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

The following Management Discussion and Analysis ("MD&A"), of Theralase Technologies Inc. ("Theralase" or the "Company") should be read in conjunction with the Company's annual consolidated financial statements for the year ended December 31, 2016. This MD&A has been filed in accordance with the provisions of National Instrument 51-102 (Continuous Disclosure Regulation). Copies of further relevant financial documents and earlier corporate filings to date may also be referenced on the regulatory website - SEDAR at www.sedar.com. This MD&A is prepared as of May 1<sup>st</sup>, 2017.

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

# Forward Looking Statements

Certain statements contained or incorporated in this MD&A, which deal with the Company's financial condition and operating results, include information, analyses and projections as to future corporate developments which are currently in the planning stage, and on the projected operating financial performance of the Company, which constitute forward-looking statements. Such forward-looking statements made with special reference to the Company's ongoing technologically complex healthcare and medical device research and development efforts, which may include in-house and independent clinical trials, testing new medical technologies and their applications, involve known and unknown risks and uncertainties that could cause actual events and results to differ materially from those estimated or anticipated and which may have been implied or expressed in such forward-looking statements. No conclusions as to the successful outcome of the ongoing and planned research and development projects in which the Company is involved are intended or implied nor can they be foreseen or predicted prior to definitive corporate announcements as to their outcome.

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. The forward-looking statements contained in this MD&A are expressly qualified by this cautionary statement.

## **Company Profile**

Theralase Technologies Inc., ("Theralase" or the "Company") was founded in 1995 and has two main divisions.

The Therapeutic Laser Technology ("TLT") division designs, develops, manufactures, markets and distributes patented and proprietary super-pulsed laser technology indicated and cleared by Health Canada and the Food and Drug Administration ("FDA") for the healing of chronic knee pain. The technology has been used off-label for healing numerous nerve, muscle and joint conditions, including arthritis, osteoarthritis and wounds. The Photo Dynamic Therapy ("PDT") division develops patented and patent pending drugs, called Photo Dynamic Compounds ("PDCs") and activates them with proprietary and patent pending laser technology to destroy specifically targeted cancers and bacteria.

Theralase is focused on a two part strategy:

 Production, marketing and distribution of the Theralase TLC-1000 and patented TLC-2000 Super Pulsed Laser Technologies to healthcare practitioners in Canada and the US, who are interested in the safe and effective treatment of nerve, muscle, tendon, ligament, joint and wound conditions through the elimination of pain, reduction of inflammation and acceleration of tissue healing. The

- corporate strategy is to systematically rollout the technology through a focused sales and marketing team commencing with Canada, followed by the US and then internationally.
- Commercialization of the patented TLC-3000 Photo Dynamic Compound ("PDC") Anti-Cancer Technology through preclinical research, clinical trials and technology development to destroy cancers for oncological applications, and to destroy bacteria for human, animal and sterilization applications. The lead cancer target is Non-Muscle Invasive Bladder Cancer ("NMIBC"), followed by brain, lung and melanoma cancers.

#### Advancing the Theralase Technology Platform

The following summarizes several scientific, clinical and business developments that management considers will fuel and accelerate near, mid and long term Company growth:

## TLC-2000: Biofeedback Laser Technology

The TLC-2000 Biofeedback Therapeutic Laser Technology possesses patented "<u>Cell Sensing</u>" technology that "<u>senses</u>" and targets injured tissue at depth with precision, unattainable by any of its competitors, enabling predetermined doses of energy to be delivered for enhanced efficacy and accelerated healing. The TLC-2000 is also a learning device that is able to deliver optimized clinical protocols based on an individual patient's optical tissue profile.

In 2016, Theralase commenced a dedicated sales and marketing program in both Canada and the US aimed at promoting the benefits and advantages of the TLC-2000 technology over existing technologies to a wide range of healthcare practitioners; through, in-depth, private demonstrations of the technology in healthcare practitioners' offices and public presentations in both Canada and the US.

As detailed in the Company's clarifying press release dated November 1, 2016, the Company's ability to achieve its revenue targets was reliant on a number of factors including:

- Ability to ramp up manufacture of the TLC-2000 to commercial production levels;
- Ability to optimize the software for ease of use and functionality;
- Ability to execute on a strategic marketing strategy, which introduced and positioned the TLC-2000 in relation to legacy and competitive products;
- Ability to recruit, train and retain an experienced sales force to levels required to attain projected sales growth; and
- Ability to attract Key Opinion Leaders ("**KOLs**") to utilize the TLC-2000 to provide support for the wide spread implementation of the technology.

A number of factors contributed to the slower than expected sales growth of the TLC-2000, including:

- delays associated with the growth of the Company's sales force in Canada and the US;
- the durability and reliability of the TLC-1000 system has slowed the initial trade-up effort;
- the substantial development time required to ramp-up the TLC-2000 to commercial levels and to optimize the software; and
- KOL recruitment remains ongoing and did not make a major impact on the market in 2016.

#### **TLC-3000: Cancer Therapy**

The patent pending multi-wavelength TLC-3000 medical laser system is currently being researched, designed and developed by Theralase for the activation of Theralase's patented and patent pending PDCs for the treatment of numerous types of cancer; known as Photo Dynamic Therapy ("PDT").

