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Zacks Small-Cap Research

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Theralase Technology Inc (V.TLT)

V.TLT: FDA approves TLC-2000. Will Health Canada Follow Suit?

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	11/02/2015
Current Price (12/01/2015)	$0.32
Target Price	**$0.60**

OUTLOOK

Theralase was recently granted FDA 510(k) clearance for their second-generation pain management device, the TLC-2000. The long-awaited approval came in November 2015. The company is currently making preparations for launch of the product in the U.S., which they think will happen sometime in Q1 2016.

Theralase is diversifying its cancer therapy pipeline using three additional PDCs for various caner indications. We are especially optimistic about its lead drug candidate TLD-1433 for the treatment of NMIBC. Phase Ib trials employing TLD-1433 with PDT are anticipated to commence by year-end. Results may be available sometime in mid-2016, which, if successful, would be a significant de-risking event for Theralase. We maintain our Buy rating.

SUMMARY DATA

52-Week High	**$0.78**
52-Week Low	**$0.25**
One-Year Return (%)	**-22.9%**
Beta	**0.34**
Average Daily Volume (sh)	**501,983**
Shares Outstanding (mil)	**96**
Market Capitalization ($mil)	**$34**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**N/A**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using #Lin Estimate	**N/A**
P/E using #Lin Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**N/A**
Type of Stock	**Large-Growth**
Industry	**Medical Devices**
Zacks Rank in Industry	

ZACKS ESTIMATES

Revenue
(in '000s of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	$361.2A	$449.3A	$134.1A	$386.1A	$1,380.6A
2015	$368.3A	$309.5A	$383.8A	$312.7E	$1,374.3E
2016					$4,572.7E
2017					$8,652.4E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-0.01A	-0.01A	-0.02A	- 0.01A	-0.03A
2015	-0.01A	-0.01A	-0.02A	- 0.02E	-0.06E
2016					-0.04E
2017					-0.02E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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WHAT'S NEW

V.TLT: FDA approves TLC-2000. Will Health Canada Follow Suit?

Third Quarter Financial Update:
Sales revenues in Q3 2015 were 186% higher at $383,791 as compared to $134,036 in Q3 2014. Revenues in Canada increased by 43% while U.S. revenues decreased by 42% and international revenues decreased by 71% from Q3 2014. The company built a new sales team in Canada which resulted in heavy selling and marketing expenses, but the expansion of the sales team helped in increasing revenues in this territory. Consequently, revenues were 15% higher and sales and marketing expenses came in 34% more than forecasted. R&D expenses totaled $1.3 million during Q3 2015, related to the development of TLC-3000 anti-cancer technology.

The net loss for the period was roughly $2 million ($0.02/share). The Photo Dynamic Therapy (PDT) division represented 88% of this loss. Operating expenses incurred resulted from the increased investment in R&D related to the anti-cancer technology as well as preparing for a Phase Ib clinical study for Non-Muscle Invasive Bladder Cancer (NMIBC) to commence in 4Q2015, and the additional SG&A expenses pertaining to the launch of the TLC-2000 device.

The company exited the quarter with a cash balance of $5.5M. To-date, Theralase has burned close to $4 million in cash through operating activities and raised roughly $7 million from the public equity offering that was completed back in March 2015.

Operational Update:
Theralase was recently granted FDA 510(k) clearance for their second-generation pain management device, the TLC-2000. The long-awaited approval came on November 25, 2015. Management had expected this approval in Q4 2014. The company is currently making preparations for launch of the product in the U.S., which they think will happen sometime in Q1 2016.

The TLC-2000 has been designed to deliver an exact dose of light energy to a targeted tissue based on the skin color and the thicknesses of various subcutaneous tissues. Additionally, it is devised to "remember" the clinical protocols that have been set up by practitioners based on the optical characteristics of the patient. Theralase was launched in 1995, and it took 5 years to develop the TLC-1000 device. The Health Canada approval come in 2002, FDA clearance in 2005 and CE Mark in 2011 for the first generation device. The company did not get a strong foothold in the U.S. market when they tried to enter in 2008 due to the struggling economy at that time or in 2011 during which time the company was ill-equipped financially and operationally.

Theralase has planned to initiate an intense sales effort from 2016 in the U.S. for their TLC-2000 device so they can begin generating revenues as soon as possible. Management plans to govern the pace of U.S. launch by providing training and resources to the Territory Sales Managers (TSMs) regarding the TLC-2000 in the five major cities of New York, Los Angeles, Miami, Chicago, and Houston to make the transition from the TLC-1000 to the TLC-2000 as seamless as possible to existing customers. This is likely to cause a drag on the bottom line initially. Currently the company has a loyal customer base of 400 clients in the U.S. Management expects the transition to the new TLC-2000 device to commence in Q1 2016 and hopes that 80% of existing customers upgrade their TLC-1000 systems to the TLC-2000 device. We do not expect an immediate ramp up in sales figures. Instead, we expect unevenness in the financial performance in Q1 2016 and suspect this trend will continue throughout the second quarter and then begin to normalize in 2H 2016. A boost in sales could materialize as the conversion gains steam, which we think may be more evident beginning in the latter half of the year. Nevertheless, 2016 and 2017 could be watershed years for Theralase. Looking ahead into the out years, we expect revenue growth to be driven by a strong demand for the TLC-2000 device in the U.S.

Approval from Health Canada should incrementally benefit both revenues and gross margins. Soon after the sales force begins to market the device in full swing in these two territories Theralase will begin their sales efforts in other regions of the globe using licensing agreements with third party distributors. The company will weigh in the benefits before finalizing the plans for ex-U.S. sales.

Since 2013, the PDT division is undergoing a lot of R&D. The operating burn increased from a little over $1 million in 2013 to ~$3M in 2014 and will come close to $5.5M in 2015. Going forward we suspect that the company will need additional financing to continue its planned operations in expanding its sales and marketing for the TLC-2000

as well as for the research and development in the PDT division until revenues generated from TLC-2000 are substantial to help the company cover their OpEx and turn cash flow positive.

Since we build a financial model over a period of ten years using DCF analysis to value Theralase, the slight push back in revenues by almost a year has not impacted our valuation.

BUSINESS BACKGROUND

Theralase Technologies Inc., headquartered in Ontario, Canada, is focused on the design, development, manufacturing and marketing of its patented super-pulsed laser technology platform that is used in a wide range of bio-stimulative and bio-destructive clinical applications in humans, as well as in animals.

Theralase operates under two divisions; the Therapeutic Laser Technology ("**TLT**") division, focused on the development and commercialization of laser-based non-invasive pain management devices and the Photo Dynamic Therapy ("**PDT**") division, focused on discovery of small, light-activated molecules and the laser systems that activate them with high anti-cancer effectiveness, microbial sterilization potency and bacterial infection control.

Theralase's current product line from the TLT division is the TLC-1000, and expected to launch in Q1 2016, the more advanced TLC-2000. The TLC-1000 device has been endorsed by Dr. James Andrews, who is a member of the American Sports Medicine Institute as well as Chair of Theralase's Medical and Scientific Advisory Board. The TLC-2000 has been designed to measure a patient's specific optical tissue characteristics based on the skin color and the thicknesses of various subcutaneous tissues. The device possesses the ability to precisely target injured tissue with clinically optimal doses of energy that is particular to the patient's condition. The dosages specific to optical tissue profiles will be stored in a Health Insurance Portability and Accountability Act ("**HIPAA**") compliant central databank and be accessible to all practitioners utilizing the TLC-2000, in a real time format. This central databank will contain the clinical protocols derived from the clinical trials using laser therapy and will be updated continuously with real time feedback of the systems that are in use by practitioners.

The Company markets its products directly through its in-house sales and marketing force as well as through a network of distributors in the Middle East, South America and Asia Pacific. Theralase plans to phase-out the TLC-1000 system over the next 3 years and incentivize its customers to upgrade to the latest technology, the TLC-2000, the commercial launch of which is expected to occur in the fourth quarter of this year. The Company is now actively working towards securing a new Current Procedural Terminology ("**CPT**") code for reimbursement of TLC-2000 laser treatments in the U.S.

Theralase's PDT division focuses on discovery of small, light-activated molecules and the laser systems that activate them with high anticancer effectiveness, microbial sterilization potency and bacterial infection control. Photo Dynamic Compounds ("**PDCs**") are drugs that are activated when exposed to light at specific wavelengths (colours) and power levels and become cytotoxic (cell killing) in oxygenated environments. The Theralase PDCs have the added capability to be activated by a wide range of laser wavelengths and also function effectively regardless of the oxygenation level present in the tissue under treatment, a major plus when dealing with cancerous tissue and certain bacteria, which tend to thrive in low oxygenated tissues.

The PDT technology involves the research and development of PDCs activated by patented and patent pending biomedical lasers for the selective destruction of cancer and bacteria. Theralase has successfully completed in□vitro analysis demonstrating destruction of brain, breast and colon cancer cell lines in 2010. In 2012, Theralase successfully completed small animal in□vivo preclinical analysis of the PDC technology with the complete destruction of colon cancer in an orthotopic mouse model. Since the treatment, the mice have been living cancer free for over 20 months, which is encouraging considering that a mouse's typical life span is only 18 to 20 months.

Non Muscle Invasive Bladder Cancer ("**NMIBC**") has been chosen as Theralase's principal cancer target for its lead PDC compound. Theralase PDCs have proven to be toxic to bladder cancer cells when activated by light (100% kill rate) at very low effective concentrations (micrograms). Theralase recently pursueddestruction of bladder cancer in an orthotopic animal model and continues to report out on this model. Theralase plans to commence a Phase 1b clinical trial in NMIBC by end of 2015 pending Health Canada approval.

Based on the clinical data from this study of the PDC technology, Theralase expects to qualify for the US Food and Drug Administration ("**FDA**") "Fast Track" designation, a process designed to facilitate the development, expedite the priority review and accelerate the approval process. Theralase believes that their PDC technology to treat cancer may potentially address an unmet medical need; hence, Theralase believes that they might have a reasonable chance of achieving Breakthrough Status, another FDA program meant to minimize approval time to get the technology onto the market to treat the patients most in need of the therapy.

The commercial launch of the TLC-3000 PDC / Laser Technology Platform is expected by late 2016 to coincide with the commencement of a Phase IIb clinical study meant to demonstrate the efficacy of TLD-1433 in the destruction

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of NMIBC in a larger patient population. After successful completion of a Phase Ib clinical trial in late 2016, the company plans to raise between $20 to $100 million dollars (based on stock price) in an up-list to the NASDAQ stock market for operating capital to complete clinical trials, commercialize the technology and pursue partnering arrangements on international distribution of its anti-cancer PDC technology.

