

# 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 unaudited condensed interim consolidated financial statements for the six-month period ended June 30, 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 August 26, 2020.

The Company's common shares are listed for trading on the TSX Venture Exchange (**Symbol: TLT**) and also 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 its current and future obligations; ability to execute its business and/or growth strategy; 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 and study risk; clinical study timing delays; patient enrolment; failure to achieve milestones; currency risk; material weakness in internal control 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 destroy various cancers, bacteria and viruses. The Company in its Medical Laser Technology (“MLT”) division designs, develops, manufactures and commercializes medical laser systems and other technologies for the activation of PDCs as well as designs, develops, manufactures and markets patented and 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.

## 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 the report date, the Company is aware of significant changes in its business as a result of COVID-19, notably unavailability of personnel, personnel working remotely or virtually 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 report.

Theralase® continues to experience reduced 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.

## Advancing the Theralase Technology Platform

The Company’s primary focus is the Photo Dynamic Therapy (“PDT”) Division, with primary objectives of preclinical research, clinical studies 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 used in a soluble form for the treatment of Non Muscle Invasive Bladder Cancer (“NMIBC”). In addition, it is able to bind with transferrin, a human glycoprotein allowing localization to cancer cells, which generally have more transferrin receptors versus healthy cells. When laser light activated, TLD-1433 has been shown to destroy bladder cancer cells through the production of singlet oxygen and/or Reactive Oxygen Species (“ROS”).

Theralase’s lead cancer indication is NMIBC.

### Phase Ib NMIBC Clinical Study

Theralase has 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) (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, the PDC was activated by laser light (525 nm, 90 J/cm<sup>2</sup>) delivered by the TLC-3200 Medical Laser System.

Theralase's Study successfully achieved the primary endpoint of safety and tolerability, secondary endpoint of pharmacokinetics, and exploratory endpoint of efficacy. The Study results demonstrate a strong efficacy signal with a 67% Complete Response ("CR") 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.

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

The Phase II NMIBC Clinical Study ("Study II") has been designed to utilize the Therapeutic Dose (0.70 mg/cm<sup>2</sup>) of TLD-1433 and focus on the treatment of approximately 100 BCG-Unresponsive NMIBC patients presenting with Carcinoma In-Situ ("CIS") in approximately 20 clinical study sites located in Canada and the US. The study has a primary endpoint of efficacy (measured by Complete Response ("CR")) at any point in time, a secondary endpoint of duration of CR at approximately 360 days post-initial CR and a tertiary endpoint of safety measured by incidence and severity of adverse events.

Health Canada granted the Company Investigational Testing Authorization ("ITA") approval (originally submitted December 2018 + amendments) to utilize its TLC-3200 Medical Laser System, in conjunction with its Clinical Trial Application ("CTA") approved lead PDC, TLD-1433 (originally submitted November 2018 + amendments), to commence enrolling and treating patients in Study II, subject to submitting a Clinical Trial Site Information Form and receipt of individual Research Ethics Board ("REB") approvals for each Canadian oncology location that will conduct Study II. The following Canadian oncology locations REB's approved the following Clinical Trial Sites to commence Study II:

<b>Study Site</b>	<b>REB Approval Date</b>
University Health Network ("UHN")	April 25, 2019
McGill University Health Centre ("MUHC")	July 30, 2019
London Health Sciences Centre ("LHSC")	October 7, 2019
Nova Scotia Health Authority ("NSHA")	February 25, 2020

On May 19, 2020, the Company received FDA Investigational New Drug ("IND") authorization to commence enrolling and treating patients in Study II in the United States. In June 2019, a conference call between the FDA and the Company, that Theralase would potentially be eligible for Fast Track Approval ("FTA") post receipt of the FDA IND authorization, based on the clinical study data collected to date. It was further discussed and agreed that Theralase would potentially be eligible for Breakthrough Therapy Designation ("BTD") and / or Accelerated Approval ("AA"), if Theralase could demonstrate clinically significant results (high safety profile and high efficacy response), similar to the safety and efficacy results observed in the Phase Ib NMIBC clinical study (high safety profile and 67% CR) at an interim analysis of approximately 20 to 25 patients enrolled and successfully treated.

