# 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 six-month period ended June 30, 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 August 29, 2016 and revised November 3, 2016.

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:

1. 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

Theralase has been very successful in executing on its strategic objectives in 2015 and 2H2016 by completing:

- 1. Health Canada Medical Device Licence (Class III) approval of its next generation TLC-2000 Therapeutic Medical Laser System
- 2. US Food and Drug Administration ("FDA") 510(k) clearance of the TLC-2000
- 3. Health Canada Clinical Trial Application ("CTA") approval
- 4. Princess Margaret Cancer Centre, University Health Network ("UHN") Research Ethics Board ("REB") approval
- 5. Demonstrated 6 month accelerated stability and 9 month long term stability of it lead anti-cancer PDC TLD-1433
- 6. Signed a Clinical Research Agreement ("**CRA**") with UHN to conduct a Phase Ib clinical study for the indication of NMIBC.

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 "Cell Sensing<sup>®</sup>" technology that "senses" and targets injured tissue at depth with exact precision, unattainable by any of its competitors, enabling exact doses of energy to be delivered for enhanced efficacy and accelerated healing. The TLC-2000 is also a learning device that remembers the most optimized protocols based on an individual patient's optical tissue profile.

The FDA has reviewed and cleared Theralase's 510(k) premarket notification and has determined that the TLC-2000 is substantially equivalent to the Theralase TLC-1000 therapeutic medical laser system for the indication of *"Adjunctive Use in the Temporary Relief of Pain Associated with Knee Disorders"* and has authorized Theralase to market the device throughout the United States commencing 4Q2015.

The TLC-2000 Biofeedback Therapeutic Laser System is approved by the Canadian Standards Association ("**CSA**") and has a Health Canada approved Medical Device Licence (Class III). The Health Canada approval allows the TLC-2000 to be commercially distributed in Canada commencing 4Q2015.

Approval of the TLC-2000 Biofeedback Therapeutic Laser System by Conformité Européene ("**CE**") is expected in 2016 for commercial distribution in Europe.

In 2016, Theralase will commence a dedicated 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.

# USA Patent: 6,413,267 Canadian Patent: 2,315,521 Belgium, Italy, United Kingdom, Germany, France, Spain Patent: 1075854

#### 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 precise 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: brain, prostate, bladder, breast and colorectal 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: breast, prostate, lung and bladder
- Activated at a variety of wavelengths allowing shallow and deep tumour destruction

The PDT division is focused on commencing and 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 NMIBC clinical trial will evaluate TLD-1433 for the primary endpoints of safety and tolerability, with a secondary endpoint of pharmacokinetics (where the PDC accumulates in the body and how it exits the body) and an exploratory endpoint of efficacy in a patient population defined by UHN uro-oncology department to enable drug approval.

To date, the Company has achieved the following milestones:

- 1. Health Canada CTA approval of TLD-1433 (completed)
- 2. UHN REB approval of the clinical protocol (completed)
- 3. 6 month accelerated stability and 9 month long term stability of it lead anti-cancer PDC TLD-1433
- 4. CRA with UHN to conduct a Phase Ib clinical study for the indication of NMIBC

Theralase has completed sterilization, biocompatibility and mechanical testing of the TLC-3400 Dosimetry Fibre Optic Cage ("**DFOC**") medical laser probes used in conjunction with the TLC-3200 Medical Laser System to

activate TLD-1433 that has absorbed into bladder cancer lesions and has submitted the information to Health Canada, via an Investigational Testing Authorization ("**ITA**") on July 29, 2016.

Health Canada required information and testing that supported:

- 1. Biocompatibility (the materials that enter the body are proven not harmful to tissue)
- 2. Mechanical testing (the materials demonstrate the characteristics of functional reliability, tensile strength and repeatability of operation)
- 3. Sterility (the materials that enter the body are demonstrated to be sterile)

The TLC-3200 PDT Laser System delivers green laser light, at a wavelength of 525 nanometers ("**nm**"), while the 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 clinical procedure for the Phase Ib study to treat NMIBC, titled "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" is to:

- 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 minutes
- Void the bladder and flush the bladder twice with sterile water to remove any excess 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-34XX DFOC device into the bladder via the cystoscope's working channel and connect it to the TLC-3200 PDT 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 to provide a uniform distribution of the laser light energy, in the correct dosage, to the bladder wall

Pending Health Canada approval of the ITA, expected in September 2016, Theralase will immediately commence enrollment of patients into a Phase Ib clinical study in the treatment of NMIBC. The primary outcome measures of the Phase Ib clinical study will be safety and tolerability, with a secondary outcome measure of pharmacokinetics (where the drug accumulates in tissue and how it exits the body) and an exploratory outcome measure of efficacy.

