

# **Management's Discussion and Analysis of Financial Condition and Operations**

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The following Management's Discussion and Analysis ("MD&A"), of **Theralase® Technologies Inc.** ("**Theralase®**" or the "**Company**") should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2020.

This MD&A has been filed in accordance with the provisions of National Instrument 51-102 (*Continuous Disclosure Obligations*). Additional information relating to the Company can be found on Sedar at [www.sedar.com](http://www.sedar.com). This MD&A is prepared as of April 28, 2021.

The Company's common shares are listed for trading on the TSX Venture Exchange (**Symbol: TLT**) and trade on the OTCQB marketplace (**Symbol: TLTF**).

## **Forward Looking Statements**

*The information provided herein is intended to provide a general outline of the operations of the Company. This document contains certain forward-looking statements and information (collectively, "Forward-Looking Statements" or "FLS") within the meaning of applicable securities laws. FLS are statements and information that are not historical facts, but instead include financial projections and estimates; statements regarding plans, goals, objectives, intentions and expectations with respect to Theralase®'s future business, operations, research and development; including: anticipated timelines for the commencement or completion of certain activities, enrolment of patients in clinical studies or other information in future periods. FLS, which may be identified by words including, without limitation, "believe", "anticipate", "should", "could", "would", "estimate", "expect", "plan", "will", "intend", "may", "pending", "objective", "exploring", "potential", "project", "possible" and other similar expressions, and the negative of such expressions, are intended to provide information about management's current plans and expectations regarding future operations.*

*FLS in this MD&A include, but are not limited to: statements with respect to: the outlook of the revenues, business and timing of initiatives; competitive environment; business strategy and objectives; research, development and/or commercialization plans, acquisition and disposition plans; preclinical and/or clinical studies: status, timing and/or strategies; the supply and demand of products or services; future revenue projections; ability to meet current and future obligations; ability to execute on business and/or growth strategies; management's assessment of future plans and/or operations; the intention and/or ability to pay dividends on the common shares of the Company.*

*Readers are cautioned not to place undue reliance on FLS as there can be no assurance that the plans, intentions or expectations, upon which they are based will occur. By their nature, FLS involve numerous assumptions, known and unknown risks and uncertainties, both general and specific, that contribute to the possibility that the predictions, forecasts, projections and other things contemplated by the FLS will not occur. Such FLS or information are based on a number of assumptions, which may prove to be incorrect, including those assumptions listed below and those discussed elsewhere in this MD&A. Some of the assumptions made by Theralase®, upon which such FLS are based, include; but are not limited to, assumptions about: the ability to continue as a going concern, the business operations continuing on a basis consistent with prior years; the ability to access financing from time to time on favourable terms or at all; the continuation of executive management, operating management, key personnel or key consultants or the non-disruptive replacement of them on reasonable terms; the ability of Theralase® to maintain reasonably stable operating and general administrative expenses; future success of current research, development, and/or commercialization activities; the ability to achieve development and/or commercial milestones; market competition; the ability to secure all necessary regulatory and/or certification approvals; geographic protection over the intellectual property in the markets in which Theralase® does business; market acceptance and/or revenue generation of products under development; the stability of current economic and business conditions, the strength of the economy in Canada, the United States and elsewhere; currency, exchange and/or interest rates and commodity prices being reasonably stable at current rates.*

*FLS reflect current expectations of management regarding future events and operating performance as of the date of this MD&A. Such information: involves significant risks and uncertainties; should not be read as guarantees of future performance and/or results; and will not necessarily be accurate indications of whether or not such results will be achieved. A number of factors could cause actual results to differ materially from the results discussed in the FLS, including, but not limited to, the risks related to: limited operating history; working capital and capital resources; ability to retain key personnel; protection of intellectual property; competition; implementation delays; strategic alliances; trade secret protection; product deficiencies; dependence on third party suppliers; volatility of share price; regulatory risks; early stage of product development; reliance on third parties; clinical study risk; clinical study timing delays; patient enrolment; failure to achieve milestones; currency risk; material weakness in internal controls over financial reporting; credit risk; product liability, clinical study liability and patent-related rights of the United States government in Photo Dynamic Therapy ("PDT") technology. See "Risk and Uncertainties".*

**ALTHOUGH THE FLS CONTAINED IN THIS MD&A ARE BASED UPON WHAT THERALASE®'S MANAGEMENT BELIEVES TO BE REASONABLE ASSUMPTIONS, THERALASE® CANNOT ASSURE READERS THAT ACTUAL RESULTS WILL BE CONSISTENT WITH SUCH INFORMATION. FLS REFLECT MANAGEMENT'S CURRENT BELIEFS AND ARE BASED ON INFORMATION CURRENTLY AVAILABLE TO THERALASE®. READERS OF THIS MD&A ARE CAUTIONED NOT TO PLACE UNDUE RELIANCE ON THERALASE®'S FLS BECAUSE A NUMBER OF FACTORS, SUCH AS THOSE REFERRED TO IN THE PARAGRAPHS ABOVE, COULD CAUSE ACTUAL FUTURE RESULTS, CONDITIONS, ACTIONS OR EVENTS TO DIFFER MATERIALLY FROM THE TARGETS, EXPECTATIONS, ESTIMATES AND/OR INTENTIONS EXPRESSED IN THE FLS CONTAINED IN THIS MD&A. THE FLS ARE MADE AS OF THE DATE OF THIS MD&A AND THERALASE® ASSUMES NO OBLIGATION TO UPDATE OR REVISE SUCH INFORMATION TO REFLECT NEW EVENTS OR CIRCUMSTANCES, EXCEPT AS MAY BE REQUIRED BY APPLICABLE LAW.**

## **Company Profile**

Theralase® is a clinical stage pharmaceutical company dedicated to the research and development of light activated Photo Dynamic Compounds (“PDCs”), their associated drug formulations and technology platforms intended to safely and effectively; treat various cancers, bacteria and viruses. The Company in its Cool Laser Technology (“CLT”) division designs, develops, manufactures and markets proprietary super-pulsed laser technology indicated and cleared by Health Canada and the Food and Drug Administration (“FDA”) for the healing of chronic knee pain and when used off-label for healing numerous nerve, muscle and joint conditions. The Company in its Anti-Cancer Therapy (“ACT”) division conducts preclinical and clinical research and development for PDCs, primarily in the treatment of cancer, with assistance from the CLT division to develop medical lasers to activate them.

## **COVID-19 Pandemic**

On March 11, 2020, the World Health Organization (“WHO”) declared the outbreak of a novel coronavirus (“COVID-19”) as a global pandemic, which continues to spread throughout Canada and around the world. As of the MD&A date, the Company is aware of significant changes in its business as a result of COVID-19, notably: reduction / unavailability of personnel, personnel working remotely or virtually, significant delays in clinical research studies and significant delays / cancellations in customer purchasing decisions. Management is uncertain of the full extent of these impacts on its financial statements and believes that the business disruption caused by COVID-19 could be temporary; however, there is uncertainty around its duration and hence the potential impact on the business cannot be fully estimated as of the date of this MD&A.

Theralase® continues to experience variations in sales and the timing of these sales due to the ongoing COVID-19 pandemic and has taken actions to reduce expenses by eliminating non-essential personnel and imposing a temporary hiring freeze, to be lifted, subject to the Canadian and United States economies demonstrating recovery from COVID-19.

Theralase® continues to experience delays in patient enrollment and treatment rates in the Phase II NMIBC clinical study due to the ongoing COVID-19 pandemic; however, these rates are expected to improve once Canada and the US recover from the COVID-19 pandemic.

## **Advancing the Theralase® Technology Platform**

The Company’s primary focus is the Anti-Cancer Therapy (“ACT”) division, with primary objectives of: preclinical research, clinical studies, research and development of PDCs and the laser light systems that activate them, intended primarily for the destruction of various cancers, bacteria and viruses.

Theralase®’s patented study drug, TLD-1433, is currently under investigation in a Phase II clinical study intended for the treatment of Non-Muscle Invasive Bladder Cancer (“NMIBC”).

Theralase®’s lead study drug, TLD-1433, has been demonstrated preclinically to bind with transferrin, a human glycoprotein, forming Rutherrin®. Various cancer cells in peer-reviewed publications have demonstrated significantly more transferrin receptors versus healthy cells, allowing the deposition of the TLD-1433 payload inside the cancer cell, versus a healthy cell, through endocytosis. When laser light activated, TLD-1433 has been demonstrated to destroy cancer cells through the production of singlet oxygen and/or Reactive Oxygen Species (“ROS”) from the inside out inducing oxidative stress, leading to a natural cell death, known as apoptosis.

The ACT division is currently in the pre-clinical research, development and clinical study evaluation phase and as a result there are no commercial benefits associated with this division at the present time, resulting in zero revenue, sales or commercial distribution of this technology.

Theralase® conducts its own research and development into ACT technology, as well as enlisting the support of external scientific, research, regulatory and clinical organizations.

### **Phase Ib NMIBC Clinical Study**

Theralase® successfully completed a Phase Ib clinical study ("**Study**") for Bacillus Calmette-Guerin ("**BCG**") - Unresponsive patients diagnosed with NMIBC; whereby, patients were treated with a Study Drug (TLD-1433) and a Study Device (TLC-3200 Medical Laser System or TLC-3200) (collectively the "**Study Treatment**").

Under the Study, entitled "*A Phase Ib Trial of Intravesical Photo Dynamic Therapy in Patients with NMIBC at High Risk of Progression, Who are Refractory to Therapy with Bacillus Calmette-Guerin and Who are Medically Unfit for or Refuse a Cystectomy*", treatment of patients commenced in March 2017. Three patients were treated at the Maximum Recommended Starting Dose ("**MRSD**") (0.35 mg/cm<sup>2</sup>) and three patients were treated at the Therapeutic Dose (0.70 mg/cm<sup>2</sup>) of TLD-1433; whereby, at both doses the PDC was activated by laser light (520 nm, 90 J/cm<sup>2</sup>) delivered by the TLC-3200.

Theralase®'s Study successfully achieved the primary objective of safety and tolerability, secondary objective of pharmacokinetics and exploratory objective of efficacy. The Study results demonstrate a strong efficacy signal with a 67% complete response ("**CR**") rate in the Therapeutic Dose group (0.70 mg/cm<sup>2</sup>) after only a single Photo Dynamic Therapy ("**PDT**") treatment, with patients five and six demonstrating CR with no presence, recurrence or progression of the disease at 18 months post treatment.