TECHNOLOGY

Therapeutic lasers belong to a specific class of lasers that do not cut or destroy tissue, but instead are used to heal and have a therapeutic curative effect on tissue. The cold laser produces an impulse of light at a specific wavelength (between 600 to 970nm) that minimizes reflection and scattering but maximizes absorption of the energy (measured in photons) at a desired depth. Cold laser therapy can be used for healing various tissue structures, such as: muscles, tendons, ligaments, joints, connective tissues, bones and treating numerous conditions such as muscular□skeletal conditions, nerve rehabilitation, wound healing, anti□aging and addiction therapy.

Theralase's TLC-2000 is a non-invasive, patent-protected, laser-based, reparative, biomedical platform technology product. It is expected to be rolled-out commercially in Q1 2016.

Bio-destructive laser therapy uses proprietary laser technology to activate the photo dynamic key of a specifically designed PDC that has an affinity to certain tissue types. When activated by light, it has the ability to destroy the target cell. There are thousands of potential applications of this technology including the destruction of cancer and bacteria. In 2006, Virginia Polytechnic had developed seven unique PDCs (mixed-metal supramolecular complexes) for exclusive worldwide license by Theralase. These PDCs are unique in that they are activated via a Type 1 reaction that is independent of oxygen, an important characteristic, as solid core tumors (i.e. breast, bladder, lung, brain, prostate, to name a few) are hypoxic (low oxygen) in nature. In 2012, Theralase in-licensed PDCs from Acadia University, which have similar characteristics to the Virginia Tech compounds, being effective in oxygenated and low-oxygenated tissue, while remaining virtually non-toxic.

Characteristics of Low Level Laser Therapy ("LLLT")

Low Level Laser Therapy ("**LLLT**") operates within a specific wavelength range (wavelength 600-970 nanometer ("**nm**")) that is non-thermal, eliminating the risk of tissue damage or other complications. Wavelength and peak power determine how deep the light will effectively penetrate into tissue. Pulsing at 50,000 milliWatts ("**mW**") up to 10,000 times per second ("**Hertz**"), the super-pulsed laser technique is able to deliver an exact dose of light energy to superficial as well as to tissue depths of up to four inches.

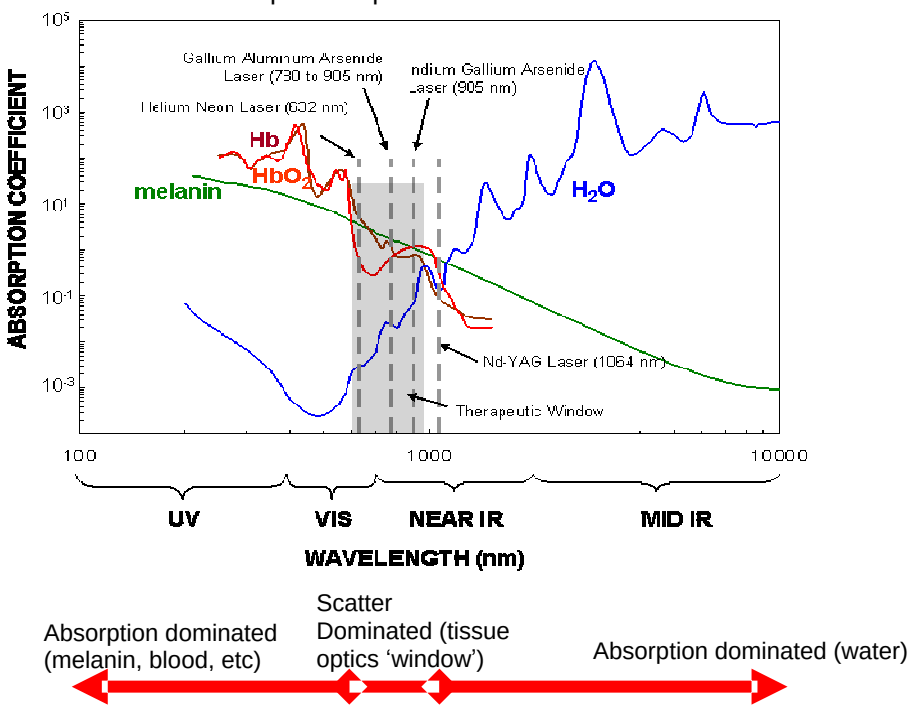


Figure 1: Therapeutic window (Source: www.theralase.com)

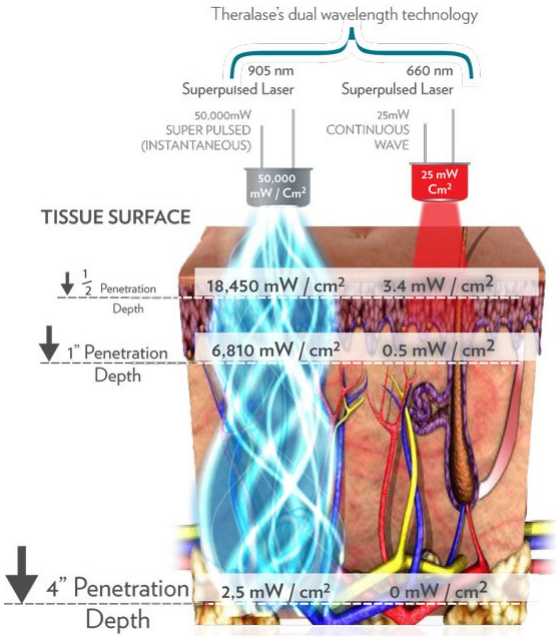


Figure 2: Tissue penetration depth at different laser strengths (Source: www.theralase.com)

Physiological Mechanism:

Photobiomodulation has been applied clinically to treat soft-tissue injuries, accelerate wound healing and increase tissue regeneration. LLLT increases cell proliferation and differentiation and amplifies cellular signaling in degenerative and inflammatory conditions. Laser light emits a coherent, narrow beam of light that can be directed at very specific "absorption" bands of the intended molecular absorbing centers, called chromophores. Mitochondria are thought to be a likely site for the initial effects of light, leading to increased Adenosine Triphosphate ("**ATP**") production, modulation of Reactive Oxygen Species ("**ROS**") and induction of transcription factors. Cytochrome c oxidase, the terminal enzyme of the mitochondrial respiratory chain, mediates the transfer of electrons from cytochrome c to molecular oxygen. It is considered as the photo-acceptor molecule responsible for photobiomodulation effects. By employing short and ultrashort light radiation pulses, up to 4" depth of penetration can be achieved. The local transient rise in temperature of cytochrome c oxidase may cause structural changes and trigger biochemical reactions such as activation or inhibition of enzymes, increased cell proliferation and migration (particularly by fibroblasts), modulation in levels of cytokines, growth factors and inflammatory mediators and increased tissue oxygenation that results in increased healing in chronic wounds, improvements in injuries and pain reduction in arthritis.

Theralase's methodology uses a three-pronged approach by activating all three known cellular pathways simultaneously to stimulate rapid healing described as follows:

1. **Nitric Oxide ("NO") pathway:** When Near Infra Red ("**NIR**") light of wavelength 905nm is absorbed by a tissue chromophore, a dissociation of NO (a physiologic regulator of cytochrome c oxidase activity) occurs from the catalytic center (iron-containing and copper-containing redox centers) of cytochrome c oxidase. 905 nm super-pulsed light increases NO levels by 700% compared to other wavelengths and technologies. As a result, it rearranges downstream signaling effects such as increasing ATP production, oxygen consumption, raising mitochondrial membrane potential and modulating production of ROS. NO signals endothelial cells to relax, leading to vasodilation (increased dilation of blood vessels); thereby, increasing blood flow and stimulating lymphatic vessels to become more porous, increasing interstitial fluid drainage which in turn, decreases swelling.

2. **ATP pathway:** ATP is the fuel inside living cells that drives all biologic reactions and has been found to be a signaling molecule. Small changes in the ATP levels, specifically, increasing the amount of this energy, can significantly improve cellular metabolism, especially in cells that lack energy or are suppressed as in wounds. When tissues are exposed to light at 660 nm wavelength, oxidative phosphorylation is initiated. The receptors, for ATP as a signaling molecule, form a channel that allows sodium and calcium ions to enter the cells. Calcium ions are a positive effector of mitochondrial function.

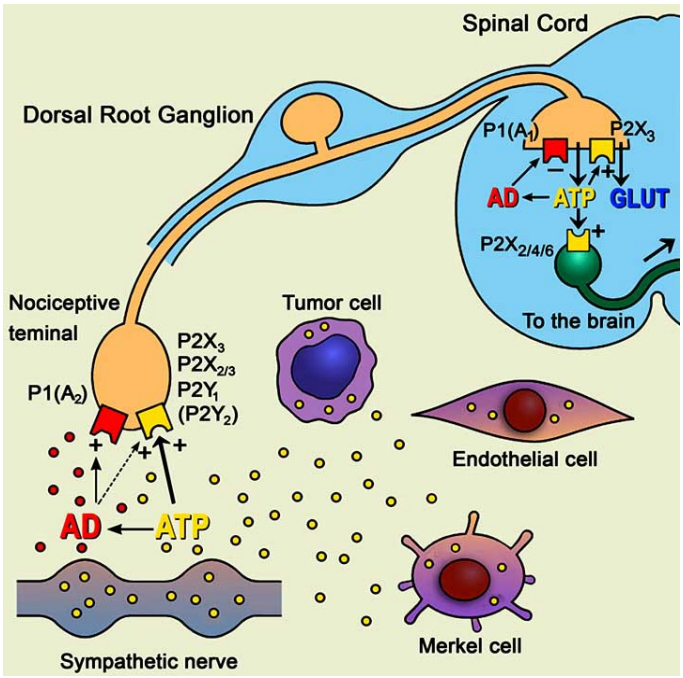


Figure 3: Hypothetical illustration of the initiation of nociception on primary afferent fibers in the periphery and purinergic relay pathways in the spinal cord[1]

3. **Lipid absorption pathway:** Since ATP regulates the cellular sodium-potassium pump; transmission of pain signals from the area can be altered by controlling ATP production. When light receptors in the bi-lipid membrane of nerve cells are activated by 905 nm laser light, the cell membrane permeability is altered that allows the reintegration of sodium back inside the nerve cell and creates a proton gradient. This in-turn decreases the C-fiber afferent nerves ("**unmyelinated**") activity by blocking depolarization and mitigates bradykinine release as well as increase levels of endorphins to reduce nociception ("**pain**").