The Phase Ib NMIBC clinical study protocol will commence by instilling a low dose of TLD-1433 drug into the bladders of three (3) patients with subsequent light activation using the TLC-3200 medical laser. These three (3) patients will then be monitored for thirty (30) days to ensure safety and tolerability of the procedure. If no adverse events are reported, then an additional six (6) patients will be enrolled at a high 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 IIb multi-center efficacy study for NMIBC will be commenced in Canada, the United States and Europe.

Theralase has a growing portfolio of intellectual property patents to comprehensively protect the Theralase PDC anti-cancer technology for many decades allowing the Company to enjoy the benefits of intellectual patent protection in the development and commercialization of its technology.

Issued USA Patents: 6,962,910, 7,612,057, 8,148,360, 8,445,475, 9,345,769

#### Pending USA Patent Applications: 61/801,674, PCT/US13/36595

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 anti-tumour 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 commences validation of its anti-cancer technology via human clinical trials in 3Q2016.

# 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/cm<sup>2</sup>) in normoxic conditions (ambient atmosphere) and in hypoxic conditions (0.5% O<sub>2</sub>). The Theralase PDCs exerted Photo Dynamic Inactivation ("**PDI**") 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 PDI 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 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 March 3, 2015, the Company closed a public offering of Units, under a Base Shelf Prospectus. On closing, the Corporation issued an aggregate of 18,181,817 Units at a price of \$0.44 per Unit for aggregate gross proceeds of approximately \$8,000,000. Each Unit consists of one common share of the Corporation and one common share purchase warrant. Each Warrant entitled the holder to acquire an additional Common Share at a price of \$0.54 for a period of 60 months following the date of issuance. In connection with the offering, the Company paid agent's fees totaling \$626,646 and issued an aggregate of 890,123 finder warrants, each finder

warrant is exercisable into one common share at an exercise price of \$0.54 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 commencement of a Phase Ib clinical study for NMIBC in 3Q2016.
- Commercial activities by the Therapeutic Laser Therapy ("**TLT**") division; specifically, the launch of the patented next generation TLC-2000 Biofeedback Therapeutic Laser System in Canada, the United States in 4Q2015 and in Europe in 2016.
- Working capital and general corporate purposes.

## **Overview of Financial Performance**

During the 6 month term ending June 30, 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 commencing clinical trials of the TLC-3000 patented anti-cancer technology in 2016, commercial launch of the patented next generation TLC-2000 Biofeedback Therapeutic Laser System in Canada and the US and maintaining moderate sales of the Theralase TLC-1000 therapeutic laser system.

# Summary of Selected Annual Information

For the years ended December 31:

	2015	2014	2013
Total revenues	1,945,246	1,380,604	1,203,620
Net profit / (loss)	(5,208,144)	(2,587,542)	(1,152,209)
Basic and diluted loss per share	\$ (0.05)	\$ (0.03)	\$ (0.02)
Total assets	7,102,123	3,817,084	2,684,877
Total liabilities	785,664	511,750	920,989
Deficit	(20,866,519)	(15,658,375)	(13,070,831)
Shareholders' Equity	 6,316,459	3,305,334	1,763,888

# Summary of Quarterly Results

	2016		2	015
	June 30	March 31	December 31	September 30
Total revenues	481,690	411,448	886,638	383,791
Net profit / (loss)	(1,310,676)	(1,145,739)	(955,065)	(1,973,960)
Basic and diluted loss per share	\$ (0.012) \$	(0.016)	\$ (0.016)	\$ (0.021)
Total assets	4,576,402	5,543,327	7,102,123	7,442,831
Total liabilities	356,694	704,445	785,664	823,491
Deficit	(23,322,939)	(22,012,258)	(20,866,519)	(19,911,454)
Shareholders' Equity	4,219,708	5,322,154	6,316,459	6,619,340

		2015		2014
	June 30	March 31	December 31	September 30
Total revenues	309,513	368,304	386,131	134,036
Net profit / (loss)	(1,345,472)	(933,643)	(849,781)	(1,048,034)
Basic and diluted loss per share	\$ (0.02)	\$ (0.01)	\$ 0.003	\$ (0.015)
Total assets	8,705,818	10,167,305	3,817,084	3,648,813
Total liabilities	339,753	474,165	511,750	376,923
Deficit	(17,937,492)	(16,592,018)	(15,658,375)	(14,808,592)
Shareholders' Equity	8,366,065	9,693,140	3,305,334	3,271,890

## Liquidity and Capital Resources

As of June 30, 2016, current assets aggregated to \$4,093,018 compared with current liabilities of \$356,694 netting working capital of \$3,736,324 and a current ratio (current assets vs. current liabilities) of approximately 11:1.