Based on the encouraging data from patients treated at the Therapeutic Dose, the Medical and Scientific Board ("**MSAB**") recommended that the Company undertake a pivotal Phase II NMIBC clinical study with a primary objective of efficacy with a larger patient sample size.

### **Phase II NMIBC Clinical Study**

Based on the recommendation of the MSAB, Theralase® designed the Phase II NMIBC clinical study ("**Study II**") to utilize the Therapeutic Dose (0.70 mg/cm<sup>2</sup>) of TLD-1433 and focus on the treatment of approximately 100 to 125 BCG-Unresponsive NMIBC patients presenting with Carcinoma In-Situ ("**CIS**") in approximately 15 clinical study sites located in Canada and the US.

Study TLD-1433-2 (NCT03945162) is an ongoing, phase II, open-label, single-arm, multi-center study conducted in Canada and the United States evaluating the safety and efficacy of the Study Treatment.

The patient population is approximately 100 to 125 patients with persistent or recurrent NMIBC CIS alone or with recurrent Ta/T1 (non-invasive/resected papillary disease/tumour that invades the subepithelial connective tissue) disease within 12 months of completion of BCG therapy (BCG-Unresponsive) or who are intolerant to BCG therapy.

The primary objective of this study is efficacy, evaluated by complete response ("**CR**") rate at any point in time.

The secondary objective for this study is duration of CR at 12 months post initial CR.

The tertiary objective is safety, evaluated by adverse events (“**AEs**”) > 3 that do not resolve within 450 days of the primary Study Treatment.

The Study Treatment consists of a Study Drug Therapeutic Dose (0.70 mg/cm<sup>2</sup>) (equivalent to 0.65 mg/cm<sup>2</sup> of active drug moiety) activated by the Study Device (TLC-3200) for an energy density of 90 J/cm<sup>2</sup>.

Patients will be enrolled into the study based upon review of inclusion and exclusion criteria during the screening period, which will last up to 45 days, prior to primary Study Treatment. The patient will be administered a primary Study Treatment on day 0 and a maintenance Study Treatment on day 180. All patients enrolled and treated by the Study Treatment will be followed until the end of the study, defined as completion of all required assessments after 15 months of follow-up post primary Study Treatment or earlier due to discontinuation or withdrawal of informed consent.

During the follow-up assessments, information on efficacy (e.g.: urine cytology, cystoscopy and where indicated CT scans and bladder / prostate biopsies) and safety (e.g.: adverse events) will be collected. Assessments will be conducted on day 0, 7, 90, 180, 187, 270, 360 and 450.

In 2018, Health Canada granted the Company both a Clinical Trial Application (“**CTA**”) for the Study Drug and an Investigational Testing Authorization (“**ITA**”) for the Study Device to allow clinical use of TLD-1433, in conjunction with the TLC-3200, to commence enrolling and treating patients in Study II.

To date, Theralase® has the following Canadian Clinical Study Sites (“**CSSs**”) open for patient enrollment and treatment:

Clinical Study Sites (Canada)	Location	Commenced
University Health Network (“ <b>UHN</b> ”)	Toronto, Ontario	April 25, 2019
McGill University Health Centre (“ <b>MUHC</b> ”)	Montreal, Quebec	July 30, 2019
London Health Sciences Centre (“ <b>LHSC</b> ”)	London, Ontario	October 7, 2019
Nova Scotia Health Authority (“ <b>NSHA</b> ”)	Halifax, Nova Scotia	February 25, 2020
University of British Columbia (“ <b>UBC</b> ”)	Vancouver, British Columbia	December 7, 2020

In 2020, the Company received FDA Investigational New Drug (“**IND**”) authorization (Study Drug and Study Device) to commence enrolling and treating patients in Study II in the United States. Theralase® has received study level approval through a central Institutional Review Board (“**IRB**”) to launch Study II in 6 US CSSs, subject to site level IRB approval.

To date the following US CSSs have received site level IRB approval to commence patient enrollment and treatment:

Clinical Study Sites (United States)	Location	Commenced
Virginia Urology (“ <b>VU</b> ”)	Richmond, Virginia	January 19, 2021
Urology Associates P.C. (“ <b>UA</b> ”)	Nashville, Tennessee	January 20, 2021
MidLantic Urology (“ <b>MU</b> ”)	Bala Cynwyd, Pennsylvania	January 25, 2021
Carolina Urologic Research Center (“ <b>CURC</b> ”)	Myrtle Beach, South Carolina	January 27, 2021
University of Wisconsin Health-Madison (“ <b>UWH</b> ”)	Madison, Wisconsin	February 24, 2021
Urology San Antonio (“ <b>USA</b> ”)	San Antonio, Texas	March 25, 2021

In 2020, the FDA granted Theralase® Fast Track Designation (“**FTD**”) for Study II. As a FastTrack designee, Theralase® will have access to early and frequent communications with the FDA to discuss Theralase®’s

development plans and ensure timely collection of the appropriate clinical data to support the approval process. The accelerated communication with the FDA potentially allows, the Study Treatment, to be the first intravesical, patient-specific, light-activated, Ruthenium-based PDC for the treatment of patients with BCG-Unresponsive NMIBC CIS, with or without papillary Ta or T1 tumors. FTD can lead to an Accelerated Approval (“AA”), Break Through Designation (“BTD”) and Priority Review, if certain criteria are met, which the FDA has previously defined to the Company for BTD to represent approximately 20 to 25 patients enrolled and treated, who demonstrate significant safety and efficacy clinical outcomes.

Study II commenced in April 2019 with an estimated completion time of approximately 3 to 4 years and an estimated cost of approximately \$9 to \$11 million. The timing and cost may vary significantly depending on numerous factors including; number of CSSs enrolling and treating patients, patient enrollment rates in total and at each CSS, patient compliance, successful achievement of Study II primary, secondary and tertiary objectives and the ability of participating CSSs to enroll and treat patients considering challenges caused by current COVID-19 pandemic restrictions.

### **Study II Clinical Study Site Update**

Patient enrollment and treatment rates have been significantly delayed due to the COVID-19 pandemic restrictions in place at various CSSs; however, they are expected to improve once Canada and the US recover from the COVID-19 pandemic. Canadian CSSs placed themselves on temporary hold commencing March 20, 2020 and resumed normal operations between August 12, 2020 and September 24, 2020. Although Canadian CSSs recruiting activities were re-commenced in 4Q2020; patient recruitment and treatment activities have been severely limited due to the second and third wave of COVID-19. With the addition of 6 additional US-based CSSs in 1Q2021, Theralase® is hopeful that patient recruitment and treatment activities will increase throughout 2021 to help achieve the Company’s strategic objectives.

Theralase® is currently focused on working with its Canadian and US-based CSSs to enroll and provide the primary Study Treatment for up to 7 additional patients in 2Q2021 for a total of 20 to 25 patients enrolled and treated in Study II. Theralase® plans to compile up to the 90, 180, 270, 360 and 450 day assessment data (urine cytology and cystoscopy) for these patients with the intent of submitting this interim data to the FDA for consideration of Breakthrough Designation (“BTD”) approval

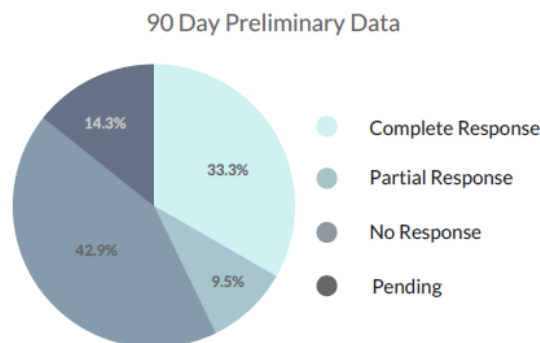
### **Study II Preliminary Clinical Data**

To date, the phase II NMIBC clinical study has enrolled and provided the primary study treatment for 18 patients (including three patients from Phase Ib study treated at the Therapeutic Dose) for a total of 21 patients.

The most recent analysis of the clinical data supports that Study II has met the primary, secondary and tertiary objectives at 180 days post initial Study Treatment, demonstrating a strong initial efficacy, duration of efficacy and high safety profile.

An analysis of the primary (Complete Response (“CR”) at any point in time) and secondary (Duration of CR) objectives, at 90 and 180 days, the CR rate (negative urine cytology and negative cystoscopy) is 33.3% and 28.60%, respectively, while the Partial Response (“PR”) rate (positive urine cytology and negative cystoscopy) is 9.5% and 9.5%, respectively, leading to a 42.8% and 38.10%, Total Response rate (CR and PR), respectively.

Assessment Day	90	%	180	%
Total (Complete Response)*	7	33.3%	6	28.6%
Total (Partial Response)	2	9.5%	2	9.5%
<b>Total Response (CR and PR)</b>	<b>9</b>	<b>42.8%</b>	<b>8</b>	<b>38.1%</b>
Total (No Response)*	9	42.9%	8	38.1%
Total (Pending)	3	14.3%	5	23.8%
<b>Total Treated*</b>	<b>21</b>	<b>100.0%</b>	<b>21</b>	<b>100.0%</b>



\* Includes three (3) patients treated at the Therapeutic Dose from the Phase Ib NMIBC Clinical Study (2 - CR and 1 - NR at 90 and 180 Days)

Comparing the 90 and 180 day assessment data, demonstrates that once a patient has obtained CR or PR, the duration of the response remains fairly durable.

In accordance with FDA guidelines to industry, the patients who have achieved a PR are being further assessed via CT scan and biopsy of the prostatic urethra to determine if upper tract Urothelial Cell Carcinoma (“UCC”) or prostatic urethra UCC can be detected to allow these patients to be re-categorized as CR.

In support of the tertiary objective, all patients have experienced some transient grade 1 or grade 2 AEs (e.g.: bladder spasms, constipation, urge incontinence, fatigue, urinary frequency, hematuria, penile discomfort, urinary urgency, pain, urinary tract infections and other) where > 80% have completely resolved with 180 days.

One patient was diagnosed with urosepsis (infection in the urinary tract) that completely resolved within 1 week, after antibiotic treatment and was considered unrelated to the Study Drug, possibly related to the Study Procedure and possibly related to the Study Device, by the PI.

