the Company's control could have a significant bearing on its ability to obtain additional financing.

The Company's September 30, 2021 condensed interim consolidated financial statements do not reflect the adjustments to the carrying amounts of assets and liabilities and the reported expenses and balance sheet classifications that would be necessary if the Company were unable to realize its assets and settle its liabilities as a going concern in the normal course of operations. Such adjustments could be material.

## RELATED PARTIES

All related parties and the respective transactions have been disclosed in Note 11 of the condensed interim consolidated financial statements for the nine-months ended September 30, 2021 and 2020.

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

Toray holds 45,630,105 Shares of the Company as at September 30, 2021, representing approximately 17.0% (December 31, 2020 - 19.3%) of Spectral's issued and outstanding Shares, calculated on a non-diluted basis.

Toray is entitled to certain pre-emptive rights, including pre-emptive rights upon issuance of additional Shares.

Toray is entitled to nominate one director (the “Toray Representative”) to the Board of Directors as long as it owns in the aggregate not less than 10% of the Shares issued and outstanding calculated on a non-diluted basis.

The principal transactions with Toray which were carried out in the ordinary course of business are:

|                                  | <b>Three-months ended<br/>September 30,</b> |             | <b>Nine-months ended<br/>September 30,</b> |             |
|----------------------------------|---|-------------|--|-------------|
|                                  | <b>2021</b>                                 | <b>2020</b> | <b>2021</b>                                | <b>2020</b> |
|                                  |   | <b>\$</b>   |  | <b>\$</b>   |
| <b>Revenue</b>                   |   |             |  |             |
| Toray Medical Co., Ltd.          | -   | -           | 52   | -           |
| <b>Purchases</b>                 |   |             |  |             |
| Toray International America Inc. | -   | -           | -  | 108         |
| <b>Due from/(to)</b>             |   |             |  |             |
| Toray Medical Co., Ltd.          |   |             | -  |             |
| Toray International America Inc. |   |             |  | -           |

2. Birch Hill Equity Partners Management Inc. (“Birch Hill”)

Birch Hill, through a number of its funds and an investee company, holds 36,210,017 Shares of the Company as at September 30, 2021 representing approximately a 13.5% (December 31, 2020 - 15.2%) ownership interest, calculated on a non-diluted basis.

Birch Hill is entitled to certain pre-emptive rights, including pre-emptive rights upon issuance of additional Shares.

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

3. Key management consists of the Company’s executive officers and its Board of Directors.

There are no other related party transactions.

**BOUGHT DEAL OFFERING**

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 Share purchase 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 (“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.

The Company has granted an over-allotment option to the Underwriters (“Over-Allotment Option”) to purchase an additional 3,529,500 Units equal to 15% of the Offering. The Over-Allotment Option will be exercisable in whole or in part, at the sole discretion of the Underwriters, for a period of 30 days from July 27, 2021. The Over-Allotment Option was not exercised.

## **OUTLOOK**

The Company’s primary focus continues to be working towards obtaining FDA approval of the PMX treatment and obtaining regulatory clearance and commercialization of Dialco’s DIMI for home and peritoneal dialysis use.

### **TIGRIS**

As previously disclosed, the Company experienced a delay in Tigris patient enrollment and onboarding of new trial sites due to the pandemic as many trial site ICUs refocused their efforts and resources on addressing the pandemic. In June of 2021, the Company anticipated a return to more normalized trial activity in the second half of 2021, however this has been impacted by the flare of COVID-19 delta variant and a fourth wave of infections affecting ICU capacity throughout most U.S. hospitals. As this wave is beginning to show a downturn of infections the Company is ramping up its Tigris trial initiatives; and trial sites are responding by reporting renewed patient screening activities. The Company is onboarding additional clinical trial sites, with twelve clinical sites open for enrollment and three clinical sites with investigator agreements in place. This provides visibility on a full fifteen sites to be screening and open for enrollment by the end of November 2021. Assuming there is no significant recurrence of COVID-19 cases in our Tigris site ICUs, the Company continues to target finalizing its Tigris trial enrollment in the second half 2022.

