

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

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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 nine-month period ended September 30, 2017. 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](http://www.sedar.com). This MD&A is prepared as of November 28<sup>th</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 and markets patented and proprietary super-pulsed laser technology indicated and cleared by Health Canada and the Food and Drug Administration ("**FDA**") for the treatment of chronic knee pain. The technology has been used off-label for treating 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 intended 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, the US and internationally, who are interested in the safe and effective treatment of chronic knee pain and in off-label use 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.

2. Commercialization of the patented TLC-3000 PDC Anti-Cancer Technology through preclinical research, clinical trials and technology development to destroy cancers for oncological applications, and to destroy bacteria. The lead cancer target, under Phase Ib clinical study is Non-Muscle Invasive Bladder Cancer (“**NMIBC**”).

## **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-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**”).

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 Study entitled, “*A Phase Ib Trial of Intravesical Photo Dynamic Therapy (“**PDT**”) in Patients with NMIBC 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*” commenced treating patients in March 2017 and to date has treated three patients at the Maximum Recommended Starting Dose (“**MRSD**”) (0.35 mg/cm<sup>2</sup>) and one patient at the Therapeutic Dose (0.70 mg/cm<sup>2</sup>) of TLD-1433 PDC, activated by laser light (525 nm, 90 J/cm<sup>2</sup>) delivered through a combination of the TLC-3200 PDT Medical Laser and TLC-3400 Laser Probe Dosimetry Fibre Optic Cage (“**DFOC**”) technology.

Enrollment for the remaining five patients to be treated at the Therapeutic Dose is currently ongoing with Theralase’s clinical partner.

Pre-defined Study objectives for patients with high risk, Ta, T1 or Carcinoma In-Situ (“**CIS**”) NMIBC are:

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

## **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 parts: In the first part, 3 subjects will be enrolled and treated with PDT (TLC-3200 / TLC-3400 Dosimetry Fibre Optic Cage (“**DFOC**”) System) at the Maximum Recommended Starting Dose (“**MSRD**”) (0.35 mg/cm<sup>2</sup>) of TLD-1433. If treatment at the MSRD does not raise significant safety concerns, as determined by the independent Data Safety Monitoring Board (“**DSMB**”), an additional 6 subjects will be enrolled and treated with PDT at the Therapeutic Dose (0.70 mg/cm<sup>2</sup>) of TLD-1433

## **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 TLC-3200 DFOC in the bladder (like an umbrella) to strategically place optical detectors at twelve (12) predetermined locations along the bladder wall to 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 sixty (60) to one hundred and twenty (120) minutes
- Void bladder to remove water

The TLC-3200 Medical Laser System emits green laser light, at a wavelength of 525 nanometers (“**nm**”), while the TLC-3200 DFOC technology monitors the laser light intended to provide a uniform distribution of the laser light energy, in the correct dosage, to the bladder wall.

## **Interim Data Results:**

- 1) As previously reported, the first three patients treated at the MRSD successfully achieved the primary, secondary and exploratory outcome measures at 90 days post treatment.
- 2) Patient four treated at the Therapeutic Dose successfully achieved the primary, secondary and exploratory outcome measures at 90 days post treatment. During the 90 day cystoscopy analysis, patient number four’s bladder surface wall was observed to be red and inflamed. The patient will continue to be monitored to see if this condition resolves.
- 3) Although not a pre-defined outcome measure of the Study, patient one, two and three have successfully achieved the primary and secondary outcome measures at 180 days post treatment.

- 4) Although not a pre-defined outcome measure of the Study, patient one, two and three have not achieved the exploratory outcome measure at 180 days post treatment.

### **Conclusions:**

Light activated TLD-1433 PDT, based on initial data, has demonstrated:

- 1) A high level of safety, tolerability and PK, in patients with high risk, Ta, T1 or CIS NMIBC, for 180 days post PDT treatment, when treated at the MRSD;
- 2) A high level of safety, tolerability and PK, in patients with high risk, Ta, T1 or CIS NMIBC, for 90 days post PDT treatment, when treated at the Therapeutic Dose;
- 3) An ability to delay recurrence and progression of NMIBC at the MRSD for between 90 to 180 days post treatment for patients, who have a clinical history or are at high risk of UUTUC and potentially longer for those that do not;
- 4) An ability to delay recurrence and progression of NMIBC at the Therapeutic Dose for 90 days post treatment.