As of August 26, 2020, 12 patients have been treated representing approximately 50% of the interim milestone to submit an analysis to the FDA in support of a BTD.

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

Theralase has successfully launched 4 Canadian study sites with 1 additional Canadian clinical study site in advanced negotiation.

Three out of four Canadian clinical study sites have re-commenced new patient enrollment and treatment in Study II, specifically:

Study Site	Location	Site Status
University Health Network (“UHN”)	Toronto, Ontario	Enrolling
London Health Sciences Centre (“LHSC”)	London, Ontario	Enrolling
Nova Scotia Health Authority (“NSHA”)	Halifax, Nova Scotia	Enrolling
McGill University Health Centre (“MUHC”)	Montreal, Quebec	COVID-19 Hold

MUHC currently remains closed due to COVID-19, for new patient enrollment and treatment; however, patients who have already been enrolled, treated and are eligible for second treatment will receive a second treatment.

Theralase® is in advanced discussions to launch a number of US based clinical study sites later in the year, subject to the United States economy recovering from the COVID-19 pandemic. The US based Trial Management Organization (“TMO”) could potentially launch 4 clinical study sites in 4Q2020 and commence Study II patient enrollment and treatment as early as 1Q2021.

### Study II Interim Data

Study II enrolled and treated 12 patients, with the following results:

Patient Status	Number of Patients	Percentage
<b>First Treatment Provided</b>	12	100.0%
<b>Patients Eligible to Receive Second Treatment</b>	8	66.7%
<b>Second Treatment to be Provided</b>	5	41.7%
<b>Second Treatment Provided</b>	3	25.0%
<b>Response at 90 Days Post Initial Treatment</b>	7	58.3%
<b>Complete Response at 90 Days Post Initial Treatment</b>	3	25.0%
<b>Patients Removed from Study II</b>	4	33.3%

Of the 7 patients, who demonstrated a Response to the Study Treatment defined as negative cystoscopy (no evidence of cancer in their bladders) or negative urine cytology (no evidence of the urothelial carcinoma cells in their urine)) at 90 days post initial treatment:

- 43% achieved a Complete Response (“CR”) (negative cystoscopy and negative urine cytology)
- 43% achieved a Response (negative cystoscopy and positive or suspicious cytology)
- 14% achieved a Response (suspicious cystoscopy and negative cytology)

The patients who responded to the Study Treatment are currently under medical review to assess the cause of the suspicious cystoscopy by directed bladder biopsy and the cause of the positive or suspicious cytology by repeating the urine cytology analysis. If found to be negative, these patients will be allocated to the CR column. If positive or suspicious again, then Computerized Tomography (“CT”) Scan imaging and/or prostatic biopsies will be conducted to rule out Upper Tract Urothelial Cell Carcinoma (“UTUCC”). If UTUCC is proven to exist, then according to FDA’s Bacillus Calmette Guérin (“BCG”)-Unresponsive Guidelines to Industry, issued in February 2018, these patients will be classified as CR, as only the bladder was treated by the Study Treatment and not non-addressable areas of the urinary system.

Of the 8 patients eligible to receive the second treatment in Study II, three patients have received their second treatment, four patients are awaiting second treatment, subject to clinical study site operating room availability and one patient is undergoing additional assessments prior to proceeding to the second treatment.

The four patients that were removed from Study II have been redirected to other treatment options available to them based on the principal investigator's assessment.

### **Study II Optimization**

On a go forward basis, all future and existing patients to be enrolled and treated (initial and second treatment) in Study II will be 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

### **Additional Oncology Targets:**

Theralase has worldwide exclusive licensing rights to the Theralase ruthenium and osmium compounds and any improvements to the compounds listed in the Company's issued and pending patents; therefore, Theralase has full commercial control on these patented and patent pending Photo Dynamic Compounds ("PDC"), including TLD-1433.