An analysis of the tertiary objective (Adverse Events (“AE”) > 4, that do not resolve within 450 days) showed that 1 patient, who had a negative cytology (no presence of cancer cells in urine) after a single Study Treatment, experienced a grade 3 (Acute Kidney Injury) that was discovered at the 30 day check-up that was considered unlikely related to the Study Drug, probably related to the Study Procedure and possibly related to the Study Device, by the Principal Investigator (“PI”). This same patient, 5 days later, experienced a grade 5 adverse event (Death due to cardiac arrest) that was considered unlikely related to the Study Drug, unlikely related to the Study Procedure and unlikely related to the Study Device, by the PI. The patient had a complex medical history, including diabetes, cardiovascular disease, as well as suffering from benign prostatic hyperplasia. Based on the patient’s history and the timing of the AE, the Company has concluded that both these events were unrelated to the Study Drug and/or Study Device.

### **Study II Optimization**

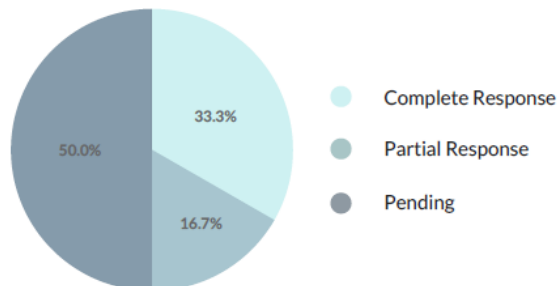
Commencing August 1, 2020, all new and existing patients to be enrolled and treated (Primary and Maintenance Study Treatment) in Study II were treated using the Study II treatment optimizations as communicated via press release on July 30, 2020, specifically:

- a) Bladder volume calculation
- b) Study drug volume calculation
- c) Study device volume calculation
- d) Study device treatment time

To date, 6 patients have received the optimized Primary Study Treatment and patients have received the optimized Maintenance Study Treatment in Study II.

A preliminary analysis of the primary objective at 90 days for patients receiving the optimized primary Study Treatment demonstrates a 33.3% CR rate, with 50.0% data pending and only 16.7% with no response.

Assessment Day	90	%
Total (Complete Response)	2	33.3%
Total (No Response)	1	16.7%
Total (Pending)	3	50.0%
<b>Total Treated</b>	<b>6</b>	<b>100.0%</b>



Although very early in the data collection and assessment phase, with significant clinical data still to be collected, an interim analysis of the clinical data, for Study Treatments (Primary and Maintenance), completed post August 1, 2020, supports that Study II continues to achieve its primary, secondary and tertiary objectives at 90 days post initial Study Treatment, demonstrating a strong initial efficacy, duration of efficacy and high safety profile.

#### **Additional Oncology Targets:**

Theralase® has championed the research and development of its Intellectual Property (“IP”) platform for PDCs, through scientific and preclinical research to fine-tune the photophysical and photochemical properties of the PDCs, by the inventor, while demonstrating Type I (oxygen independent) and II (oxygen dependent) photoreactions and activation in hypoxia.

By combining these PDCs with transferrin (human glycoprotein), as a delivery system it has been pre-clinically demonstrated that transferrin is able to significantly:

- Increase the resistance of TLD-1433, the lead drug candidate, to photobleaching (loss of potency of the PDC over time)
- Increase ROS production (ability to destroy cancer cells quickly and effectively)
- Increase selective tumour uptake (destruction of cancer cells, while sparing healthy cells) through the Transferrin Receptor (“TfR”)
- Increase anti-cancer efficacy (efficiency in cancer cell destruction)
- Decrease systemic toxicity (damage to healthy cells and/or organs)

This makes Rutherrin® (TLD-1433 + transferrin) attractive for systemic treatment of recurrent, deep seated and/or progressive cancers. The Company continues to conduct extensive scientific and preclinical research towards new oncology indications and has developed significant expertise and IP assets regarding its patented PDCs, in pursuit of this goal.

Once Rutherrin®'s Maximum Tolerated Dose (“**MTD**”) and hence Human Equivalent Dose (“**HED**”) limits have been determined through non-Good Laboratory Practices (“**GLP**”) and GLP toxicology studies, Theralase® plans to inject Rutherrin® systemically into patients via a Phase Ib clinical study, planned for 2022, to allow localization to various cancer cells, including Glioblastoma Multiforme (“**GBM**”) and Non-Small Cell Lung Cancer (“**NSCLC**”) and then activate Rutherrin® with radiation to safely and effectively, destroy the cancer of interest.

Rutherrin®, if proven successful, would thus be able to “hunt” cancer cells and when activated by radiation “destroy” them; wherever, they may reside in the body.

The Company has demonstrated a significant anti-cancer efficacy of Rutherrin®, when activated by laser light or radiation treatment across, numerous preclinical in-vitro (cell lines) and in-vivo (animal) models focused on GBM and NSCLC.

Due to the limitations of using laser light to activate Rutherrin® in deep oncological targets, Theralase®'s research strongly suggests that Rutherrin® may be activated with radiation therapy, which is able to increase the ‘tumour’s damage zone’ and the effectiveness of Theralase®'s Anti-Cancer Therapy (“**ACT**”) beyond the reach of light in the body.

### **Additional Virus Targets**

Theralase® executed a Sponsored Research Agreement (“**SRA**”) with the University of Manitoba (“**UM**”) Medical Microbiology department in 3Q2020 to commence development of a coronavirus vaccine utilizing Theralase®'s patented and proprietary PDCs. The primary objective of the SRA was to investigate the efficacy of Theralase®'s lead PDC to destroy a variety of viruses; including: H1N1 Influenza, Zika and coronaviruses (Biological Safety Level (“**BSL**”) 2). The secondary objective was to optimize the concentration of PDC required, the activation methodology and how to potentially administer the treatment to humans to be used as a vaccine (prevention of a patient from contracting COVID-19) (BSL-3).

The Company’s PDC technology was effective in the destruction of Influenza and Zika viruses at low nanomolar concentrations and were expanded to include coronavirus (BSL-2).

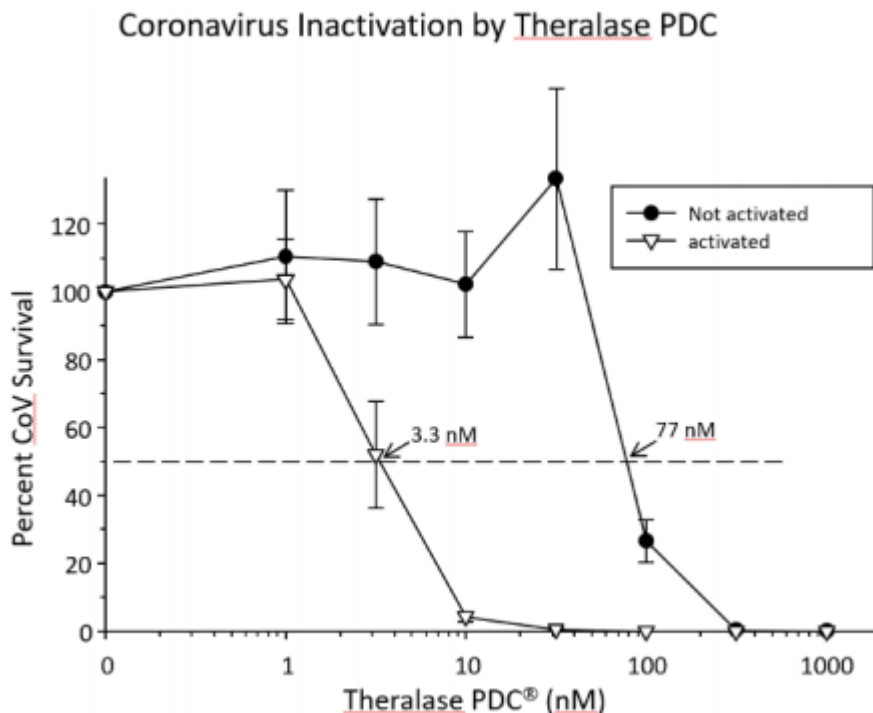
As a cautionary note, COVID-19 is caused by coronavirus (BSL-3), not coronavirus (BSL-2).

A rapid test was established to measure coronavirus destruction and using this new assay the Theralase® PDC technology was able to destroy coronavirus (BSL-2) with drug doses 5 times lower than what was used to kill Influenza H1N1 virus and Zika virus. These drug doses are significantly lower than those used by the Company to treat cancers and are considered safe for human use.

All coronaviruses are highly similar in their structure and these new results strongly suggest that Theralase®'s proposed vaccine could be highly effective against the SARS-CoV-2 virus responsible for COVID-19. Further studies have shown that the human coronavirus (CoV) appears to be much more sensitive to the action of the activated Theralase® PDC vaccine, with as low a dose of 3.3 nM required to inactivate 50%; whereas; 9.2nM was required to inactivate the same amount of Influenza H1N1 and 12 nM was required inactivate the same amount of Zika Virus. Similarly, the amount of PDC required to inactivate 99.9% of each virus are 61 nM for CoV, 322 nM for Zika Virus and 497 nM for Influenza H1N1; thus, the Theralase® PDC is 3 to 5 times more effective against CoV compared to the other tested viruses.



The Theralase® compound is also effective without activation, but on average, its activation results in a 4.2 fold enhancement of Zika Virus inactivation, a 12 fold enhancement of Influenza H1N1 inactivation and an 18.7 fold enhancement of CoV inactivation.



Human coronavirus OC-43 stocks were treated with 32 µg/mL (PDC)- activator and with indicated concentrations of Theralase® PDC incubated 30 minutes, either activated or not as indicated, and residual virus infectivity determined by immunofocus assay. Horizontal dashed line indicates 50% effective inhibitory dose n=3; error bars are Standard Error of Means

In April 2021, Theralase® executed a Collaborative Research Agreement (“**CRA**”) with the National Microbiology Laboratory, Public Health Agency of Canada (“**PHAC**”) for the research and development of a Canadian-based SARS-CoV-2 (“**COVID-19**”) vaccine. Under the terms of the agreement, Theralase® and PHAC are collaborating on the development and optimization of a COVID-19 vaccine by treating the SARS-CoV-2 virus grown on cell lines with Theralase®’s patented PDC and then light activating it with Theralase®’s proprietary TLC-3000A light technology to inactivate the virus and create the fundamental building blocks of a COVID-19 vaccine. This inactivated virus would then be purified and used to inoculate naive animals followed by challenge with the SARS-CoV-2 virus, to ascertain the efficacy of the vaccine. The project is entitled, “**Photo Dynamic Compound Inactivation of SARS-CoV-2 Vaccine**” and commenced in mid-April 2021.

The Company does not claim or profess that they have the ability to treat, cure or prevent the contraction of the COVID-19 coronavirus.