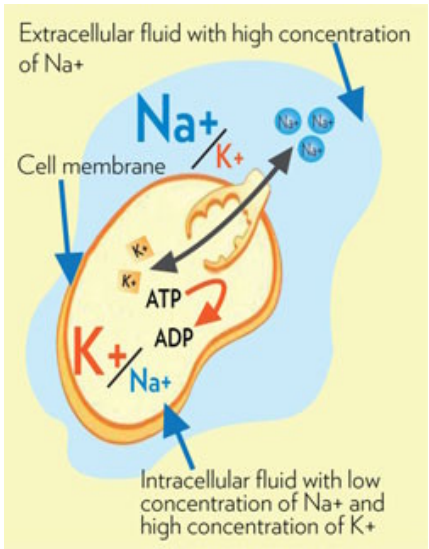


Figure 4: The energy to drive the sodium-potassium pump is released by hydrolysis of ATP. In order to decrease pain, the sodium ions need to repatriate into the cell and the potassium ions need to be released outside the cell through the sodium potassium pump or through the permeability of the bilipid cellular membrane, both activated by 905 nm laser light. (Source: www.theralase.com)

[1] Burnstock, Geoffrey. "Purinergic receptors and pain." Current pharmaceutical design 15, no. 15 (2009): 1717-1735.

PRODUCTS

TLC-1000: Therapeutic Laser Technology
The TLC-1000 Therapeutic Laser System, a high-end, high power therapeutic laser system is in wide-spread use in Canada and has made a small entrance into the U.S market. Theralase employs dual-pulsed (905 nanometer ("**nm**") Near Infra Red ("**NIR**") and 660 nm (visible red)) laser technology to accelerate healing by eliminating pain, reducing inflammation and accelerating tissue healing, while staying below the Maximal Permissible Exposure ("**MPE**") tolerance for tissue (< 500 mW). The TLC□1000 is FDA, Health Canada and Conformité Européenne ("**CE**") approved.

Theralase plans to phase-out the TLC-1000 by the end of 2017 and introduce their next generation laser system, the TLC-2000 with a biofeedback technology in Q1 2016.

TLC-2000: Biofeedback Therapeutic Laser Technology
The TLC□2000 laser system is the new next-generation patented technology that delivers an exact dose of energy to a targeted tissue location and structure, taking into account physical characteristics such as skin pigmentation, fat and muscle content. It is devised to "**remember**" the clinical protocols performed by practitioners based on a patient's physical and hence optical tissue characteristics. In July 2002, Theralase was granted U.S. Patent No. 6.413.267 covering the proprietary design of therapeutic laser devices which monitor and control high-power, deeper penetration, clinical healthcare laser therapy. In Nov 2004, Theralase was granted the European patent No. 1075854, and Theralase validated the patent in a select list of major EU national economies: Germany, France, U.K., Italy, Spain and Belgium.

TLC-2000: Rollout
A commercial roll out of the device is expected in U.S. in Q1 2016 and in Canada in 2016, pending Health Canada approval. Theralase's goal is to incentivize their existing customers by offering a trade-up credit (based on the date of manufacture of the TLC-1000 owned by the practitioner) to the 1200 existing customers in Canada and the US to upgrade to the new device as well as to increase the customer base globally.

Theralase plans to operate a direct sales force with Territory Sales Managers ("**TSMs**") based in Calgary, Vancouver, Toronto, Montreal, New York, Los Angeles, Miami, Chicago and Houston in 2016. The company expects to deploy an aggressive sales and marketing strategy through these additional TSMs that can help expansion into these markets. They also plan to offer their customers new ways of financing their products. The company has used third-party distributors to market its devices internationally including Europe, South America and Asia Pacific which will continue to be the strategy for international sales of the TLC-2000. The strategy adopted by the sales force is to make a presence at major healthcare and industry conferences as well as focused seminar and webinar presentations to present the clinical, scientific and financial benefits of Theralase's technology to healthcare practitioners. Additionally, they propose to personally contact and visit all existing customers as well as other practitioners that use competing technologies to demonstrate the TLC-2000. The marketing plan will include clinical, technical, scientific, financial, sales and marketing information about the new technology. The corporate head office, in addition to housing executive management, finance, sales and marketing functions will also support an ISO-13485 certified, Health Canada, FDA and CE approved facility to manufacture the Theralase line of therapeutic lasers, as well as aftermarket sales and service support for all of Theralase's healthcare customers.

Theralase is migrating the business from a one-time capital equipment purchase model, where they sell the units for a one-time cost of approximately $16,000, to a recurring revenue model, where they will lease the units to health care clinics, hospitals and practitioners. Theralase expects this new model to provide more affordability for customers and facilitate more rapid penetration into currently untapped markets. With the recurring revenue model, Theralase expects to reach out to customers more frequently and build a more loyal customer base. From the recurring revenue system, Theralase has the ability to capture data sets that track consumer trends and preferences on a much more granular level compared to their traditional model. This, in turn, may lead to optimized pricing and packaging to meet customer needs. The ability to fine tune pricing and incentives based on this data will enable increases in consumerization as practitioners demand the flexibility and personalization these instruments provide.

Osteoarthritis ("OA") Treatment
The disability and treatment costs associated with musculo-skeletal disorders in an aging population and in obese

individuals is expected to increase in the future. LLLT offers an alternative to other treatments such as medication, joint surgery and electrotherapy. It is non-toxic and does not create dependency. Theralase's therapeutic laser system has now been proven clinically effective in the relief of chronic knee pain and for the treatment of OA. An independent blinded, randomized, controlled clinical study was conducted to evaluate the Theralase laser system. Theralase's dual wavelength, multiple diode laser cluster probe with five super-pulsed 905 nm NIR laser diodes, each emitting 40 mW of average power and four continuous wave (CW) 660 nm visible red laser diodes, each emitting at 25 mW was evaluated in combination with standard chiropractic techniques on 126 patients presenting with OA and knee pain. The efficacy of the study was evaluated by the assessment of subject pain levels via the Visual Analog Scale ("**VAS**") measurement, a validated assessment tool widely accepted by the medical community, especially, neurology and orthopedic specialists. Improvement in VAS was significant for pain relief, with a statistical and clinical significance of $p < 0.01$ from baseline to the 30-day follow-up. The results of the clinical study were dramatic and have proven clearly that the Theralase therapeutic laser system is clinically and statistically effective in reducing pain in these debilitating conditions.

Addiction Rehabilitation and Weight Loss
Therapeutic lasers provide effective treatment for smoking, drug and alcohol addictions, as well as weight loss, by stimulating specific acupuncture points in the ear. This triggers the brain to release neurotransmitters (such as endorphins, serotonin and dopamine) that help to break the addiction cycle. Theralase combines this treatment with behavioral modification addiction counseling and nutritional guidance to create addiction rehabilitation and weight loss programs.

The nucleus accumbens mediates the release of the neurotransmitter dopamine, which plays a major role in reward-motivated behavior, but dopamine itself is released from the Ventral Tegmental Area ("**VTA**"). The VTA releases dopamine to the nucleus accumbens, the prefrontal cortex, amygdala and septum, all of which play an important role in the reward circuit. When an acupoint (an acupuncture nerve point) is stimulated, the brain releases neurotransmitters that eliminate cravings from addiction withdrawal. Theralase commissioned an investigation to study the effectiveness of laser acupuncture, in combination with counseling, on smoking cessation by applying up to 5 laser acupuncture treatments over a 2 week period. The goal was to reduce the amount of tobacco products consumed by subjects by at least 25% as measured from baseline to 30 day follow up. The treatment group consisted of a relatively equal representation of male and female subjects with an average age in the mid to late forties. A Theralase therapeutic laser system was applied to specific ear and body acupuncture points. The results of the clinical study demonstrated that at the 30 day follow-up end point, 405 (73.8%) subjects had reduced their consumption of tobacco products by 25% or more, with 373 of those subjects (92.0%) completely eliminating the use of tobacco products and 32 of those subjects (8.0%) showing a reduction of at least 25%. This non-pharmacologic and non-invasive therapeutic modality exceeds the effectiveness of other therapeutic options currently available for smoking cessation treatment, including the nicotine patch, nicotine gum and other pharmaceutical alternatives. (www.theralase.com).

Anti-Aging
Theralase's anti-aging system is designed for facial rejuvenation and the treatment of various dermatological conditions. By combining laser/acupuncture facial points and both NIR and visible red light, treatments are designed to improve skin appearance and health through the production of collagen and elastin, both essential for healthier, more youthful skin.

Post-Surgical Healing: Tummy Tuck, Breast Augmentation, C-Section
Light therapy has been known to improve vascularity ("**circulation**") by increasing the formation of new capillaries. New capillaries speed up the healing process by supplying additional oxygen and nutrients needed for healing and stimulate the production of collagen. One of the secondary mechanisms of light therapy is increased collagen synthesis. Collagen is the most common protein found in the body and is the essential protein used to repair and replace damaged tissue. It is the substance that holds cells together, along with elastin, thus forming a high degree of elasticity. Increasing both collagen and elastin production will decrease scar tissue at the injured site and bring tissue back to its original healthy form (www.theralase.com).

The parameters of wavelength, effective dose, beam penetration, and pulses (peak power and repetition rates) dictate the effect LLLT will have and results are subjective to tissue damage, chronicity and health of the patient.

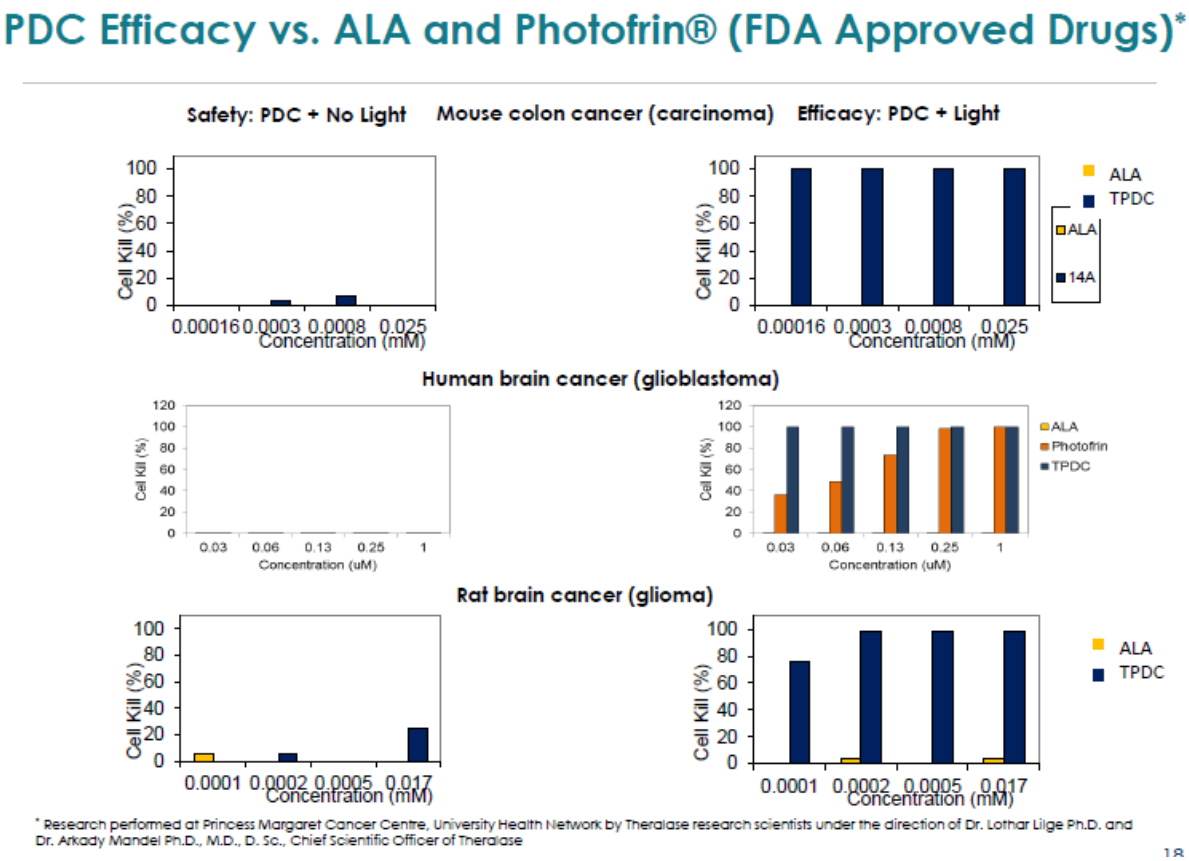
TLC□3000: Cancer Therapy

Cancer Treatment
Destroying cancerous tumors and preventing cancer from recurring are important benchmarks in developing new cancer therapies. PDCs are drugs that get activated when exposed to light and become cytotoxic in oxygenated

