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

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, 2018. 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 may also be referenced on the regulatory website at www.sedar.com. This MD&A is prepared as of November 28<sup>th</sup>, 2018.

The Company's common shares are listed for trading on the TSX Venture Exchange (Symbol: TLT).

# 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") within the meaning of applicable securities laws. Forward-looking statements 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. Forward-looking statements, 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.

Although the Company believes that the expectations reflected in such forward-looking statements are reasonable, such statements involve risks and uncertainties that may cause actual results or events to differ materially from those anticipated and no assurance can be given that these expectations will be realized and undue reliance should not be placed on such statements. Risk factors that could cause actual results or events to differ materially from the forward-looking statements include, without limitation: (i) the inherent uncertainty involved in scientific research, device or drug development, including with respect to costs and difficulties in predicting accurate timelines for the commencement or completion of certain activities; (ii) the risks associated with delay or inability to complete preclinical or clinical studies successfully and the long lead-times and high costs associated with obtaining regulatory approval to market any device or drug, which may result from successful completion of such studies; (iii) need to secure additional financing on terms satisfactory to the Company or at all; (iv) clinical studies that yield negative results or results that do not justify future clinical development, (v) the Company's clinical development plan for its clinical studies does not proceed in the manner or on the timelines anticipated by the Company or at all; and (vi) those risks and uncertainties affecting the Company as more fully described in this MD&A under the heading "Risk and Uncertainties". Certain material factors and assumptions are applied in making the forward-looking statements; including, without limitation, that the risk factors will not cause the Company's actual results or events to differ materially from the forward-looking statements.

Furthermore, the forward-looking statements contained in this MD&A are made as of the date hereof and the Company does not undertake any obligations to update publicly or to revise any of the included forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law. The forward-looking statements contained in this MD&A are expressly qualified by this cautionary statement.

# **Company Profile**

Theralase® is a clinical stage pharmaceutical company dedicated to the research and development of light activated Photo Dynamic Compounds ("PDCs") and their associated drug formulations and technology platforms intended to safely and effectively treat cancer. The Company in its Therapeutic Laser Division designs, manufactures and distributes patented and proprietary super-pulsed cool laser technology for the treatment of knee pain, and in off-label use, the treatment of numerous nerve, muscle and joint conditions.

# Advancing the Theralase Technology Platform

#### **Non-Brokered Private Placement**

On May 14, 2018 the Company closed a non-brokered private placement of Units, issuing an aggregate of 5,104,000 Units at a price of \$0.20 per Unit for aggregate gross proceeds of approximately \$1,020,800. Each Unit consisted of one common share of the Company and one non-transferable common share purchase warrant (each, a "Warrant"). Each Warrant entitles the holder to acquire an additional Common Share at a price of \$0.30 for a period of 24 months following the date of issuance. An aggregate of 750,000 Units representing gross proceeds of \$150,000 were issued to certain insiders of the Corporation.

On October 3, 2018 the Company closed a non-brokered private placement of Units, issuing an aggregate of 3,157,059 units at a price of \$0.35 per Unit for aggregate gross proceeds of approximately \$1,104,970. Each Unit consists of one common share of the Company and one non-transferable common share purchase warrant (each, a "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 920,000 Units representing gross proceeds of \$322,000 were issued to certain insiders of the Corporation.

#### **Anti- Cancer Therapy**

On May 19, 2018, Theralase's Medical and Scientific Advisory Board ("MSAB") was convened to examine the clinical results obtained on the first six patients enrolled and treated in the Phase IB Non-Muscle Invasive Bladder Cancer ("NMIBC") Clinical Study ("Study") utilizing TLD-1433-based Photo Dynamic Therapy ("PDT"); specifically evaluating: the primary endpoint of safety and tolerability, the secondary endpoint of pharmacokinetics (movement and exit of drug within tissue) and the exploratory endpoint of efficacy primarily at 90 days and secondarily at 180 days.

