# 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 six-month period ended June 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 July 25<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 product 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 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

# **Anti- Cancer Therapy**

On May 19, 2018, Theralase's MSAB was convened to examine the clinical results obtained on the first six patients enrolled and treated in the Study utilizing TLD-1433-based Photo Dynamic Therapy ("PDT"); specifically: 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.

The MSAB is comprised of world-renowned experts in bladder cancer and 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 Medical and Scientific Advisory Board ("MSAB") concluded that the Phase Ib Non-Muscle Invasive Bladder Cancer ("NMIBC") clinical study ("Study") has met its objectives and unanimously voted for the early termination of the Study based on successfully achieving its primary and secondary endpoints after six patients.

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". The treatment was well tolerated by the patient, who demonstrated no tumour recurrence or presence of disease at the 180 day clinical and cystoscopy assessment. The patient has met Study endpoints demonstrating achievement of the primary, secondary and exploratory endpoints at 180 days post treatment and marks a new achievement for the Company.

## **About the Study**

The Study is being used to evaluate TLD-1433, Theralase's lead PDC, for the primary endpoint of safety and tolerability, secondary endpoint of pharmacokinetics (movement and exit of drug within tissue) and exploratory endpoint of efficacy.

# **Study Outcome Endpoints:**

- 1) <a href="Primary: Evaluate safety and tolerability">Primary: Evaluate safety and tolerability</a>. (Measured by patients who experience Adverse Events ("AEs") Grade 4 or greater that do not resolve within thirty (30) days; whereby: Grade 1 = Mild AE, Grade 2 = Moderate AE, Grade 3 = Severe AE, Grade 4 = Life-threatening or disabling AE, Grade 5 = Death)
- 2) <u>Secondary:</u> Evaluate the pharmacokinetics. (movement and exit of drug within tissue) of TLD-1433 (Measured by TLD-1433 concentration levels in plasma and urine over 72 hours.)
- 3) Exploratory: Evaluate efficacy. (Measured by Recurrence Free Survival ("RFS"), defined as the interval from Day 0 (Day of PDT treatment) to documented recurrence or death from any cause, whichever occurs first. Recurrence is defined as any new tumour growth (i.e.: any biopsy-confirmed new or recurrent tumour), evaluated at 90 days for the first three patients treated at the MRSD and primarily at 90 days for the last six patients treated at the Therapeutic Dose and secondarily at 180 days post treatment)

The Company is planning to submit the design of a Phase II NMIBC Clinical Study to Health Canada and the FDA, with a primary endpoint of efficacy.

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

During the six-month period ended June30th, 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 1b NMIBC clinical study.

## Summary of Selected Annual Information

For the years ended December 31:

		2017	2016	2015
Total revenues	\$	2,342,508 \$	1,918,893 \$	1,945,246
Net loss	Ş	(6,093,596)	(4,921,248)	(5,208,145)
Basic and diluted loss per share	\$	(0.05) \$	(0.05) \$	(0.05)
Total assets	\$	3,322,707 \$	6,240,783 \$	7,102,123
Total liabilities		1,277,142	549,742	785,664
Deficit		(31,881,363)	(25,787,767)	(20,866,519)
Shareholders' Equity	\$	2,045,565 \$	5,691,041 \$	6,316,459

# Summary of Quarterly Results

Shareholders' Equity

		20	18	
For the period ending:		March 31		June 30
Total revenues	\$	441,193	\$	469,497
Net loss		(1,004,068)		(885,283)
Basic and diluted loss per share	\$	(0.008)	\$	(0.007)
As at:		March 31		June 30
Total assets	Ś	2.865.364	Ś	2.675.199

As at:	 March 31	June 30
Total assets	\$ 2,865,364	\$ 2,675,199
Total liabilities	1,843,450	1,460,411
Deficit	(32,885,431)	(33,770,714)
Shareholders' Equity	\$ 1,021,914	\$ 1,214,788
	 ·	

Shareholders' Equity	Ş	1,021,914	Ş	1,214,/88	_			
				20	17			
For the period ending:	Mar	ch 31	Jun	e 30		tember 30	D	ecember 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	Se	eptember 30	D	ecember 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)

4,303,268 \$

For the three-month period ended June 30, 2018 total revenue decreased to \$469,497 from \$509,306 for the same period in 2017, an 8% decrease. The decrease in revenues is attributed to a decrease in clinic revenue.

3,789,581 \$

3,105,867 \$

2,045,565

Cost of sales for the three-month period ended June 30, 2018 was \$189,464 (40% of revenue) resulting in a gross margin of \$280,033 or 60% of revenue, compared to a cost of sales of \$186,831 (37% of revenue) in 2017, resulting in a gross margin of \$322,475 or 63% of revenue. The cost of sales decrease, year over year, is attributed to decreasing revenues, while fixed costs remain constant and variable costs decreased as a direct proportion to products sold.

Selling and marketing expenses for the three-month period ended June 30, 2018 decreased to \$218,330 or 47% of sales, from \$487,279 or 96% of sales in 2017, a 49% decrease. Selling and marketing expenses decreased year over year, due to the termination of certain sales and marketing personnel and decreased spending in advertising.