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 June 30, 2016 the Company had cash and cash equivalents of 2,077,465. 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 and, accordingly, management may pursue alternate financing sources to fund the Company's development and commercialization efforts, in the future, that are similar to the financing secured through the public offering that took place on March 3, 2015 (note 9). Nevertheless, there is no assurance that these initiatives will be successful.

#### **Results of Operations**

	2016	2015	2014
Sales Revenue	\$ 803,366	\$ 564,008	\$ 751,618
Service Revenue	46,045	43,015	52,003
Clinic Revenue	21,758	18,820	17,161
Other Revenue	 21,969	51,974	39,655
	893,138	677,817	860,438

For the six-month period ended June 30, 2016, total revenue increased from \$677,817 to \$893,138 for the same period in 2015, a 32% increase. In Canada, revenue decreased 12% to \$497,378 from \$562,890, in the US, revenue increased 219% to \$316,756 from \$99,343 and international revenue increased 407% to \$79,004 from \$15,584. The decrease in Canadian revenue in 2Q2016 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 and the learning curves associated with training and developing a new sales force.

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 dramatically increasing sales of the TLC-2000 across Canada and the United States in 2016. 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 six-month period ended June 30, 2016 was \$302,879 (34% of revenue) resulting in a gross margin of \$590,259 or 66% of revenue, compared to a cost of sales of \$243,394 (36% of revenue) in 2015, resulting in a gross margin of \$434,423 or 64% 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 six-month period ended June 30, 2016 were \$665,727 representing 75% of sales, compared with \$402,598 or 59% in 2015, and consisted of the following items:

	2016			2015	2014
Sales salaries	\$	420,038	\$	246,087	\$ 124,180
Advertising		88,214		29,979	76,908
Commission		40,823		40,813	30,540
Travel		82,025		62,802	56,117
Stock based compensation		9 <i>,</i> 885		4,760	14
Amortization and depreciation allocation		24,742		18,157	13,957
Total selling expenses		\$665,727	\$	402,598	\$301,716

The increase is primarily due to increased spending in marketing and sales personnel, which will augment sales in future financial quarters, aiding in 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 six-month period ended June 30, 2016 were \$1,452,732 representing a 47% increase from \$982,841 in 2015, and consisted of the following items:

	2016	2015	2014
Insurance	\$ 39 <i>,</i> 907	\$ 31,191	\$ 26,594
Professional fees	117,195	140,509	52,737
Rent	40,600	40,600	40,600
General and administrative expenses	470,590	295,450	161,885
Administrative salaries	433,458	290,236	233,318
Director and advisory fees	39,301	46,389	4,600.00
Stock based compensation	292,870	124,924	21,459
Amortization and depreciation allocation	18,810	13,542	9,793
Total administrative expenses	\$ 1,452,732	\$ 982,841	\$ 550,986

Increases in administrative expenses are attributed to the following:

- General and administrative expenses increased 47% due to increased spending on investor relations and research scientist activities
- Stock based compensation increased by 134% as a result of vesting of stock options to certain employees, directors and officers of the Company in 2Q2016

• Administrative salaries increased by 49% as a result of hiring clinical and educational staff.

# Research and Development Costs

Gross research and development expenses totaled \$925,504 for the six-month period ended June 30, 2016 compared to \$1,356,664 in 2015 (32% decrease). Research and development expenses represented 31% of the Company's operating expenses for the period 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 six-month period ended June 30, 2016 was \$2,456,417, which included \$422,726 of net non-cash expenses (amortization, stock-based compensation expense, foreign exchange gain/loss and lease inducements). This compared to a net loss for the same period in 2015 of \$2,279,117, which included \$197,152 of net non-cash expenses. The PDT division represented \$1,669,988 of this loss (70%). The increase in net loss is due to increased investment in research and development of the TLC-3000, sales, marketing and administrative personnel, all related to the commencement of a Phase Ib clinical study for NMIBC and sales of the next generation TLC-2000 therapeutic medical laser system, respectively.