The MSAB is comprised of leading experts in bladder cancer and science that have been retained by the Company to provide advice and strategic guidance on the research, development and commercialization of the TLD-1433-based PDT technology in the treatment of patients inflicted with NMIBC.

On May 30, 2018 the Company announced "Theralase Successfully Completes the Phase Ib Non-Muscle Invasive Bladder Cancer Clinical Study." Theralase's MSAB concluded that the Phase Ib NMIBC Clinical Study had achieved its objectives.

After reviewing the clinical data presented by Girish Kulkarni, MD, PhD, FRCSC, an Associate Professor at the University of Toronto, Department of Surgery and the Principal Investigator of the Study, the MSAB unanimously recommended the early termination of the Study due to achievement of the primary and secondary endpoints. The MSAB also recommended that the clinical data collected from the first three patients treated at the Maximum Recommended Starting Dose ("MRSD") (0.35 mg/cm²) and the three patients treated at the Therapeutic Dose (0.70 mg/cm²) were sufficient to support the conclusion that the Study had successfully achieved the Study's primary and secondary endpoints and had adequately addressed the Study's scientific, technical and clinical questions, as per the approved Study design and clinical protocol. The MSAB recommendation to the Company was to terminate the Study based on the six patients treated to date and suggested that the Company pursue a pivotal Phase II NMIBC clinical study approval with Health Canada and the FDA with efficacy as the primary endpoint.

On July 16, 2018, the Company announced "Theralase Demonstrates Anti-Cancer Technology Prevents Recurrence of Bladder Cancer at 180 Days Post-Treatment. Patient Five Demonstrates No Clinical Evidence of NMIBC at 180 Day Cystoscopy Analysis".

On August 13, 2018, the Company announced "Theralase Achieves Exploratory Efficacy Endpoint in Phase Ib Non Muscle Invasive Bladder Cancer Clinical Study for Patients Five and Six, Patient Five and Six Demonstrate No Clinical Evidence of NMIBC at 180 Day Cystoscopy Analysis". Both patients were treated with the optimized clinical treatment procedure. The treatment was well tolerated by both patients, who demonstrated no tumour recurrence or presence of disease at the 180 day clinical and cystoscopy assessment. The patients have met Study endpoints demonstrating achievement of the primary, secondary and exploratory endpoints at 180 days post treatment and marked a new achievement for the Company.

On September 10, 2018 the Company announced that "Health Canada Approves Commencement of Phase II Clinical Study". Study II titled, "A Phase II Clinical Study of Intravesical Photo Dynamic Therapy in Patients with BCG-Unresponsive Non-Muscle Invasive Bladder Cancer or Patients Who are Intolerant to BCG Therapy" will utilize the Therapeutic Dose (0.70 mg/cm²) of TLD-1433 and will focus on the treatment of approximately 100 NMIBC patients in approximately 20 clinical sites located in Canada, the US and internationally, with a primary endpoint of efficacy, subject to Health Canada approval of the Study Device and the respective oncology centers Review Ethics Board ("REB") approval.

On November 8, 2018, the Company announced "Theralase Provides Update on 9 months Post Treatment Cystoscopy Analysis - Patient Five Cancer-Free After Single PDT Treatment." The treatment was well tolerated by the patient, who demonstrated no tumour recurrence or presence of disease at the 270 day clinical and cystoscopy assessment. The patient has met Study endpoints demonstrating achievement of the primary, secondary and exploratory endpoints at 270 days post treatment and marks a new achievement for the Company.

Oncology sites will be launched in Canada, pending Health Canada Approval (ITA & UHN REB pending), in the US, pending Food and Drug Administration approval, and internationally, pending international regulatory approval.

The primary endpoint of the Study II design will be:

**Efficacy** - Evaluated by Complete Response ("**CR**") in patients with Carcinoma In-Situ ("**CIS**") with or without resected papillary disease at 90 days post-treatment with duration of CR evaluated at 360 days post-treatment.