Theralase's platform of patented and patent pending PDCs have repeatedly demonstrated through the preclinical phase:

- >> 99% cancer cell kill at very low concentrations (< 0.8μM) leading to high efficacy across numerous cell lines, including: bladder, brain and colon cancers
- Virtually 0% toxicity at high concentrations (> 100μM) with no side effects leading to very high safety profile
- More effective at killing cancer cells than FDA approved drugs (668,000 x ALA, 198 x PHOTOFRIN®)
- Excellent specificity and selectivity with a rapid evacuation from healthy cells and a high light fluence required for activation
- Ultra low systemic toxicity as the PDC has less than 0.02% systemic infiltration into the blood stream in the destruction of NMIBC
- Water soluble, small molecule that readily penetrates cellular membrane and localizes to the organelles
- Able to treat solid core hypoxic tumours, using a Type 1 and Type 2 activation, such as: bladder, brain and colon cancers
- Activated at a variety of wavelengths allowing shallow and deep tumour destruction

The PDT division is focused on successfully completing a Phase Ib clinical trial for patients afflicted with NMIBC, utilizing its novel next generation light-activated, anti-cancer drug, TLD-1433.

The Phase Ib clinical trial is designed as follows:

**Lead Institution:** Princess Margaret Cancer Centre, University Health Network ("UHN")

Lead Scientific Principal Investigator: Lothar Lilge Ph.D.

Lead Clinical Principal Investigator: Girish Kulkarni MD

## Title:

A Phase Ib Trial of Intravesical Photodynamic Therapy in Patients with Non-Muscle Invasive Bladder Cancer at High Risk of Progression Who are Refractory to Therapy with Bacillus Calmette-Guerin ("BCG") and Who are Medically Unfit for or Refuse a Cystectomy

# **Objectives:**

**Primary**: Evaluate the safety and tolerability of PDT employing TLD-1433 and controlled uniform laser light (TLC-3200 System) in subjects with high risk, Ta/T1 or Tis NMIBC that are intolerant or refractory to BCG, and who are not candidates or refuse radical cystectomy

Secondary: Evaluate the pharmacokinetics ("PK") of TLD1433

Exploratory: Efficacy of PDT employing TLD-1433 and controlled uniform laser light (TLC-3200 System)

#### Methodology:

Phase Ib, open-label, single-arm, single-center study conducted in Canada. BCG intolerance or refractory disease are defined as inability to tolerate or failure to achieve a tumour-free state after at least one induction (a minimum of 5 instillations) followed by either a second induction (a minimum of 5 instillations) or at least 2 maintenance instillations. Subjects experiencing disease relapse within 12 months or less after finishing the second course of BCG therapy are also considered refractory. 2 phases: In the first phase, 3 subjects will receive PDT (TLC-3200 System) employing 0.35 mg/cm² (maximum recommended starting dose) TLD1433. If treatment with the maximum recommended starting dose does not raise significant safety concerns, as determined by the safety monitoring committee, an additional 6 subjects will receive PDT with 0.70 mg/cm² (therapeutic dose) TLD1433

## **NMIBC PDT Treatment:**

- Intravesically instill a sterile water based solution of TLD-1433 via catheter, through the urethra, into the bladder of a patient inflicted with NMIBC, who has failed standard of care and who is not indicated or refuses to have their bladder removed
- Allow the solution of TLD-1433 to absorb into any resident bladder cancer tumours for approximately sixty (60) minutes
- Void the bladder and flush the bladder three times with sterile water to remove any non-adhering TLD-1433 solution not absorbed by any bladder tumours
- Admit the patient into the operating room and administer a general anesthetic
- Insert a rigid cystoscope through the urethra of the patient into the bladder
- Fill the bladder with sterile water to provide shape to the bladder
- Insert the TLC-3400 DFOC device into the bladder via the cystoscope's working channel and connect it to the TLC-3200 Medical Laser System
- Deploy the DFOC in the bladder (like an umbrella) to strategically place optical detectors at twelve (12) predetermined locations along the bladder wall to precisely monitor the laser light, intended to provide a uniform distribution of laser light energy, in the correct dosage, to the bladder wall
- Activate PDC for approximately thirty (30) minutes
- Void bladder to remove destroyed bladder cancer cells

The TLC-3200 Medical Laser System delivers green laser light, at a wavelength of 525 nanometers ("nm"), while the Dosimetry Fibre Optic Cage ("DFOC") technology precisely monitors the laser light to provide a uniform distribution of the laser light energy, in the correct dosage, to the bladder wall.

The Phase Ib NMIBC clinical study protocol commenced by instilling a low dose of TLD-1433 PDC into the bladders of three (3) patients with subsequent light activation using the TLC-3200 medical laser. These patients were treated on March 30, 2017, April 12, 2017 and April 18, 2017. These three (3) patients are currently being monitored for thirty (30) days to ensure safety and tolerability of the procedure. If no Significant Adverse Events ("SAEs") are reported, then an additional six (6) patients will be enrolled at a therapeutic dose, followed by light activation and follow-up monitoring for six (6) months.

If safety and tolerability of the procedure is demonstrated in these nine (9) patients, the Phase Ib study results will support Health Canada approval and a Phase II multi-center efficacy study for NMIBC will be commenced in Canada, the United States and Europe.

Theralase's anti-cancer technology pipeline includes numerous highly effective drug candidates, in various advanced stages of preclinical development. Theralase will continue to validate its extensive data with

additional cancer animal models and toxicology analyses to bring these PDC drug candidates online for various cancer and bacterial applications.

## **TLC-3000: Cancer Vaccine Research**

In Q22014, preclinical animal testing performed at UHN demonstrated that Theralase's lead PDC intended for the destruction of cancer demonstrated an ability to render animals immune to repeated exposures of the same cancer. This initial data was presented at the 37<sup>th</sup> Annual American Society for Photobiology that took place in San Diego, California in June 2014.

In previous research conducted at UHN by Theralase, mice were injected with 350,000 colon cancer cells (murine cell line CT26.CL25) to produce tumours that were allowed to grow to approximately five millimeters in size. They were treated with an intra-tumoural injection of one of Theralase's lead PDCs (3 mg/kg TLDOsH2IP) and then illuminated by Near Infrared ("NIR") light (808 nm, 600 J cm-2) to activate the PDC. The vast majority of tumours were completely destroyed, with the PDC treatment demonstrating prolonged tumour regression.