### **Discussion:**

Patients one and two have a previous history of Upper Urinary Tract Urothelial Carcinoma (“UUTUC”) diagnosed prior to their PDT treatment, while patients 3 and 4 are at high risk of UUTUC. This clinical observation, along with peer-reviewed clinical research<sup>1,2</sup> raises the possibility that the source of patient one, two and three’s recurrent NMIBC may have originated by seeding in the bladder from these extravesical sites, potentially confounding the exploratory outcomes for these patients (In this NMIBC patient population, 80% of patients recur, while 50% of patients progress). The extravesical upper tract locations of all treated patients were not exposed to the PDT treatment in the Study.

Although patient one, two and three, treated at the MRSD (1/2 of Therapeutic Dose), recurred at 180 days post treatment; there was no sign of progression of the disease; indicating, that they may benefit from multiple PDT treatments, delivered between 90 to 180 days post treatment.

The interim data obtained to date suggests that the Theralase PDT treatment was able to achieve the primary, secondary and exploratory objectives of the Study at both the MRSD and Therapeutic Dose, delaying recurrence and more importantly delaying progression of NMIBC, for more than 90 days post PDT treatment, which would be of particular benefit for NMIBC patients; especially, patients who do not have a previous history of UUTUC.

Enrollment and treatment of the remaining five patients to be treated at the Therapeutic Dose will provide additional data on the ability to achieve the primary, secondary and exploratory outcome measures at this dose and if so, up to which timepoint.

According to the literature, previous intravesical chemotherapeutic agents have been shown to reduce tumour recurrences; however, none of these agents has proven to be of benefit in preventing disease progression.<sup>3, 4, 5, 6</sup>

BCG, an attenuated strain of Mycobacterium bovis, which is used as a vaccine against tuberculosis, has been shown to prolong the time to development of muscle invasion<sup>7, 8</sup>; however, despite a high initial complete response rate with BCG, a significant number of participants will eventually fail BCG therapy with notable local and systemic toxicities being observed with continued, prolonged use of BCG.<sup>9</sup>

Patients with BCG-refractory NMIBC have a 50% chance of disease progression and radical cystectomy should be recommended<sup>10</sup>; however, for patients who refuse cystectomy or who are too ill for major surgery, alternative methods may be considered, but at the risk for interval disease progression.<sup>11</sup>

For such high-risk patients, failing treatment with intravesical BCG, for whom cystectomy is not an option, further BCG therapy or other intravesical therapies; including: immunotherapy, chemotherapy, device-assisted therapy or sequential combination therapy is recommended.<sup>12, 13, 14, 15</sup>

Intravesical therapy for patients with NMIBC, who are not candidates for or who refuse cystectomy, presents an opportunity for a new therapy, such as Theralase's PDT technology, provided that the therapy:

- 1) Requires a limited number of treatments to be delivered
- 2) Provides high safety and minimal toxicity to the patient
- 3) Can delay recurrence and/or disease progression for a reasonable length of time

The initial data obtained to date by Theralase suggests that the Company's PDT technology is able to achieve these objectives.

<sup>1</sup> Azémar, MD, Comperat, E, Richard, F, Cussenot, O, Rouprêt, M (2011). Bladder recurrence after surgery for upper urinary tract urothelial cell carcinoma: frequency, risk factors, and surveillance. *Urol Oncol.*; 29(2):130-6 (ISSN: 1873-2496)

<sup>2</sup> Sternberg, IA, Chen, LY, Herr, HW, Donat, SM, Bochner, BH, Dalbagni, G, Urology Service, Department of Surgery, Memorial Sloan-Kettering Cancer Center, New York, NY (2013). Upper tract imaging surveillance is not effective in diagnosing upper tract recurrence in patients followed for non-muscle invasive bladder cancer. *J Urol*; 190(4):1187-91. doi:10.1016/j.juro.2013.05.020

<sup>3</sup> Martínez-Piñeiro, AJ (1990). Cancer of the bladder: where are we? *Arch Esp Urol*. 1990;43 Suppl 2:109-12.

