

# 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 Company's unaudited condensed interim consolidated financial statements for the nine-month period ended September 30, 2019. 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 November 29, 2019.

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, as well as 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 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 cancer. 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.

## **Advancing the Theralase Technology Platform**

On October 31, 2019, Kipton Lade, Chief Executive Officer – Device Division, departed the employ of the Company and Shawn Shirazi, Ph.D., Chief Executive Officer - Drug Division, was appointed the sole CEO of the Company.

Dr. Shirazi, obtained his B.Sc. in Chemistry from York University (Toronto, Ontario, Canada) and a M.Sc. and Ph.D. in Pharmacology from the University of Ottawa (Ottawa, Ontario, Canada).

Dr. Shirazi possesses 20 years of hands-on experience in: pharmaceutical drug formulation and development, clinical study management, Good Manufacturing Practices (“GMP”) international drug manufacture, international regulatory guidelines and quality assurance in GMP drug manufacture. He has held senior roles with both start-ups and large pharmaceutical organizations, including: Executive Director and Vice President of Research and Development for Torpharm Inc (Division of Apotex), Senior Director Global Research and Development of Perrigo Company (NYSE: PRGO) and Chief Operating Officer – North America for *Daxinganling Lingonberry Boreal Biotech Co. Ltd.* (leading manufacturer of high quality plant extracts, based in China), During his career, Dr. Shirazi has led the generic drug development programs for numerous pharmaceutical organizations, resulting in multiple “First To File” drug applications, allowing product exclusivity, as well as global leadership of research and development and merger and acquisition portfolios.

## **Non-Brokered Private Placement**

On January 9, 2019, the Company closed a non-brokered private placement of Units, issuing an aggregate of 4,095,157 Units at a price of \$0.35 per unit for aggregate gross proceeds of approximately \$1,433,305. Each Unit consisted of one common share of the Company and one non-transferable common share purchase warrant. Each warrant entitles the holder to acquire an additional Common Share at a price of \$0.50 for a period of 24 months following the date of issuance. An aggregate of 542,857 units, representing gross proceeds of \$190,000, were issued to certain insiders of the Company.

## **Oversubscribed Public Offering**

On August 22, 2019, the Company closed an oversubscribed public offering of Units, under a Short Form Prospectus. On closing, the Corporation issued an aggregate of 57,500,000 Units at a price of \$0.30 per Unit for aggregate gross proceeds of approximately \$17,250,000. Each Unit consisted of one common share of the Company and one common share purchase warrant. Each warrant entitles the holder to acquire an additional Common Share at a price of \$0.35 for a period of 60 months following the date of closing.

The Company has allocated the proceeds of the public offering as follows:

- Research, development and clinical study expenses of the Phase II Non-Muscle Invasive Bladder Cancer (“**NMIBC**” Clinical Study (“**Study II**”))
- TLC-2000 rework costs;
- Working capital and general corporate purposes.

### **Anti- Cancer Technology**

The Company’s primary focus is the Anti-Cancer Technology (“**ACT**”) Division, with the primary objective of the preclinical and clinical research and development of PDCs and the laser light systems that activate them, intended for the destruction of specific cancers.

Theralase’s study drug, TLD-1433, is used in a soluble form for the treatment of NMIBC. In addition, it is able to bind with endogenous transferrin, a human glycoprotein allowing localization to cancer cells, which generally have more transferrin receptors versus healthy cells. When laser light activated, it 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 high-risk, Bacillus Calmette-Guerin (“**BCG**”) -Unresponsive patients diagnosed with NMIBC.

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

Theralase’s NMIBC Study successfully achieved the primary endpoint of safety and tolerability, secondary endpoint of pharmacokinetics, and exploratory endpoint of efficacy. The Study results demonstrated 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 cancer-free status with no presence, recurrence or progression of the disease, 540 days post treatment.

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

The Phase II NMIBC Clinical Study (“**Study II**”) utilizes the Therapeutic Dose (0.70 mg/cm<sup>2</sup>) of TLD-1433, focusing 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 has granted the Company Investigational Testing Authorization (“**ITA**”) approval (December 2018) to utilize its TLC-3200 Medical Laser System, in conjunction with its Clinical Trial Application (“**CTA**”) approved lead PDC, TLD-1433 (November 2018 amended June 2019), 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. On

April 25, 2019 the University Health Network Research Ethics Board (“UHN-REB”) approved the commencement of Study II.