In this latest research, the same mice who received the initial, successful PDT were re-injected with the same number of colon cancer cells, 13 to 23 days later. With no further treatment intervention, mice in these experiments demonstrated either a small tumour regrowth which quickly regressed (40%), or in the majority of animals no tumour regrowth at all (60%), suggesting a short-term immune-mediated ("immune memory response") tumour rejection.

To further prove the resilience of the PDT treatment, these same animals were then injected a third time with an additional 350,000 colon cancer cells at ten months post PDT treatment. None of these animals showed any sign of tumour regrowth (100%), even at 3 months post follow up, suggesting the presence of a long-term antitumour immunity, responsible for complete tumour rejection.

To strengthen the data, control experiments were conducted where age matched mice without prior tumour exposure or PDT treatment were injected with the same number of colon cancer cells; whereby, the majority of these mice proceeded to develop tumours and did not survive more than one month following the injection.

This potential short and long term anti-cancer memory response suggests a major breakthrough in cancer research and may provide substantial treatment benefit and survival advantage to cancer patients. Technology that is able to rapidly and effectively destroy "patient-specific" cancer cells, prevent their recurrence and provide long lasting protection against local and distant metastasis, offers immense clinical benefit to cancer patients and the facilities that treat their disease.

This is one of the first preclinical trials to show that it's possible to generate a long-term anticancer memory response. For the first time in Theralase's research program, Theralase demonstrated that NIR PDT leads not only to long standing clearance of colon cancer cells, but also provides long lasting protection against further tumour cell challenge in young (eight to ten weeks old) and older (ten to eleven month old) mice. It is the Company's first step toward the long-term goal of developing an affordable and practical vaccine to prevent cancer recurrence. This research will prove invaluable as the Company commenced validation of its anti-cancer technology via human clinical trials in NMIBC in 4Q2016.

#### TLC-3000: Destruction of Bacteria

Previously, Theralase presented scientific data supporting the application of Theralase's advanced sterilization platform technology enabling 8 log kill (99.999999%) of life threatening infectious microorganisms, such as

Staphylococcus Aureus ("S. aureus"), Escherichia Coli ("E. coli") and Listeria Monocytogenes ("Listeria") bacteria. Theralase's PDCs were effective in oxygenated ("normoxic") and in non-oxygenated ("hypoxic") conditions. These results demonstrate that the unique PDT effect of Theralase's patented compounds does not depend on oxygen availability and they are able to act both as Type 1 ("oxygen independent") and as Type 2 ("oxygen dependent") photosensitizers.

The photodynamic antibacterial effects of this new class of photosensitizers were evaluated against a strain of S. aureus (ATCC 25923) and a methicillin-resistant strain of S. aureus (MRSA, ATCC 33592). Bacterial samples were dosed with a range of photosensitizer concentrations (0.3-12  $\mu$ M) and exposed to 530 nm light (90 J/cm²) in normoxic conditions (ambient atmosphere) and in hypoxic conditions (0.5%  $O_2$ ). The Theralase PDCs exerted Photo Dynamic Anti-Bacterial Effect ("PDABE") of the Staphylococcus aureus and Methicillin-resistant Staphylococcus aureus in normoxia with an 8 log kill (99.999999%) providing a complete sterilization effect in microgram concentrations. The Theralase PDCs maintained this PDABE potency under hypoxic conditions (low oxygen), with one of the PDCs becoming even more active in low-oxygen environments.

The observation of activity in hypoxia maintains that there exists an oxygen-independent, Type 1 photo process for this new class of compounds in addition to the typical Type 2 pathway mediated by singlet oxygen.

From a commercial viewpoint, the higher the "kill rate" in normoxic and hypoxic conditions combined with the shortest time to accomplish this task, the more favorably physicians, scientists and hospital administrators will view the disinfection approach.

Theralase plans to commercialize its anti-bacterial PDT technology in the future, in one or all of the following applications: animal indications, human indications, food processing equipment sterilization, hospital treatment room sterilization, medical equipment sterilization, bacterial load elimination in wounds and other bacteria destruction applications.

# **Public Offering**

On November 10, 2016, the Company closed a public offering of Units, under a Base Shelf Prospectus. On closing, the Corporation issued an aggregate of 14,236,666 Units at a price of \$0.30 per Unit for aggregate gross proceeds of approximately \$4,271,000. Each Unit consists of one common share of the Company and one common share purchase warrant. Each Warrant entitled the holder to acquire an additional Common Share at a price of \$0.30 for a period of 60 months following the date of issuance. In connection with the offering, the Company paid agent's fees totaling \$237,119 and issued an aggregate of 526,933 finder warrants, each finder warrant is exercisable into one common share at an exercise price of \$0.375 per share for a period of 60 months after the closing of the offering.

The Company has allocated the proceeds of the Private Placement to:

- Fund research and development activities by the Photo Dynamic Therapy ("PDT") division; specifically, the Phase Ib clinical study for NMIBC in 4Q2016.
- Commercial activities by the Therapeutic Laser Therapy ("**TLT**") division; specifically, the commercialization of the patented next generation TLC-2000 Biofeedback Therapeutic Laser System in Canada and the United States in 2017.
- Working capital and general corporate purposes.

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

During the year ending December 31, 2016 under review, the Company's financial performance and its operating results reflect the continued and significant investment by the Company into its future prosperity through research and development initiatives aimed at successful: completion of clinical trials of the TLC-3000 patented anti-cancer technology for NMIBC, commercialization of the patented next generation TLC-2000 Biofeedback Therapeutic Laser System in Canada and the US, implementation of a recurring revenue model and maintaining moderate sales of the Theralase TLC-1000 therapeutic laser system.