### **ACT Research Centre**

In April 2021, the Company launched the Theralase® Anti-Cancer Therapy (“**ACT**”) research center located within the Li Ka Shing Knowledge Institute of St. Michael’s Hospital, Unity Health Toronto, relocating its research team from University Health Network (“**UHN**”).

The ACT research center is a fully equipped laboratory dedicated exclusively to Theralase® ACT research and development, as Theralase® advances towards commercialization with its lead PDC, TLD-1433, as well as its systemic and targeted formulation – Rutherrin®. A partnership with the Li Ka Shing Knowledge Institute of

Unity Health provides access to additional expertise, advisory networks and opportunities to accelerate product development and commercialization.

### **Intellectual Property Portfolio Growth**

Theralase® received the following decisions to grant a patent in 2020 and 1Q2021:

<b>Country</b>	<b>Patent Title</b>
China	Apparatus and Method for Multiwavelength Photo Dynamic Therapy
India	Metal-Glycoprotein Complexes and Their use as Chemotherapeutic Compounds
Russia	Metal-Glycoprotein Complexes and Their use as Chemotherapeutic Compounds
United States	Apparatus and Method for Multiwavelength Photo Dynamic Therapy
Canada	Metal-Based Coordination Complexes as Photodynamic Compounds and their Use.

#### **Apparatus and Method for Multiwavelength Photo Dynamic Therapy**

This patent allows the treatment of new oncological applications, including targeting cancers that are able to be reached through an orifice in the body, but are too deep in tissue to have the instilled PDC adequately activated by low wavelength visible laser light, for example, esophageal cancer. The multiwavelength PDT system advances the clinical utility of Photo Dynamic Therapy (“PDT”) by expanding the volume of tissue able to be treated. By using various laser light sources to activate the PDCs at differing depths in the target tissue simultaneously or sequentially, Theralase® may be able to significantly increase the overall destruction of the cancerous tissue.

#### **Metal-Glycoprotein Complexes and Their use as Chemotherapeutic Compounds**

This patent is critical to providing IP protection of Theralase®’s systemic and targeted ACT, which allow PDCs and their associated drug formulations to be systemically injected to “hunt” cancer cells of interest for various cancer conditions and effectively “destroy” them when activated by laser light or radiation, safely and effectively.

#### **Metal-Based Coordination Complexes as Photodynamic Compounds and their Use.**

This invention relates to metal-based coordination complexes that are useful as therapeutic and diagnostic agents. The invention further relates to photodynamic compounds that can be activated with ultraviolet to infrared (UV-IR) light, particularly near infrared light, that are useful as therapeutic and diagnostic agents. In particular, the invention provides tunable metal-based photodynamic compounds that are coordination complexes derived from organic ligands. The photodynamic compounds can be activated by light to destroy unwanted cells, for example hyperproliferative cells and microbial cells. The photodynamic compounds can also be activated by light to destroy viruses.

Theralase® received the following trademarks in 2020 and 1Q2021:

<b>Country</b>	<b>Trademark</b>
China	Rutherrin®

## **Research Publications**

Theralase® published the following research publications in 2020 and 1Q2021:

### **Optimizing Interstitial Photodynamic Therapy Planning with Reinforcement Learning-Based Diffuser Placement (Peer reviewed and published on ResearchGate.net)**

*ResearchGate is a professional network for scientists and researchers used to share, discover, and discuss research.*

Interstitial Photo Dynamic Therapy (“iPDT”) has shown promising results recently as a minimally invasive stand-alone or intraoperative cancer treatment. The development of non-toxic photosensitizing drugs with improved target selectivity has increased its efficacy; however, personalized treatment planning that determines the number of photon emitters, their positions and their input powers while taking into account tissue anatomy and treatment response are lacking to further improve outcomes. New algorithms that generate high-quality plans by optimizing over the light source positions, along with their powers, to minimize the damage to organs-at-risk while eradicating the tumor were developed by using simulated-annealing as a baseline algorithm to place the sources. Algorithms were simulated on virtual brain tumors modeling real glioblastoma multiforme cases, assuming a 5-ALA PPIX induced photosensitizer that is activated at 635 nm wavelength. The algorithm generated plans that achieved an average of 46% less damage to organs-as-risk compared to the manual placement used in current clinical studies. Having a general and high-quality planning system makes iPDT more effective and applicable to a wider variety of oncological indications paving the way for more clinical trials.

This work was supported by Ontario Research Fund, Theralase®, Intel Inc. and International Business Machines (“IBM”).

### **Minimal Required PDT Light Dosimetry for Non-Muscle Invasive Bladder Cancer (Peer reviewed and published in the Journal of Biomedical Optics (“JBO”))**

*JBO is an acclaimed peer reviewed scientific journal covering the landscape of optical technology and biomedical research.*

Dosimetry data from Theralase®’s Phase Ib clinical study reinforces the advanced capabilities of Theralase®’s cutting-edge Anti-Cancer Therapy (“ACT”) to safely and effectively destroy NMIBC without damaging healthy bladder tissue. Human bladders are unique and have different shapes, volumes and bladder wall reflectances. As a result, the irradiance (laser light energy delivered per square centimeter) will vary significantly depending on the physical properties of an individual patient’s bladder. Despite the irregularity of bladders, Theralase®’s ACT can detect these bladder permutations to help prevent safety events from occurring, if the laser light energy is directed too close to a bladder wall.

### **Anticancer Photodynamic Therapy Using Ruthenium (II) and Osmium (II)-Based Complexes as Photosensitizers (Open access peer reviewed chapter published on IntechOpen)**

*IntechOpen Limited is an academic publisher that provides content for free electronically.*

In vitro and in vivo results demonstrate that transition metal-based complexes, such as: Ruthenium (II) and Osmium (II) PDCs have enviable physical characteristics including:

- Being able to be activated at a wide range of wavelengths (allowing for activation at various tissue depths)

- Having a high singlet oxygen quantum yield (ability to efficiently convert photons of light into cancer killing Reactive Oxygen Species (“ROS”))

## **Overview of Financial Performance**

During the twelve-month period ended December 31, 2020, the Company's financial performance and its operating results reflected the continued investment by the Company into its future prosperity through research, development and clinical initiatives culminating in the successful completion of the Phase Ib NMIBC clinical study and the launch of a Phase II NMIBC Study.

## **Summary of Selected Audited Annual Information**

(expressed in Canadian Dollars)

For the twelve-month periods ended December 31:

	<b>2020</b>	<b>2019</b>
Total revenues	\$ 929,122	\$ 964,051
Net loss	(5,598,540)	(7,413,914)
Basic and diluted loss per share	\$ (0.027)	\$ (0.051)
Total assets	\$ 10,020,782	\$ 15,470,090
Total liabilities	857,133	1,614,647
Deficit	(48,506,467)	(42,652,154)
Shareholders' Equity	\$ 9,163,649	\$ 13,855,443

## **Summary of Quarterly Results**

(expressed in Canadian Dollars)

	<b>2020</b>			
	<b>March 31</b>	<b>June 30</b>	<b>September 30</b>	<b>December 31</b>
<b>For the period ending:</b>				
Total revenues	\$ 111,543	\$ 181,910	\$ 234,021	\$ 401,648
Net loss	(1,643,856)	(1,623,770)	(1,448,147)	(882,767)
Basic and diluted loss per share	\$ (0.008)	\$ (0.008)	\$ (0.007)	\$ (0.004)
<b>As at:</b>				
Total assets	\$ 13,755,006	\$ 11,965,651	\$ 10,803,457	\$ 10,020,782
Total liabilities	1,279,104	867,009	944,419	857,133
Deficit	(44,296,010)	(46,107,474)	(47,623,698)	(48,506,467)
Shareholders' Equity	\$ 12,475,902	\$ 11,098,642	\$ 10,803,457	\$ 9,163,649

	<b>2019</b>			
<b>For the period ending:</b>	<b>March 31</b>	<b>June 30</b>	<b>September 30</b>	<b>December 31</b>
Total revenues	\$ 121,179	\$ 249,257	\$ 144,455	\$ 449,160
Net loss	(1,125,471)	(1,486,797)	(1,786,777)	(3,014,869)
Basic and diluted loss per share	\$ (0.01)	\$ (0.01)	\$ (0.01)	\$ (0.02)
<b>As at:</b>	<b>March 31</b>	<b>June 30</b>	<b>September 30</b>	<b>December 31</b>
Total assets	\$ 4,282,441	\$ 3,832,825	\$ 17,557,553	\$ 15,470,090
Total liabilities	1,149,643	1,278,548	947,522	1,614,647
Deficit	(36,363,711)	(37,850,508)	(39,637,285)	(42,652,154)
Shareholders' Equity	\$ 3,132,798	\$ 2,554,277	\$ 16,610,031	\$ 13,855,443

For the three-month period ended December 31, 2020, total revenue decreased to \$401,648 from \$449,160 for the same period in 2019, an 11% decrease. The decrease in revenues is primarily attributed to the COVID-19 pandemic.

Cost of sales for the three-month period ended December 31, 2020 was \$275,452 (69% of revenue) resulting in a gross margin of \$126,196 or 31% of revenue compared to a cost of sales of \$529,256 which included a one-time provision for inventory of \$277,896 in 2019. Removing the inventory provision, adjusted cost of sales was \$251,360 (55% of revenue) resulting in an adjusted gross margin of \$197,800 (45% of revenue). The cost of sales increase, year over year, is attributed to a write-down of obsolete inventory of \$19,557 and decreased revenues, while fixed costs remained constant.

Selling and marketing expenses for the three-month period ended December 31, 2020 decreased to \$114,019 or 28% of sales, from \$210,429 or 47% of sales in 2019, a 46% decrease. Selling and marketing expenses decreased year over year, due to a decrease in marketing personnel and decreased spending in advertising and travel due to the COVID-19 pandemic.

Administrative expenses for the three-month period ended December 31, 2020 were \$548,082 representing a 32% decrease from \$806,126 in 2019.

The decreases in administrative expenses are attributed to the following:

- Administrative salaries decreased by 34%, as a result of decreases in administrative personnel due to the COVID-19 pandemic.
- Stock based compensation decreased by 51%, as no options were granted in 2020.

Net research and development expenses totaled \$358,319 for the three-month period ended December 31, 2020 compared to \$1,928,670 in 2019, an 81% decrease. Research and development expenses decreased primarily due to decreased expenses for conducting a Phase II NMIBC clinical study as the COVID-19 pandemic delayed patient enrollment and treatment.

### **Liquidity and Capital Resources**

As of December 31, 2020, current assets aggregated \$8,915,619 compared with current liabilities of \$821,409 netting working capital of \$8,094,210 and a current ratio (current assets versus current liabilities) of approximately 11:1.