<sup>4</sup> Lamm, Donald L. M.D., Blumenstein, Brent A. Ph.D., Crawford, E. David M.D., Montie, James E. M.D., Scardino, Peter M.D., Grossman, H. Barton M.D., Stanisc, Thomas H. M.D., Smith Jr., Joseph A., M.D., Sullivan, Jerry M.D., Sarosdy, Michael F. M.D., Crissman, John D. M.D., and Coltman, Charles A. M.D. (1991) A Randomized Trial of Intravesical Doxorubicin and Immunotherapy with Bacille Calmette–Guérin for Transitional-Cell Carcinoma of the Bladder, *N Engl J Med* 1991; 325:1205-1209, DOI: 10.1056/NEJM199110243251703

<sup>5</sup> Melekos, MD, Chionis, H, Pantazakos, A, Fokaefs, E, Paranychianakis, G, Dauaher, H (1993). Intravesical bacillus Calmette-Guerin immunoprophylaxis of superficial bladder cancer: results of a controlled prospective trial with modified treatment schedule. *J Urol*. 1993 Apr;149(4):744-8.

<sup>6</sup> Shelley, Mike, Court, JB, Kynaston, H, Wilt, Timothy, Coles, Bernadette, Mason, Malcolm (2003). Intravesical Bacillus Calmette-Guérin versus mitomycin C for Ta and T1 bladder cancer. *Cochrane Database of Systematic Reviews*, John Wiley & Sons, Ltd, DOI: 10.1002/14651858.CD003231, US: <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD003231/abstract>

<sup>7</sup> Herr, Harry W. (1988), Bladder cancer: Pelvic lymphadenectomy revisited, *Journal of Surgical Oncology*, Wiley Subscription Services, Inc., <http://dx.doi.org/10.1002/jso.2930370407>, 10.1002/jso.2930370407

<sup>8</sup> Sylvester, RJ, van der Meijden, AP, Lamm, DL (2002). Intravesical bacillus Calmette-Guerin reduces the risk of progression in patients with superficial bladder cancer: a meta-analysis of the published results of randomized clinical trials. *J Urol*. 2002 Nov;168(5):1964-70. PMID: 12394686, DOI: 10.1097/01.ju.0000034450.80198.1c

<sup>9</sup> Herr, H. W., Badalament, R. A., Amato, D. A., Laudone, V. P., Fair, W. R., Whitmore, W. F., Lamm, D. L. (1989). Superficial bladder cancer treated with bacillus Calmette-Guerin: A multivariate analysis of factors affecting tumor progression. *Journal of Urology*, 141(1), 22-29.

<sup>10</sup> Sylvester, Richard J., van der Meijden, Adrian P.M., Oosterlinck, Willem, Witjes, J. Alfred, Bouffoux, Christian, Denis, Louis, Newling, Donald W.W., Kurth, Karlheinz (2005). Predicting Recurrence and Progression in Individual Patients with Stage Ta T1 Bladder Cancer Using EORTC Risk Tables: A Combined Analysis of 2596 Patients from Seven EORTC Trials, *European Urology*, Volume 49, Issue 3, March 2006, Pages 466-477, <https://doi.org/10.1016/j.eururo.2005.12.031>

<sup>11</sup> O'Donnell, Michael A. (2012). Treatment of non-muscle-invasive bladder cancer, <http://ether.stanford.edu/urology/Treatment%20of%20non-muscle-invasive%20bladder%20cancer.pdf>

<sup>12</sup> Hall, M. C., Chang, S. S., Dalbagni, G., Pruthi, R. S., Seigne, J. D., Skinner, E. C., Schellhammer, P. F. (2007). Guideline for the Management of Nonmuscle Invasive Bladder Cancer (Stages Ta, T1, and Tis): 2007 Update. *Journal of Urology*, 178(6), 2314-2330. DOI: 10.1016/j.juro.2007.09.003