# **Summary of Selected Annual Information**

# For the years ended December 31:

		2016	2015	2014
Total revenues	\$	1,918,893	\$ 1,945,246	\$ 1,380,604
Net loss		(4,921,248)	(5,208,144)	(2,587,542)
Basic and diluted loss per share	\$	(0.05)	\$ (0.05)	\$ (0.03)
Total assets	\$	6,240,783	\$ 7,102,123	\$ 3,817,084
Total liabilities		549,742	785,664	511,750
Deficit	(	(25,787,767)	(20,866,519)	(15,658,375)
Shareholders' Equity	\$	5,691,041	\$ 6,316,459	\$ 3,305,334

# **Summary of Quarterly Results**

	2016										
De	ecember 31	Se	eptember 30		June 30		March 31				
\$	712,167	\$	313,588	\$	481,690	\$	411,448				
	(1,069,226)		(1,461,903)		(1,244,380)		(1,145,739)				
\$	(0.00)	\$	(0.01)	\$	(0.01)	\$	(0.02)				
Do	ecember 31	Se	ptember 30		June 30		March 31				
\$	6,240,783	\$	3,417,731	\$	4,576,402	\$	6,026,599				
	549,742		563,229		356,694		704,445				
	(25,787,767)		(24,784,842)				(22,012,258)				
\$	5,691,041	\$	2,854,502	\$	4,219,708	\$	5,322,154				
			2015								
De	ecember 31	Se	ptember 30		June 30		March 31				
\$	883,638	\$	383,791	\$	309,513	\$	368,304				
	(955,067)		(1,973,960)		(1,345,474)		(933,643)				
\$	(0.02)	\$	(0.02)	\$	(0.00)	\$	(0.01)				
D	ecember 31	Se	ptember 30		June 30		March 31				
\$	7,102,123	\$	7,442,831	\$	8,705,818	\$	10,167,305				
	785,664		823,491		339,753		474,165				
	(20,866,519)		(19,911,454)		(17,937,492)		(16,592,018)				
\$	6,316,459	\$	6,619,340	\$	8,366,065	\$	9,693,140				
	\$ \$ \$ \$ \$ \$ \$ \$ \$	\$ 712,167 (1,069,226) \$ (0.00) December 31 \$ 6,240,783 549,742 (25,787,767) \$ 5,691,041 December 31 \$ 883,638 (955,067) \$ (0.02) December 31 \$ 7,102,123 785,664 (20,866,519)	\$ 712,167 \$ (1,069,226) \$ (0.00) \$   December 31 Se \$ 6,240,783 \$ 549,742 (25,787,767) \$ 5,691,041 \$   December 31 Se \$ 883,638 \$ (955,067) \$ (0.02) \$   December 31 Se \$ 7,102,123 \$ 785,664 (20,866,519)	December 31         September 30           \$ 712,167         \$ 313,588           (1,069,226)         (1,461,903)           \$ (0.00)         \$ (0.01)           December 31         September 30           \$ 6,240,783         \$ 3,417,731           549,742         563,229           (25,787,767)         (24,784,842)           \$ 5,691,041         \$ 2,854,502           2015           December 31         September 30           \$ 883,638         \$ 383,791           (955,067)         (1,973,960)           \$ (0.02)         \$ (0.02)           December 31           \$ 7,102,123         \$ 7,442,831           785,664         823,491           (20,866,519)         (19,911,454)	December 31         September 30           \$ 712,167         \$ 313,588         \$ (1,069,226)         (1,461,903)           \$ (0.00)         \$ (0.01)         \$           December 31         September 30         \$ 6,240,783         \$ 3,417,731         \$ 549,742         563,229           (25,787,767)         (24,784,842)         \$ 5,691,041         \$ 2,854,502         \$           December 31         September 30           \$ 883,638         \$ 383,791         \$ (955,067)         (1,973,960)         \$ (0.02)         \$           \$ 7,102,123         \$ 7,442,831         \$ 785,664         823,491         \$ (20,866,519)         (19,911,454)	December 31         September 30         June 30           \$ 712,167         \$ 313,588         \$ 481,690           (1,069,226)         (1,461,903)         (1,244,380)           \$ (0.00)         \$ (0.01)         \$ (0.01)           December 31         September 30         June 30           \$ 6,240,783         \$ 3,417,731         \$ 4,576,402           549,742         563,229         356,694           (25,787,767)         (24,784,842)         (23,322,939)           \$ 5,691,041         \$ 2,854,502         \$ 4,219,708           2015           December 31         September 30         June 30           \$ 883,638         \$ 383,791         \$ 309,513           (955,067)         (1,973,960)         (1,345,474)           \$ (0.02)         \$ (0.02)         \$ (0.00)           December 31         September 30         June 30           \$ 7,102,123         \$ 7,442,831         \$ 8,705,818           785,664         823,491         339,753           (20,866,519)         (19,911,454)         (17,937,492)	December 31         September 30         June 30           \$ 712,167         \$ 313,588         \$ 481,690         \$ (1,069,226)         (1,461,903)         (1,244,380)         \$ (0.01)				