Patient CR is defined as at least one of the following:

- 1) Negative cystoscopy and negative (including atypical) urine cytology
- 2) Positive cystoscopy with biopsy-proven benign or low-grade NMIBC
- 3) Negative cystoscopy with malignant urine cytology, if cancer is found in the upper tract or prostatic urethra and random bladder biopsies are negative

The secondary endpoint of the Study design will be:

**Safety** - Evaluated by the incidence and severity of Adverse Events ("**AEs**") Grade 4 or higher that do not resolve within 360 days post-treatment; whereby:

Grade 1 = Mild

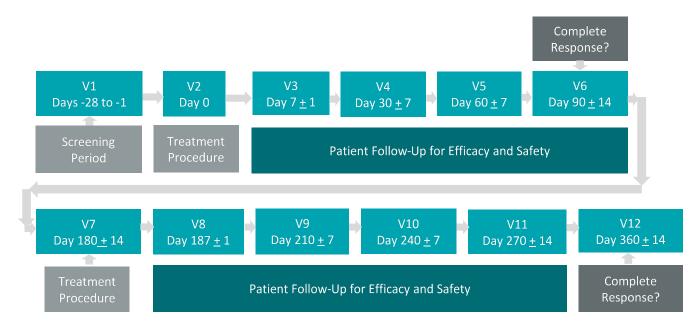
Grade 2 = Moderate

Grade 3 = Severe

Grade 4 = Life-threatening or disabling

Grade 5 = Death

# **Proposed Clinical Treatment Plan:**



#### **Overview of Financial Performance**

During the nine-month period ended September 30th, 2018 under review, the Company's financial performance and its operating results reflected the continued investment by the Company into its future prosperity through research and development initiatives culminating in the successful completion of the Phase Ib NMIBC clinical study.

# Summary of Selected Annual Information

For the years ended December 31:

	2017		2016	2015		
Total revenues Net loss	\$ 2,342,508	\$	,,	\$	1,945,246	
Basic and diluted loss per share	\$ (6,093,596) \$ (0.05)		(4,921,248) (0.05)	\$	(5,208,145) (0.05)	
Total assets	\$ 3,322,707	\$	-, -,	\$	7,102,123	
Total liabilities Deficit	1,277,142 (31,881,363)		549,742 (25,787,767)		785,664 (20,866,519)	
Shareholders' Equity	\$ 2,045,565	\$	5,691,041	\$	6,316,459	

# **Summary of Quarterly Results**

				2040							
	2018										
For the period ending:		March 31		June 30	30-Sep						
Total revenues	\$	441,193	\$	469,497	\$	365,940					
Net loss		(1,004,068)		(885,283)		(722,817)					
Basic and diluted loss per share	\$	(0.008)	\$	(0.007)	\$	(0.006)					
Acab		Namel 24		l 20		20.6					

As at:	 March 31	June 30	30-Sep		
Total assets	\$ 2,865,364 \$	2,675,199 \$	3,147,237		
Total liabilities	1,843,450	1,460,411	2,590,263		
Deficit	(32,885,431)	(33,770,714)	(34,493,531)		
Shareholders' Equity	\$ 1,021,914 \$	1,214,788 \$	556,974		

		2017										
For the period ending:		March 31		June 30	September 30			December 31				
Total revenues	\$	507,428	\$	509,306	\$	337,520	\$	988,254				
Net loss		(1,472,184)		(1,765,840)		(1,655,749)		(1,199,823)				
Basic and diluted loss per share	\$	(0.014)	\$	(0.014)	\$	(0.014)	\$	(0.007)				
As at:		March 31		June 30	S	eptember 30		December 31				
Total assets	Ś	4.821.300	Ś	4.382.203	Ś	3.626.255	Ś	3.322.707				

As at:	March 31	June 30	 September 30	December 31		
Total assets	\$ 4,821,300	\$	4,382,203	\$ 3,626,255	\$	3,322,707
Total liabilities	518,032		592,622	520,388		1,277,142
Deficit	(27,259,951)		(29,025,790)	(30,681,538)		(31,881,363)
Shareholders' Equity	\$ 4,303,268	\$	3,789,581	\$ 3,105,867	\$	2,045,565

For the three-month period ended September 30, 2018 total revenue increased to \$365,940 from \$337,520 for the same period in 2017, an 8% increase. The increase in revenues is attributed to an increase in international sales to \$50,065 from \$nil for the same period in 2017.