### **DIALCO**

The Dialco team is focused on the DIMI usability trial to obtain FDA clearance for in home use, and expects first patient enrollment in Q1 2022 with primary study completion in Q4 2022. The timing of the start of the DIMI usability trial for home hemodialysis has also been impacted by the COVID pandemic and the recent surge of the delta variant. Dialysis clinics are experiencing severe staffing shortages as they work to accommodate current patients as well as responding to an increase in patients with COVID related kidney injury requiring dialysis.

Management believes the 35 patient usability trial represents a prime commercialization opportunity to demonstrate positive real world experience and the versatility of DIMI amongst Dialco’s clinical trial partners, who are also potential DIMI customers.

The Company expects to continue to generate revenue in 2021 pursuant to its existing commercial arrangements for EAA™, its proprietary biological reagents and SAMI machines and disposables.

### **COVID-19 PANDEMIC**

As of the date of this MD&A, there has not been a material adverse impact on the Company’s business due to the COVID-19 pandemic, other than the impacts on the Tigris trial and the DIMI usability trial as described below. The Company is in close contact with all of its suppliers, manufacturers and distributors and it has

not experienced any material issues such as business interruption, requests for change in terms, supply shortages or similar negative impacts. The ultimate long-term impact of COVID-19 is highly uncertain and cannot be predicted with confidence.

Recruitment of patients into the Tigris trial has been negatively impacted by the COVID-19 pandemic. As of the date of this MD&A, there were twelve initiated clinical sites and all sites have resumed screening and are open for enrollment.

The Company's operations could be negatively impacted if the pandemic does not recede or if new variants arise that create new waves of infection, which may result in a diversion of intensive care unit (ICU) resources, a change in patient intake patterns and needs or reduced availability of physicians and/or support staff, which in turn has had a negative impact on enrollment in Tigris and timelines for completion of Tigris. Further, the COVID-19 outbreak could result in adverse effects on the Company's business and operations due to prioritization of clinic resources toward the outbreak or if quarantines and/or restrictions (such as travel restrictions) impede physician, staff or patient movement or interrupt healthcare services.

Should the COVID-19 pandemic in the U.S. prolong limited ICU access at Tigris sites, there is a risk that last patient enrollment could be delayed. The Company has developed mitigation strategies to reduce or eliminate any timing delays, including increasing the number of Tigris sites from ten to fifteen. The Company has developed comprehensive on-line training and site support to mitigate any travel restrictions. The Company has added clinical resources following the hiring of Dr. John Kellum as of March 1, 2021, as CMO.

The timing of the start of the DIMI usability trial for home hemodialysis has been negatively impacted by the COVID-19 pandemic, as dialysis clinics are experiencing severe staffing shortages as they work to accommodate current patients while responding to an increase of patients with COVID related kidney injury requiring dialysis.

## **BUSINESS RISKS**

The Company's operations are exposed to a variety of risk factors inherent in new product development. The Company's short operating history in its new endeavours makes prediction of future operating results difficult. Actual future results may differ significantly from those projected in any forward-looking statements. Key business risks for the Company are detailed in its most recent Annual Information Form, which is available at [www.sedar.com](http://www.sedar.com).

## **RISK MANAGEMENT**

### **1. FINANCIAL RISK MANAGEMENT**

In the normal course of business, the Company is exposed to a number of financial risks that can affect its operating performance. These risks are: credit risk, liquidity risk and market risk. The Company's overall risk management program and prudent business practices seek to minimize any potential adverse effects on the Company's financial performance.

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

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

- i. Cash: The Company places its cash with Canadian Schedule I banks.
- ii. Trade and other receivables: The Company sells its products to distribution partners in major markets. The credit risk associated with the accounts receivable pursuant to these agreements is evaluated during initial negotiations and on an ongoing basis. There have been no events of default under these agreements. As at September 30, 2021 and 2020, no significant accounts receivable balances were considered impaired or past due.