De	cember 31	September 30			June 30	March 31		
\$	386,131	\$	134,036	\$	499,258	\$	368,304	
	(849,781)		(1,048,034)		(345,653)		(933,643)	
\$	0.00	\$	(0.02)	\$	(0.01)	\$	(0.01)	
De	cember 31	Se	ptember 30		June 30	N	larch 31	
\$	3,817,084	\$	3,648,813	\$	4,116,005	\$ 1	.0,167,305	
	511,750		376,923		322,582		474,165	
(:	15,658,375)	(	(14,808,592)		(13,760,558)	(1	.6,592,018)	
\$	3,305,334	\$	3,271,890	¢	3,793,423	ς .	9,693,140	
	\$ \$ <b>De</b>	\$ 0.00 December 31 \$ 3,817,084 511,750 (15,658,375)	\$ 386,131 \$ (849,781) \$ 0.00 \$ <b>December 31 Se</b> \$ 3,817,084 \$ 511,750 (15,658,375)	\$ 386,131 \$ 134,036 (849,781) (1,048,034) \$ 0.00 \$ (0.02) December 31 September 30 \$ 3,817,084 \$ 3,648,813 511,750 376,923 (15,658,375) (14,808,592)	December 31         September 30           \$ 386,131         \$ 134,036         \$ (849,781)         (1,048,034)         \$ 0.00         \$ (0.02)         \$           \$ 0.00         \$ (0.02)         \$         \$ 0.02         \$           December 31         September 30         \$ 3,817,084         \$ 3,648,813         \$ 511,750         376,923         \$ (15,658,375)         (14,808,592)	December 31         September 30         June 30           \$ 386,131         \$ 134,036         \$ 499,258           (849,781)         (1,048,034)         (345,653)           \$ 0.00         \$ (0.02)         \$ (0.01)           December 31         September 30         June 30           \$ 3,817,084         \$ 3,648,813         \$ 4,116,005           511,750         376,923         322,582           (15,658,375)         (14,808,592)         (13,760,558)	December 31         September 30         June 30         N           \$ 386,131         \$ 134,036         \$ 499,258         \$           (849,781)         (1,048,034)         (345,653)         \$           \$ 0.00         \$ (0.02)         \$ (0.01)         \$           December 31         September 30         June 30         N           \$ 3,817,084         \$ 3,648,813         \$ 4,116,005         \$ 1           511,750         376,923         322,582           (15,658,375)         (14,808,592)         (13,760,558)         (1	

## Liquidity and Capital Resources

As of December 31, 2016, current assets aggregated to \$5,617,125 compared with current liabilities of \$549,742 netting working capital of \$5,067,383 and a current ratio (current assets vs. current liabilities) of approximately 10:1.

The Company's objective is to maintain a sufficient capital base to support future research, development and strategic business initiatives allowing the Company to invest in its future and hence maintain investor, creditor and market confidence. The capital structure of the Company consists of cash, cash equivalents and shareholders' equity. The Company makes every attempt to manage its liquidity to minimize shareholder dilution where possible.

As of December 31, 2016, the Company had cash and cash equivalents of 2,970,198. Sales of the TLC-1000 and 2000, the company's existing product lines, have not been sufficient in and of themselves to enable the Company to fund all its continuing development and commercialization efforts. The Company has successfully raised capital through equity offerings in 2015 and 2016; however, there is no assurance that these initiatives will be successful. Management believes that the Company has sufficient cash on hand to meet its operating and working capital needs for the next twelve months.

## **Results of Operations**

	2016	2015	2014
Sales Revenue	\$ 1,754,569	\$ 1,727,798	\$ 1,187,769
Service Revenue	90,660	96,543	76,375
Clinic Revenue	46,988	38,655	38,827
Other Revenue	 26,676	82,250	77,633
	 1,918,893	1,945,246	1,380,604

For the year ended December 31, 2016, total revenue decreased slightly to \$1,918,893 from \$1,945,246 for the same period in 2015, a 1% decrease. In Canada, revenue decreased 16% to \$1,423,181 from \$1,691,087. In the US, revenue increased 94% to \$416,812 from \$214,744 and international revenue increased 100% to \$78,900 from \$39,415. The decrease in Canadian revenue in 2016 and the corresponding increase in US and international revenue is attributable to the Company systematically building its sales and marketing teams in the Canadian and US market, the learning curves associated with training and developing a new sales force and the ramp-up strategy of successfully commercializing the TLC-2000 therapeutic laser system.

Now that the TLC-2000 is FDA 510(k) cleared and Health Canada approved, Theralase is focusing on recruiting a high performing sales and marketing team in Canada and the US with the mandate of increasing sales of the TLC-2000 across Canada and the United States in 2017. Once these strategic markets have been established and running independently, Theralase will focus on growing its international revenues through exclusive international distribution agreements.

#### Cost of sales

Cost of sales for the year ended December 31, 2016 was \$796,569 (42% of revenue) resulting in a gross margin of \$1,122,324 or 58% of revenue, compared to a cost of sales of \$629,607 (32% of revenue) in 2015, resulting in a gross margin of \$1,315,639 or 68% 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.

#### **Operating Expenses**

Selling and marketing expenses for the year ended December 31, 2016 were \$1,614,680 representing 84% of sales, compared with \$1,086,354 or 56% of sales in 2015, and consisted of the following items:

	2016	2015	2014
Sales salaries	\$ 946,317	\$ 622,633	\$ 296,314
Advertising	300,931	140,411	99,532
Commission	94,159	133,111	51,325
Travel	193,718	135,397	120,993
Stock based compensation	21,756	16,875	1,938
Amortization and depreciation allocation	57,797	37,927	28,076
Total selling expenses	\$ 1,614,680	\$1,086,354	\$598,178

The increase is primarily due to increased spending in marketing and sales personnel, which will augment sales in future financial quarters, aiding in future sales of the TLC-2000. Selling expenses are expected to continue to increase in the future as the Company expands in Canada, the US and international markets. On-going investment in: sales personnel, marketing events and advertising are necessary expenses to generate and increase revenues in subsequent financial quarters.