Cost of sales for the three-month period ended September 30, 2018 was \$126,975 (35% of revenue) resulting in a gross margin of \$238,965 or 65% of revenue, compared to a cost of sales of \$164,153 (49% of revenue) in 2017, resulting in a gross margin of \$173,367 or 51% of revenue. The cost of sales decrease, year over year, is attributed to slightly increased revenues, while fixed costs remained constant and the termination of certain production personnel.

Selling and marketing expenses for the three-month period ended September 30, 2018 decreased to \$174,610 or 48% of sales, from \$509,130 or 151% of sales in 2017, a 66% decrease. Selling and marketing expenses decreased year over year, due to the restructuring of the Canadian and US sales and marketing departments resulting in the termination of certain sales and marketing personnel and decreased spending in advertising.

Administrative expenses for the three-month period ended September 30, 2018 were \$257,016 representing a 63% decrease from \$699,785 in 2017.

Decreases in administrative expenses are attributed to the following:

- Administrative salaries decreased by 67% due to the termination and/or resignation of certain administrative staff.
- Legal fees decreased by 125%.

Net research and development expenses totaled \$536,735 for the three-month period ended September 30, 2018 compared to \$610,870 in 2017, a 12% decrease. Research and development expenses decreased primarily due to decreased expenses for conducting the Phase Ib NMIBC clinical study. Research and development expenses represented 56% of the Company's operating expenses for the nine-month period ended September 30, 2018 and represent investment into the research and development of the Company's anti-cancer technology.

# Liquidity and Capital Resources

As of September 30, 2018, current assets aggregated to \$2,411,383 compared with current liabilities of \$2,590,263 netting working capital deficiency of \$178,880 and a current ratio (current assets vs. current liabilities) of approximately 0.93:1.

These conditions indicate the existence of material uncertainties that casts 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 raise capital to continue to develop and commercialize its products and continues to develop 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, 2018, the Company had cash and cash equivalents of \$499,704. 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 2015, 2016 and 2018. 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**

	2018				
Sales Revenue	\$	1,190,131	\$	1,197,531	
Service Revenue		52,179		86,087	
Clinic Revenue		6,728		52,144	
Other Revenue		27,592		18,492	
		1,276,630		1,354,254	

For the nine-month period ended September 30, 2018, total revenue decreased to \$1,276,630 from \$1,354,254 for the same period in 2017, a 6% decrease. In Canada, revenue decreased 19% to \$847,870 from \$1,046,508. In the US, revenue decreased 7% to \$253,742 from \$272,305 and international revenue increased 393% to \$175,018 from \$35,441. The increase in international revenue in 2018 and the corresponding decrease in Canadian and US revenue is attributable to the Company hiring an International Sales Manager and restructuring the Canadian and US sales and marketing departments.

## Cost of sales

Cost of sales for the nine-month period ended September 30, 2018 was \$559,296 (44% of revenue) resulting in a gross margin of \$717,334 or 56% of revenue, compared to a cost of sales of \$558,221 (41% of revenue) in 2017, resulting in a gross margin of \$796,033 or 59% 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 cost of sales increase, year over year, is attributed to discounted sales pricing for the TLC-1000 and TLC-2000 product lines.

#### **Operating Expenses**

For the nine-month period ended September 30, 2018, selling and marketing expenses decreased to \$673,814 or 53% of sales, from \$1,407,387 or 104% of sales in 2017, a 52% decrease and consisted of the following items:

	2018	2017
Sales salaries	\$ 461,191	\$ 959,205
Advertising	67,011	182,623
Commission	56,274	71,691
Travel	38,432	114,284
Stock based compensation	816	9,339
Amortization and depreciation allocation	50,090	70,245
Total selling expenses	\$673,814	\$ 1,407,387

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 and decreased spending in advertising.