Theralase has steered the research and development of these PDCs through scientific and preclinical research to fine-tune the photophysical and photochemical properties of the PDCs, by the inventor, while demonstrating Type I and II photoreactions and activation in hypoxia, by combining these PDCs with transferrin, as a delivery system. Transferrin significantly increases the photobleaching resistance (loss of potency of the PDC over time), Reactive Oxygen Species ("ROS") production (ability to destroy cancer cells quickly and effectively), selective tumour uptake (destruction of cancer cells, while sparing healthy cells), anti-cancer efficacy (efficiency in cancer cell destruction) and decreasing systemic toxicity (damage to healthy cells) of the PDCs. 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 intellectual property regarding its patented PDCs, in pursuit of this goal.

Rutherrin® (patented formulation of the Company's lead PDC (TLD-1433) combined with transferrin) enables a preferential and targeted delivery of TLD-1433 inside cancer cells, with a mandate of "hunting" and "destroying" cancer cells wherever they may reside in the body.

The Company has demonstrated significant anti-cancer efficacy of Rutherrin®, when activated by laser light or radiation treatment across numerous preclinical models; including: Glio Blastoma Multiforme ("GBM") and Non-Small Cell Lung Cancer ("NSCLC").

The Company is planning to commence toxicology studies with Rutherrin® to determine the maximum recommended human dose of the drug, when administered systemically into the human body, via intravenous injections.

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 the anti-cancer therapy 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 to commence development of a coronavirus vaccine and therapy utilizing Theralase's patented and proprietary PDCs. According to the SRA, UM will conduct experiments in conjunction with Theralase for the research and development of a coronavirus vaccine and therapeutic to be further evaluated in animal then human clinical testing in 2021. \*

The primary objective of the SRA executed between the UM and Theralase® is to investigate the ability of Theralase's® lead PDC in the destruction of a variety of viruses; including: H1N1 Influenza, Zika, coronaviruses and of course COVID-19. The secondary objective is 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) and as a therapeutic (treatment of a patient who has already contracted COVID-19). The research is primarily directed to in-vitro (Petri dish of viruses) analysis, but based on these initial experiments, Theralase hopes to expand the work, in conjunction with Dr. Coombs, to in-vivo (small animal) analysis, toxicology (optimized doses for human delivery) and finally human testing through Phase I (safety), Phase II (efficacy) and eventually Phase III (efficacy in a larger population) clinical studies. If successful through a Phase III clinical study, and with the successful regulatory approval of Health Canada, the technology could be commercialized across Canada for the benefit of all Canadians.\*

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

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

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

The estimated timing of completion of Study II is approximately 3 years; including regulatory assessments; however this timeline, may vary significantly depending on numerous factors including: number of enrolling and treating oncology clinical study sites, oncology clinical study site patient enrollment rates, patient compliance, treatment success and/or successful achievement of clinical Study II endpoints.

### **Overview of Financial Performance**

During the six-month period ended June 30, 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 the Phase II NMIBC Study.

## Summary of Selected Annual Information

(expressed in Canadian Dollars)

For the twelve-month periods ended December 31:

	<b>2019</b>	<b>2018</b>
Total revenues	\$ 964,051	\$ 1,734,072
Net loss	(7,413,914)	(3,356,877)
Basic and diluted loss per share	\$ (0.051)	\$ (0.026)
Total assets	\$ 15,470,090	\$ 3,564,419
Total liabilities	1,614,647	2,565,780
Deficit	(42,652,154)	(35,238,240)
Shareholders' Equity	\$ 13,855,443	\$ 998,639

## Summary of Quarterly Results

(expressed in Canadian Dollars)