Administrative expenses for the year ended December 31, 2016 were \$2,546,706 representing a 4% increase from \$2,452,328 in 2015, and consisted of the following items:

		2016	2015	2014
Insurance	\$	83,147	\$ 64,384	\$ 53,461
Professional fees		304,249	284,715	137,109
Rent		93,513	93,707	87,541
General and administrative expenses		674,578	846,986	491,950
Administrative salaries		865,465	698,001	478,570
Director and advisory fees		82,896	75,104	50,401
Stock based compensation		413,585	361,446	129,645
Amortization and depreciation allocation		29,273	27,985	20,104
Total administrative expenses	\$:	2,546,706	\$ 2,452,328	\$ 1,448,781

Increases in administrative expenses are attributed to the following:

Insurance expenses increased 29% due to increased product liability coverage

- Stock based compensation increased by 15%, as a result of vesting of stock options to certain employees, directors and officers of the Company in 2016
- Administrative salaries increased by 24%, as a result of hiring clinical and educational staff.

#### Research and Development Costs

Gross research and development expenses totaled \$1,867,621 for the year ended December 31, 2016 compared to \$3,029,369 in 2015 (38% decrease). The decrease in research and development expenses is a direct result of the Health Canada and FDA regulatory clearance of the TLC-2000 therapeutic laser technology in December 2015, allowing commercialization of this technology. The TLC-2000 therapeutic laser system is undergoing software, firmware and hardware optimizations to successfully commercialize this technology and successfully implement a recurring revenue model. Research and development expenses represented 38% of the Company's operating expenses for the year and represent direct investment into the research and development expenses of the TLC-3000 anti-cancer technology.

# Net Profit (Loss)

The net loss for the year ended December 31, 2016 was \$4,921,248, which included \$613,521 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 in 2015 of \$5,208,144, which included \$648,361 of net non-cash expenses. The PDT division represented \$2,813,381 of this loss (57%) in 2016. The decrease in net loss is due to decreased investment in research and development of the next generation TLC-2000 therapeutic laser technology, while maintaining investment in research and development of the TLC-3200 Medical Laser and TLC-3400 Dosimetry Fibre Optic Cage related to the support of a Phase Ib clinical study for NMIBC and sales, marketing and administrative personnel initiatives, related to the successful commercialization of the next generation TLC-2000 therapeutic medical laser system and its recurring revenue model.

#### Cash Flows

Funds used in operating activities, prior to net changes in other operating items, amounted to \$4,880,393 for the year ended December 31, 2016, compared to funds used in operating activities of \$5,044,101 in 2015. Funds used in operating activities after taking into account net changes in other non-cash operating items were \$4,266,873 for the year ended December 31, 2016, compared to funds used of \$4,395,740 for the same period in 2015.

Funds used in investing for the year ended December 31, 2016 amounted to \$294,612 compared to \$248,496 for 2015. The increase is a result of increased spending on tools, dies and equipment related to the TLC-2000 therapeutic laser technology, as this program is maturing.

For the year ended December 31, 2016, funds obtained from financing activities amounted to \$3,804,348, compared to \$7,710,999 obtained in financing activities for 2015. The difference is related to proceeds from the public offering, which closed March 3, 2015 versus the November 10, 2016 public offering.

## 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 \$53,979.

#### Commitments

As of December 31, 2016, the Company's commitments consisted of the following:

	Total			2017	2018	
Lease obligations (a)	\$	49,000	\$	49,000		
Lease obligations (b)		2,505		2,004	5	01
Research Agreement (c)		14,000		14,000	-	<u> </u>
Total	\$	65,505	\$	65,004	\$ 5	01

- a) Lease obligations under a lease agreement related to the Company's premises, commenced on August 1, 2012 and expires on July 31, 2017. Under the terms of this lease, the Company is required to pay a proportionate share of operating costs, realty taxes and utilities, in addition to the minimum rental payments. The future minimum lease payments are shown in the table above.
- b) Lease obligations under a lease agreement related to the Company's office equipment, commenced on April 1, 2014 and expires on May 1, 2018. Under the terms of this lease, the Company is required to minimum rental payments of \$167 per month. The future minimum lease payments are shown in the table above.
- c) Research Commitments under a research collaboration agreement with University Health Network for the TLC-3000 cancer therapy project. Under the terms of this agreement, the Company is required to pay \$126,000 for the period from March 1, 2016 through to February 28, 2017. The Company has paid \$105,000 relating to this commitment, in which \$14,000 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 December 31, 2016, the share capital of the Company consisted of 121,284,026 common shares. Each common share entitles the holder to one vote per share.

As of December 31, 2016, there were 10,085,000 options outstanding, of which 5,271,667 were vested and exercisable into an equivalent number of the Company's common shares.

As of December 31, 2016, there were 35,290,539 warrants outstanding. Each whole warrant entitles the holder thereof to purchase one additional common share. The warrants are exercisable as follows: 1,455,000 at a price of \$0.38 until April 13, 2017, 19,071,940 at a price of \$0.54 until March 3, 2020 and 14,763,599 at a price \$0.375 until November 10, 2021.

#### **Segmented Information**

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

The TLT division is responsible for all aspects of the Company's therapeutic laser business, which researches, designs and manufactures products used by healthcare practitioners predominantly for the healing of pain. The

PDT division is responsible for the research, development and commercialization of Photo Dynamic Compounds ("PDCs") primarily for the destruction of cancer.