The Company's objective is to maintain a sufficient capital base to support future research, development and strategic business initiatives allowing the Company to invest in its future and maintain investor, creditor and market confidence. The capital structure of the Company consists of cash, cash equivalents and shareholder's equity.

Sales of the TLC-1000 and TLC-2000, the Company's existing product lines, have not been sufficient in and of themselves to enable the Company to fund its continuing research, development and commercialization efforts.

The Company's ability to continue as a going concern is dependent upon achieving a profitable level of operations and obtaining additional financing, neither of which is assured. The Company has successfully raised capital through previous equity offerings; however, there is no guarantee that the Company will be able to raise additional capital on terms and conditions agreeable to the Company or at all.

On August 22, 2019, the Company closed a public offering of Units for gross proceeds of \$17,250,000.

As of December 31, 2020, the Company has cash and cash equivalents of \$7,880,243 and as a result the Company believes that it will be able to continue as a going concern for at least 12 months from the date of these audited consolidated financial statements.

### **Results of Operations**

For the year ended December 31, 2020, total revenue decreased to \$929,112 from \$964,051 for the same period in 2019, a 4% decrease.

	<b>2020</b>	<b>2019</b>
Sales Revenue	\$ 828,287	\$ 879,439
Service Revenue	82,586	55,795
Clinic Revenue	105	7,167
Other Revenue	18,144	21,650
	<b>\$ 929,122</b>	<b>\$ 964,051</b>

The TLC-2000 represented 52% of sales for the year ended December 31, 2020 and 65% of sales for the same period in 2019.

In Canada, revenue decreased 2% to \$815,159 in 2020 from \$835,402 in 2019.

In the US, revenue decreased 9% to \$87,923 in 2020 from \$96,575 in 2019.

International revenue decreased 19% to \$26,041 for 2020 from \$32,074 in 2019.

Predominantly flat total revenue in 2020 is primarily attributed to the COVID-19 pandemic as most health care practitioners elected to temporarily close their practices and place any purchasing decisions on temporary or permanent hold.

### **Cost of Sales**

Cost of sales for the year ended December 31, 2020 was \$659,442, which included a on-time write-down of inventory of \$131,983, resulting in an adjusted cost of sales of \$527,459 or 57% of revenue with an adjusted

gross margin of \$401,663 or 43% of revenue. In comparison cost of sales for the same period in 2019 was \$903,296, which included a one-time provision for inventory of \$277,896, resulting in an adjusted cost of sales of \$625,400 or 65% revenue with an adjusted gross margin of \$338,651 or 35% of revenue.

Cost of sales is represented by the following costs: raw materials, subcontracting, direct and indirect labour and the applicable share of manufacturing overhead.

The gross margin increase, as a percentage of sales, year over year, is attributed to a decrease in labour and material costs and a one-time inventory provision of \$277,896 in 2019.

### Operating Expenses

For the year ended December 31, 2020, selling expenses decreased to \$447,882, from \$716,343 in 2019, a 37% decrease and consisted of the following items:

	2020	2019
Sales salaries	\$ 260,285	\$ 404,608
Advertising	84,107	161,777
Commission	43,665	55,892
Travel	10,637	53,740
Stock based compensation	1,329	2,813
Amortization and depreciation allocation	47,860	37,513
<b>Total selling expenses</b>	<b>\$ 447,882</b>	<b>\$ 716,343</b>

The decrease in selling expenses is primarily due to the restructuring of the Canadian and US sales and marketing departments, as a result of the COVID-19 pandemic, resulting in the resignation and/or termination of certain non-essential sales and marketing personnel and significantly reduced travel expenditures.

Administrative expenses for the year ended December 31, 2020, decreased to \$2,070,261 from \$2,604,808 in 2019, a 21% decrease and consisted of the following items:

	2020	2019
Insurance	\$ 43,087	\$ 48,993
Professional fees	482,138	316,236
Rent	39,967	50,675
General and administrative expenses	269,762	447,025
Administrative salaries	476,608	1,176,607
Settlement	85,000	-
Director and advisory fees	69,886	127,247
Stock based compensation	556,057	363,274
Amortization and depreciation allocation	47,755	74,751
<b>Total administrative expenses</b>	<b>\$ 2,070,261</b>	<b>\$ 2,604,808</b>

The decrease in administrative expenses is primarily attributed to decreased spending on general and administrative expenses (40%), director and advisory fees (45%) and administrative salaries (59%) due to the COVID-19 pandemic, resulting in the termination of certain non-essential administrative personnel.

The settlement expense relates to termination / severance pay to certain employees that were terminated from the employment of the Company.

Stock based compensation expense increased 53% in 2020 due to the September 2019 option grant.

### Research and Development Expense

Net research and development expenses for the year ended December 31, 2020 decreased to \$3,448,243 from \$4,159,724 in 2019, a 17% decrease, and consisted of the following items:

	<b>2020</b>		<b>2019</b>
Research and development (net of investment tax credit)	\$ 2,951,008	\$	3,997,739
Stock based compensation	354,647		28,479
Amortization and depreciation allocation	142,588		133,506
<b>Total research and development expenses</b>	<b>\$ 3,448,243</b>	<b>\$</b>	<b>4,159,724</b>

The decrease in research and development expenses for the year ended December 31, 2020 is attributed primarily to the delay in patient enrollment and treatment in Study II due to the COVID-19 pandemic. Research and development expenses represented 59% of the Company's operating expenses and represents investment into the research and development of the Company's ACT technology.

### Net Profit (Loss)

The net loss for the year ended December 31, 2020 was \$5,598,540 which included \$1,202,017 of net non-cash expenses (i.e.: amortization, stock-based compensation expense and foreign exchange gain/loss). This compared to a net loss in 2019 of \$7,413,914 which included \$677,224 of net non-cash expenses. The ACT division represented \$4,282,813 of this loss (76%) for the year ended December 31, 2020.

The decrease in net loss is primarily attributed to the following:

- 1) Delay in patient enrollment and treatment due to the COVID-19 pandemic, resulting in decreased research and development expenses in Study II.
- 2) Decreased salaries due to the COVID-19 pandemic, resulting in the termination of certain non-essential administrative, research and production personnel.

### Cash Flows

Funds used in operating activities, prior to net changes in other operating items, amounted to \$4,396,523 for the year ended December 31, 2020, compared to funds used in operating activities of \$6,736,690, in 2019. Funds used in operating activities, after taking into account net changes in other non-cash operating items were \$4,446,166 for the year ended December 31, 2020, compared to funds used of \$6,566,462 for the same period in 2019. The decrease is a result of decreased research and development expenses in Study II and reduced administrative, research and production salaries due to the COVID-19 pandemic.

Funds used in investing for the year ended December 31, 2020 amounted to \$164,576 compared to \$533,208 for 2019. The increase is primarily a result of decreased spending on equipment related to Study II.

Funds obtained from financing activities amounted to \$57,595 for the year ended December 31, 2020, compared to \$18,614,521 obtained in financing activities for 2019.



The public offering, which closed August 22, 2019 and the non-brokered private placement, which closed January 9, 2019 along with the exercise of warrants are responsible for the funding activities in 2019.

### **Assets (other than Cash)**

The Company holds essential and valuable intellectual property rights and assets; including: patents, trademarks, development and other related costs.

### **Commitments**

As of December 31, 2020, the Company's commitments consisted of the following:

	Total	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
Research Commitments (a)	\$ 58,250	\$ 58,250	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Research Agreement (b)	24,969	24,969	-	-	-	-	-	-	-	-	-	-
Research Agreement (c)	303,225	228,225	7,500	7,500	7,500	7,500	7,500	7,500	7,500	7,500	7,500	7,500
Research Agreement (d)	22,400	22,400	-	-	-	-	-	-	-	-	-	-
<b>Total</b>	<b>408,844</b>	<b>333,844</b>	<b>7,500</b>	<b>7,500</b>	<b>7,500</b>	<b>7,500</b>	<b>7,500</b>	<b>7,500</b>	<b>7,500</b>	<b>7,500</b>	<b>7,500</b>	<b>7,500</b>

- a) Research Commitments under a research collaboration agreement with University Health Network for the Ontario Research Fund project. Under the terms of this agreement, the Company is required to pay \$348,600 for the period from June 1, 2017 through to June 1, 2021. The Company has paid \$290,080 relating to this commitment, of which \$58,520 is the remaining commitment.
- b) Research Commitments under a research agreement with a Trial Management Organization for the TLC-3000 cancer therapy project. Under the terms of this agreement, the Company is required to pay \$126,324 (U.S. \$96,800) for the period from July 23, 2019 through to December 31, 2022. The Company has paid \$101,355 (U.S. \$76,400) relating to this commitment, of which \$24,969 (U.S. \$20,400) is the remaining commitment.
- c) Research Commitments under a research agreement with Alphora Research Inc. for the TLC-3000 cancer therapy project. Under the terms of this agreement, the Company is required to pay \$939,000 for the period from September 27, 2019 through to April 30, 2031. The Company has paid \$635,775 relating to this commitment, of which \$303,225 is the remaining commitment.
- d) Research Commitments under a research collaboration agreement with University Health Network for the Sponsored Research Agreement. Under the terms of this agreement, the Company is required to pay \$184,789 for the period from March 1, 2020 through to February 28, 2021. The Company has paid \$162,389 relating to this commitment, of which \$22,400 is the remaining commitment.

The Company indemnifies its directors and officers against any and all costs, charges and expenses, including settlement of claims in respect of any civil, criminal or administrative action incurred in the performance of their service to the Company to the extent permitted by law. The Company maintains liability insurance for its officers and directors.

## Lease Liabilities and Right-of-Use-Assets

	Property	Office Equipment	Total
<b>Right-of-use Assets</b>			
Balance at January 1, 2019	\$ 185,479	\$ 7,022	\$ 192,501
Depreciation charge for the period	49,461	1,793	51,254
<b>Balance at December 31, 2019</b>	<b>\$ 136,018</b>	<b>\$ 5,229</b>	<b>\$ 141,247</b>
Balance at January 1, 2020	\$ 136,018	\$ 5,229	\$ 141,247
Depreciation charge for the period	49,461	1,793	51,254
<b>Balance at December 31, 2020</b>	<b>\$ 86,557</b>	<b>\$ 3,436</b>	<b>\$ 89,993</b>
<b>Lease Liabilities</b>			
Balance at January 1, 2019	\$ 185,479	\$ 7,022	\$ 192,501
Interest charge for the period <sup>(1)</sup>	11,905	451	12,356
Lease payments for the period <sup>(2)</sup>	(58,075)	(2,160)	(60,235)
<b>Balance at December 31, 2019</b>	<b>\$ 139,309</b>	<b>\$ 5,313</b>	<b>\$ 144,622</b>
Balance at January 1, 2020	\$ 139,309	\$ 5,313	\$ 144,622
Interest charge for the period <sup>(1)</sup>	9,321	360	9,681
Lease payments for the period <sup>(2)</sup>	(59,800)	(2,160)	(61,960)
<b>Balance at December 31, 2020</b>	<b>\$ 88,830</b>	<b>\$ 3,513</b>	<b>\$ 92,343</b>

(1) Lease payments are discounted using an incremental borrowing rate of 8%.