<sup>13</sup> Van Rhijn, B. W.G., Van Der Kwast, T. H., Kakiashvili, D. M., Fleshner, N. E., Van Der Aa, M. N.M., Alkhateeb, S., Bangma, C. H., Jewett, M. A.S., Zlotta, A. R. (2010). Pathological stage review is indicated in primary pT1 bladder cancer. *BJU International*, 106: 206–211. doi:10.1111/j.1464-410X.2009.09100.x

<sup>14</sup> Lightfoot, Andrew J., Rosevear, Henry M., O'Donnell, Michael A. (2011). Recognition and Treatment of BCG Failure in Bladder Cancer, *The Scientific World Journal*. 11. 602-13. 10.1100/tsw.2011.30.

<sup>15</sup> Yates. D.R., Brausi, M.A., Catto, J.W., Dalbagni, G., Rouprêt, M., Shariat, S.F., Sylvester, R.J., Witjes, J.A., Zlotta, A.R., Palou-Redorta, J. (2012). Treatment options available for bacillus Calmette-Guérin failure in non-muscle-invasive bladder cancer. *Eur Urol*. 2012 Dec;62(6):1088-96. doi: 10.1016/j.eururo.2012.08.055.

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 other drug candidates, in various stages of preclinical development. Theralase will continue to validate its preclinical data with additional cancer animal models and toxicology analyses to potentially bring these PDC drug candidates online for various cancer and bacterial 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 PDT division; specifically, the Phase Ib clinical study for NMIBC.
- Commercial activities by the TLT division; specifically, the advancement of the patented next generation TLC-2000 Therapeutic Laser System in Canada, the United States and internationally in 2018.
- Working capital and general corporate purposes.

### **Overview of Financial Performance**

During the nine-month period ending September 30, 2017 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, advancement of the patented next generation TLC-2000 Therapeutic Laser System in Canada, the United States and internationally, implementation of a recurring revenue model for the TLC-2000 and maintaining moderate sales of the Theralase TLC-1000 therapeutic laser system.

The Company is focused on advancing the TLC-2000 and implementing a recurring revenue model in 2018.

## 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 profit / (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

	2017			2016
	September 30	June 30	March 31	December 31
Total revenues	337,520	509,306	507,428	712,167
Net profit / (loss)	(1,655,749)	(1,765,839)	(1,472,184)	(1,069,226)
Basic and diluted loss per share	\$ (0.014)	\$ (0.014)	\$ (0.014)	\$ (0.003)
Total assets	3,626,255	4,382,203	4,821,300	6,240,783
Total liabilities	520,388	592,622	518,032	549,742
Deficit	(30,681,538)	(29,025,790)	(27,259,951)	(25,787,767)
Shareholders' Equity	3,105,867	3,789,581	4,303,268	5,691,041

	2016			2015
	September 30	June 30	March 31	December 31
Total revenues	313,588	481,690	411,448	883,638
Net profit / (loss)	(1,461,903)	(1,244,380)	(1,145,739)	(955,067)
Basic and diluted loss per share	\$ (0.014)	\$ (0.012)	\$ (0.016)	\$ (0.016)
Total assets	3,417,731	4,576,402	6,026,599	7,102,123
Total liabilities	563,229	356,694	704,445	785,664
Deficit	(24,784,842)	(23,322,939)	(22,012,258)	(20,866,519)
Shareholders' Equity	2,854,502	4,219,708	5,322,154	6,316,459

	2015			2014
	September 30	June 30	March 31	December 31
Total revenues	383,791	309,513	368,304	386,131
Net profit / (loss)	(1,973,960)	(1,345,474)	(933,643)	(849,781)
Basic and diluted loss per share	\$ (0.021)	\$ (0.003)	\$ (0.01)	\$ 0.003
Total assets	7,442,831	8,705,818	10,167,305	3,817,084
Total liabilities	823,491	339,753	474,165	511,750
Deficit	(19,911,454)	(17,937,492)	(16,592,018)	(15,658,375)
Shareholders' Equity	6,619,340	8,366,065	9,693,140	3,305,334

## Liquidity and Capital Resources

As of September 30, 2017, current assets aggregated to \$3,626,255 compared with current liabilities of \$520,388 netting working capital of \$3,105,867 and a current ratio (current assets vs. current liabilities) of approximately 7:1.