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

		2016	<u>.</u>		2015			2014	
	TLT	PDT	Total	TLT	PDT	Total	TLT	PDT	Total
Sales	\$ 1,918,893	\$ -	\$ 1,918,893	\$ 1,945,246	\$ -	\$ 1,945,246	\$ 1,380,604	\$ -	\$ 1,380,604
Cost of Sales	796,569	-	796,569	629,607	-	629,607	459,323	-	459,323
Gross Margin	1,122,324	-	1,122,324	1,315,639	-	1,315,639	921,281	-	921,281
Operating Expenses									
Selling expenses	1,614,678	-	1,614,678	1,086,354	-	1,086,354	598,178	-	598,178
Administrative expenses	1,278,647	1,268,059	2,546,706	1,380,010	1,072,318	2,452,328	908,597	540,184	1,448,781
Research and development expenses	337,296	1,530,325	1,867,621	431,933	2,597,436	3,029,369	472,451	982,850	1,455,301
(Gain) loss on foreign exchange	14,898	14,898	29,796	(7,891)	-	(7,891)	(4,550)	-	(4,550)
Interest expense	99	99	198	397	398	795	9,769	9,769	19,538
Interest income	(15,429)	-	(15,429)	(37,171)	-	(37,171)	(8,424)	-	(8,424)
	3,230,189	2,813,381	6,043,571	2,853,632	3,670,152	6,523,784	1,976,020	1,532,804	3,508,823
Loss and comprehensive loss for the year	\$(2,107,865)	\$(2,813,381)	\$(4,921,248)	\$(1,537,993)	\$(3,670,152)	\$(5,208,145)	\$(1,054,739)	\$(1,532,804)	\$(2,587,542)
Total Assets	\$ 5,951,273	\$ 289,510	\$ 6,240,783	\$ 6,935,393	\$ 166,730	\$ 7,102,123	\$ 3,208,401	\$ 608,683	\$ 3,817,084
Total Liabilities	495,497	54,245	549,742	545,485	240,179	785,664	341,225	170,525	511,750

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

	2016						2015		2014					
		Canada	USA	International		Canada	USA	International		Canada	USA	International		
Sales		\$1,423,181	\$416,812	\$78,900	\$	1,691,087	\$214,744	\$39,415		\$857,723	\$283,784	\$239,097		
Cost of Sales		590,789	173,027	32,753		543,245	69,019	17,343		266,147	87,973	105,203		
Selling Expenses		1,305,151	309,527	-		948,570	117,113	20,671		466,236	127,772	4,170		
	\$	(472,759) \$	(65,743)	\$ 46,147	\$	199,271	\$ 28,612	\$ 1,402	\$	125,339	\$ 68,039	\$129,723		

As of December 31, 2016, and December 31, 2015, the Company's long-lived assets used in operations are all located in Canada.

## Selected Financial Information and Accounting Policies

The Consolidated Interim Financial Statements for the year ended December 31, 2016, 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, 2016. Please refer to the Company's historic 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 values 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)
- 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 December 31, 2016, 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 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 December 31, 2016, no cash equivalents were held (2015-\$Nil) (2014-\$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 consolidated financial statements as of December 31, 2016, December 31, 2015 and for the years ending December 31, 2016, 2015 and 2014 have been prepared in accordance with IFRS. In addition, and subject to certain transition exceptions and exemptions, the Company's management has consistently applied the same accounting policies in the IFRS consolidated statement of financial position as of January 1, 2010 and throughout comparative periods as if these policies had always been in effect.

The policies applied in the consolidated financial statements as of December 31, 2016, December 31, 2015 and for the years ending December 31, 2016, 2015 and 2014 are based on IFRS issued and outstanding as of November 29, 2016 which is the date at which the Company's Board of Directors approved the audited annual 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 audited consolidated financial statements of December 31, 2016, December 31, 2015 and for the years ending December 31, 2016, 2015 and 2014.

#### Accounting standards issued

The International Accounting Standards Board ("IASB") has issued the following standards, which have not yet been adopted by the Corporation. Each of the new standards is effective for annual years beginning on or after January 1, 2015 with the exception of IFRS 9. The Company has not yet begun the process of assessing the impact that the new and amended standards will have on its financial statements.

The following is a description of the new standards:

IFRS 9, Financial Instruments ("IFRS 9") was issued in final form in July 2014 by the IASB and will replace IAS 39 Financial Instruments: Recognition and Measurement. IFRS 9 uses a single approach to determine whether a financial asset is measured at amortized cost or fair value, replacing the multiple rules in IAS 39. The approach in IFRS 9 is based on how an entity manages its financial instruments in the context of its business model and the contractual cash flow characteristics of the financial assets. Most of the requirements in IAS 39 for classification and measurement of financial liabilities were carried forward unchanged to IFRS 9. The new standard also requires a single impairment method to be used, replacing the multiple impairment methods in

IAS 39. IFRS 9 also includes requirements relating to a new hedge accounting model, which represents a substantial overhaul of hedge accounting which will allow entities to better reflect their risk management activities in the financial statements. The most significant improvements apply to those that hedge non-financial risk, and so these improvements are expected to be of particular interest to non-financial institutions. IFRS 9 is effective for annual periods beginning on or after January 1, 2018. Earlier application is permitted.

**IFRS 15, Revenue from contract with customers** ("**IFRS 15**") was issued in May 2014 and specifies how and when revenue is recognised as well as provides users of financial statements with more informative, relevant disclosures. The standard provides a single, principles based five-step model to be applied to all contracts with customers.

The core principle of IFRS 15 is that an entity recognizes 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 receive in exchange for those goods and services. IFRS 15 will require enhanced disclosures about revenue, provide guidance for transactions that were not previously addressed comprehensively (particularly, service revenue and contract modifications) and improve guidance for multiple –element arrangements.

IFRS 15 is effective for annual periods beginning on or after January 1, 2018. Earlier application is permitted. The company has not yet assessed the impacts of adopting this standard on its consolidated 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 Controls and Procedures**

The Chief Executive Officer and Chief Financial Officer evaluated the effectiveness of the Company's disclosure controls and procedures for the year ending December 31, 2016. Based on that evaluation, the Chief Executive Officer and the Chief Financial Officer concluded that the design and operation of the Company's disclosure controls and procedures were not effective as of December 31, 2016 to provide reasonable assurance that material information relating to the Company would be made known to them by others and information required to be disclosed by the Company in its annual filings, interim filings or other reports filed or submitted by it under securities legislation is recorded, processed, summarized and reported within the time periods specified in the securities legislation.