On October 1, 2019, the Company filed an Investigational New Drug (“IND”) application with the U.S. Food and Drug Administration (“FDA”). In June 2019, a conference call with the FDA confirmed that the Company’s clinical protocol of Study II met FDA Guidance for Industry dated February 2018 on “BCG-Unresponsive Non-Muscle Invasive Bladder Cancer: Developing Drugs and Biologics for Treatment”. On November 25, 2019, Theralase received a letter from the FDA placing the IND on Full Clinical Hold pending resolution of specific deficiencies identified in the letter. Theralase is currently addressing these deficiencies and expects to provide the FDA with a Clinical Hold Complete Response prior to December 31, 2019 for review by the FDA. Subject to FDA review and approval of the Clinical Hold Complete Response, Theralase should be in a position to receive FDA IND approval in early 2020.

The Company has three sites open for patient enrollment and treatment; specifically, University Health Network (“UHN”), McGill University Health Centre (“MUHC”) and London Health Sciences Centre (“LHSC”). All sites are actively recruiting and screening new patients for enrollment in Study II. To date, 4 patients have been treated at UHN and 1 patient treated at MUHC.

The Company has identified three additional clinical study sites located in Canada and are at various stages of the on-boarding process. The Company is specifically targeting strategic clinical sites throughout Canada and the US (subject to FDA Investigational New Drug (“IND”) approval) that serve large populations able to support patient enrollment and treatment. The Company anticipates that patient enrollment and treatment will escalate as it launches additional clinical study sites.

When the Phase II NMIBC clinical study is well underway with the majority of the approximately 20 study sites open and recruiting patients, the Company expects to expand the breadth of indications by investigating an additional cancer indication in a Phase Ib clinical study.

The ACT division is currently under clinical development 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 from regulatory approval(s), but may vary significantly depending on numerous factors including: number of onboarded oncology study sites, oncology study site patient enrollment rates, patient compliance, treatment success and/or successful achievement of clinical Study II endpoints.

### **Overview of Financial Performance**

During the nine-month period ended September 30, 2019 under review, 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 Annual Information

(expressed in Canadian Dollars)

For the years ended December 31:

	2018		2017		2016	
Total revenues	\$	1,734,072	\$	2,342,508	\$	1,918,893
Net loss		(3,356,877)		(6,093,596)		(4,921,288)
Basic and diluted loss per share	\$	(0.026)	\$	(0.049)	\$	(0.049)
Total assets	\$	3,564,419	\$	3,322,707	\$	6,240,783
Total liabilities		2,565,780		1,277,142		549,742
Deficit		(35,238,240)		(31,881,363)		(25,787,767)
Shareholders' Equity	\$	998,639	\$	2,045,565	\$	5,691,041

## Summary of Quarterly Results

(expressed in Canadian Dollars)

	2019							
	Sept 30		June 30		March 31			
<b>For the period ending:</b>								
Total revenues	\$	144,455	\$	249,257	\$	121,179		
Net loss		(1,786,777)		(1,486,797)		(1,125,471)		
Basic and diluted loss per share	\$	(0.01)	\$	(0.01)	\$	(0.01)		
<b>As at:</b>								
Total assets	\$	17,557,553	\$	3,832,825	\$	4,282,441		
Total liabilities		947,522		1,278,548		1,149,643		
Deficit		(39,637,285)		(37,850,508)		(36,363,711)		
Shareholders' Equity	\$	16,610,031	\$	2,554,277	\$	3,132,798		
	2018							
	December 31		September 30		June 30		March 31	
<b>For the period ending:</b>								
Total revenues	\$	457,442	\$	365,940	\$	469,497	\$	441,193
Net loss		(744,709)		(722,817)		(885,283)		(1,004,068)
Basic and diluted loss per share	\$	(0.00)	\$	(0.01)	\$	(0.01)	\$	(0.01)
<b>As at:</b>								
Total assets	\$	3,564,419	\$	3,147,237	\$	2,675,199	\$	2,865,364
Total liabilities		2,565,780		2,590,262		1,460,411		1,843,450
Deficit		(35,238,240)		(34,493,531)		(33,770,714)		(32,885,431)
Shareholders' Equity	\$	998,639	\$	556,975	\$	1,214,788	\$	1,021,914

## Liquidity and Capital Resources

As of September 30, 2019, current assets aggregated to \$16,712,454 compared with current liabilities of \$850,128 netting working capital of \$15,862,326 and a current ratio (current assets vs. current liabilities) of approximately 21:1.