environments. Theralase PDCs are drugs that get activated when exposed to light in a wide range of wavelengths and become cytotoxic in both oxygenated and non-oxygenated environments. Photo Dynamic Therapy ("**PDT**") is a treatment that uses a drug, called a photosensitizer or photosensitizing agent and a particular type of light. When photosensitizers are exposed to a specific wavelength of light, they produce a form of oxygen, known as Reactive Oxygen Species ("**ROS**") that oxidizes and kills nearby cells. Each photosensitizer is activated by light of a specific wavelength. This wavelength determines how far the light can travel into the body; thus, doctors use specific photosensitizers and wavelengths of light to treat different areas of the body with PDT.

The two drugs that FDA approved for treating cancer are Aminolevulinic acid ("**ALA**") and Porfimer sodium ("**Photofrin®**"). ALA is a drug that is applied to the surface of the skin on the face or scalp to treat actinic keratosis ("**AK**"), a skin condition that can become cancerous. A special blue light, rather than laser light, is used to activate this drug. A methyl ester of ALA is one of several other forms of ALA that have been developed and penetrates cancer cells very easily. It was approved by the FDA in July 2004 for treatment of some types of AK of the face and scalp. Methyl ester of ALA is activated with a red light. Photofrin® is the most widely used and studied photosensitizer ans is activated by red laser light. It is approved by the FDA to treat patients with pre-cancerous conditions that may lead to esophageal and endobronchial cancer.

The proprietary TLC-3000 medical laser system has been custom designed by Theralase for the activation of Theralase's patented PDCs, resulting in the successful destruction of cancer cell lines in-vitro and in-vivo. Theralase PDCs are small molecules that are able to localize to the nucleus of any cancer cell and are not as limited in scope as monoclonal antibodies, which require a specific marker or protein sequence on the outside of the cell to localize. In the treatment of bladder cancer, the Theralase PDCs only remain in the bladder for less than an hour and are barely detectable in the blood stream, thus providing a very high safety profile and ultra-low toxicity versus ALA and Photofrin® which are systemically injected into the blood stream. Theralase's PDCs have been scientifically demonstrated to be 668,000 times more effective then ALA and 198 times more effective than Photofrin® in an analysis done in-vitro. The Theralase PDCs have shown up to a 100% kill rate in cancer cells at very low concentrations (< 0.8µM) when light activated and virtually 0% when not light activated even at high



concentrations (> 100µM) leading to a very high safety profile.

Figure 5: Theralase's PDC efficacy as compared to 2 FDA approved drugs (ALA and Photofrin®) (Source: www.theralase.com)

In early 2010, the Ontario Cancer Institute at Princess Margaret Cancer Centre, part of the University Health Network ("**UHN**") demonstrated complete destruction of breast cancer cells in-vitro following administration of Theralase's patented PDCs and subsequent activation with the TLC-3000 light source. In Q2 2010, Theralase conducted a pre-clinical study where it evaluated a variety of cancer cell lines in an in-vivo small animal model. Theralase received the necessary approvals on its Animal Utilization Protocol by the UHN Ethics Review Committee in Q3 2010, allowing hands-on evaluation of the PDCs in a small animal model. Theralase's research team headed by Lothar Lilge, Ph.D., the principal scientific investigator of the PDCs and a senior researcher at the world renowned Ontario Cancer Institute, Princess Margaret Cancer Centre, evaluated the toxicity of the patented PDCs on small animals by choosing an escalating dose analysis whose result showed that the patented PDCs were as safe as any PDC presently approved on the market by a factor of 10.

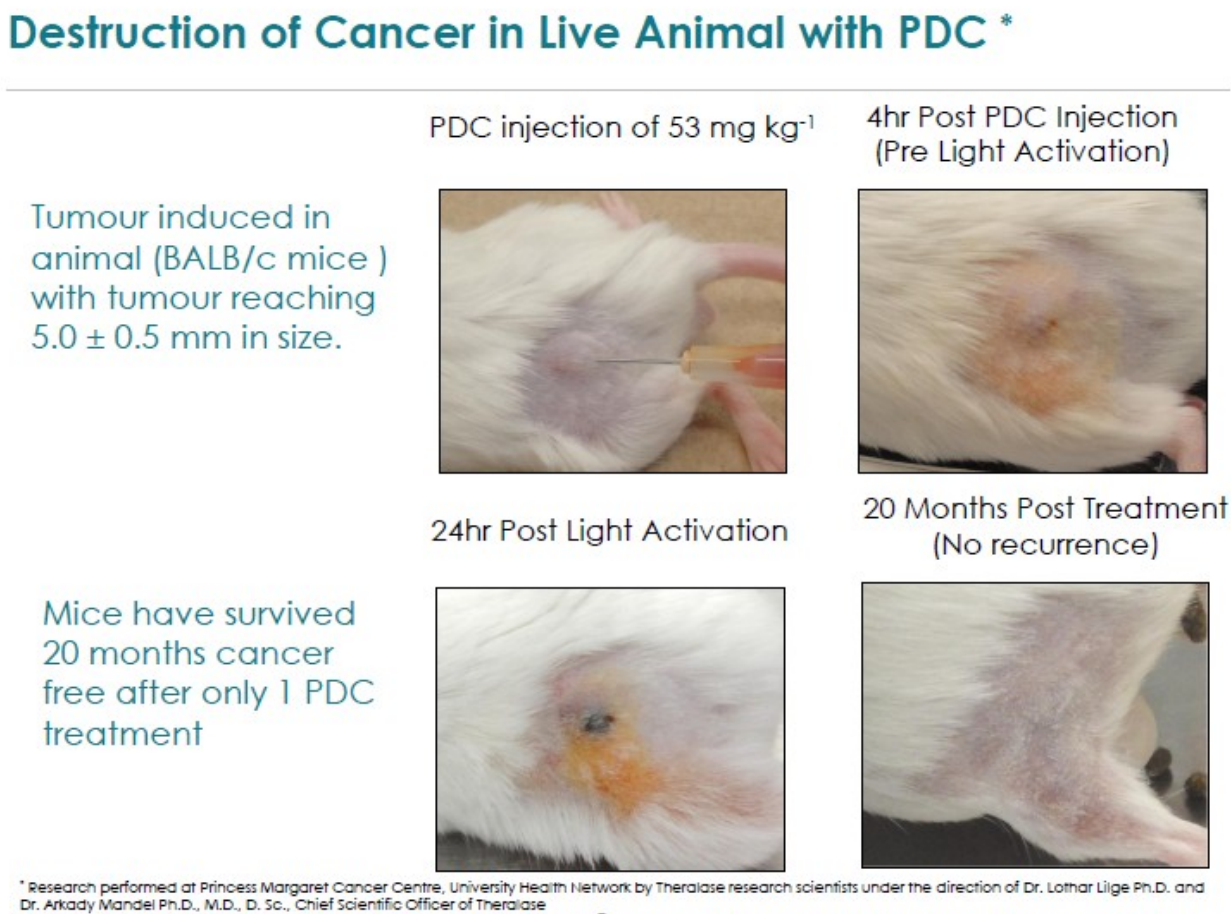


Figure 6: in-vivo Tumors Treated with PDT in a mouse (Source: www.theralase.com)

Having successfully completed the toxicity study in a small animal in-vivo model, Theralase's next strategic step forward in the company's cancer therapy research program was to demonstrate the efficacy of the PDCs in the destruction of tumors in a small animal in-vivo model. In the study, approximately 350,000 cells from a colon cancer line were injected subcutaneously into mice and the tumors were allowed to grow to five millimeters in size. Half the mice were used as a control group where no therapy was administered. The remaining animals were administered with Theralase's lead PDC by intra-tumor injection where the PDCs enter the cancer cell and lock onto the cell cytoplasm, particularly the mitochondria. The PDC was allowed to distribute within the cancerous tumor for four hours and was then activated by Theralase's proprietary laser light source for 32 minutes. The light activated PDCs destroyed the mitochondria of the cell through the production of ROS inducing natural cell death known as apoptosis, destroying the tumor from the inside out. After a few weeks, the tumors were no longer visible on the treated mice and there was no development of scar tissue. All mice were monitored and examined daily. Complete destruction of colon cancer was achieved in the subcutaneous mouse model. The mice survived cancer free for over 20 months post treatment, which is remarkable considering that mice have a normal life span of 18 to 20 months; therefore, the mice lived their entire lives cancer free.