Administrative expenses for the three-month period ended June 30, 2018 were \$588,105 representing a 28% decrease from \$821,992 in 2017. Decreases in administrative expenses are attributed to the following:

- Administrative salaries decreased by 36% due to the termination and/or resignation of certain administrative staff.
- Stock based compensation decreased 51% due to certain current employees forfeiting all non-vested and non-exercised options totaling 4,300,000 and certain terminated or resigned employees forfeiting all non-vested and non-exercised options totaling 175,000.
- General and administrative expenses decreased 31% due to decreased investment in investor relations and recruiting expenses

Net research and development expenses totaled \$365,149 for the three-month period ended June 30, 2018 compared to \$765,246 in 2017, a 52% decrease. Research and development expenses decreased primarily due to decreased expenses for conducting the Phase Ib NMIBC clinical study. Research and development expenses represented 41% of the Company's operating expenses for the three-month period ended June 30, 2018 and represent investment into the research and development of the Company's anti-cancer technology.

# Liquidity and Capital Resources

As of June 30, 2018, current assets aggregated to \$1,900,152 compared with current liabilities of \$1,460,411 netting working capital of \$439,741 and a current ratio (current assets vs. current liabilities) of approximately 1.3:1.

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 market its products and continues to develop sales opportunities that could result in additional sales of its products in the future.

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

As of June 30, 2018, the Company had cash and cash equivalents of \$83,474. 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	2017		
Sales Revenue	\$ 853,667 \$	916,455		
Service Revenue	31,269	48,581		
Clinic Revenue	3,714	39,072		
Other Revenue	 22,040	12,626		
	910,690	1,016,734		

For the six-month period ended June 30, 2018, total revenue decreased to \$910,690 from \$1,016,734 for the same period in 2017, a 10% decrease. In Canada, revenue decreased 22% to \$602,277 from \$769,840. In the US, revenue decreased 13% to \$183,460 from \$211,453 and international revenue increased 252% to \$124,953 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 six-month period ended June 30, 2018 was \$432,321 (47% of revenue) resulting in a gross margin of \$478,369 or 53% of revenue, compared to a cost of sales of \$394,068 (39% of revenue) in 2017, resulting in a gross margin of \$622,666 or 61% 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 line.

# **Operating Expenses**

For the six-month period ended June 30, 2018, selling and marketing expenses decreased to \$499,204 or 55% of sales, from \$898,258 or 88% of sales in 2017, a 44% decrease and consisted of the following items:

	2018	2017
Sales salaries	\$ 361,707	\$ 593,924
Advertising	38,245	129,543
Commission	38,516	47,200
Travel	27,493	72,775
Stock based compensation	1,516	8,270
Amortization and depreciation allocation	31,727	46,546
Total selling expenses	\$499,204	\$ 898,258

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 six-month period ended June 30, 2018 decreased to \$1,143,191 from \$1,522,916 in 2017, representing a 25% decrease, and consisted of the following items:

	2018	2017
Insurance	\$ 26,170	\$ 51,047
Professional fees	419,511	246,902
Rent	49,531	40,600
General and administrative expenses	210,739	415,046
Administrative salaries	371,054	501,358
Director and advisory fees	18,078	42,620
Stock based compensation	33,102	201,203
Amortization and depreciation allocation	15,006	24,140
Total administrative expenses	\$ 1,143,191	\$ 1,522,916

Decreases in administrative expenses are attributed to the following:

- Administrative salaries decreased by 26% due to the termination and/or resignation of certain administrative staff.
- Stock based compensation decreased 84% 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 175,000.
- General and administrative expenses decreased 49% due to decreased investment in investor relations and recruiting expenses

# Research and Development Expense

Net research and development expenses for the six-month period ended June 30, 2018 decreased to \$730,104 from \$1,433,968 in 2017, a 49% decrease, and consisted of the following items:

	2018	2017
Research and development	\$ 658,161 \$	1,372,081
Stock based compensation	\$ 13,508 \$	26,288
Amortization and depreciation allocation	\$ 58,435 \$	35,599
Gross research and development expenses	730,104	1,433,968
Less: Investment tax credits	-	
Net research and development expenses	\$ 730,104 \$	1,433,968

Research and development expenses decreased primarily due to decreased expenses for conducting the Phase Ib NMIBC clinical study and placing the software, firmware and hardware changes of the TLC-2000 on temporary hold. Research and development expenses represented 31% of the Company's operating expenses for the six-month period ended June 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 six-month period ended June 30, 2018 was \$1,889,351 which included \$155,265 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 \$3,238,023, which included \$333,825 of net non-cash expenses. The PDT division represented \$955,802 of this loss (51%) for the six-month period ended June 30, 2018.

The decrease in net loss is primarily due to three reasons:

- 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 \$1,734,086 for the six-month period ended June 30, 2018, compared to funds used in operating activities of \$2,904,197 in 2017. Funds used in operating activities after taking into account net changes in other non-cash operating items were \$1,080,751 for the six-month period ended June 30, 2018, compared to funds used of \$2,902,579 for the same period in 2017.