The company closed a public offering of Units for gross proceeds of \$17,250,000 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 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 September 30, 2019, the Company had cash and cash equivalents of \$14,975,634. 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>2019</b>	<b>2018</b>
Sales Revenue	\$ 446,168	\$ 1,190,131
Service Revenue	47,084	52,179
Clinic Revenue	6,123	6,728
Other Revenue	15,516	27,592
	<b>\$ 514,891</b>	<b>\$ 1,276,630</b>

For the nine-month period ended September 30, 2019, total revenue decreased to \$446,168 from \$1,190,131 for the same period in 2018, a 63% decrease. In Canada, revenue decreased 44% to \$477,502 from \$847,870. In the US, revenue decreased 91% to \$23,926 from \$253,742 and international revenue decreased 92% to \$13,463 from \$175,018. The decrease in total revenue in 2019 is due to the restructuring of the sales and marketing departments resulting in the termination of certain sales and marketing personnel.

### Cost of sales

Cost of sales for the nine-month period ended September 30, 2019 was \$374,040 (73% of revenue) resulting in a gross margin of \$140,851 or 27% of revenue, compared to a cost of sales of \$559,296 (44% of revenue) in 2018, resulting in a gross margin of \$717,334 or 56% 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 as a percentage of sales decrease, 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 nine-month period ended September 30, 2019, selling and marketing expenses decreased to \$505,914 or 98% of revenues, from \$673,814 or 53% of revenues in 2018, a 25% decrease and consisted of the following items:

	<b>2019</b>	<b>2018</b>
Sales salaries	\$ 303,150	\$ 461,191
Advertising	74,655	67,011
Commission	30,185	56,274
Travel	40,104	38,432
Stock based compensation	988	816
Amortization and depreciation allocation	56,832	50,090
<b>Total selling expenses</b>	<b>\$ 505,914</b>	<b>\$ 673,814</b>

The decrease in selling and marketing expenses is primarily due to the restructuring of the Canadian and US sales and marketing departments, resulting in the termination of certain sales and marketing personnel.

Administrative expenses for the nine-month period ended September 30, 2019 increased to \$1,798,682 from \$1,400,207 in 2018, representing a 28% increase, and consisted of the following items:

	<b>2019</b>	<b>2018</b>
Insurance	\$ 36,688	\$ 33,270
Professional fees	236,649	365,592
Rent	32,827	74,296
General and administrative expenses	348,151	333,670
Administrative salaries	838,088	449,121
Director and advisory fees	116,742	27,879
Stock based compensation	120,566	92,621
Amortization and depreciation allocation	68,971	23,758
<b>Total administrative expenses</b>	<b>\$ 1,798,682</b>	<b>\$ 1,400,207</b>

The increase in administrative expenses is attributed to increased spending on administrative salaries (87%) and director and advisory fees (319%)

#### Research and Development Expense

Net research and development expenses for the nine-month period ended September 30, 2019 increased to \$2,231,054 from \$1,266,839 in 2018, a 76% increase, and consisted of the following items:

	<b>2019</b>	<b>2018</b>
Research and development (net of investment tax credit)	\$ 2,155,137	\$ 1,156,650
Stock based compensation	12,731	19,693
Amortization and depreciation allocation	63,186	90,496
<b>Total research and development expenses</b>	<b>\$ 2,231,054</b>	<b>\$ 1,266,839</b>

Research and development expenses for the nine-month period ended September 30, 2019 increased primarily due to increased expenses for commencing the Study II. As of March 25, 2019, the Company has recommenced development of the TLC-2000 laser system. Research and development expenses represented 58% of the Company's operating expenses for the nine-month period ended September 30, 2019 and represent investment into the research and development of the Company's ACT technology.

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

The net loss for the nine-month period ended September 30, 2019 was \$4,399,045 which included \$331,830 of net non-cash expenses (i.e.: amortization, stock-based compensation expense, foreign exchange gain/loss and

lease inducements). This compared to a net loss for the same period in 2018 of \$2,612,168, which included \$155,265 of net non-cash expenses. The ACT division represented \$2,558,002 of this loss (58%) for the nine-month period ended September 30, 2019.

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

- 1) Increased investment in research, development and clinical expense of Study II.
- 2) Decreased sales of the TLC-1000 and TLC-2000.

## Cash Flows

Funds used in operating activities, prior to net changes in other operating items, amounted to \$4,067,215 for the nine-month period ended September 30, 2019, compared to funds used in operating activities of \$2,333,981 in 2018. Funds used in operating activities after taking into account net changes in other non-cash operating items were \$4,655,818 for the nine-month period ended September 30, 2019, compared to funds used of \$644,538 for the same period in 2018. The increase is primarily a result of investor deposits received in 2018 of \$1,201,396 for the January 9, 2019 private placement.