(2) Lease payments do not include variable property lease payments of \$39,997 (2019 - \$51,250).

Principal repayments of the Company's leased premises and office equipment until maturity are as follows:

	Property	Office Equipment	Total
2021	54,669	1,949	56,619
2022	34,160	1,564	35,724
	<b>\$ 88,829</b>	<b>\$ 3,513</b>	<b>\$ 92,343</b>

## Share Capital Analysis

As of April 28, 2021, the share capital of the Company consisted of 204,275,875 common shares. Each common share entitles the holder to one vote per share.

As of April 28, 2021, there were 14,405,000 options outstanding, of which 6,815,000 were vested and exercisable into an equivalent number of the Company's common shares.

As of April 28, 2021, there were 72,473,931 warrants outstanding. Each whole warrant entitles the holder thereof to purchase one additional common share. The warrants are exercisable as follows: 4,555,266 at a price of \$0.375 until November 10, 2021, 3,165,009 at a price of \$0.50 until October 3, 2022, 4,095,157 at a price of \$0.50 until January 9, 2023, 3,159,000 at a price of \$0.30 until May 14, 2022 and 57,499,500 at a price of \$0.30 until August 22, 2024.

As of April 28, 2021, there were 2,023,077 broker compensation units that were issued in connection with the August 22, 2019 public offering. Each broker compensation unit entitles the holder thereof to acquire one common share and one common share purchase warrant at a price of \$0.35 per unit until August 22, 2024.

## Segmented Information

For management purposes, the Company is organized into two separate reportable operating divisions; the Anti-Cancer Therapy (“ACT”) division and the Cool Laser Therapy (“CLT”) division. The ACT division is responsible for the research and development of PDCs for the treatment of cancer with assistance from the CLT division to develop medical lasers to activate them. The CLT division is responsible for the Company’s medical laser business, which researches, develops, manufactures and distributes cool laser systems to healthcare practitioners predominantly for the healing of pain.

The following table displays revenue and direct expenses from the ACT and CLT division for the year ended December 31:

	2020			2019		
	CLT	ACT	Total	CLT	ACT	Total
Sales	\$ 929,122	\$ -	\$ 929,122	\$ 964,051	\$ -	\$ 964,051
Cost of sales	659,442	-	659,442	903,296	-	903,296
<b>Gross margin</b>	<b>269,680</b>	<b>-</b>	<b>269,680</b>	<b>60,755</b>	<b>-</b>	<b>60,755</b>
<b>Operating Expenses</b>						
Selling expenses	447,882	-	447,882	716,343	-	716,343
Administrative expenses	955,673	1,114,588	2,070,261	1,742,759	862,049	2,604,808
Research and development expense:	230,936	3,217,307	3,448,243	455,617	3,704,107	4,159,724
(Gain) loss on foreign exchange	(2,080)	(2,079)	(4,160)	7,520	7,521	15,041
Interest expense	4,840	4,840	9,680	6,178	6,178	12,356
Interest income	(51,843)	(51,843)	(103,686)	(33,603)	-	(33,603)
	1,585,408	4,282,813	5,868,220	2,894,814	4,579,855	7,474,669
<b>Loss for the period</b>	<b>\$ (1,315,728)</b>	<b>\$ (4,282,813)</b>	<b>\$ (5,598,540)</b>	<b>\$ (2,834,059)</b>	<b>\$ (4,579,855)</b>	<b>\$ (7,413,914)</b>
Total Assets	\$ 2,837,811	\$ 7,182,971	\$10,020,782	\$ 4,527,182	\$10,942,908	\$15,470,090
Total Liabilities	419,166	437,967	857,133	776,651	837,996	1,614,647

The following table displays revenue and direct expenses from TLT division product sales by product line and geographic area for the years ended December 31:

	2020			2019		
	Canada	USA	International	Canada	USA	International
<b>Sales by Product Line</b>						
TLC-1000	\$ 411,391	\$ 25,525	\$ 7,347	\$ 264,870	\$ 54,345	\$ 13,463
TLC-2000	403,768	62,398	18,694	570,532	42,230	18,611
	815,159	87,923	26,040	835,402	96,575	32,074
<b>Expenses</b>						
Cost of Sales	578,556	62,404	18,482	782,753	90,490	30,053
Selling Expenses	376,408	49,873	21,601	635,105	50,465	30,773
	954,965	112,276	40,083	1,417,858	140,955	60,826
	<b>\$ (139,806)</b>	<b>\$ (24,353)</b>	<b>\$ (14,043)</b>	<b>\$ (582,456)</b>	<b>\$ (44,380)</b>	<b>\$ (28,752)</b>

As of December 31, 2020 and 2019, the Company's long-lived assets used in operations are all located in Canada. Timing of revenue is recognized at a point in time.

### **Selected Financial Information and Accounting Policies**

The audited consolidated financial statements for the year ended December 31, 2020, and all other financial statements referred to herein, have been prepared in accordance with International Financial Reporting Standards ("IFRS"), consistently applied, and all amounts and currencies reported therein, and in this MD&A, are in Canadian dollars, unless otherwise noted. The ongoing accounting policies are more particularly described in the Notes to the Audited Consolidated Financial Statements for the year ended December 31, 2020. Please refer to the Company's annual and quarterly financial statement filings, including material interim press releases, on Sedar at [www.sedar.com](http://www.sedar.com).

### **Use of Financial Instruments**

The Company's financial instruments consists of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities. The fair value of cash, accounts receivable, accounts payable and accrued liabilities approximate carrying value because of the short-term nature of these instruments.

IFRS 7 Financial Instruments Disclosures establishes a fair value hierarchy that reflects the significance of inputs used in making fair value measurements as follows:

- Level 1: quoted prices in active markets for identical assets or liabilities;
- Level 2: inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly (i.e. as prices) or indirectly (i.e. from derived prices); and
- Level 3: inputs for the asset or liability that are not based upon observable market data.

The carrying amounts of cash and cash equivalents, accounts receivable and accounts payable and accrued liabilities approximate fair value due to the short-term maturities of these instruments.

Assets are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. As of December 31, 2020 and 2019, the Company's cash and cash equivalents are categorized as Level 1. There were no financial instruments categorized as Level 2 or 3.

(i) Credit risk:

Credit risk is the risk of financial loss to the Company if a customer or counterparty to a financial instrument fails to meet its contractual obligations and arises principally from the Company's trade and other receivable. The amounts reported in the consolidated balance sheets are net of allowances for credit losses, estimated by the Company's management based on prior experience and its assessment of the current economic environment. The Company reviews its trade receivable accounts regularly and reduces amounts to their expected realizable values by adjusting the allowance for credit losses when management determines that the account may not be fully collectible. The Company has adopted credit policies in an effort to minimize those risks. The carrying value of trade and other receivables represent the Company's maximum exposure to credit risk.

(ii) Liquidity risk:

Liquidity risk is the risk that the Company will not be able to meet its financial obligations as they come due. The Company manages its liquidity risk by continuously monitoring forecasted and actual cash

flows, as well as anticipated investing and financing activities. The Company does not have material long-term financial liabilities.

(iii) Interest rate risk:

Interest rate risk is the risk that changes in interest rates will affect the Company's income or the value of the financial instruments held. Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market interest rates.

The Company's exposure to interest rate risk is as follows:

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Cash and cash equivalents	Short-term fixed and variable interest rate
Short-term investments	Short-term fixed interest rate
Financed trade receivables	Short-term and long-term fixed interest rate

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(iv) Foreign currency exchange risk:

The Company is exposed to foreign currency exchange risk. This risk arises from the Company's holdings of US dollar denominated cash, trade and other receivables and payables and accrued liabilities. Changes arising from this risk could impact the Company's reported foreign currency exchange gains or losses.

The Company has not entered into any conventional or other financial instruments designed to minimize its investment risk, currency risk or commodity risk. No off-balance sheet arrangements have been established nor are there any pending proposals or indicated business requirements to this effect.

**Critical Accounting Policies, Estimates and Judgments**

As noted above, the Company's audited consolidated financial statements as of December 31, 2020 and 2019 and for the years ended December 31, 2020 and 2019 have been prepared in accordance with IFRS. The policies applied are based on IFRS issued and outstanding as of April 28, 2021 which is the date at which the Company's Board of Directors approved the audited consolidated financial statements.

Additionally, the preparation of consolidated financial statements in accordance with IFRS often requires management to make estimates about and apply assumptions or subjective judgment to future events and other matters that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures. Assumptions, estimates and judgments are based on historical experience, expectations, current trends and other factors that management believes to be relevant at the time at which the audited consolidated financial statements are prepared. Management reviews, on a regular basis, the Company's accounting policies, assumptions, estimates and judgments, in order to ensure that the audited consolidated financial statements are presented fairly and in accordance with IFRS.

Critical accounting estimates and judgments are those that have a significant risk of causing material adjustment and are often applied to matters or outcomes that are inherently uncertain and subject to change. As such, management cautions that future events often vary from forecasts and expectations and that estimates routinely require adjustment. A summary of those areas where the Company's management believe critical accounting policies affect the significant judgments and estimates used in the preparation of the financial statements can be found in note 2 to the audited consolidated financial statements of December 31, 2020 and 2019 and for the years ended December 31, 2020 and 2019.

## Disclosure of Internal Controls

Management has established processes, which are in place to provide them sufficient knowledge to support management representations that they have exercised reasonable diligence that:

- (i) the financial statements do not contain any untrue statement of material fact or omit to state a material fact required to be stated or that is necessary to make a statement not misleading in light of the circumstances under which it is made, as of the date of and for the periods presented by the financial statements; and
- (ii) the financial statements fairly present in all material respects the financial condition, financial performance and cash flows of the Company, as of the date of and for the periods presented by the financial statements.