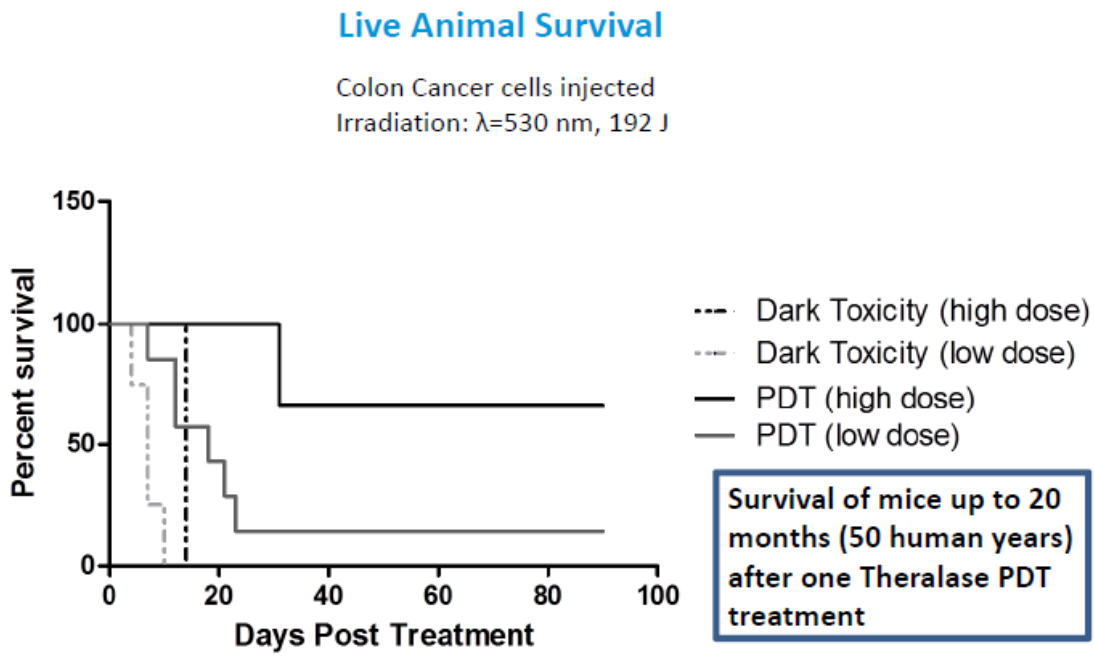


Figure 7: Survival period of mouse post treatment with PDC anti-cancer technology (Source: www.theralase.com)

In 2013, Theralase's proprietary PDC technology was approved for use in a live animal bladder cancer model by UHN Research Ethics Board ("**REB**"). Theralase is currently pursuing the destruction of bladder cancer in an orthotopic animal model. Theralase hopes to complete the bladder cancer clinical protocol and commence a Phase 1b human clinical trial to prove the safety and efficacy of its PDC technology by end of 2015. This development would accelerate the company's advancement towards commercializing its advanced bladder cancer therapy.

The lead PDCs have advanced towards international patent protection under a filed Patent Cooperation Treaty ("**PCT**") application. Once approved at this phase, the Company expects to gain widespread patent coverage of the PDCs across numerous countries. The lead PDCs have completed toxicity analysis and GMP manufacturing ramp up via Contract Manufacturing Organizations ("**CMO**"); both mandatory prerequisites in the evolution towards an approved Investigational New Drug ("**IND**") application from the FDA and a CTA from Health Canada. With larger quantities of the PDCs in hand and an approved IND and CTA, Theralase would be in a position to commence a Phase 1b human clinical trial for the lead indication of bladder cancer, by Q4 2015.

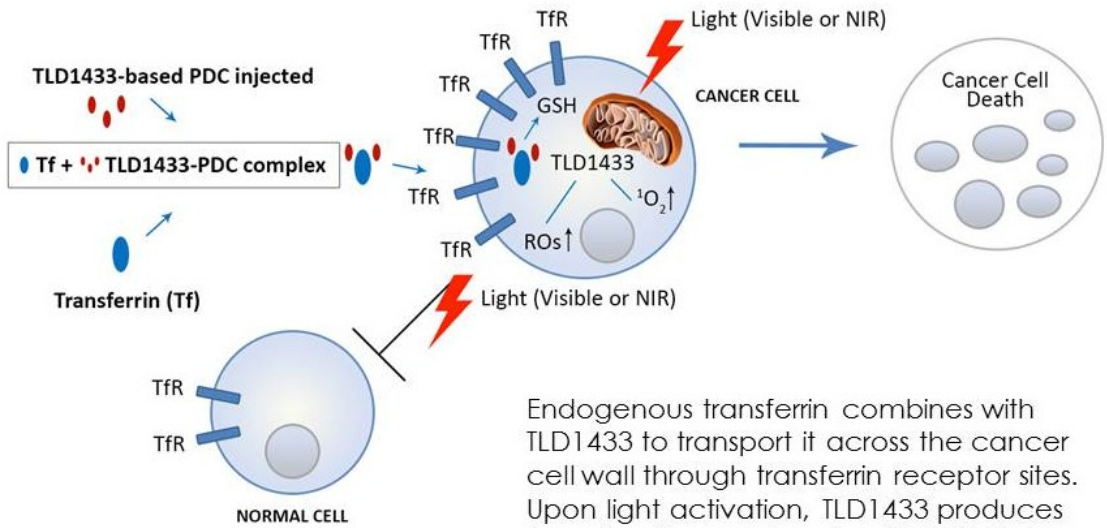
Theralase's discovery – PDC compound TLD 1433…

Theralase has already demonstrated from previous preclinical studies that NIR PDT not only destroys colon cancer cells, but also generates a long-term anti-cancer memory response in mice (eight to ten weeks old as well as ten to eleven months old).

Transferrin (iron-binding blood plasma glycoprotein) occurs in the body naturally and controls the level of free-floating iron in body fluids. If a biological cell has a transferrin receptor ("**TfR**") on its surface, transferrin is able to bind more effectively to that specific cell.

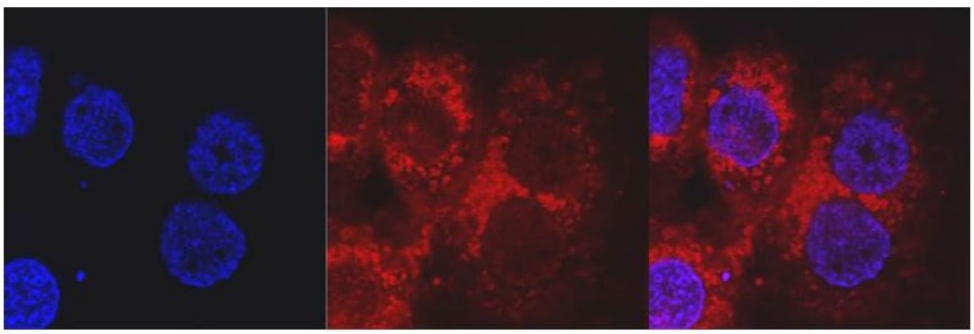
It has been shown in studies that transferrin receptors are overexpressed for a variety of cancers and are known to transform normal cells into cancer cells. When TLD 1433 directly binds to transferrin to the form of Rutherrin, it develops the ability to localize into the mitochondria that is present in the cytoplasm of the cancer cell. When activated by NIR light, the cancerous cell is destroyed through apoptosis ("**natural cell death**").

TLD1433: Mechanisms of Action



Endogenous transferrin combines with TLD1433 to transport it across the cancer cell wall through transferrin receptor sites. Upon light activation, TLD1433 produces Reactive Oxygen Species ("**ROS**") that destroys the mitochondria inducing cell death via apoptosis.

Cellular Localization



Mitochondria localization providing TLD1433 mediated cancer cell kill

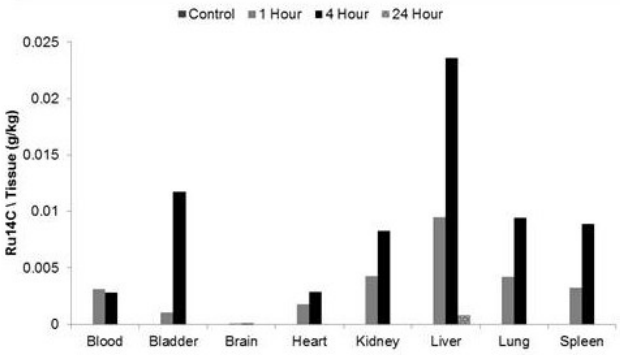
The Ruthenium complex TLD1433 was incubated for 16 hours at a concentration of 1 μM in AY27 rat bladder cancer cells and SCC4 cells. Nucleus was stained by DAPI (blue, left figure) and TLD1433 was detected by red fluorescence (middle figure). TLD1433 is not localized in the cell nucleus (overlay, right figure), but rather shows localization in the cytoplasm (organelles).

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More recently, on 14 May 2015, Theralase announced that its lead PDC, TLD-1433, emits a fluorescent signature when light activated in a Non-Muscle Invasive Bladder Cancer ("**NMIBC**") animal model. The advantages of using the compound are now three-fold. Firstly, the compound can be employed as a diagnostic tool to detect the presence of cancer cells and micro-metastases. Secondly, it can be used to determine sufficient uptake of TLD 1433 into the cancer cells. Finally, it can be used to determine if the cancer cells that have absorbed the drug have been destroyed after light activation. This technology is very promising as it can help clinicians visualize and distinguish diseased tissue from healthy ones at a cellular and molecular level.

The graph below indicates that TLD 1433 does not enter the blood stream in any appreciable quantities, thus providing a very high safety profile and ultra-low toxicity.

Biological Accumulation



10 mg/kg of TLD1433 was injected via the mouse tail vein and tissues were collected at 1, 4, and 24 hours post injection. Quantification was performed via ICP-MS at parts-per-billion resolution and results were normalized for tissue weight.

Concentration infused in the bladder	50 µg/mL
Concentration detected in the blood	0.01 µg/mL

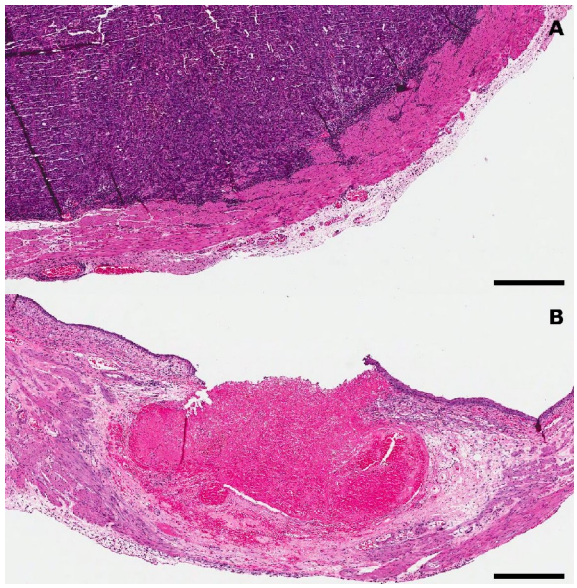
TLD1433 was infused into the Fischer 344 rat bladder (50 µg/mL, 0.01 mg/cm^2) and left in the bladder for 60 minutes. Blood was collected and analyzed for TLD1433 accumulation

TLD1433 is cleared within 24 hours after systemic injection.

TLD1433 has less than 0.02% leakage into the bloodstream, post intravesical bladder installation, highlighting very high safety profile

…TLD-1433 – an effective drug for non-muscle as well as muscle invasive bladder cancer…

Recent research involving the PDT of TLD-1433 in an orthotopic rat bladder tumor model demonstrated that the drug was effective in treating Muscle Invasive Bladder Cancer ("**MIBC**"). The rat's bladder was infused with 1.5 million AY27 cancer cells per milliliter. In one hour, the cancer cells attached to the bladder wall and the tumor was allowed to grow in size in a period of two to three weeks. One hour post infusion of TLD-1433, the bladder was washed to remove excess and unabsorbed drug. Green laser light was for applied for therapy. Histological examination revealed the complete destruction of the tumor. Although there were large areas of hemorrhage, necrosis ("**cell kill**"), and inflammation throughout the depth of the tumor, blood vessels of the submucosa, the muscle layer and urothelium distal from the tumor area remained unaffected by the treatment.