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 September 30, 2017, the Company had cash and cash equivalents of \$845,371. Sales of the TLC-1000 and TLC-2000, the company's existing product lines, have not been sufficient in and of themselves to enable the Company to fund all its continuing development and commercialization efforts. The Company has successfully raised capital through equity offerings in 2015 and 2016; however, there is no guarantee that the Company will be able to raise any additional capital or on terms and conditions agreeable to the Company.

## Results of Operations

	2017	2016	2015
Sales Revenue	\$ 1,197,531	\$ 1,087,743	\$ 916,299
Service Revenue	86,087	65,420	56,585
Clinic Revenue	52,144	35,533	25,510
Other Revenue	18,492	18,030	63,214
	<b>1,354,254</b>	<b>1,206,726</b>	<b>1,061,608</b>

For the nine-month period ended September 30, 2017, total revenue increased to \$1,354,254 from \$1,206,726 for the same period in 2016, a 12% increase. In Canada, revenue increased 44% to \$1,046,508 from \$728,277. In the US, revenue decreased 32% to \$272,305 from \$399,445 and international revenue decreased 55% to \$35,441 from \$79,004. The increase in Canadian revenue in 2017 and the corresponding decrease in US and international revenue is attributable to the Company systematically building its sales and marketing teams commencing with the Canadian market, the learning curves and attrition associated with training and developing a new sales force in the US and the ramp-up strategy of successfully commercializing the TLC-2000 therapeutic laser system.

Theralase is focused on advancing the TLC-2000 to allow for a recurring revenue model in 2018.

### Cost of sales

Cost of sales for the nine-month period ended September 30, 2017 was \$558,221 (41% of revenue) resulting in a gross margin of \$796,033 or 59% of revenue, compared to a cost of sales of \$414,794 (34% of revenue) in 2016, resulting in a gross margin of \$791,932 or 66% 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.

Cost of sales increased primarily by the retention of external engineering teams in order to advance the TLC-2000 therapeutic laser system software, firmware and hardware to support the Company mandate of successfully commercializing the TLC-2000 for a recurring revenue model in 2018.

## Operating Expenses

Selling and marketing expenses for the nine-month period ended September 30, 2017 were \$1,407,387 representing 104% of sales, compared with \$1,114,180 or 92% of sales in 2016, and consisted of the following items:

	<b>2017</b>	<b>2016</b>	<b>2015</b>
Sales salaries	\$ 959,205	\$ 685,752	\$ 436,169
Advertising	182,623	171,398	107,004
Commission	71,691	52,693	69,787
Travel	114,284	149,091	98,815
Stock based compensation	9,339	14,195	9,742
Amortization and depreciation allocation	70,245	41,051	28,581
<b>Total selling expenses</b>	<b>\$1,407,387</b>	<b>\$1,114,180</b>	<b>\$750,098</b>

The increase is primarily due to increased spending on sales and marketing personnel, intended to augment sales in future financial quarters. 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 future financial quarters.

Administrative expenses for the nine-month period ended September 30, 2017 were \$2,222,701 representing a 11% increase from \$1,993,897 in 2016, and consisted of the following items:

	<b>2017</b>	<b>2016</b>	<b>2015</b>
Insurance	\$ 77,728	\$ 60,564	\$ 46,819
Professional fees	472,382	145,732	182,990
Rent	74,039	60,900	60,900
General and administrative expenses	466,172	594,187	514,603
Administrative salaries	737,408	643,843	483,820
Director and advisory fees	52,350	79,694	65,961
Stock based compensation	306,183	377,806	242,923
Amortization and depreciation allocation	36,439	31,170	21,194
<b>Total administrative expenses</b>	<b>\$2,222,701</b>	<b>\$1,993,897</b>	<b>\$1,619,210</b>

Increases in administrative expenses were attributed to the following:

- Insurance expenses increased 28% due to increased product liability coverage
- Professional fees increased by 224%, as a result of increased patent related fees for the PDT division.
- Administrative salaries increased by 15%, as a result of hiring clinical and educational staff.