In contrast to the certificate required under National Instrument 52-109 *Certification of Disclosure in Issuers' Annual and Interim Filings* (NI 52-109), the Company utilizes the Venture Issuer Basic Certificate, which does not include representations relating to the establishment and maintenance of Disclosure Controls and Procedures (“**DC&P**”) and Internal Control over Financial Reporting (“**ICFR**”), as defined in NI 52-109.

In particular, the certifying officers filing the Certificate are not making any representations relating to the establishment and maintenance of:

- (i) controls and other procedures designed to provide reasonable assurance that information required to be disclosed by the issuer in its annual filings, interim filings or other reports filed or submitted under securities legislation is recorded, processed, summarized and reported within the time periods specified in securities legislation; and
- (ii) a process to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with the issuer's GAAP. The Company's certifying officers are responsible for ensuring that processes are in place to provide them with sufficient knowledge to support the representations they are making in the certificate.

Investors should be aware that inherent limitations on the ability of certifying officers of a venture issuer to design and implement on a cost-effective basis DC&P and ICFR as defined in NI 52-109 may result in additional risks to the quality, reliability, transparency and timeliness of interim and annual filings and other reports provided under securities legislation.

In connection with the audits of the Company's consolidated financial statements for the years' ended December 31, 2020 and 2019, the Company's independent registered public accountants identified certain material weaknesses in the Company's internal control over financial reporting. Such material weaknesses continue to exist as of December 31, 2020. A “material weaknesses” is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses relate to not having a full segregation of duties within members of its accounting staff dedicated to financial reporting functions so that all journal entries and account reconciliations are reviewed by someone other than the preparer, heightening the risk of error or fraud, and a proper system for updating inventory values as of the end of each reporting period. If the Company is unable to remediate the material weakness, or other control deficiencies are identified, the Company may not be able to report its financial results accurately, prevent fraud or file its periodic reports as a public company in a timely manner.

## **Risks and Uncertainties**

The Company's operations involve certain risks and uncertainties that are inherent to the Company's industry. The most significant known risks and uncertainties faced by the Company are described below.

### **COVID-19 Pandemic**

On March 11, 2020, the World Health Organization declared the outbreak of a novel coronavirus ("COVID-19") as a global pandemic, which continues to spread throughout Canada and around the world. As of April 28, 2021, the Company is aware of significant changes in its business, as a result of the COVID-19 pandemic, resulting in the resignation and/or termination of certain non-essential personnel, personnel working remotely or virtually, delayed patient enrollment and treatment in Study II and significant delays / cancellations in customer purchase decisions. Management is uncertain of the full extent of these impacts on its financial statements and believes that the business disruption caused by COVID-19 could be temporary; however, there is uncertainty around its duration and hence the potential impact on the business cannot be fully estimated.

### **Limited Operating History**

The Company is still in the development and commercialization stages of its businesses and therefore will be subject to the risks associated with early stage companies, including uncertainty of the success and acceptance of its products, uncertainty of revenues, markets and profitability and the continuing need to raise additional capital. The Company's business prospects must be considered in light of the risks, expenses and difficulties frequently encountered by companies in this stage of development. Such risks include the evolving and unpredictable nature of the Company's business, the Company's ability to anticipate and adapt to a developing market, acceptance by consumers of the Company's products, the ability to identify, attract and retain qualified personnel and the ability to generate sufficient revenue or raise sufficient capital to carry out its business plans. There can be no assurance that the Company will be successful in adequately mitigating these risks.

### **Working Capital and Capital Resources**

The Company has not been able to consistently generate sufficient profits from its revenue to provide the financial resources necessary to continue to have sufficient working capital for the development of its products and marketing activities. There is no assurance that future revenues will be sufficient to generate the required funds to continue product development, business development and marketing activities or that additional funds required for such working capital will be available from financings.

These conditions indicate the existence of material uncertainties that cast substantial doubt about the Company's ability to continue as a going concern. The Company's ability to continue as a going concern is dependent upon achieving a profitable level of operations and obtaining additional financing, neither of which is assured. The Company has been able, to date, to raise capital to continue to market its products and continues to develop sales opportunities which could result in additional sales of its products in the future.

In order to achieve its long term development and commercialization strategy for the Company's range of therapeutic laser systems and PDC anti-cancer technology, the Company may need to raise additional capital through the issuance of shares, collaboration agreements or strategic partnerships that would allow the Company to finance its activities. There is no assurance that additional funds will be available as required or that they may be available on acceptable terms and conditions. Additional financing may also result in dilution of shareholder value.

### **Key Personnel**

The Company's success is dependent upon its ability to attract and retain a highly qualified work force, and to establish and maintain close relationships with research centers. Competition is intense and the Company's

success will depend, to a great extent, on its senior and executive managers, scientific personnel and academic partners. The loss of one or more of its key employees or the inability to attract and retain highly skilled personnel could have a material adverse effect on the Company's development of its products, operations or business prospects.

### **Protection of Intellectual Property**

The Company's success will depend in part on its ability to obtain patents, protect its trade secrets and operate without infringing the exclusive rights of other parties. There is no guarantee that any patent that will be granted to the Company will bring any competitive advantage to the Company, that its patent protection will not be contested by third parties, or that the patents of competitors will not be detrimental to the Company's commercial activities. It cannot be assured that competitors will not independently develop products similar to the Company's products, that they will not imitate the Company's products or that they will not circumvent or invalidate patents granted to the Company.

Although the Company does not believe that its products infringe the proprietary rights of any third parties, there can be no assurance that infringement or invalidity claims (or claims for indemnification resulting from infringement claims) will not be asserted or prosecuted against the Company or that any such assertions or prosecutions, valid or otherwise, will not materially adversely affect the Company's business, financial condition or results of operations. Irrespective of the validity of the successful assertion of such claims, the Company could incur significant costs and diversion of resources with respect to the defense thereof, which could have a material adverse effect on the Company. The Company's performance and ability to develop markets and compete effectively are dependent to a significant degree on its proprietary and patented technology. The Company relies on its patents and trade secrets, as well as confidentiality agreements and technical measures, to establish and protect its proprietary right. While the Company will endeavor to protect its intellectual property, there can be no assurance that the steps taken will prevent misappropriation or that agreements entered into for that purpose will be enforceable. The laws of certain other countries may afford the Company little or no effective protection of its intellectual property.

### **Competition**

Many of the Company's current and potential competitors have longer operating histories, larger customer bases, greater name and brand recognition and significantly greater financial, sales, marketing, engineering, scientific, technical and other resources than the Company. These competitors have research and development capabilities that may allow them to develop new or improved products that may compete with the Company's products. New technologies and the expansion of existing technologies may also increase competitive pressures on the Company. Increased competition may result in reduced operating margins as well as loss of market share and could result in decreased usage in the Company's products and may have a material adverse effect on the Company.

### **Implementation Delays**

Many of the Company's products will be in development, testing or preliminary stage and there may be delays or other problems in the introduction of the Company's products. The Company cannot predict when customers that are in a testing or preliminary use phase of the Company's products will adopt a broader use of the products. The market for the Company's products is relatively new and continues to evolve. The Company's products will involve changes in the manner in which businesses have traditionally used such products. In some cases, the Company's customers will have little experience with products offered by the Company. The Company will have to spend considerable resources educating potential customers about the value of the Company's products. It is difficult to assess, or predict with any assurance, the present and future size of the potential market for the Company's products or its growth rate, if any. The Company cannot predict whether or not its products will achieve market acceptance.



### **Strategic Alliances**

The Company's ability to successfully complete the research and development of its products and its growth and marketing strategies are based, in significant part, in the strategic alliances it has in place and the licenses and agreements securing those strategic alliances. The Company's success will depend upon the ability to seek out and establish new strategic alliances and working relationships. There can be no assurance that existing strategic alliances and working relationships will not be terminated or adversely modified in the future, nor can there be any assurance that new relationships, if any, will afford the Company the same benefits as those currently in place.

### **Trade Secret Protection**

Because the Company relies on third parties to develop its products, the Company must share trade secrets with them. The Company seeks to protect its proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with its collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically restrict the ability of its collaborators, advisors, employees and consultants to publish data potentially relating to its trade secrets. The Company's academic collaborators typically have rights to publish data, provided that the Company is notified in advance and may delay publication for a specified time in order to secure its intellectual property rights arising from the collaboration. In other cases, publication rights are controlled exclusively by the Company, although in some cases the Company may share these rights with other parties. The Company also conducts joint research and development programs which may require the Company to share trade secrets under the terms of research and development collaboration or similar agreements. Despite the Company's efforts to protect its trade secrets, the Company's competitors may discover the Company's trade secrets, either through breach of these agreements, independent development or publication of information including the Company's trade secrets in cases where the Company does not have proprietary or otherwise protected rights at the time of publication. A competitor's discovery of the Company's trade secrets may impair the Company's competitive position and could have a material adverse effect on the Company's business and financial condition.

### **Product Deficiencies**

Given that the Company's products are either fairly new, or are in various stages of development, there may be difficulties in product design, performance and reliability which could result in lost revenue, delays in customer acceptance of the Company's products and legal claims against the Company, which would be detrimental, perhaps materially to the Company's market reputation and ability to generate further sales. Serious defects are frequently found during the period immediately following the introduction of new products or enhancements to existing products and undetected errors or performance problems may be discovered in the future. Product defects may expose the Company to liability claims, for which the Company may not have sufficient liability insurance.

### **Dependence on Third Party Suppliers**

The Company has established relationships with certain third-party suppliers upon whom, it relies to provide key materials and components for completion of its products. In the event of the inability of these third parties to supply such materials and components in a timely manner or to supply materials and components that continue to meet the Company's quality, quantity or cost requirements, the Company would be required to purchase these materials and components from other suppliers. There is no assurance that other suppliers can be found in such circumstances who can supply the materials and components in a timely manner or that meet the Company's quality, quantity or cost requirements.

### **Volatility of Share Price**

The market price of the Company's common shares is subject to volatility. General market conditions as well as differences between the Company's financial, scientific and clinical results, and the expectations of investors,

as well as securities analysts can have a significant impact on the trading price of the Company's common shares.

### **Regulatory Approvals**

The Company is directly and indirectly engaged in the design, manufacture, sale and international marketing of therapeutic and medical laser equipment, as well as the research and development of light activated PDCs, all of which are subject to regulatory oversights, audits and controls by various national regulatory agencies (i.e.: FDA, Health Canada, CE) and authoritative quality standards bodies (i.e.: UL, CSA, ISO and TUV), which all possess strict quality certification procedures. The Company is in full compliance with all the governing regulatory and quality standards and approval requirements pertaining to the medical laser devices it currently designs, manufactures and markets and the PDCs it researches and develops. No assurance can be given that current regulations relating to regulatory approval will not change or become more stringent and product approvals may be withdrawn if compliance with regulatory standards is not maintained.