Administrative expenses for the nine-month period ended September 30, 2018 decreased to \$1,400,207 from \$2,222,701 in 2017, representing a 38% decrease, and consisted of the following items:

	2018	2017
Insurance	\$ 33,270 \$	77,728
Professional fees	365,592	472,382
Rent	74,296	74,039
General and administrative expenses	333,670	466,172
Administrative salaries	449,121	737,408
Director and advisory fees	27,879	52,350
Stock based compensation	92,621	306,183
Amortization and depreciation allocation	23,758	36,439
Total administrative expenses	\$ 1,400,207 \$	2,222,701

Decreases in administrative expenses are attributed to the following:

- Administrative salaries decreased by 39% due to the termination and/or resignation of certain administrative staff.
- Stock based compensation decreased 70% due to certain current employees forfeiting all non-vested and non-exercised stock options totaling 4,300,000 and certain terminated or resigned employees forfeiting all non-vested and non-exercised options totaling 240,000.

 General and administrative expenses decreased 28% due to decreased investment in investor relations and recruiting expenses

# Research and Development Expense

Net research and development expenses for the nine-month period ended September 30, 2018 decreased to \$1,266,839 from \$2,044,838 in 2017, a 38% decrease, and consisted of the following items:

	2018	2017
Research and development	\$ 1,156,650 \$	1,940,284
Stock based compensation	\$ 19,693 \$	39,151
Amortization and depreciation allocation	\$ 90,496 \$	65,403
Gross research and development expenses	1,266,839	2,044,838
Less: Investment tax credits	-	
Net research and development expenses	\$ 1,266,839 \$	2,044,838

Research and development expenses for the nine-month period ended September 30, 2018 decreased primarily due to decreased expenses for conducting the Phase Ib NMIBC clinical study and placing the software, firmware and hardware modifications of the TLC-2000 laser system on temporary hold. Research and development expenses represented 38% of the Company's operating expenses for the nine-month period ended September 30, 2018 and represent investment into the research and development of the Company's anti-cancer technology.

# Net Profit (Loss)

The net loss for the nine-month period ended September 30, 2018 was \$2,612,168 which included \$278,187 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 2017 of \$4,893,771, which included \$543,891 of net non-cash expenses. The PDT division represented \$1,537,218 of this loss (59%) for the nine-month period ended September 30, 2018.

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

- 1) Decreased investment in research and development in the Phase Ib NMIBC clinical study.
- 2) Decreased investment in external engineering resources to redesign the software, firmware and hardware of the TLC-2000 therapeutic laser.
- 3) Decreased sales, marketing and administrative costs.

#### Cash Flows

Funds used in operating activities, prior to net changes in other operating items, amounted to \$2,333,981 for the nine-month period ended September 30, 2018, compared to funds used in operating activities of \$4,349,880 in 2017. Funds used in operating activities after taking into account net changes in other non-cash operating items were \$644,538 for the nine-month period ended September 30, 2018, compared to funds used of \$3,817,141 for the same period in 2017.

Funds used in investing for the nine-month period ended September 30, 2018 amounted to \$120,108 compared to \$261,609 for 2017. The decrease is primarily a result of decreased spending on tools, dies and equipment related to the TLC-3200 Medical Laser and TLC-3000 Medical Laser System technology.

Funds obtained from financing activities amounted to \$1,010,448 for the nine-month period ended September 30, 2018, compared to \$1,953,925 obtained in financing activities for 2017. The non-brokered private placement, which closed May 14, 2018 is responsible for the funding activities in 2018, while the exercising of warrants in 2017 is responsible for the funding activities in 2017.