## Research and Development Costs

Gross research and development expenses totaled \$2,044,838 for the nine-month period ended September 30, 2017 compared to \$1,598,175 in 2016 (28% increase). The increase in research and development expenses is a direct result of the ongoing Phase Ib clinical trial for NMIBC. Research and development expenses represented 37% 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 nine-month period ended September 30, 2017 was \$4,893,771 which included \$543,891 of net non-cash expenses (i.e.: amortization, stock-based compensation expense, foreign exchange gain/loss and lease inducements). This compared to a net loss for the same period in 2016 of \$3,918,320, which included \$573,593 of net non-cash expenses. The PDT division represented \$2,422,067 of this loss (50%).

The increase in net loss was primarily due to three reasons:

- 1) Increased investment in research and development of the TLC-3200 Medical Laser and TLC-3400 Dosimetry Fibre Optic Cage (“DFOC”) used to activate the PDC TLD-1433, via laser light energy for patients being treated in the Phase Ib NMIBC clinical study.
- 2) Increased investment in external engineering resources to redesign the software, firmware and hardware of the TLC-2000 therapeutic laser to allow advancement towards a recurring revenue model in 2018.
- 3) Increased sales, marketing and administrative personnel, related to maintaining / increasing sales of the existing TLC-2000 therapeutic laser system.

## Cash Flows

Funds used in operating activities, prior to net changes in other operating items, amounted to \$4,349,880 for the nine-month period ended September 30, 2017, compared to funds used in operating activities of \$3,344,727 for the same period in 2016. Funds used in operating activities after taking into account net changes in other non-cash operating items were \$3,817,141 for the nine-month period ended September 30, 2017, compared to funds used of \$3,372,253 for the same period in 2016.

Funds used in investing for the nine-month period ended September 30, 2017 amounted to \$261,609 compared to \$171,886 for 2016. The increase is a result of increased spending on tools, dies and equipment related to the TLC-3200 Medical Laser and TLC-3400 DFOC.

For the nine-month period ended September 30, 2017, funds obtained from financing activities from the exercising of warrants amounted to \$1,953,925, compared to \$nil obtained in financing activities for 2016.

## 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 \$41,732.

## Commitments

As of September 30, 2017, the Company’s commitments consisted of the following:

	Total	2017	2018	2019	2020	2021	2022
Lease obligations (a)	\$ 294,400	9,584	57,504	57,887	59,797	59,797	49,831
Lease obligations (b)	\$ 1,260	540	720	-	-	-	-
Research Agreement (c)	\$ 47,600	28,560	19,040	-	-	-	-
Research Agreement (d)	\$ 38,374	15,041	23,333	-	-	-	-
Research Agreement (e)	\$ 262,080	-	86,520	58,520	58,520	58,520	-
Total	\$ 643,714	53,725	187,117	116,407	118,317	118,317	49,831

- a) Lease obligations under a lease agreement related to the Company’s premises, commenced on October 1,

2017 and expires on September 30, 2022. Under the terms of this lease, the Company is required to pay a proportionate share of operating costs, realty taxes and utilities, in addition to the minimum rental payments. The future minimum lease payments are shown in the table above.

- b) Lease obligations under a new lease agreement related to the Company's office equipment, commenced on May 1, 2017 and expires on May 1, 2018. Under the terms of this lease, the Company is required to minimum rental payments of \$180 per month. This new lease agreement supersedes the old agreement in which the minimum monthly rental payment was \$167. 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 \$156,240 for the period from March 1, 2017 through to February 28, 2018. The Company has paid \$108,640 relating to this commitment, in which \$47,600 is the remaining commitment.
- d) Research Commitments under a research collaboration agreement with a clinical research organization for the TLC-3000 cancer therapy project. Under the terms of this agreement, the Company is required to pay \$70,000 for the period from April 25, 2017 through to April 25, 2018. The Company has paid \$31,626 relating to this commitment, in which \$38,374 is the remaining commitment.
- e) 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 \$348,600 for the period from June 1, 2017 through to June 1, 2021. The Company has paid \$86,520 in June 2017 relating to this commitment, in which \$262,080 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 September 30, 2017, the share capital of the Company consisted of 126,481,526 common shares. Each common share entitles the holder to one vote per share.