### **Early Stage of Product Development**

Given the early stage of the Company's product development, the Company can make no assurance that its research and development programs will result in regulatory approval or commercially viable products. To achieve profitable operations, the Company alone or with others, must successfully develop, gain regulatory approval and market its future products. To obtain regulatory approvals for its product candidates being developed and to achieve commercial success, clinical studies must demonstrate that the product candidates are safe and tolerable for human use and that they demonstrate efficacy equal to or greater than standard of care.

Many product candidates never reach the stage of clinical testing and even than those that do have only a small chance of successfully completing clinical development and gaining regulatory approval. Product candidates may fail for a number of reasons, including, but not limited to: being unsafe for human use or due to the failure to provide therapeutic benefits equal to or better than the standard of treatment at the time of testing. Unsatisfactory results obtained from a particular study relating to a research and development program may cause the Company or its collaborators to abandon commitments to that program. Positive results of early preclinical research may not be indicative of the results that may be obtained in later stages of preclinical or clinical research. Similarly, positive results from early-stage clinical studies may not be indicative of favorable outcomes in later-stage clinical studies. The Company can make no assurance that any future studies, if undertaken, will yield favorable results.

### **Reliance on Third Parties**

The Company relies and will continue to rely on third parties to conduct a significant portion of its preclinical and clinical development activities. Preclinical activities include: in-vivo studies providing access to specific disease models, pharmacology and toxicology studies and assay development. Clinical development activities include: trial design, regulatory submissions, clinical patient recruitment, clinical trial monitoring, clinical data management and analysis, safety monitoring and project management. If there is any dispute or disruption in the Company's relationship with third parties, or if they are unable to provide quality services in a timely manner and at a feasible cost, the Company's active development programs may face delays. Further, if any of these third parties fails to perform as the Company expects or if their work fails to meet regulatory requirements, the Company's testing could be delayed, cancelled or rendered ineffective.

### **Clinical Study Risk**

Before obtaining marketing approval from regulatory authorities for the sale of the Company's product candidates, the Company must conduct preclinical studies in animals and extensive clinical studies in humans to demonstrate the safety, tolerability and efficacy of the product candidates. Clinical testing is expensive and difficult to design and implement, can take many years to complete and has uncertain outcomes. The outcome

of preclinical experiments and early clinical studies may not predict the success of later clinical studies, and interim results of a clinical study do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical studies due to lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier studies. The Company does not know whether the clinical studies it may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market any of the Company's product candidates in any jurisdiction. A product candidate may fail for safety, tolerability or efficacy reasons at any stage of the testing process. A major risk the Company faces is the possibility that none of the Company's product candidates under development will successfully gain market approval from Health Canada, the FDA or other regulatory authorities, resulting in the Company being unable to derive any commercial revenue from them after investing significant amounts of capital in multiple stages of preclinical and clinical testing.

From time to time, scientific studies or clinical studies on various aspects of biopharmaceutical products are conducted by academic researchers, competitors or others. The results of these studies, when published, may have a significant effect on the market for the biopharmaceutical product that is the subject of the study. The publication of negative results of scientific studies or clinical studies or adverse safety events related to the Company's product candidates, or the therapeutic areas in which the Company's product candidates compete, could adversely affect the Company's share price and the Company's ability to finance future development of its product candidates; hence, the Company's business and financial results could be materially and adversely affected.

#### **Clinical Study Timing Delays**

The Company cannot predict whether any clinical studies will begin as planned, will need to be restructured, or will be completed on schedule, or at all. The Company's product development costs may increase significantly if the Company experiences delays in clinical testing. Significant clinical study delays could shorten any periods during which the Company may have the exclusive right to commercialize its product candidates or allow the Company's competitors to bring products to market before the Company, which would impair the Company's ability to successfully commercialize its product candidates and may harm the Company's financial condition, results of operations and / or prospects. The commencement and completion of clinical studies for the Company's products may be delayed for a number of reasons, including delays related, but not limited, to:

- failure by regulatory authorities to grant permission to proceed or placing the clinical study on hold;
- patients failing to enroll or remain in the Company's studies at the rate the Company expects;
- suspension or termination of clinical studies by regulators for many reasons, including concerns about patient safety or tolerability
- any changes to the Company's manufacturing process that may be necessary or desired;
- delays or failure to obtain clinical supply from contract manufacturers of the Company's products necessary to conduct clinical studies;
- product candidates demonstrating a lack of safety, tolerability or efficacy during clinical studies;
- patients choosing an alternative treatment for the indications for which the Company is developing any of its product candidates or participating in competing clinical studies;
- patients failing to complete clinical studies due to dissatisfaction with the treatment, side effects or other reasons;
- reports of clinical testing on similar technologies and products raising safety, tolerability and/or efficacy concerns;
- competing clinical studies and scheduling conflicts with participating clinicians;
- clinical investigators not performing the Company's clinical studies on their anticipated schedule, dropping out of a study, or employing methods not consistent with the clinical study protocol,

- regulatory requirements or other third parties not performing data collection and analysis in a timely or accurate manner;
- failure of the Company’s Contract Research Organizations, to satisfy their contractual duties or meet expected deadlines;
- inspections of clinical study sites by regulatory authorities, Review Ethics Boards (“REB”), or Institutional Review Boards (“IRBs”) or ethics committees finding regulatory violations that require the Company to undertake corrective action, resulting in suspension or termination of one or more sites or the imposition of a clinical hold on the entire study;
- one or more IRBs or ethics committees rejecting, suspending or terminating the study at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the study; or
- failure to reach agreement on acceptable terms with prospective clinical study sites.

The Company’s product development costs may increase if the Company experiences delays in testing or approval or if the Company needs to perform more or larger clinical studies than planned. Additionally, changes in regulatory requirements and policies may occur, and the Company may need to amend study protocols to reflect these changes. Amendments may require the Company to resubmit its study protocols to regulatory authorities or IRBs or ethics committees for re-examination, which may impact the cost, timing or successful completion of that study. Delays or increased product development costs may have a material adverse effect on the Company’s business, financial condition and prospects.

#### **Patient Enrollment**

As the Company’s product candidates advance from preclinical testing to clinical testing, and then through progressively larger and more complex clinical studies, the Company may need to enroll an increasing number of patients that meet the Company’s eligibility criteria. There is significant competition for recruiting cancer patients in clinical studies, and the Company may be unable to enroll the patients it needs to complete clinical studies on a timely basis or at all. The factors that affect the Company’s ability to enroll patients are largely uncontrollable and include, but are not limited to, the following:

- size and nature of the patient population;
- eligibility, inclusion and exclusion criteria for the study;
- design of the clinical study protocol;
- competition with other companies for clinical sites or patients;
- the perceived risks and benefits of the product candidate under study;
- the patient referral practices of physicians; or
- the number, availability, location and accessibility of clinical study sites

#### **Failure to Achieve Milestones**

From time to time, the Company may announce the timing of certain events it expects to occur, such as the anticipated timing of results from the Company’s clinical studies or product sales. These statements are forward-looking and are based on the best estimates of management at the time relating to the occurrence of such events; however, the actual timing of such events may differ from what has been publicly disclosed. The timing of events such as initiation or completion of a clinical study, filing of an application to obtain regulatory approval or announcement of additional clinical studies for a product candidate or adoption / sales of the Company’s products may ultimately vary from what is publicly disclosed. These variations in timing may occur as a result of different events, including the nature of the results obtained during a clinical study or during a research phase or any other event having the effect of delaying the publicly announced timeline. The Company undertakes no obligation to update or revise any forward-looking information, whether as a result of new information, future events or otherwise, except as otherwise required by law. Any variation in the timing of

previously announced milestones could have a material adverse effect on the Company's business plan, financial condition or operating results and the trading price of common shares.

### **Currency Risk**

The Company's primary risks are exposure to foreign currency exchange risk. These risks arise from the Company's holdings of US and Canadian dollar denominated cash, accounts receivable and accounts payable. Changes arising from these risks could impact the Company's reported foreign exchange gains or losses. The Company limits its exposure to foreign currency risk by holding US denominated cash in amounts of up to 100% of forecasted twelve month US dollar expenditures; thereby, creating a natural hedge against foreign currency fluctuations and limiting foreign currency risk to translation of US dollar balances at the balance sheet date.

### **Credit Risk**

Credit risk is the risk of financial loss to the Company, if a customer or counterparty to a financial instrument fails to meet its contractual obligations and arises principally from the Company's accounts receivable. The amounts reported in the balance sheet are net of allowances for bad debts, estimated by the Company's management based on prior experience and their assessment of the current economic environment. The Company reviews its trade receivable accounts regularly and reduces amounts to their expected realizable values by adjusting the allowance for doubtful accounts as soon as the account is determined not to be fully collectible. The Company has adopted credit policies in an effort to minimize these risks.

### **Product Liability**

The Company has obtained product liability insurance coverage in the aggregate of \$5,000,000. This coverage is limited, and a product liability claim could potentially be greater than this coverage. The Company's profitability would be adversely affected by any successful product liability claim in excess of its insurance coverage.

### **Clinical Trial Liability**

The Company has obtained clinical trial liability insurance coverage in the aggregate of \$5,000,000. This coverage is limited, and a clinical trial liability claim could potentially be greater than this coverage. The Company's profitability would be adversely affected by any successful product liability claim in excess of its insurance coverage.

### **Patent-Related Rights of the U.S. Government in PDT Technology**

Some of Theralase®'s licensed patented PDT technology was developed with US federal government funding. When new technologies are developed with US government funding, the government obtains certain rights in any resulting patents, including a nonexclusive license authorizing the government to use the invention for noncommercial purposes. These rights may permit the government to disclose Theralase®'s confidential information to third parties and to exercise "march-in" rights to use or allow third parties to use Theralase®'s patented technology. The government can exercise its march-in rights if it determines that action is necessary because Theralase® fails to achieve practical application of the US government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations or to give preference to US industry. In addition, US government-funded inventions must be reported to the government and US government funding must be disclosed in any resulting patent applications. Furthermore, Theralase®'s rights in such inventions are subject to government license rights and certain restrictions on manufacturing products outside the United States.

April 28, 2021

Kristina Hachey, CPA  
Chief Financial Officer