## **b. Liquidity Risk**

Liquidity risk is the risk that the Company will encounter difficulty in meeting obligations associated with its financial liabilities as they become due. The Company is exposed to liquidity risk, as it continues to have net cash outflows to support its operations. The Company's objective for liquidity risk management is to maintain sufficient liquid financial resources to meet commitments and obligations in the most cost effective manner possible.

The Company achieves this by maintaining sufficient cash and managing working capital. The Company monitors its financial resources on a weekly basis and updates its expected use of cash resources on the latest available data.

The Company will need additional capital to fund its clinical and regulatory programs and commercialization of the Toraymyxin™ therapeutic. Potential sources of capital could include equity and/or debt financings, the collection of revenues resulting from commercialization activities and/or new strategic partnerships.

There can be no assurance that the Company will be able to obtain sufficient capital to meet any or all of the Company's needs. The availability of equity or debt financing will be affected by, among other things, the ability to obtain regulatory approvals, the market acceptance of its products, the state of the capital market generally, strategic alliance agreements and other relevant commercial considerations. In addition, if the Company raised additional funds by issuing equity securities, its existing security holders will likely experience dilution, and any incurrence of additional debt would result in debt service obligations and could require the Company to agree to operating and financial covenants that would restrict its operations. Any failure on the Company's part to raise additional funds on terms favourable to it, or at all, may require it to significantly change or curtail its current or planned operations in order to conserve cash until such time, if ever, that sufficient proceeds from operations are generated, and could result in the Company not taking advantage of business opportunities, the curtailment of its product development programs, the sale or assignment of rights to its technologies and/or products and the inability to file market approval applications at all or in time to competitively market its products.

All of the Company's financial liabilities, except for lease liabilities, are classified as current liabilities. Trade and other payables were \$1,335 as at September 30, 2021 (December 31, 2020 - \$2,141) with all of them having expected settlement dates within one year.

## **c. Market Risk**

- i. Currency risk: The majority of the Company's revenue is denominated in U.S. dollars and Euros. As at September 30, 2021, cash included US\$1,401 (December 31, 2020 - US\$3,405). Trade and other receivables included a total of US\$21 (December 31, 2020 - US\$52 and €1). Trade and other payables included a total of US\$315 (December 31, 2020 - US\$1,041). There

is no active hedging program currently in place due to the relatively short time frame for settlement of these balances. A 10% change in the U.S. dollar/Canadian dollar, Euro/Canadian dollar exchange rates on the September 30, 2021 amounts would impact loss by \$141.

- ii. Interest rate risk: The Company has no significant exposure to fluctuations in interest rates.

## **2. CAPITAL RISK MANAGEMENT**

The Company's primary objective when managing capital is to safeguard its ability to continue as a going concern and to provide returns for shareholders by ensuring it maintains sufficient levels of cash for working capital and operating purposes, as well as funding to pursue the commercialization efforts of its core products. Capital consists of share capital, contributed surplus, other equity reserves, and deficit. In order to maintain or adjust the capital structure, the Company may issue new Shares from time to time.

## **CRITICAL ACCOUNTING ESTIMATES**

The condensed interim consolidated financial statements of Spectral are prepared in accordance with IFRS as set out in the CPA Canada Handbook. The Company has identified the accounting policies and estimates that are critical to the understanding of the Company's operation and financial results in the consolidated financial statements. Certain policies are selected by management and approved by the Finance and Audit Committee of the Board of Directors. These policies are set out in Note 3 (xxiv.) of the consolidated financial statements for the years ended December 31, 2020 and 2019. Certain policies are more significant than others and are, therefore, considered critical accounting estimates. Accounting policies are considered to be critical if they rely on a substantial amount of judgment in their application or if they result from a choice between accounting alternatives and that choice has a material impact on the reported results or financial position.

Management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the condensed interim consolidated financial statements and the reported amounts of revenue and expenses during the reporting period. The most significant estimates are related to the accrual estimates made for clinical trial and regulatory program expenses, recognition and measurement of leases, and the assessment of performance obligations for contracts where technology transfers, licensing, manufacturing support and where one or more other goods or services are bundled into a single contract. Actual results could differ from those estimates.