# Cash Flows

Funds used in operating activities prior to net changes in other operating items amounted to \$2,033,690 for the six-month period ended June 30, 2016, compared to funds used in operating activities of \$2,081,965 in 2015. Funds used in operating activities after taking into account net changes in other non-cash operating items were \$2,190,827 for the six-month period ended June 30, 2016, compared to funds used of \$2,030,666 for the same period in 2015.

Funds used in investing for the six-month period ended June 30, 2016 amounted to \$72,562 compared to \$98,337 for 2015. The decrease is a result of decreased spending on tools, dies and equipment related to the TLC-2000 Biofeedback technology, as these programs mature.

For the six-month period ended June 30, 2016, funds obtained from financing activities amounted to \$Nil, compared to \$7,216,618 obtained in financing activities for 2015. The decrease is due to proceeds from the public offering on March 3, 2015.

# 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 \$64,281.

# Commitments

As of June 30, 2016, the Company's commitments consisted of the following:

	Total 2016			2017	2018
Lease obligations (a)	\$ 91,000	\$	42,000	\$ 49,000	\$ -
Lease obligations (b)	3,507		1,002	2,004	501
Research Agreement (c)	77,000		77,000		
Total	\$ 171,507	\$	120,002	\$ 51,004	\$ 501

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 or accrued \$49,000 relating to this commitment, in which \$77,000 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 June 30, 2016, the share capital of the Company consisted of 107,047,360 common shares. Each common share entitles the holder to one vote per share.

As of June 30, 2016, there were 10,085,000 options outstanding, of which 4,425,000 were vested and exercisable into an equivalent number of the Company's common shares.

As of June 30, 2016, there were 20,526,940 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 and 19,071,940 at a price of \$0.54 until March 3, 2020.

#### 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 six-month period ended June 30:

		2016			2015				2014	
	TLT	PDT	Total	TLT	PDT	Total		TLT	PDT	Total
Sales	\$ 893,138	\$-	\$ 893,138	\$ 677,817 \$	- \$	677,817	\$	860,437	\$-\$	860,437
Cost of Sales	302,879	-	302,879	243,394	-	243,394		245,828	-	245,828
Gross Margin	590,259	-	590,259	434,423	-	434,423	_	614,609	-	614,609
Operating Expenses										
Selling expenses	665,727	-	665,727	402,598	-	402,598		301,716	-	301,716
Administrative expenses	715,447	737,285	1,452,732	570,512	412,329	982,841		344,857	206,129	550,986
Research and development expenses	-	925,504	925,504	288,132	1,068,532	1,356,664		180,740	260,906	441,646
(Gain) loss on foreign exchange	7,099	7,099	14,198	(12,970)	-	(12,970)		49	-	49
Interest expense	99	99	198	140	140	280		6,545	6,546	13,091
Interest income	(11,684)	-	(11,684)	(15,872)	-	(15,872)		(3,153)	-	(3,153)
	1,376,687	1,669,988	3,046,675	1,232,539	1,481,002	2,713,540		830,754	473,582	1,304,335
Loss and comprehensive loss for the period	\$ (786,429)	\$ (1,669,988)	)\$ (2,456,417)	\$ (798,116) \$	(1,481,002) \$	(2,279,117)	\$	(216,144)	\$ (473,582) \$	(689,726)
Total Assets	\$ 4,582,404	\$ 123,067	\$ 4,705,471	\$ 8,348,906 \$	356,912 \$	8,705,818	\$	4,028,214	\$ 87,791 \$	4,116,005
Total Liabilities	335,710	82,747	418,457	255,500	85,446	340,946		277,002	45,580	322,582

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

	2016				2014								
		Canada	USA	International	 Canada	USA	Int	ternational	Canada		USA	Inte	ernational
Sales		\$497,378	\$316,756	\$79,004	 \$562,890	\$99,343		\$15,584	\$508,523	4,0	\$215,107		\$136,807
Cost of Sales		160,420	107,697	34,762	202,134	35,674		5,586	55,928		55,928		60,195
Selling Expenses		427,653	226,929	11,144	385,870	15,793		935	99,804		99,804		4,170
	\$	(90,695) \$	(17,870)	\$ 33,098	\$ (25,114) \$	47,876	\$	9,063	\$ 352,791	\$	59,375	\$	72,442

As of June 30, 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 six-month period ended June 30, 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, 2015. Please refer to the Company's historic annual and quarterly financial statement filings, including material interim press releases, on the regulatory website -- <u>www.SEDAR.com</u>.