Funds used in investing for the nine-month period ended September 30, 2019 amounted to \$41,556 compared to \$120,108 for 2018. The decrease is primarily a result of decreased spending on tools, dies and equipment related to the TLC-3200 Medical Laser System technology.

Funds obtained from financing activities amounted to \$18,639,039 for the nine-month period ended September 30, 2019, compared to \$1,010,448 obtained in financing activities for 2018. The non-brokered private placement, which closed January 9, 2019, short form prospectus public offering, which closed August 22, 2019, and 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. The depreciated book value of these assets is \$7,703.

## Commitments

As of September 30, 2019, the Company's commitments consisted of the following:

	Total	2019	2020	2021	2022	2023
Lease obligations (a)	\$ 179,400	\$ 14,950	\$ 59,800	\$ 59,800	\$ 44,850	-
Lease obligations (b)	\$ 6,840	\$ 540	\$ 2,160	\$ 2,160	\$ 1,980	-
Research Commitments (c)	\$ 117,040	\$ -	\$ 58,520	\$ 58,520	\$ -	-
Research Agreement (d)	\$ 8,400	\$ 8,400	\$ -	\$ -	\$ -	-
Research Agreement (e)	\$ 93,496		\$ 31,165	\$ 31,165	\$ 31,165	-
Research Agreement (f)	\$ 1,000,000	250,000	\$ 750,000	-	-	-
<b>Total</b>	<b>\$ 1,405,176</b>	<b>\$ 273,890</b>	<b>\$ 901,645</b>	<b>\$ 151,645</b>	<b>\$ 77,995</b>	<b>-</b>

- a) Lease obligations under a lease agreement related to the Company's premises, commenced on October 1, 2017 and expires on September 30, 2022. Under the terms of this lease, the Company is required to pay a proportionate share of operating costs, realty taxes and utilities, in addition to the minimum rental payments. The future minimum lease payments are shown in the table above.

- b) Lease obligations under a lease agreement related to the Company's office equipment, commenced on May 1, 2017 and expires on November 1, 2022. The future minimum lease payments are shown in the table above.
- c) Research Commitments under a research collaboration agreement with University Health Network for the Ontario Research Fund therapy 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 \$231,560 relating to this commitment, in which \$117,040 is the remaining commitment.
- d) Research Commitments under a sponsored research agreement with University Health Network for the TLC-3000 cancer therapy project. Under the terms of this agreement, the Company is required to pay \$128,800 for the period from November 1, 2018 through to October 31, 2019. The Company has paid \$120,400 relating to this commitment, in which \$8,400 is the remaining commitment.
- e) 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 USD\$96,800 for the period from July 23, 2019 through to December 31, 2022. The Company has paid USD\$26,200 relating to this commitment, in which USD\$70,600 is the remaining commitment.
- f) 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 \$1,000,000 for the period from September 27, 2019 through to April 30, 2020.

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.

### **Share Capital Analysis**

As of November 29, 2019, the share capital of the Company consisted of 204,275,375 common shares. Each common share entitles the holder to one vote per share.

As of November 29, 2019, there were 16,840,000 options outstanding, of which 4,470,000 were vested and exercisable into an equivalent number of the Company's common shares.

As of November 29, 2019, there were 91,546,372 warrants outstanding. Each whole warrant entitles the holder thereof to purchase one additional common share. The warrants are exercisable as follows: 19,071,940 at a price of \$0.54 until March 3, 2020, 4,555,266 at a price \$0.375 until November 10, 2021, 3,159,000 at a price of \$0.30 until May 14, 2020, 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 and 57,500,000 at a price of \$0.30 until August 22, 2024.

### **Segmented Information**

For management purposes, the Company is organized into two separate reportable operating divisions; (1) ACT division and (2) MLT division. The ACT 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 ACT division to activate PDCs and researches, develops, manufactures and distributes therapeutic laser to healthcare practitioners predominantly for the healing of pain.