	<b>2020</b>			
	<b>March 31</b>	<b>June 30</b>		
<b>For the period ending:</b>				
Total revenues	\$ 111,543	\$ 293,453		
Net loss	(1,643,856)	(3,267,624)		
Basic and diluted loss per share	\$ (0.008)	\$ (0.016)		
<b>As at:</b>	<b>March 31</b>	<b>June 30</b>		
Total assets	\$ 13,755,006	\$ 11,965,651		
Total liabilities	1,279,104	867,009		
Deficit	(44,296,010)	(46,107,474)		
Shareholders' Equity	\$ 12,475,902	\$ 11,098,642		
	<b>2019</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	\$ 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

## Liquidity and Capital Resources

As of June 30, 2020, current assets aggregated to \$10,790,395 compared with current liabilities of \$802,412 netting working capital of \$9,987,983 and a current ratio (current assets vs. current liabilities) of approximately 13:1.

The company closed a public offering of Units for gross proceeds of \$17,250,000 on August 22, 2019, 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 issuance of these interim condensed interim consolidated financial statements. 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. Historically, the Company has been able to raise capital to continue to market its products and continues to develop sales opportunities that could result in additional sales of its products in the future.

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.

As of June 30, 2020, the Company had cash and cash equivalents of \$9,610,914. 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 has successfully raised capital through equity offerings in 2018 and 2019. 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.

## Results of Operations

	<b>2020</b>	<b>2019</b>
Sales Revenue	\$ 266,895	\$ 316,137
Service Revenue	20,995	37,358
Clinic Revenue	65	4,930
Other Revenue	5,499	12,011
	<b>\$ 293,453</b>	<b>\$ 370,436</b>

For the six-month period ended June 30, 2020, total revenue decreased to \$293,453 from \$370,436 for the same period in 2019, a 21% decrease. The TLC-2000 represented 38% of sales for the six-month period ended June 30, 2020 and 51% of sales for the same period in 2019. In Canada, revenue decreased 23% to \$255,146 in 2020 from \$333,047 in 2019. In the US, revenue decreased 49% to 12,267 in 2020 from \$23,926 in 2019. International revenue increased 93% to \$26,041 for 2020 from \$13,463 in 2019. The decrease in total revenue in 2020 is primarily attributed to the COVID-19 pandemic as most health care practitioners elected to temporarily close their practices and any purchasing decisions on temporary or permanent hold.

### Cost of sales

Cost of sales for the six-month period ended June 30, 2020 was \$230,095 which included a one-time provision for inventory of \$77,075 resulting in an adjusted cost of sales of \$153,020 or 52% of revenue with an adjusted gross margin of \$140,433 or 48% of revenue, compared to a cost of sales of \$267,644 or 72% of revenue in 2019, resulting in a gross margin of \$102,792 or 28% 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 decrease, as a percentage of sales, year over year, is attributed to decreased sales and fixed production salaries for the TLC-1000 and TLC-2000 product lines.

### Operating Expenses

For the six-month period ended June 30, 2020, selling expenses decreased to \$229,998, from \$344,501 in 2019, a 33% decrease and consisted of the following items:

	<b>2020</b>	<b>2019</b>
Sales salaries	\$ 132,156	\$ 202,152
Advertising	50,787	59,987
Commission	13,021	22,463
Travel	7,819	22,147
Stock based compensation	999	478
Amortization and depreciation allocation	25,216	37,274
<b>Total selling expenses</b>	<b>\$ 229,998</b>	<b>\$ 344,501</b>

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

Administrative expenses for the six-month period ended June 30, 2020 decreased to \$965,824 from \$1,062,087 in 2019, a 9% decrease and consisted of the following items:

	<b>2020</b>	<b>2019</b>
Insurance	\$ 19,598	\$ 24,455
Professional fees	253,834	163,913
Rent	18,803	21,884
General and administrative expenses	141,642	270,918
Administrative salaries	190,974	456,895
Director and advisory fees	36,840	30,889
Stock based compensation	279,024	47,503
Amortization and depreciation allocation	25,111	45,630
<b>Total administrative expenses</b>	<b>\$ 965,824</b>	<b>\$ 1,062,087</b>

The decrease in administrative expenses is primarily attributed to decreased spending on general and administrative expenses (48%) and administrative salaries (58%) due to the restructuring of the administrative department, resulting in the termination of certain administrative personnel.