Funds used in investing for the six-month period ended June 30, 2018 amounted to \$100,125 compared to \$236,394 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-3400 Dosimetry Fibre Optic Cage.

Funds obtained from financing activities amounted to \$1,010,448 for the six-month period ended June 30, 2018, compared to \$1,100,800 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 \$26,948.

#### Commitments

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

	Total	2018	2019	2020	2021	2022
Lease obligations (a)	\$ 256,064	28,752	57,887	59,797	59,797	49,831
Research Agreement (b)	\$ 175,560	-	58,520	58,520	58,520	
Total	\$ 431,624	28,752	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 July 25, 2018 the share capital of the Company consisted of 131,585,526 common shares. Each common share entitles the holder to one vote per share.

As of July 25, 2018, there were 5,835,000 options outstanding, of which 3,714,999 were vested and exercisable into an equivalent number of the Company's common shares.

As of July 25, 2018, there were 34,714,539 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 and 5,113,300 at a price of \$0.30 until May 14, 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 six-month periods ended June, 2018 and 2017:

-												
	2018						2017					
		TLT		PDT		Total		TLT		PDT		Total
Sales	\$	910,690	\$	-	\$	910,690	\$	1,016,734	\$	-	\$	1,016,734
Cost of Sales		432,321		-		432,321		394,068		-		394,068
Gross Margin		478,369		-		478,369		622,666		-		622,666
Operating Expenses												
Selling expenses		499,204		-		499,204		898,258		-		898,258
Administrative expenses		849,937		293,254		1,143,191		1,044,665		478,251		1,522,916
Research and development expenses		69,293		660,811		730,104		399,633		1,034,335		1,433,968
(Gain) loss on foreign exchange		1,405		1,406		2,811		6,823				6,823
Interest expense		331		331		662		37		36		73
Interest income		(8,252)		-		(8,252)		(1,349)		-		(1,349)
		1,411,918		955,802		2,367,720		2,348,067		1,512,622		3,860,689
Loss for the period	\$	(933,549)	\$	(955,802)	\$	(1,889,351)	\$	(1,725,401)	\$	(1,512,622)	\$	(3,238,023)
Total Assets	\$	2,433,489	\$	241,710	\$	2,675,199	\$	4,532,537	\$	288,763	\$	4,821,300
Total Liabilities		1,173,630		286,781		1,460,411		389,683		128,349		518,032

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

		2018					2017					
	Canada		USA	Int	ernational	_	Canada		USA	Inte	ernational	
Sales	\$ 602,277	\$	183,460	\$	124,953		\$ 769,840	\$	211,453	\$	35,441	
Cost of Sales	288,596		80,467		63,258		323,540		57,061		13,467	
Selling Expenses	349,629		68,807		80,767	_	557,731		329,382		11,145	
	\$ (35,948)	\$	34,186	\$	(19,072)	_	\$ (111,431)	\$	(174,990)	\$	10,829	

As of June 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 six-month period ended June 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 -- <a href="https://www.SEDAR.com">www.SEDAR.com</a>.

#### 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.

Assets are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. As of June 30, 2018, the Company's Cash and Cash Equivalents are categorized as Level 1 measurement. Fair value of other financial assets is determined based on transaction value and is categorized as Level 1 measurement.

#### (i) 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 condensed interim consolidated 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 those risks.

Cash equivalents are held in high-grade, bankers' acceptance and other low risk investments with no exposure to liquidity or other risk associated with Asset-Backed Securities. These financial instruments are classified as held for trading as they may periodically be traded before their maturity date; however, the majority of these financial instruments are classified as held to maturity and would not result in a significant risk of fair value changes if held to maturity. As of June 30, 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 does not expect a movement in the interest rate to have a significant impact on the Company's financial position.

## (iv) Foreign currency exchange 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 three 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.

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 June 30, 2018 and audited financial statements as of December 31, 2017 and for the six-month period ended June 30, 2018 and 2017 have been prepared in accordance with IFRS.

The policies applied in the interim condensed consolidated financial statements as of June 30, 2018, and audited financial statements as of December 31, 2017 and for the six-month period ended June 30, 2018 and 2017 are based on IFRS issued and outstanding as of July 24, 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 June 30, 2018, and audited financial statements as of December 31, 2017 and for six-month period ended June 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 ("IFRS 15") 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 cumulated revenue recognized or the related assets and liabilities on the transition date. The following is the Company's new 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 goods are 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 new 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:

Financial assets/liabilities	Original classification (IAS 39)	New classification (IFRS 9)
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 shall recognize 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 standards 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 our consolidated financial statements for the years ended December 31, 2017 and 2016, our independent registered public accountants identified certain material weaknesses in our internal control over financial reporting. Such material weaknesses continue to exist as of June 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 our 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 we are unable to remediate the material weakness, or other control deficiencies are identified, we may not be able to report our financial results accurately, prevent fraud or file our 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 stage 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, 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 a 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 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 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, studies or clinical studies on various aspects of biopharmaceutical products are conducted by academic researchers, competitors or others. The results of these studies or 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 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.

July 25, 2018

Arkady Mandel

Interim Chief Executive Officer and Chief Scientific Officer