Images of MIBC in control (A) and PDT treated (B) bladders. In all images, the scale bar represent 0.5 mm. In the control, the highly proliferative cancel cells have infiltrated the deeper muscle layer in multiple locations. In the PDT treated bladder with 6.0 mg/mL TLD-1433, the tumor had invaded the muscle layer, but has become completely necrotic due to PDT treatment. The muscle and urothelial tissue flanking the tumor remains healthy and do not show signs of inflammation or necrosis.

Research to Combat Bacteria and Food Contamination

In the U.S. alone, more than 99,000 people die each year from bacterial infections. While this cost on human life is high, the financial toll is equally staggering. The World Health Organization ("**WHO**") has called healthcare associated infections one of the largest causes of avoidable harm and unnecessary deaths in the developed world. The Centers for Disease Control and Prevention estimate such infections add an additional $35 to $45 billion in costs to the U.S. healthcare system annually.

Bacterial infection, ranging from superficial skin infections to severe invasive diseases, is recognized as a very serious health threat, representing a major cause of mortality and adding financial burden to already-stretched health care systems. PDCs have been proven to target and destroy bacteria associated with the contamination of food. Photodynamic Inactivation ("**PDI**") of pathogenic bacteria is a unique approach that combines a photosensitizing drug ("**PS**") and light to generate cytotoxic singlet oxygen and other reactive oxygen species ("**ROS**"). This oxidative burst leads to nonspecific damage with multi-faceted targets, including the cytoplasmic membrane, intracellular proteins and DNA.

In April 2012, Theralase presented new scientific data supporting the application of Theralase's advanced sterilization platform technology that kills 99.99% of life threatening infectious microorganisms, such as Staphylococcus aureus ("**S. aureus**"). This organism is responsible for both Hospital Acquired Infections ("**HAI**") and Community Acquired Infections ("**CAI**") that range from relatively minor skin and soft tissue infections to life□threatening systemic infections.

STRATEGIC OPPORTUNITY

Therapeutic Market

WHO estimates that 20% of individuals worldwide have some degree of chronic pain that has direct health-care associated costs. Treatment options include pharmacological approaches, interventional techniques including nerve blocks, surgery, implantable drug-delivery systems, spinal-cord stimulators, exercise, physical rehabilitation, psychological treatments, interdisciplinary treatment, complementary and alternative treatments.

In 2016, Theralase expects to continue expansion of its sales and marketing initiatives in the US market, while maintaining its dominant position in Canada. Theralase has established its direct Canadian sales force (5 TSMs covering all provinces and territories) and marketing force (6 representatives marketing to all provinces and territories) in 2015. In 2016, Theralase will expand its direct sales and marketing force into the US market, focusing on the 5 largest states of New York, California, Florida, Illinois and Texas. In 2017, Theralase will grow its sales internationally through the strategic partnering with exclusive international medical product distributors. It is estimated that currently there are approximately 1,600 and 6,800 competitive therapeutic laser devices in use in Canada and the U.S., respectively. Propelled by increased usage of laser equipment for minimally invasive treatments and cosmetic therapies, market segments such as therapeutic lasers are witnessing increased demand. Asia-Pacific represents the fastest growing regional market with a CAGR of 11.7%.

Bladder Cancer Market

$3.98 Billion is spent annually for bladder cancer treatment in the U.S. There are 77,000 new cases in the US each year; 386,000 new bladder cancer cases annually worldwide. Bladder cancer is the most expensive cancer to treat, costing between $100,000 to $200,000 per patient, with a recurrence rate of up to 80%. Standard treatment has remained relatively unchanged with no new drugs approved since 1998.

In the early stage of the disease (**Ta, T1**), the standard of care is a procedure known as Trans-Urethral Resection of the Bladder Tumor ("**TURBT**"), which involves a surgical excision ("**scraping**") of the tumor from the bladder wall followed by treatment with bacillus Calmette-Guérin ("**BCG**"), a bacteria originally used for the vaccination of tuberculosis. The 5-year survival rate at this stage of the disease is 75%. In the mid-stage of the disease (**T2, T3a/b**), the entire bladder is removed along with nearby reproductive organs and lymph nodes in a procedure called a radical cystectomy, providing a 5 year survival rate of 31 to 63% depending on progression of disease. In the late stage of bladder cancer (**T4**), the disease has spread beyond the bladder to distant sites, such as the bones, liver and lungs and is generally regarded as incurable with a 5-year survival rate of less than 21%.

The standard of care for all types of cancer focuses around three main disciplines: surgery (**to remove the cancerous tissue and any tissue surrounding it**), radiation therapy (**to destroy the cancerous tumor with ionizing radiation**) and finally chemotherapy (**to destroy the cancerous tumor with cytotoxic (cell killing) drugs**). All of the aforementioned therapies have severe side effects, affect Quality of Life ("**QOL**") and diminish the effectiveness of the immune system, the very system that helps the body combat disease. The Theralase PDC anti-cancer technology works by destroying only the cancerous tissue and leaving healthy tissue intact without causing any serious side effects or QOL concerns.

MEDICAL REIMBURSEMENT

LLLT is usually paid for in cash at clinics, as it has limited Current Procedural Terminology ("**CPT**") code coverage. Currently, other pre-existing codes are in use for reimbursement purposes depending upon the state legislation and insurance plans. The CPT code 97026 (**application of a modality; infrared**), has been used in the past since the laser emits light in the infrared spectrum. In January 2004, a HCPCS level 2 code, S8948, was added that is specific to cold laser therapy.

Theralase expects to secure a new CPT code for reimbursement for laser treatments in the U.S. for its new patented TLC-2000 technology. Under the Health Insurance Portability and Accountability Act of 1996 ("**HIPAA**"), CPT codes are updated annually and effective for use on January 1 of each year. The American Medical Association ("**AMA**") prepares an annual update so that the new CPT books are available in the fall of each year, preceding their effective date to allow for implementation. With the implementation of the Patient Protection and Affordable Care Act ("**PPACA**"), the device could make even more headway in the mainstream health care system with over 8 million Americans expected to be added to the medical insurance system.

VALUATION

Theralase technology is currently well positioned in the market. The launch of a new product, an improving economy and an aggressive sales and marketing strategy will help boost their sales in the coming years.

Thus far the sales of medical laser systems might have suffered to some degree due to the global economic downturn, especially in the U.S. since 2008 and Europe in 2012, although we think lack of sufficient capital and personnel to significantly increase sales might have also been a factor. Over the long-term, the noninvasive application of the medical laser equipment business is projected to grow due to greater awareness and increased government budgets for healthcare. According to a new market report published by Transparency Market Research, the global market for medical laser systems was valued at $909 million in 2011 and it is expected to reach an estimated value of $2.0 billion in 2018, implying a CAGR of 12.5%.

Business Update for 2H 2015:

In June Theralase actively participated at several investor conferences, including Small-Cap Stars Spring Conference held in New York City as well as at the Biotechnology Industry Organization in Pennsylvania.

Six months post filing of the application, the TLC-2000 biofeedback therapeutic laser device received approval from the Canadian Standards Association ("**CSA**"), which conducted an in-depth review of the technical testing results and approved the product in accordance with the latest international medical standards, including Canadian and U.S. standards. Post CSA approval, management released commercial versions of TLC-2000 to its team of Key Opinion Leaders ("**KOLs**") and Territory Sales Managers ("**TSMs**") for obtaining feedback in order to make any final refinements before device launch. The KOLs have been instrumental in providing guidance to construct the specifications of the next generation TLC-2000 from a healthcare practitioner's point of view. Based on their advice, management made necessary adjustments to the Graphical User Interface ("**GUI**") as well as to clarify the specifications; however, the device itself did not undergo a change in design. The TSMs have been given the opportunity to become familiar with the operation of the product and the GUI so that they are able to explain the intricacies of the technology to solicit interest in the new product to build a 'pre-sales' book of potential purchasers.

The TLC-2000 device is pending Health Canada approval (application submitted in Feb 2015), which is expected sometime before the end of this year. The slight delay from the prior expectation to launch the device by Q3 2015 is attributable to the time that Health Canada takes to respond to the application with questions. Although the approval had been expected to be granted within about 2 months of submitting the application, in reality the response time may end up being closer to 180 days. The regulatory agency may take 45-to 75 days to review the application. If Health Canada responds with questions and management replies shortly afterwards, it could take another 45 to 75 days for the regulatory agency to review and respond back, further tying up the application and resulting in additional delays to the launch timeline. We expect approval to come through by end of 2015.

While revenue has been somewhat of a disappointment in the current year, as has the delays with the TLC-2000 Health Canada approval, we continue to look for the company to turn cash flow positive following launch of the device in the 3 major markets (Canada, U.S. and Europe), which we think could happen by the end of 2016.

Theralase anticipates commencing patient enrollment for the Phase Ib NMIBC clinical trial by end of 2015 pending approval.

The sole current contributor to our modeled revenue is from the TLC-2000. Revenue from the expanded markets from the pain therapy applications that may materialize would be incremental, and provide potential upside, to our model. Theralase currently has about 1,200 customers in the U.S., Canada and other international markets for the TLC-1000 product, with Canada contributing 72% of revenue. Theralase was granted the FDA approval for the TLC-2000 in November 2015. Starting in first quarter of 2016, Theralase plans to begin phasing out the TLC-1000 product in the U.S. in 2016 by converting existing customers currently using the TLC-1000 to trade-up to the TLC-2000 model. Theralase hopes to completely phase out of the TLC-1000 technology by the end of 2018 in the U.S. The sales effort will also target new customers with its TLC-2000 technology.

In the new revenue model, the practitioners enter into a 60 month lease structured payment plan (60 payments @ between $330 to $700 per month, with an average monthly payment of $500). Theralase allows unlimited use of the device and will provide unlimited warranty on the technology, training, ongoing service and marketing / customer referrals during the lease term. At the end of the term, the customer can choose to continue with monthly payments into perpetuity, sign another 60 month lease with the next generation smart laser system or return the device. The equipment will be billed in full on date of delivery by a third party leasing company and then through Pre-Authorized Chequing ("**PAC**") thereafter; thus, allowing real-time payments and control over non-payment by practitioners.