### Research and Development Expense

Net research and development expenses for the six-month period ended June 30, 2020 increased to \$2,219,057 from \$1,303,375 in 2019, a 70% increase, and consisted of the following items:

	<b>2020</b>	<b>2019</b>
Research and development (net of investment tax credit)	\$ 1,922,623	\$ 1,254,317
Stock based compensation	234,345	7,376
Amortization and depreciation allocation	62,089	41,682
<b>Total research and development expenses</b>	<b>\$ 2,219,057</b>	<b>\$ 1,303,375</b>

Research and development expenses for the six-month period ended June 30, 2020 increased primarily due to increased expenses for operating Study II. Research and development expenses represented 67% of the Company's operating expenses for the six-month period ended June 30, 2020 and represent investment into the research and development of the Company's PDT technology.

### **Net Profit (Loss)**

The net loss for the six-month period ended June 30, 2020 was \$3,267,624 which included \$642,709 of net non-cash expenses (i.e.: amortization, stock-based compensation expense and foreign exchange gain/loss). This compared to a net loss for the same period in 2019 of \$2,612,268 which included \$194,361 of net non-cash expenses. The PDT division represented \$2,385,877 of this loss (73%) for the six-month period ended June 30, 2020.

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

- 1) Increased investment in the clinical expense of Study II.
- 2) Decreased sales of the TLC-1000 and TLC-2000 due to market uncertainty directly attributable to the COVID-19 pandemic.

### **Cash Flows**

Funds used in operating activities, prior to net changes in other operating items, amounted to \$2,624,915 for the six-month period ended June 30, 2020, compared to funds used in operating activities of \$2,417,907 in 2019. Funds used in operating activities, after taking into account net changes in other non-cash operating items were \$2,862,007 for the six-month period ended June 30, 2020, compared to funds used of \$2,757,439 for the same period in 2019. The increase is a result of additional expenses due to Study II.

Funds used in investing for the six-month period ended June 30, 2020 amounted to \$46,464 compared to \$28,859 for 2019. The increase is primarily a result of increased spending on equipment related to Study II.

Funds obtained from financing activities amounted to \$29,165 the six-month period ended June 30, 2020, compared to \$2,887,324 obtained in financing activities for 2019. The non-brokered private placement, which closed January 9, 2019 and the exercise of warrants are responsible for the funding activities in the six-month period ended June 30, 2019.

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

The Company holds essential and valuable intellectual property rights and assets, including: patents, trademarks, development and other related costs. The depreciated book value of these assets is \$5,125.

## Commitments

As of June 30, 2020, the Company's commitments consisted of the following:

	Total	2020	2021	2022	2023
Research Commitments (a)	\$ 58,520	\$ -	\$ 58,520	\$ -	-
Research Agreement (b)	91,695	30,565	30,565	30,565	-
Research Agreement (c)	341,370	341,370	-	-	-
Research Agreement (d)	89,600	67,200	22,400	-	-
<b>Total</b>	<b>\$ 581,185</b>	<b>\$ 439,135</b>	<b>\$ 111,485</b>	<b>\$ 30,565</b>	<b>-</b>

- a) Research Commitments under a research collaboration agreement with University Health Network (“UHN”) 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 (“TMO”) for Study II. Under the terms of this agreement, the Company is required to pay \$126,324 (USD \$96,800) for the period from July 23, 2019 through to December 31, 2022. The Company has paid \$34,629 (USD \$26,200) relating to this commitment, of which \$91,695 (USD \$70,600) is the remaining commitment.
- c) Research Commitments under a research agreement with Alphora Research Inc. for Study II. Under the terms of this agreement, the Company is required to pay \$939,000 for the period from September 27, 2019 through to October 31, 2020. The Company has paid \$597,360 relating to this commitment, of which \$341,370 is the remaining commitment.
- d) Research Commitments under a research collaboration agreement with UHN 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 \$95,189 relating to this commitment, of which \$89,600 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