# 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 \$22,479.

#### Commitments

As of September 30, 2018, the Company's commitments consisted of the following:

	Total	2018	2019	2020	2021	2022
		(remaining)				
Lease obligations (a)	\$ 241,688	14,376	57,887	59,797	59,797	49,831
Research Agreement (b)	\$ 175,560	-	58,520	58,520	58,520	-
Total	\$ 417,248	14,376	116,407	118,317	118,317	49,831

- a) Lease obligations under a lease agreement related to the Company's premises, commenced on October 1, 2017 and expiring 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) Research Commitments under a research collaboration agreement with University Health Network for the anti-cancer 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 \$172,500 in June 2018 relating to this commitment, in which \$175,560 is the remaining commitment.

The Company indemnifies its directors and officers against any and all costs, charges and expenses, including settlements 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 28, 2018, the share capital of the Company consisted of 134,742,585 common shares. Each common share entitles the holder to one vote per share.

As of November 28, 2018, there were 5,770,000 options outstanding, of which 3,703,332 were vested and exercisable into an equivalent number of the Company's common shares.

As of November 28, 2018, there were 37,880,898 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, 10,538,599 at a price \$0.375 until November 10, 2021, 5,113,300 at a price of \$0.30 until May 14, 2020 and 3,157,059 at a price of \$0.50 until October 3, 2020.

# Segmented Information

For management purposes, the Company is organized into two separate reportable operating divisions: Photo Dynamic Therapy ("PDT") division and the Therapeutic Laser Therapy ("TLT") division.

The PDT division is responsible for the research, development and commercialization of Photo Dynamic Compounds ("PDCs") intended primarily for the treatment of cancer. The TLT division is responsible for the Company's therapeutic laser business, which researches, designs and manufactures products used by healthcare practitioners primarily for the healing of pain.

The following table displays revenue and direct expenses from the PDT and TLT division for the nine-month periods ended September 30, 2018 and 2017:

-		2018			2017	
	TLT	PDT	Total	TLT	PDT	Total
Sales	\$ 1,276,630	\$ -	\$ 1,276,630	\$ 1,354,254	\$ -	\$ 1,354,254
Cost of Sales	559,296	-	559,296	558,221	-	558,221
Gross Margin	717,334	-	717,334	796,033	-	796,033
Operating Expenses						
Selling expenses	673,814	-	673,814	1,407,387	-	1,407,387
Administrative expenses	848,373	551,834	1,400,207	1,298,420	924,281	2,222,701
Research and development expenses	282,562	984,277	1,266,839	547,089	1,497,749	2,044,838
(Gain) loss on foreign exchange	776	777	1,553	18,531	-	18,531
Interest expense	331	331	662	36	36	72
Interest income	(13,573)	-	(13,573)	(3,727)	=	(3,727)
	1,792,283	1,537,218	3,329,502	3,267,737	2,422,066	5,689,804
Loss for the period	\$ (1,074,949)	\$ (1,537,218)	\$ (2,612,168)	\$ (2,471,704)	\$ (2,422,066)	\$ (4,893,771)
Total Assets	\$ 2,189,590	\$ 221,793	\$ 2,411,383	\$ 3,319,827	\$ 308,038	\$ 3,627,865
Total Liabilities	2,199,120	391,142	2,590,262	338,838	153,109	491,947

The following table displays revenue and direct expenses from TLT division product sales by geographic area for the nine-month periods ended September 30, 2018 and 2017:

	2018						2017					
	 Canada		USA	Int	ernational		Canada		USA	Inte	ernational	
Sales	\$ 847,870	\$	253,742	\$	175,018	\$	1,046,508	\$	272,305	\$	35,441	
Cost of Sales	378,139		100,488		80,669		432,045		111,645		14,531	
Selling Expenses	 473,326		84,766		115,722		1,034,918		327,261		45,208	
	\$ (3,595)	\$	68,488	\$	(21,373)	\$	(420,455)	\$	(166,601)	\$	(24,298)	

As of September 30, 2018, and December 31, 2017, the Company's long-lived assets used in operations are all located in Canada.