Our financial model includes the assumption that 80% of current customers from Canada and the U.S. adopt this new technology over the coming years, ending 2019. The short-term catalyst will be to successfully convince existing customers to upgrade to the new technology. A long term goal will be to build a relationship to maintain the customer base so that they continue to lease the equipment to perpetuity or until the next generation laser system becomes commercial. We also assume 80% of the customer base renews their lease at the end of their 60 month lease term. Further, we expect Theralase to build a customer base of 6000 globally over the next decade for this device by targeting new customers in the U.S., Europe, and Canada from 2016 onwards. In Europe and in the international market, the technology maturity, governmental regulations, and currency fluctuations influence the marketing strategy and as Theralase does not have a strong history in these markets, we project that the thrust of the sales and distribution may commence in 2017, growing at a rate of 12.5% per year over the next ten years.

RECOMMENDATION

Investment Considerations

Strong advisory board and management team
Theralase is backed by a strong management team with significant knowledge and expertise along with a strong portfolio of IP and the ability to get regulatory approvals for therapeutic lasers.

Short-term catalysts
We believe that the company's focus on global market segments with significant unmet needs, the continued positive results from on-going pre-clinical trials and the upcoming TLC-2000 product launch bodes well for increased revenue coming from the laser therapy division in 2015. Expansion in international markets, Brazil, Russia, India and China ("**BRIC**") countries with emerging economies that are increasing their uptake of medical devices due largely to growing medical awareness and economic prosperity, an aging population, government focus on healthcare infrastructure and expansion of medical insurance coverage, represents one of the best potential avenues for growth in 2017 and beyond.

Theralase will validate its PDC technology in this animal cancer orthopedic model to support an Investigational New Drug ("**IND**") application in the US and Clinical Trial Application ("**CTA**") that will allow Theralase to conduct both a Phase Ib and IIb human clinical trial for NMIBC to prove the safety and efficacy of its PDC technology in 2016 and 201`7. The company will expand its platform of cancer indications in 2016 to include: : lung, brain and melonoma.

Sales and Revenue
We view Theralase's pipeline as holding significant potential. While revenue has been modest to-date, particularly relative to future potential, it has helped fund the company's R&D efforts. Theralase needs to strengthen its implementation of the logistical and servicing issues to handle all the necessary sales and promotion until international operations become more mature and profitable.

Theralase is well-positioned to deliver increasing revenue and Earnings Per Share ("**EPS**") due to expanding use of its cold laser therapy system. The company's portfolio of high margin products targets attractive growth areas such as chiropractic and physical therapy centers. We also expect to see positive results from clinical trials employing the PDT technology that could drive upside to outperform estimates. Lastly, we view Theralase as an attractive acquisition target given its position as a laser therapeutics company with a unique technology, expanding menu and growing installed base.

Valuation
2015 and 2016 look to be exciting years for Theralase. The near term milestones include the clinical trials for bladder cancer treatment in humans commencing in late 2015 as well as the TLC-2000 roll-out in Q1 2016. Based on the slight delay in expected launch, we have pushed out our revenue estimates for the TLC-2000 device to Q1 2016. We are optimistic about the PDC technology and given the successful clinical trials thus far, we believe that this technology could become the standard for cancer treatment.

Theralase is expected to burn cash of about $3M as they prepare to launch TLC-2000 in the U.S. and Europe in 2016 and 2017, respectively. The bulk of this amount will likely be used in 2016 due to ramping up of the inventory and increase in sales and marketing expenses; however, we suspect that the company will need additional financing to continue its planned operations in expanding its sales and marketing for the TLC-2000 as well as for the research and development in the PDT division until revenues generated from TLC-2000 are substantial to help the company cover their OpEx. We expect sales to improve through the third and fourth quarters of 2016, with significant revenue ramp up in 2017, helping Theralase turn cash flow positive by 2018. Our outlook is still intact and we maintain our Buy rating on Theralase.

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Risk Factors

Sole product: In view of the technological progress in the medical device field, research and product development life-cycles can become a lengthy process. Theralase has invested a significant amount of time in getting each of their products commercialized; hence, a majority of their revenue will be generated from the TLC-2000 for the foreseeable future, as the TLC-3000 PDC technology is still in the pre-clinical stages of development.

Medical Reimbursement: Insurance companies consider laser therapy as belonging to the category of alternative therapy that is in the experimental and investigational stage because there is inadequate evidence of its effectiveness. Laser therapy methodologies are not standardized for the treatment of wound healing, or pain of various etiologies in various anatomical sites and the physiological effects from photobiomodulation are not completely understood. The major concern is in its parameters of use, such as: wavelength, power, irradiation dose, and effects on different medical conditions. The studies involving LLLT may not be in conflict, and may represent fundamental, but poorly understood, differences in treatment approaches. Furthermore, although positive effects were found in studies, it was not clear that the pain relief achieved was large enough to replace conventional therapies that impact reimbursement amounts. Thus far there has been very little indication of reimbursement amounts from public or private insurance companies for cold laser therapy. The U.S. government is the leading payer for most of health care, and under PPACA, the government's role in reimbursing for medical technology may increase. Yet two-thirds of all requests for reimbursement are denied today, and the timeframe to process the reimbursement requests and the approved amounts are big unknowns for such companies introducing new devices.

Model-Based Assumptions are prone to large variations: The growth of innovation and development of technology in the field of medical devices and healthcare is enormous. The medical device market changes frequently in terms of technology and marketing. Lack of adequate planning and regulatory strategy for a chosen market can cause higher development costs and unexpected delays resulting in a longer development cycle. The estimated financial model entails assumptions based on available current information, best-guesses and management's publicly available reports. Our projected revenue growth from the sales of TLC-2000 commencing in 2016 and beyond is largely best-guesses based on existing customers upgrading from TLC-1000 to TLC-2000 as well as growth in the customer base. Revenue could underperform relative to our model if the customer base does not grow at our assumed forecast or is less correlated to revenue growth than what we are assuming. As cold laser therapies become more prevalent among practitioners, it is very difficult to gauge whether our estimates (particularly in the out-years) will prove accurate. Achieving our price objective includes, but is not limited to: clinical, regulatory, competitive, reimbursement and financial risks. Theralase may require substantial funding to advance the clinical progress of its candidates, which could be dilutive to current shareholders.

Income Statement

Theralase Technologies Inc.

	2014 A	Q1 A	Q2 A	Q3 A	Q4 E	2015 E	2016 E	2017 E	2018 E	2019 E	2020 E
Revenue	$1,380,604.0	$368,304.0	$309,513.0	$383,792.0	$312,700.0	$1,374,309.0	$4,572,500.0	$8,652,350.0	$11,971,100.0	$12,000,600.0	$14,804,280.0
YOY Growth	*14.7%*	*2.0%*	*-38.0%*	*186.3%*	*-19.0%*	*-0.5%*	*232.7%*	*89.2%*	*38.4%*	*0.2%*	*23.4%*
TLC-1000 COGS	$354,865.8	$92,076.0	$108,238.0	$134,327.2	$92,750.0	$427,391.2	$0.0	$0.0	$0.0	$0.0	$0.0
TLC-1000 margin	*100.0%*	*75.0%*	*75.0%*	*65.0%*	*65.0%*	*75.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*
TLC-2000 COGS	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$1,237,500.0	$2,056,230.0	$2,598,750.0	$2,461,140.0	$2,985,948.0
TLC-2000 margin	*75.0%*	*75.0%*	*75.0%*	*75.0%*	*65.0%*	*65.0%*	*70.0%*	*73.2%*	*75.0%*	*75.8%*	*76.2%*
TLC-3000 COGS	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
TLC3000 margin	*0.0%*						*0.0%*	*75.0%*	*75.0%*	*75.0%*	*75.0%*
COGS	$354,865.8	$92,076.0	$108,238.0	$134,327.2	$92,750.0	$427,391.2	$1,237,500.0	$2,056,230.0	$2,598,750.0	$2,461,140.0	$2,985,948.0
margin	*25.0%*		*35.0%*	*35.0%*	*29.7%*	*31.1%*	*27.1%*	*23.8%*	*21.7%*	*20.5%*	*20.2%*
Cost of Goods Sold	$459,323.0	$135,156.0	$108,238.0	$114,356.0	$92,750.0	$450,500.0	$1,237,500.0	$2,056,230.0	$2,598,750.0	$2,461,140.0	$2,985,948.0
Gross Income	$921,281.0	$233,148.0	$201,275.0	$269,436.0	$219,950.0	$923,809.0	$3,335,000.0	$6,596,120.0	$9,372,350.0	$9,539,460.0	$11,818,332.0
Gross Margin	*66.7%*	*63.3%*	*65.0%*	*70.2%*	*70.3%*	*67.2%*	*72.9%*	*76.2%*	*78.3%*	*79.5%*	*79.8%*
Selling Expenses	$598,178	$184,488	$218,110	$347,500	$300,000	$1,050,098	$1,600,375	$3,028,323	$2,633,642	$2,640,132	$3,256,942
Administrative Expenses	$1,448,781	$456,123	$526,718	$636,369	$650,000	$2,269,210	$2,382,671	$2,501,804	$2,626,894	$2,758,239	$2,896,151
(Gain) Loss on Foreign Exchange	($4,550)	($15,228)	$2,258	$1,075	$0	($11,895)	$0	$0	$0	$0	$0
Interest Expense	$19,538	$67.00	$212.00	$0	$0	$279	$0	$0	$0	$0	$0
Interest Income	($8,424)	($4,303)	($11,569)	($14,046)	$0	($29,918)	$0	$0	$0	$0	$0
SG&A	$2,053,523.0	$621,147.0	$735,729.0	$970,898.0	$950,000.0	$3,277,774.0	$3,983,045.5	$5,530,126.5	$5,260,536.2	$5,398,370.9	$6,153,092.5
%SG&A	*148.7%*	*168.7%*	*237.7%*	*253.0%*	*303.8%*	*238.5%*	*87.1%*	*63.9%*	*43.9%*	*45.0%*	*41.6%*
R&D	$1,455,301.0	$545,645.0	$811,019.0	$1,272,499.0	$800,000.0	$3,429,163.0	$3,652,058.60	$3,889,442.40	$2,227,923.84	$1,977,923.8	$1,677,923.8
% R&D	*105.4%*	*148.2%*	*262.0%*	*331.6%*	*255.8%*	*249.5%*	*79.9%*	*45.0%*	*18.6%*	*16.5%*	*11.3%*
Operating Income	($2,587,543.0)	($933,644.0)	($1,345,473.0)	($1,973,961.0)	($1,530,050.0)	($5,783,128.0)	($4,300,104.1)	($2,823,448.9)	$1,883,889.9	$2,163,165.2	$3,987,315.7
Operating Margin	-	-	-	-	-	-	-	-	*15.7%*	*18.0%*	*26.9%*
Total Other Expense (Income) - Stock based compensation	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($2,587,543.0)	($933,644.0)	($1,345,473.0)	($1,973,961.0)	($1,530,050.0)	($5,783,128.0)	($4,300,104.1)	($2,823,448.9)	$1,883,889.9	$2,163,165.2	$3,987,315.7
Taxes (benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$1,395,560.5
Tax Rate	*35.0%*	*35.0%*	*35.0%*	*35.0%*	*35.0%*	*35.0%*	*35.0%*	*35.0%*	*35.0%*	*35.0%*	*35.0%*
Other Tax	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Net Income	($2,587,543.0)	($933,644.0)	($1,345,473.0)	($1,973,961.0)	($1,530,050.0)	($5,783,128.0)	($4,300,104.1)	($2,823,448.9)	$1,883,889.9	$2,163,165.2	$2,591,755.2
Net Margin									*15.7%*	*18.0%*	*17.5%*
EPS	($0.03)	($0.01)	($0.01)	($0.02)	($0.02)	($0.06)	($0.04)	($0.02)	$0.02	$0.02	$0.02
Diluted Shares O/S	74,979,539	81,392,501	90,103,734	95,957,158	95,957,158	90,852,638	110,957,158	120,957,158	121,957,158	122,957,158	123,957,158

Source: Zacks Investment Research *Anita Dushyanth*

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Roger Dumoulin-White
P. Eng., President & CEO
Mr. Dumoulin-White founded Theralase in 1995 and has over 29 years as a senior manager with private and public companies. As an award-winning entrepreneur, he has pioneered Low-Level Laser Therapy for use in treating pain, inflammation and for tissue regeneration of neural muscular skeletal conditions and wound healing. He is responsible for developing patented PDCs that are able to target and destroy cancer and bacteria, when light activated by Theralase's proprietary laser technology.