## **CONTINGENCIES AND COMMITMENTS**

- i. The Company has committed to expenditures for its clinical and regulatory program, which are disclosed in Note 5 of the condensed interim consolidated financial statements for the nine-months ended September 30, 2021 and 2020. In addition, the Company is committed to certain future lease payments primarily in connection with the leased premises.

The contractual undiscounted cash flows of the Company's lease liabilities are as follows:

|   | <b>September 30, 2021</b> |
|---|---------------------------|
|   | <b>\$</b>                 |
| Not later than one year   | 138                       |
| Later than one year and not later than five years               | -                         |
| <b>Total undiscounted lease liability at September 30, 2021</b> | <b>138</b>                |

- ii. Directors and officers are indemnified by the Company for various items including, but not limited to, costs to settle lawsuits or actions due to their association with the Company, subject to certain restrictions. The Company has purchased directors' and officers' liability insurance to mitigate the costs of any potential future lawsuits or actions. The term of the indemnification covers the period during which the indemnified party served as a director or officer of the Company.

In the normal course of business, the Company has entered into agreements that include indemnities in favour of third parties, such as purchase and sale agreements, confidentiality agreements, engagement letters with advisors and consultants, leasing contracts and license agreements. These indemnification arrangements may sometimes require such third parties to compensate counterparties for losses as a result of breaches in representations, covenants and warranties provided by the Company or as a result of litigation or other third party claims or statutory sanctions that may be suffered by the counterparties as a consequence of the relevant transaction. In some instances, the terms of these indemnities are not explicitly defined. No accruals have been required to be made as at September 30, 2021 with respect to these agreements.

## **FINANCIAL INSTRUMENTS AND FAIR VALUES**

Financial assets and financial liabilities have been classified into categories that determine their basis of measurement and, for items measured at fair value, whether changes in fair value are recognized within operating loss in the consolidated statement of loss and comprehensive loss.

The Company has designated the following classifications for its financial assets and financial liabilities:

Cash, trade and other receivables are classified as financial assets at amortized cost with a total carrying value of \$11,490 at September 30, 2021 (December 31, 2020 - \$6,067).

Trade and other payables are classified as other financial liabilities, which are measured at amortized cost using the effective interest rate method, with a total carrying value of \$1,335 at September 30, 2021 (December 31, 2021 - \$2,141).

Cash, trade and other receivables, lease liabilities and trade and other payables are reflected in the condensed interim consolidated financial statements at carrying values that approximate fair values because of the short-term maturities of these financial instruments.

## **DISCLOSURE CONTROLS AND INTERNAL CONTROLS**

### **Management's responsibility for financial reporting**

#### *Disclosure controls and procedures and internal controls over financial reporting*

As at September 30, 2021, management has disclosure controls and procedures ("DC&P") that provide reasonable assurance that information required to be disclosed by the Company in its filings under Canadian securities legislation is recorded, processed, summarized and reported in a timely manner. The system of DC&P includes, among other things, the Company's Corporate Disclosure and Whistleblower policies and Code of Conduct, the review and approval procedures of the Disclosure Committee and continuous review and monitoring procedures by senior management.

As at September 30, 2021, management has designed internal controls over financial reporting ("ICFR") within the Company in order to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with IFRS. These controls were designed based on the framework established by Internal Control - Integrated Framework: 2013 issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Due to its inherent limitations, ICFR may not prevent or detect misstatements. In addition, the design of any system of control is based upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all future events, no matter how remote, or that the degree of compliance with the policies or procedures may not deteriorate. Accordingly, even effective ICFR can only provide reasonable, not absolute, assurance of achieving the control objectives for financial reporting.

#### *Changes in internal controls over financial reporting*

There have been no changes to the Company's internal controls over financial reporting during the nine-months ended September 30, 2021 that have materially affected, or are reasonably likely to materially affect, its internal controls over financial reporting.