# 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 June 30, 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 June 30, 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 June 30, 2016, December 31, 2015 and for the six-month periods ending June 30, 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 June 30, 2016, December 31, 2015 and for the six-month periods ending June 30, 2016, 2015 and 2014 are based on IFRS issued and outstanding as of August 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 June 30, 2016, December 31, 2015 and for the six-month periods ending June 30, 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**") IFRS 9 *Financial Instruments* 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, 2017. 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.

**IAS 1, Presentation of Financial Statements** ("IAS 1") was amended by the IASB in December 2014. The amendments are designed to further encourage companies to apply professional judgement in determining what information to disclose in the financial statements.

The amendment is effective for annual periods beginning on or after January 1, 2016. Earlier application is permitted.

# **Disclosure Controls and Procedures**

The Chief Executive Officer and Chief Financial Officer evaluated the effectiveness of the Company's disclosure controls and procedures as of June 30, 2016 and for the six-month period ending June 30, 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 effective as of June 30, 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 June 30, 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 effective and provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with IFRS.

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.

#### Capital Resources

In order to achieve its long-term development and commercialization strategy for the Company's range of biomedical laser systems and PDCs, the Company may need to raise additional capital through the issuance of shares, collaboration agreements or partnerships that would allow the Company to finance its activities. Nothing guarantees that additional funds will be available or that they may be acquired according to acceptable terms and conditions. Additional financing may result in dilution of shareholder value.

#### Volatility of Share Price

The market price of the Company's 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 shares.

#### **Regulatory Approvals**

The Company is directly and indirectly engaged in the design, manufacture, sale and marketing of biomedical laser equipment, a category of medical device which is subject to regulatory oversights, audits and controls by various national regulatory agencies (FDA, Health Canada, CE) and authoritative quality standards bodies (UL, CSA, ISO and TUV), all with 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. No assurance can be given that current regulations relating to regulatory approval will not change or become more stringent and it must be noted that product approvals may be withdrawn if compliance with regulatory standards is not maintained.

#### Licenses and Patents

The Company's success will depend in part on its ability to obtain licenses and patents, protect its trade secrets and operate without infringing the exclusive rights of other parties. There is no guarantee that any license and patent that will be granted to the Company will bring any competitive advantage to the Company, that its license and patent protection will not be contested by third parties, or that the licenses and 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 licenses and patents granted to the Company.

#### Currency Risk

The Company is exposed to currency risk through export sales, primarily in US dollars. Changes in exchange rates may result in foreign exchange gains or losses. The Company does not use derivative instruments to reduce its exposure to foreign currency risk and does not anticipate using any hedging strategies in a material

way in the immediate future. Management will continue to assess the situation and may, as a result, change its approach to hedging foreign exchange currency fluctuations.

## Credit Risk

The Company's financial instruments that are exposed to concentrations of credit risk consist primarily of cash, cash equivalents and accounts receivable. Cash and cash equivalents are in place with major financial institutions. The Company, in the normal course of business, is exposed to credit risk from its customers substantially all of whom are in the medical industry. These accounts receivable are subject to normal industry credit risks. The Company manages its credit risk through its credit evaluation, approval and monitoring processes.

## Human Resources

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 executives, scientific staff, and collaborators. The loss of key personnel could compromise the rhythm and success of product development.

## Product Liability

The Company has obtained product liability insurance coverage in the total amount of \$2,000,000. These insurance coverages are a limited guarantee and a product liability claim could potentially be greater than these coverages. The Company's profitability would be adversely affected by a successful product liability claim in excess of its insurance coverage.

## Outlook

2016 and 2017, will be exciting years as the Company systematically grows its revenues through sales of the TLC-2000 next generation therapeutic laser to healthcare practitioners throughout Canada and the US. In addition, the Company plans to successfully complete a "first-in-man" 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 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 so dramatically heal tissue.

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 executing on its strategic objective of enrolling patients in a Phase Ib human clinical trial for the treatment of NMIBC in late 3Q2016.

Due to the on-going requirement of capital to fund the Company's growth in 2016 and 2017 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 2016 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 these initiatives will dramatically increase shareholder value as the Company achieves its strategic objectives in 2016.

November 3, 2016



Roger Dumoulin-White President and CEO