Arkady Mandel
MD, Ph.D., D.Sc., Chief Scientific Officer
Dr. Mandel has over 20 years of experience as a key founder of therapeutic uses of lasers in dermatology and other areas of clinical medicine. He is an experienced executive manager of research and development teams dedicated to the field of biotechnology, drug development and photobiology. He has published over 100 original scientific papers to his name, combined with over 200 international patents attributed to his research. He is an editor of many peer reviewed scientific and medical journals.

Kristina Hachey
CPA, Chief Financial Officer
Ms. Hachey is a Chartered Professional Accountant and has over 18 years of experience in finance and financings in public and private companies.

Wayne Embree
VP of Engineering
Mr. Embree has 38 years of experience in designing and managing design teams in the production of high tech electronic devices and is leading a team of 9 full time and part time engineers in the commercialization of the TLC-2000 therapeutic laser technology.

David Smith
Director of Sales
Mr. Smith possesses 25 years' experience at the executive level managing medical device sales in Canada, the U.S, and international markets. He has demonstrated a track record of success in previous senior sales positions with Eli Lilly, Baxter and Philips Healthcare. David's educational background includes completion of an Executive Program for Strategic Sales Management from the Graduate School of Business, University of Chicago, as well as an undergraduate degree in Physical and Health Education from McMaster University.

Alan Chan
Director of Marketing
Mr. Chan brings over 25 years of marketing experience from the pharmaceutical and medical device industries, where he was in leadership positions launching several billion-dollar products in global markets. He was a pioneer in the creation of the medical aesthetics market, when he led the launch of Botox cosmetics and helped grow it to the billion dollar industry that it is today. Alan possesses the experience and vision to help Theralase command a dominant role in the therapeutic laser market with the launch of the TLC-2000.

SCIENTIFIC AND MEDICAL ADVISORY BOARD (SMAB)
The SMAB is comprised of international Key Opinion Leaders ("**KOLs**") and esteemed scientists with broad expertise in biomedical and clinical research, drug discovery and development, as well as medical device engineering and manufacturing. The SMAB plays an active role in Theralase pipeline's development with evaluation of in-licensing and partnership opportunities. The board members comprise of:

James Andrews, MD, is a founding member of Andrews Sports Medicine and Orthopedic Center in Birmingham, Alabama. He is a founder of the American Sports Medicine Institute ("**ASMI**") a non-profit institute dedicated to injury prevention, education and research in orthopedics and sports medicine. Dr.Andrews is internationally known and recognized for his skills as an orthopedic surgeon as well as his scientific and clinic research contributions in knee, shoulder and elbow injury prevention and treatment. Dr.Andrews is Senior Consultant for the Washington Redskins Professional Football team and Medical Director for the Tampa Bay Rays Professional Baseball Team and the Ladies Professional Golf Association.

Jeffrey Dugas, MD. Dr. Dugas serves as an orthopedic consultant to collegiate and professional teams. Dr. Dugas has been widely published in medical journals for clinical studies on orthopedic surgery and sports medicine injuries. He has received numerous awards and honors in his specialized field of orthopedics and sports medicine and is a member of many professional medical organizations, including: the American Medical Association, American Medical Society for Sports Medicine, American Orthopedic Society for Sport Medicine, American Academy of Orthopedic Surgeons, the American Society for Shoulder and Elbow Surgery, and the International Cartilage Repair Society. Dr. Dugas is a 1994 graduate of the Duke University School of Medicine, a practicing orthopedic surgeon, Fellowship Director and a senior staff member of ASMI.

Lyle Cain, MD, serves as an orthopedic consultant to collegiate and professional sports teams. Dr. Cain serves as a Member of Advisory Board at IntelliCell BioSciences, Inc. He is a member of a wide range of professional orthopedic medical committees and institutes, including: the American Medical Association, the American Academy of Orthopedic Surgeons, the American Orthopedic Society for Sports Medicine, and the International Cartilage Repair Society. Dr. Cain is a 1994 graduate of the University of Alabama Medical School, a practicing orthopedic surgeon, Fellowship Director and a senior staff member of ASMI.

Kevin Wilk, PT, DPT, serves as Vice President and National Director of Clinical Education Research at Physiotherapy Associates, Inc. Dr. Wilk is a Founder and serves as an Associate Clinical Director of Champion Sports Medicine in Birmingham, Alabama. He serves as Managing Director of the Andrews Orthopedic and Sports Medicine and as Director of Rehabilitative Research for the American Sports Medicine Institute. He has had a distinguished career as a clinical physical therapist, researcher and educator for over 29 years. He has made significant contributions to laboratory research, bio-mechanical research and clinical outcome studies and is recognized as a leading authority in rehabilitation of sports injuries and orthopedic lesions.

Michael Jewett, MD, FRCSC, FACS, Professor of Surgery in the Division of Urology at the University of Toronto, a member of the Department of Surgical Oncology at Princess Margaret Cancer Centre and the Division of Urology at University Health Network. Dr. Jewett is internationally known for his contributions in the fields of bladder, testis and kidney cancer fundamental and clinical research. He has been the Principal Investigator/Co-Principal Investigator on over 60 Phase I-Phase III clinical trials and the Lead Principal Investigator of several Cooperative Group Trials. He is a recent Past-President of the Canadian Urology Association and a member of many urological and surgical oncology societies worldwide. Dr. Jewett has published over 175 original medical research papers.

Lothar Lilge, PhD, Professor in the Department of Medical Biophysics at the University of Toronto, Senior Scientist Ontario Cancer Institute, Princess Margaret Cancer Centre. Dr. Lilge's research is focused on PDT, optical diagnostics, destruction of cancer and bacteria by light activated PDTs and the use of light as a microscopic tool for biomedical research. He has published over 30 original scientific papers and is an editor of peer reviewed scientific journals. Dr. Lilge is a much sought after speaker at many international medical and scientific conferences.

Ashish Kamat, MD, is a Uro-oncologist. Internationally recognized expert in urologic oncology and an authority in the management of urologic cancers. Expertise in bladder cancer, organ sparing and minimally invasive techniques. He maintains an active research portfolio with a focus on efforts to develop novel therapies and identifying predictors of response to therapy (e.g. intravesical immunotherapy), as a first step towards personalized cancer therapeutics. He has initiated, led and been active in several large studies including multinational trials in bladder cancer, with findings published in high impact journals.

Michael O'Donnell, MD, is a Uro-oncologist. Has a long history of focusing on bladder immunology and bladder cancer immunotherapy, particularly the anti-cancer mechanisms of bacillus Calmette-Guerin ("BCG") and its enhancement with combination therapies. He recently headed a national trial of bladder cancer treatment utilizing BCG plus interferon (a natural protein which induces healthy cells to combat disease) comprised of over 1,000 patients and holds several U.S. patents for his work.

Brian Wilson, Ph.D, is a Senior Scientist and Head of the Applied Biophotonics group at Princess Margaret Cancer Centre, UHN Professor in the Department of Medical Biophysics at the University of Toronto. The primary research focus of the Applied Biophotonics group is the development and application of new therapeutic and diagnostic techniques based on the use of lasers and other optical technologies.

STRATEGIC PARTNERSHIPS

Princess Margaret Cancer Centre □ University Health Network is a medical centre that comprises three teaching hospitals affiliated with the University Of Toronto Faculty Of Medicine, including Princess Margaret Cancer Centre, home of the Ontario Cancer Institute, Toronto General Hospital and Toronto Western Hospital, an organization that generates in excess of $1 Billion in revenue annually.

Ontario Centers of Excellence, Photonics Division is an Ontario and Canadian government funded knowledge, partnership and commercialization portal for the research and development of photonic technologies partnering academia with industry to commercialize cutting-edge technology.

Virginia PolyTechnic Institute (VirginiaTech)

Founded in 1872, Virginia Tech has approximately 135 campus buildings, a 2,600-acre main campus, off-campus educational facilities in six regions, a study-abroad site in Switzerland, and a 1,800-acre agriculture research farm near the main campus. Researchers at Virginia Tech are the American inventors of one platform of PDCs used by Theralase in its anti-cancer research.

Acadia University

Founded in 1838, when Baptist leaders reached a breaking point in their ability to access higher education, they created their own university and removed barriers for themselves and others. Researchers at Acadia University are the Canadian inventors of a second platform of PDCs used by Theralase in its anti-cancer research.

Buffalo Niagara Medical Campus (BNMC)

Founded in 2001, The BNMC is a consortium of the region's premier health care, life sciences research, and medical education institutions, all co-located on 120 acres in downtown Buffalo, New York. The BNMC is dedicated to the cultivation of a world-class medical campus for clinical care, research, education, and entrepreneurship.

Scripps Research Institute (TSRI)

The Scripps Research Institute (TSRI) is a nonprofit research institution whose philosophy emphasizes the creation of basic knowledge in the biosciences for its application in medicine, the pursuit of fundamental scientific advances through interdisciplinary programs and collaborations, and the education and training of researchers preparing to meet the scientific challenges of the future.

Mayo Clinic

Mayo Clinic is a world renowned, nonprofit worldwide leader in medical care, research and education for people from all walks of life.

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The current distribution is as follows: Buy/Outperform- 16.2%, Hold/Neutral- 75.7%, Sell/Underperform – 7.1%. Data is as of midnight on the business day immediately prior to this publication.