As of September 30, 2017, there were 10,390,000 options outstanding, of which 5,536,668 were vested and exercisable into an equivalent number of the Company's common shares.

As of September 30, 2017, there were 29,610,539 warrants outstanding. Each whole warrant entitles the holder thereof to purchase one additional common share. The warrants are exercisable as follows: 19,071,940 at a price of \$0.54 until March 3, 2020 and 10,538,599 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 nine-month period ended September 30:

	2017			2016			2015		
	TLT	PDT	Total	TLT	PDT	Total	TLT	PDT	Total
Sales	\$ 1,354,254	\$ -	\$ 1,354,254	\$ 1,206,726	\$ -	\$ 1,206,726	\$ 1,061,608	\$ -	\$ 1,061,608
Cost of Sales	558,221	-	558,221	414,794	-	414,794	357,750	-	357,750
Gross Margin	796,033	-	796,033	791,932	-	791,932	703,858	-	703,858
<b>Operating Expenses</b>									
Selling expenses	1,407,387	-	1,407,387	1,114,180	-	1,114,180	750,098	-	750,098
Administrative expenses	1,298,420	924,281	2,222,701	986,665	1,007,232	1,993,897	1,006,214	612,996	1,619,210
Research and development expenses	547,089	1,497,749	2,044,838	244,142	1,354,033	1,598,175	437,310	2,191,854	2,629,164
(Gain) loss on foreign exchange	18,531	-	18,531	6,341	6,341	12,682	(11,895)	-	(11,895)
Interest expense	36	36	72	285	285	198	140	140	280
Interest income	(3,727)	-	(3,727)	(9,253)	-	(9,253)	(29,919)	-	(29,919)
	3,267,736	2,422,067	5,689,804	2,342,359	2,367,892	4,709,879	2,151,947	2,804,991	4,956,937
Loss for the period	\$ (2,471,703)	\$ (2,422,067)	\$ (4,893,771)	\$ (1,550,427)	\$ (2,367,892)	\$ (3,918,319)	\$ (1,448,089)	\$ (2,804,991)	\$ (4,253,079)
Total Assets	\$ 3,319,827	\$ 308,038	\$ 3,627,865	\$ 3,306,596	\$ 111,135	\$ 3,417,731	\$ 7,202,759	\$ 217,840	\$ 7,420,599
Total Liabilities	338,838	153,109	491,947	480,482	82,747	563,229	390,756	432,734	823,490

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

	2017			2016			2015		
	Canada	USA	International	Canada	USA	International	Canada	USA	International
Sales	\$ 1,046,508	\$ 272,305	\$ 35,441	\$ 728,277	\$ 399,445	\$ 79,004	\$ 885,562	\$ 136,382	\$ 39,665
Cost of Sales	432,045	111,645	14,531	244,221	135,811	34,762	294,882	45,415	17,453
Selling Expenses	1,034,918	327,261	45,208	727,021	375,198	11,960	720,459	22,159	7,410
	\$ (420,455)	\$ (166,601)	\$ (24,298)	\$ (242,965)	\$ (111,564)	\$ 32,282	\$ (129,780)	\$ 68,808	\$ 14,802

As of September 30, 2017 and December 31, 2016, 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 nine-month period ended September 30, 2017, 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 nine-month period ended September 30, 2017. Please refer to the Company's historic annual and quarterly financial statement filings, including material interim press releases, on the regulatory website -- [www.SEDAR.com](http://www.SEDAR.com).