## Internal Control over Financial Reporting

As of December 31, 2016, an evaluation of the effectiveness of internal controls over financial reporting, as defined in the rules of the Canadian Securities Administrators, was carried out to provide reasonable assurance regarding the reliability of financial reporting and financial statement compliance with IFRS. Based on that evaluation, the President and Chief Executive Officer and the Chief Financial Officer have concluded that the internal controls over financial reporting of the Company were not effective with respect to reasonable

assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with IFRS.

A material weakness is a control deficiency, or a combination of control 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 a limited number of personnel assigned to positions that involve processing financial information, resulting in a lack of segregation of duties so that all journal entries and account reconciliations are reviewed by someone other than the preparer, heightening the risk of error or fraud. 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. Due to our small size and early stage of our business, segregation of duties may not always be possible and may not be economically feasible. We have limited capital resources and have given priority in the use of those resources to our research and development efforts. As our operations grow and become more complex, we intend to hire additional personnel in financial reporting and other areas. However, there can be no assurance of when, if ever, we will be able to remediate the identified material weakness.

All control systems, no matter how well designed, have inherent limitations, including the possibility of human error and the circumvention or overriding of the controls or procedures. As a result, there is no certainty that disclosure controls and procedures or internal control over financial reporting will prevent all errors or all fraud.

#### 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.

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.

The Company has key man life insurance in place on the President and CEO in the amount of \$500,000.

# **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 trials 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 trials may not be indicative of favorable outcomes in later-stage clinical trials. 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 Trial/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 trials 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 studies and early clinical trials may not predict the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier trials. The Company does not know whether the clinical trials 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 trials on various aspects of biopharmaceutical products are conducted by academic researchers, competitors or others. The results of these studies or trials, 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 trials 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 Trial Timing Delays**

The Company cannot predict whether any clinical trials 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 if the Company experiences delays in clinical testing. Significant clinical trial 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 trials 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 trial on hold;
- patients failing to enroll or remain in the Company's trials at the rate the Company expects;
- suspension or termination of clinical trials 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 trials;
- product candidates demonstrating a lack of safety, tolerability or efficacy during clinical trials;
- patients choosing an alternative treatment for the indications for which the Company is developing any of its product candidates or participating in competing clinical trials;
- patients failing to complete clinical trials 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 trials and scheduling conflicts with participating clinicians;
- clinical investigators not performing the Company's clinical trials on their anticipated schedule, dropping out of a trial, or employing methods not consistent with the clinical trial 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 trial 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 trial: or
- failure to reach agreement on acceptable terms with prospective clinical trial 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 trials 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 trial. 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 trials, 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 trials, and the Company may be unable to enroll the patients it needs to complete clinical trials 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 trial;
- 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 trial 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 trials 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 trial, filing of an application to obtain regulatory approval or announcement of additional clinical trials 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 trial 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.

#### Outlook

2017 and 2018, should prove to be exciting years as the Company undertakes initiatives to optimize the next generation TLC-2000 therapeutic medical laser system to successfully commercialize this technology and launch its recurring revenue model. As a result of these initiatives, Theralase hopes to systematically grow its revenues of the TLC-2000 to healthcare practitioners throughout Canada and the US.

Sales of the TLC-2000 therapeutic laser system have not met expectations to date; however, the latest initiatives are designed to optimize the TLC-2000 therapeutic laser system to successfully launch it commercially and to successfully implement its recurring revenue model.

The latest independent scientific and clinical research continues to confirm that the Company's proprietary and patented therapeutic laser technology has a higher safety and effectiveness as compared to other competitive technologies. The Company continues to invest in scientific and clinical research aimed at unlocking the cellular mechanisms of action as to how and why the Theralase laser light can be so effective in the healing of tissue.

In addition, the Company commenced a "<u>first-in-man</u>" Phase Ib clinical trial using its state-of-the-art Photo Dynamic Therapy ("**PDT**") aimed at proving the safety and tolerability as primary outcome measures, pharmacokinetics (where the PDC accumulates in the body and how it exits the body) and an exploratory endpoint of efficacy in the treatment of Non-Muscle Invasive Bladder Cancer ("**NMIBC**").

The Phase Ib NMIBC clinical study protocol commenced by instilling a low dose of TLD-1433 PDC into the bladders of three (3) patients with subsequent light activation using the TLC-3200 medical laser. These patients were treated on March 30, 2017, April 12, 2017 and April 18, 2017. These three (3) patients are currently being monitored for thirty (30) days to ensure safety and tolerability of the procedure. If no Significant Adverse

Events ("SAEs") are reported, then an additional six (6) patients will be enrolled at a therapeutic dose, followed by light activation and follow-up monitoring for six (6) months.

If safety and tolerability of the procedure is demonstrated in these nine (9) patients, the Phase Ib study results will support Health Canada approval and a Phase II multi-center efficacy study for NMIBC will be commenced in Canada, the United States and Europe.

The Company continues to research and develop its patented TLC-3000 medical laser and Photo Dynamic Compound ("PDC") technology aimed at the destruction of cancer by monitoring the safety and tolerability of the first three (3) patients enrolled and treated in a Phase Ib NMIBC human clinical trial.

Due to the on-going requirement of capital to fund the Company's growth in 2017 and 2018, in both divisions, the Company may investigate equity financing options in order to achieve its strategic initiatives and unlock shareholder value.

One of the Company's primary focuses for 2017 remains to increase common share liquidity, thus allowing shareholders the opportunity to participate in the Company's growth on their specific investing terms.

The Company feels that the successful achievement of these strategic initiatives will increase shareholder value in 2017 and 2018.

May 1, 2017

Roger Dumoulin-White President and CEO

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