The following table displays revenue and direct expenses from the ACT and MLT division for the nine-month periods ended September 30, 2019 and 2018:

	2019			2018		
	MLT	ACT	Total	MLT	ACT	Total
Sales	\$ 514,891	\$ -	\$ 514,891	\$ 1,276,630	\$ -	\$ 1,276,630
Cost of Sales	374,040	-	374,040	559,296	-	559,296
Gross Margin	140,851	-	140,851	717,334	-	717,334
<b>Operating Expenses</b>						
Selling expenses	505,914	-	505,914	673,814	-	673,814
Administrative expenses	1,079,360	719,322	1,798,682	848,373	551,834	1,400,207
Research and development expenses	401,511	1,829,543	2,231,054	282,562	984,277	1,266,839
Loss on foreign exchange	4,488	4,488	8,976	776	777	1,553
Interest expense	4,649	4,649	9,298	331	331	662
Interest income	(14,028)	-	(14,028)	(13,573)	-	(13,573)
	1,981,894	2,558,002	4,539,896	1,792,283	1,537,219	3,329,502
Loss for the period	\$ (1,841,043)	\$ (2,558,002)	\$ (4,399,045)	\$ (1,074,949)	\$ (1,537,219)	\$ (2,612,168)
Total Assets	\$ 17,336,488	\$ 221,065	\$ 17,557,553	\$ 2,189,590	\$ 221,793	\$ 2,411,383
Total Liabilities	769,019	178,503	947,522	2,199,120	391,142	2,590,262

The following table displays revenue and direct expenses from MLT division product sales by geographic area for the nine-month periods ended September 30, 2019 and 2018:

	2019			2018		
	Canada	USA	International	Canada	USA	International
Sales	\$ 477,502	\$ 23,926	\$ 13,463	\$ 847,870	\$ 253,742	\$ 175,018
Cost of Sales	346,879	17,381	9,780	378,139	100,488	80,669
Selling Expenses	500,259	5,655	-	473,326	84,766	115,722
	\$ (369,636)	\$ 890	\$ 3,683	\$ (3,595)	\$ 68,488	\$ (21,373)

As of September 30, 2019, and December 31, 2018, the Company's long-lived assets used in operations are all located in Canada.

## Selected Financial Information and Accounting Policies

The unaudited condensed interim consolidated financial statements for the six-month period ended June 30, 2019, 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, 2018. 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 September 30, 2019 and December 31, 2018, 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 September 30, 2019, no cash equivalents were held (2018-\$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 unaudited condensed interim consolidated financial statements as of September 30, 2019 and 2018 and for the nine-month period ended September 30, 2019 and 2018 have been prepared in accordance with IFRS.

The policies applied in the unaudited condensed interim consolidated financial statements as of September 30, 2019 and 2018 and for the nine-month period ended September 30, 2019 and 2018 are based on IFRS issued and outstanding as of November 29, 2019 which is the date at which the Company's Board of Directors approved the audited condensed consolidated financial statements.

Additionally, the preparation of audited 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, 2018 and 2017 and for the years ended December 31, 2018 and 2017.

### **Adoption of New Accounting Standards**

On January 1, 2019, the Company implemented *IFRS 16, Leases* ("*IFRS 16*"). The impact of implementation of IFRS 16 is described below.

***IFRS 16, Leases*** ("***IFRS 16***") was issued in January 2016 and specifies how to recognize, measure, present and disclose leases. The standard provides a single lease accounting model, requiring the recognition of assets and liabilities for all leases, unless the lease term is 12 months or less or the underlying asset has a low value. Lessor accounting; however, remains largely unchanged from IAS 17 and the distinction between operating and finance leases is retained. The standard will affect primarily the accounting for the Company's operating leases. This will result in additional right-to-use assets, as well as lease liabilities. The standard is effective for annual periods beginning on or after January 1, 2019 and the Company is required to apply IFRS 16 to all contracts that are not complete on the date of initial application. The Company applied the modified retrospective approach to remaining lease payments as at January 1, 2019, without restatement of comparative figures presented for 2018 as previously reported under IAS 17. Upon the initial application as of January 1, 2019, a right of use asset and lease liability was recorded with respect to the Company's leased premises, with no net impact on retained earnings. As this lease was previously classified as an operating lease under IAS 17, the lease liability has been measured at the present value of the remaining lease payments, discounted using the incremental borrowing

rate as at the date of initial application. Additionally, the right of use asset has been measured at an amount equal to the lease liability. The result of the initial application of IFRS 16 on January 1, 2019 was to record a right of use asset of \$181,042 and a lease liability of \$181,042. When measuring the lease liability, the Company discounted the remaining lease payments (the operating lease commitments as of December 31, 2018 of \$226,013), using its incremental borrowing rate, estimated to be 8%.

## **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, 2018 and 2017, 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 September 30, 2019. 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 the it's financial results accurately, prevent fraud or file the it's 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.

### **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 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 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.

November 29, 2019

Kristina Hachey  
Chief Financial Officer