# Selected Financial Information and Accounting Policies

The Interim Condensed Consolidated Financial Statements for the nine-month period ended September 30, 2018, 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, 2017. Please refer to the Company's annual and quarterly financial statement filings, including material interim press releases, on the regulatory website -- 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, 2018 and December 31, 2017, 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, 2018, no cash equivalents were held (2017-\$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 interim condensed consolidated financial statements as of September 30, 2018 and audited financial statements as of December 31, 2017 and for the nine-month period ended September 30, 2018 and 2017 have been prepared in accordance with IFRS.

The policies applied in the interim condensed consolidated financial statements as of September 30, 2018, and audited financial statements as of December 31, 2017 and for the nine-month period ended September 30, 2018 and 2017 are based on IFRS issued and outstanding as of November 28, 2018 which is the date at which the Company's Board of Directors approved the interim condensed consolidated financial statements.

Additionally, the preparation of consolidated financial statements in accordance with IFRS often requires management to make estimates about and apply assumptions or subjective judgment to future events and other matters that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures. Assumptions, estimates and judgments are based on historical experience, expectations, current trends and other factors that management believes to be relevant at the time at which the 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 unaudited interim condensed consolidated financial statements of September 30, 2018, and audited financial statements as of December 31, 2017 and for ninemonth period ended September 30, 2018 and 2017.

# **Adoption of New Accounting Standards**

On January 1, 2018, the Company implemented IFRS 15, "Revenue From Contracts with Customers" ("IFRS 15") and IFRS 9, "Financial Instruments" ("IFRS 9"), in accordance with IAS 8, "Accounting Policies, Changes in Accounting Estimates and Errors". The impacts on implementation of IFRS 15 and IFRS 9 are described below.

#### **IFRS 15**

The Company adopted all of the requirements of IFRS 15 Revenue from Contracts with Customers as of January 1, 2018. IFRS 15 utilizes a methodical framework for entities to follow in order to recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods and services. The change did not impact the cumulative revenue recognized or the related assets and liabilities on the transition date.

The following is the Company's accounting policy for revenue from contracts with customers under IFRS 15:

The Company designs, develops, manufactures and markets patented and proprietary super-pulsed laser technology. Sales are recognized when control of the products has transferred to the Company's customers, being when the products are shipped to the customer. Once products are shipped to the Company's customers, the risks of obsolescence and loss have been transferred to the customer, and either: the customer has accepted the products in accordance with the sales order, the acceptance provisions have lapsed, or the Company has objective evidence that all criteria for acceptance have been satisfied. A portion of the Company's sales take place on a trial basis, where the Company will deliver inventory to customer locations that has not yet been purchased. The revenue from these sales is recognized when the customer purchases the inventory.

No element of financing is deemed present as the sales are made with credit terms standard for the market. The Company's obligation to provide a refund for faulty products under the standard warranty terms is recognized as a provision. Historically, the Company's annual returns for products sold have been negligible.

A receivable is recognized when the product is shipped as this is the point in time that the consideration is unconditional because only the passage of time is required before the payment is due. The adoption of IFRS 15 resulted in no impact to the opening accumulated deficit, nor to the opening balance of accumulated comprehensive income on January 1, 2018.

#### IFRS 9

The Company adopted all of the requirements of IFRS 9 Financial Instruments ("IFRS 9") as of January 1, 2018. IFRS 9 replaces IAS 39 Financial Instruments: Recognition and Measurement ("IAS 39"). IFRS 9 utilizes a revised model for recognition and measurement of financial instruments and a single, forward-looking"expected loss" impairment model. Most of the requirements in IAS 39 for classification and measurement of financial liabilities were carried forward in IFRS 9, so the Company's accounting policy with respect to financial liabilities is unchanged.