The Company leases premises consisting of its office and manufacturing facilities. On adoption of IFRS 16, as of January 1, 2019, a liability of \$185,479 was established, representing the lease payments of \$58,075 in 2019, \$59,800 in 2020, \$59,800 in 2021 and \$44,850 in 2022, discounted using an incremental borrowing rate of 8.0%.

The Company leases office equipment. On adoption of IFRS 16, as of January 1, 2019, a liability of \$7,022 was established, representing the lease payments of \$2,160 in 2019, \$2,160 in 2020, \$2,160 in 2021 and \$1,980 in 2022, discounted using an incremental borrowing rate of 8.0%

	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	24,731	896	25,627
<b>Balance at June 30, 2019</b>	<b>\$ 160,748</b>	<b>\$ 6,126</b>	<b>\$ 166,874</b>
Balance at January 1, 2020	\$ 136,018	\$ 5,229	\$ 141,247
Depreciation charge for the period	24,731	896	25,627
<b>Balance at June 30, 2020</b>	<b>\$ 111,287</b>	<b>\$ 4,333</b>	<b>\$ 115,620</b>
<b>Lease Liabilities</b>			
Balance at January 1, 2019	\$ 185,479	\$ 7,022	\$ 192,501
Interest charge for the period	5,782	219	6,001
Lease payments for the period <sup>(1)</sup>	(28,750)	(1,080)	(29,830)
<b>Balance at June 30, 2019</b>	<b>\$ 162,511</b>	<b>\$ 6,161</b>	<b>\$ 168,672</b>
Balance at January 1, 2020	\$ 139,309	\$ 5,313	\$ 144,622
Interest charge for the period	5,163	198	5,361
Lease payments for the period <sup>(1)</sup>	(29,900)	(1,080)	(30,980)
<b>Balance at June 30, 2020</b>	<b>\$ 114,572</b>	<b>\$ 4,431</b>	<b>\$ 119,003</b>
Current portion of lease liabilities	\$ 52,533	\$ 1,873	\$ 54,406
Non-current portion of lease liabilities	\$ 62,039	\$ 2,558	\$ 64,597

(1) Lease payments does not include variable property lease payments of \$9,401 (2019-\$10,942).

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

	Property	Office Equipment	Total
2020	\$ 23,684	\$ 844	\$ 24,528
2021	52,294	1,864	54,158
2022	38,594	1,723	40,317
	<b>\$ 114,572</b>	<b>\$ 4,431</b>	<b>\$ 119,003</b>

### Share Capital Analysis

As of August 26, 2020, 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 August 26, 2020, there were 16,010,000 options outstanding, of which 3,373,333 were vested and exercisable into an equivalent number of the Company's common shares.

As of August 26, 2020, 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 \$0.375 until November 10, 2021, 3,165,009 at a price of \$0.50 until October 3, 2020, 4,095,157 at a price of \$0.50 until January 9, 2021, 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 August 26, 2020, 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; (1) PDT division and (2) MLT division. The PDT division is responsible for the research and development of PDCs for the treatment of cancer. The MLT division is responsible for the Company's medical laser business, which researches, develops, commercializes and manufactures lasers used by the PDT division to activate PDCs and researches, develops, manufactures and distributes therapeutic lasers to healthcare practitioners predominantly for the healing of pain.