## Use of Financial Instruments

The Company's financial instruments consists of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities. The fair 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 September 30, 2017, 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 September 30, 2017, no cash equivalents were held (2016-\$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 unaudited, interim condensed consolidated financial statements as of September 30, 2017 and audited financial statements as of December 31, 2016 and for the nine-month period ended September 30, 2017, 2016 and 2015 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 unaudited, interim condensed consolidated financial statements as of September 30, 2017, and audited financial statements as of December 31, 2016 and for the nine-month period ended September 30, 2017, 2016 and 2015 are based on IFRS issued and outstanding as of November 28, 2017 which is the date at which the Company's Board of Directors approved the interim condensed consolidated financial statements.

Additionally, the preparation of the unaudited, interim condensed 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 interim condensed 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 interim condensed consolidated financial statements are presented fairly and in accordance with IFRS.

Critical accounting estimates and judgments are those that have a significant risk of causing material adjustment and are often applied to matters or outcomes that are inherently uncertain and subject to change. As such, management cautions that future events often vary from forecasts and expectations and that estimates routinely require adjustment. A summary of those areas where the Company's management believe critical accounting policies affect the significant judgments and estimates used in the preparation of the financial statements can be found in note 2 to the unaudited interim condensed consolidated financial statements of September 30, 2017 and audited financial statements as of December 31, 2016 and for nine-month period ended September 30, 2017, 2016 and 2015.

## 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 nine-month period ending September 30, 2017. 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 September 30, 2017 to provide reasonable assurance that material information related 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 September 30, 2017, 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.

### **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 effect 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 effect 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**

2018 should prove to be an exciting year for the Company, as it undertakes initiatives to advance the next generation TLC-2000 therapeutic medical laser system to 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, the US and internationally in subsequent years.

The latest independent scientific and clinical research confirms that the Company's proprietary and patented therapeutic laser technology has a high safety and effectiveness, compared to other competitive technologies. The Company continues to invest in scientific, preclinical and clinical research aimed at unlocking the cellular mechanisms of action as to how and why the Theralase laser light is effective in the healing of tissue and when combined with PDCs, effective in the destruction of tissue.

The Company commenced a "first-in-man" Phase Ib clinical trial using its Photo Dynamic Therapy ("PDT") aimed at evaluating the safety and tolerability as a primary outcome measure, pharmacokinetics (where the PDC accumulates in the body and how it exits the body), as a secondary outcome measure and efficacy, as an exploratory outcome measure, in the treatment of Non-Muscle Invasive Bladder Cancer ("NMIBC").

### **Interim Data Results:**

- 1) As previously reported, the first three patients treated at the MRSD successfully achieved the primary, secondary and exploratory outcome measures at 90 days post treatment.
- 2) Patient four treated at the Therapeutic Dose successfully achieved the primary, secondary and exploratory outcome measures at 90 days post treatment. During the 90 day cystoscopy analysis, patient number four's bladder surface wall was observed to be red and inflamed. The patient will continue to be monitored to see if this condition resolves.
- 3) Although not a pre-defined outcome measure of the Study, patient one, two and three have successfully achieved the primary and secondary outcome measures at 180 days post treatment.
- 4) Although not a pre-defined outcome measure of the Study, patient one, two and three have not achieved the exploratory outcome measure at 180 days post treatment.

### **Conclusions:**

Light activated TLD-1433 PDC, based on initial data, has demonstrated:

- 1) A high level of safety, tolerability and PK, in patients with high risk, Ta, T1 or CIS NMIBC, for 180 days post PDT treatment, when treated at the MRSD;
- 2) A high level of safety, tolerability and PK, in patients with high risk, Ta, T1 or CIS NMIBC, for 90 days post PDT treatment, when treated at the Therapeutic Dose;
- 3) An ability to delay recurrence and progression of NMIBC at the MRSD for between 90 to 180 days post treatment for patients, who have a clinical history or are at high risk of UUTUC and potentially longer for those that do not;
- 4) An ability to delay recurrence and progression of NMIBC at the Therapeutic Dose for 90 days post treatment.

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 other international countries.

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.

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

November 28, 2017

A handwritten signature in black ink, appearing to read 'Roger Dumoulin-White', is written over a horizontal line.

Roger Dumoulin-White  
President and CEO