As a result of the adoption of IFRS 9, management has changed its accounting policy for financial assets retrospectively, for assets that continued to be recognized at the date of initial application. The change did not impact the carrying value of any financial assets or financial liabilities on the transition date. The following is the Company's accounting policy for financial instruments under IFRS 9:

# (i) Classification

The Company classifies its financial instruments in the following categories: at Fair Value Through Profit and Loss ("FVTPL"), at Fair Value Through Other Comprehensive Income (loss) ("FVTOCI") or at amortized

cost. The Company determines the classification of financial assets at initial recognition. The classification of debt instruments is driven by the Company's business model for managing the financial assets and their contractual cash flow characteristics. Equity instruments that are held for trading are classified as FVTPL. For other equity instruments, on the day of acquisition the Company can make an irrevocable election (on an instrument-by-instrument basis) to designate them as at FVTOCI. Financial liabilities are measured at amortized cost, unless they are required to be measured at FVTPL (such as instruments held for trading or derivatives) or if the Company has opted to measure them at FVTPL. The Company completed a detailed assessment of its financial assets and liabilities as at January 1, 2018. The following table shows the original classification under IAS 39 and the new classification under IFRS 9:

	Original classification (IAS	New classification (IFRS
Financial assets/liabilities	<u>39)</u>	<u>9)</u>
Accounts receivables	Amortized cost	Amortized cost
Accounts payable and accrued		
liabilities	Amortized cost	Amortized cost

The Company did not restate prior periods as it recognized the effects of retrospective application to stockholders' equity at the beginning of the 2018 annual reporting period, which also includes the date of initial application. The adoption of IFRS 9 resulted in no impact to the opening accumulated deficit nor to the opening balance on January 1, 2018.

# (ii) Measurement

# Financial assets and liabilities at amortized cost

Financial assets and liabilities at amortized cost are initially recognized at fair value plus or minus transaction costs, respectively, and subsequently carried at amortized cost less any impairment.

#### Financial assets and liabilities at FVTPL

Financial assets and liabilities carried at FVTPL are initially recorded at fair value and transaction costs are expensed in the consolidated statements of operations. Realized and unrealized gains and losses arising from changes in the fair value of the financial assets and liabilities held at FVTPL are included in the consolidated statements of net (loss) income in the period in which they arise.

# (iii) Impairment of financial assets at amortized cost

The Company recognizes a loss allowance for expected credit losses on financial assets that are measured at amortized cost. At each reporting date, the Company measures the loss allowance for the financial asset at an amount equal to the lifetime expected credit losses, if the credit risk on the financial asset has increased significantly since initial recognition. If at the reporting date, the financial asset has not increased significantly since initial recognition, the Company measures the loss allowance for the financial asset at an amount equal to the twelve month expected credit losses. The Company recognizes in the consolidated statements of

net operations, as an impairment gain or loss, the amount of expected credit losses (or reversal) that is required to adjust the loss allowance at the reporting date to the amount that is required to be recognized.

# (iv) Derecognition

#### Financial assets

The Company derecognizes financial assets only when the contractual rights to cash flows from the financial assets expire, or when it transfers the financial assets and substantially all of the associated risks and rewards of ownership to another entity. Gains and losses on derecognition are generally recognized in the consolidated statements of net operations.

# **Accounting Standards Issued but Not Yet Applied**

The IASB has issued the following standard which have not yet been adopted by the Company. The Company has not yet begun the process of assessing the impact that the new standard will have on its financial statements. *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. IFRS 16 is effective for annual periods beginning on or after January 1, 2019.

#### 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 consolidated financial statements for the years ended December 31, 2017 and 2016, 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, 2018. A "material weakness" 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 weakness 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 Corporation's ability to continue as a going concern. The Corporation'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 Corporation 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 ("CROs"), 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 total amount of \$5,000,000, with up to \$2,000,000 per occurrence. This coverage is limited and a product liability claim could potentially be greater than these coverages. 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 U.S. federal government funding. When new technologies are developed with U.S. 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 U.S. government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations or to give preference to U.S. industry. In addition, U.S. government-funded inventions must be reported to the government and U.S. 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 28, 2018

Arkady Mandel

Interim Chief Executive Officer and Chief Scientific Officer