The following table displays revenue and direct expenses from the PDT and MLT division for the six-month periods ended June 30:

	2020			2019		
	MLT	PDT	Total	MLT	PDT	Total
Sales	\$ 293,454	\$ -	\$ 293,454	\$ 370,436	\$ -	\$ 370,436
Cost of sales	230,095	-	230,095	267,644	-	267,644
Gross margin	63,359	-	63,359	102,792	-	102,792
<b>Operating Expenses</b>						
Selling expenses	229,998	-	229,998	344,501	-	344,501
Administrative expenses	590,902	374,922	965,824	692,236	369,851	1,062,087
Research and development expenses	209,154	2,009,903	2,219,057	217,721	1,085,654	1,303,375
(Gain) loss on foreign exchange	(1,631)	(1,630)	(3,261)	4,209	4,208	8,417
Interest expense	2,681	2,681	5,362	6,001	-	6,001
Interest income	(85,997)	-	(85,997)	(9,321)	-	(9,321)
	945,108	2,385,876	3,330,983	1,255,347	1,459,713	2,715,060
Loss for the period	\$ (881,749)	\$ (2,385,876)	\$ (3,267,624)	\$ (1,152,555)	\$ (1,459,713)	\$ (2,612,268)
Total Assets	\$ 3,552,358	\$ 8,413,293	\$ 11,965,651	\$ 3,650,696	\$ 182,129	\$ 3,832,825
Total Liabilities	637,726	229,283	867,009	1,034,486	244,062	1,278,548

The following table displays revenue and direct expenses from TLT division product sales by product line and geographic area for the six-month periods ended June 30:

	2020			2019		
	Canada	USA	International	Canada	USA	International
<b>Sales by Product Line</b>						
TLC-1000	\$ 161,073	\$ 12,267	\$ 7,347	\$ 164,121	\$ 5,075	\$ 13,463
TLC-2000	94,073	-	\$ 18,694	168,926	18,851	-
	255,146	12,267	26,041	333,047	23,926	13,463
<b>Expenses</b>						
Cost of Sales	200,058	9,619	20,418	240,630	17,287	9,727
Selling Expenses	195,081	23,745	11,172	338,846	5,655	-
	395,139	33,364	31,590	579,476	22,942	9,727
	\$ (139,993)	\$ (21,097)	\$ (5,549)	\$ (246,429)	\$ 984	\$ 3,736

As at June 30, 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 unaudited condensed interim consolidated financial statements for the six-month period ended June 30, 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, 2019. 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 at June 30, 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 accounts receivable. The amounts reported in the condensed interim consolidated balance sheets are net of allowances for bad debts, 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 doubtful accounts 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.

Cash equivalents are held in high-grade, bankers' acceptance and other low risk investments with no exposure to liquidity or other risk associated with Asset-Backed Securities. These financial instruments are classified as held for trading as they may periodically be traded before their maturity date; however, the majority of these financial instruments are classified as held to maturity and would not result in a significant risk of fair value changes if held to maturity. As of June 30, 2020, no cash equivalents were held (2019-\$Nil).

(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. The Company is subject to interest rate risk on its cash; however, it does not expect a movement in interest rates to have a significant impact on the Company's financial position.

(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 condensed interim consolidated financial statements as of June 30, 2020 and 2019 and for the six-month periods ended June 30, 2020 and 2019 have been prepared in accordance with IFRS. The policies applied are based on IFRS issued and outstanding as of August 26, 2020 which is the date at which the Company's Board of Directors approved the unaudited condensed interim consolidated financial statements.

Additionally, the preparation of interim 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 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 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, 2019 and 2018 and for the years ended December 31, 2019 and 2018.

### **Disclosure of Internal Controls**

Management has established process 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 audited consolidated financial statements for the years ended December 31, 2019 and 2018, 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 June 30, 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 relates 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 August 26, 2020, the Company is aware of significant changes in its business as a result of COVID-19, notably unavailability of personnel, personnel working remotely or virtually 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 as of the date of this report.

### **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 affect 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 affect 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 affect 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 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 counter-party 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.

August 26, 2020

Kristina Hachey  
Chief Financial Officer