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Zacks Small-Cap Research

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Theralase Technology Inc (V.TLT)

V.TLT: Interim Update: Clinical Trials show promise; Insight from management, Waiting for TLC-2000 roll-out

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	12/02/2014
Current Price (2/25/2015)	$0.54
Target Price	**$1.00**

OUTLOOK

Theralase hopes to displace its current device TLC-1000 with its next generation TLC-2000 biofeedback laser therapeutic device that will be launched mid 2015 in Canada. The trials employing Photo Dynamic Therapy (PDT) technology for the treatment of bladder cancer in animal models have been successful thus far. Theralase is preparing to commence Phase 1/2 trials to treat bladder cancer in humans using this technology. We maintain our Outperform rating.

SUMMARY DATA

52-Week High	**$0.78**
52-Week Low	**$0.21**
One-Year Return (%)	**27%**
Beta	**-0.16**
Average Daily Volume (sh)	**443,200**
Shares Outstanding (mil)	**81.5**
Market Capitalization ($mil)	**$44**
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)
2013	$342.9 A	$508.8 A	$313.4 A	$388.4 A	$1,553.6 A
2014	$361.2 A	$449.3 A	$134.1 A	$1,600.0 E	$2,555.0 E
2015					$5,696.0 E
2016					$10,027.5 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-0.005 A	-0.001 A	-0.003 A	-0.002 A	-0.01 A
2014	-0.01 A	-0.01 A	-0. 02 A	$0.00 E	-0.03 E
2015					$0.00 E
2016					$0.03 E

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

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WHAT'S NEW

New additions to management: Theralase's management has brought in several key new members to the Scientific and Medical Advisory Board. Dr. Ashish M. Kamat from the Department of Urology, Division of Surgery at the University of Texas MD Anderson Cancer Center located in Houston, Texas, Michael A. O'Donnell, MD, Professor of Urology, University of Iowa, and Dr. Brian C. Wilson from the Applied Biophotonics group at Princess Margaret Cancer Centre, University Health Network and Department of Medical Biophysics at the University of Toronto.

Trial to commence with TLC-3000 with Photo Dynamic Compounds (PDCs) in humans: Management has planned an aggressive strategy in building and developing their laser device for cancer application.

Theralase has an ongoing collaborative research and development program for their PDC technology at two renowned research centers, Princess Margaret Cancer Center as well as the University of Toledo. Both centers conducted experiments on orthotropic rat models to validate the PDCs used by Theralase in their preclinical trials.

The experiment was performed by infusing the rat bladder urothelium (inner lining) with cancer cells. Once the tumor increased in size to 1X1 mm, TLD1433 (PDC) was infused into the bladder. Sixty minutes post incubation, the PDC was removed from the bladder. The rats were separated into two groups: One group was used to assess preferential uptake of the PDC in healthy versus cancerous urothelium. The other group was used to assess PDT efficacy in the destruction of bladder cancer (150 mW / cm2 of visible red laser light for 30 minutes). Additionally, Theralase employed visual inspection and Inductively Coupled - Plasma Mass Spectrometry (ICP-MS) to assess and quantify TLD1433 localization and efficacy in healthy versus cancerous urothelium,

Results: Visual and clinical inspection using ICP-MS analysis revealed that there was a preferential uptake of TLD1433 in damaged and cancerous urothelium. When activated by visible red laser light, the PDC destroyed only the cancer cells via necrosis without affecting the surrounding healthy bladder tissue, thus demonstrating clear efficacy. The amount of PDC that entered the blood stream pre/post treatment was negligible supporting a very strong safety profile.

We are very pleased that the preliminary study has not only produced encouraging results but has demonstrated safety and efficacy of the PDC. TLD1433 has shown to have the highest overall performance among other PDCs in the green and red laser light spectrums for multiple cancer cell lines, including glioma (primary brain tumors that originate from the supportive cells of the brain) and bladder cancer. Additional applications using this technology are expected to follow in the future.

Theralase is currently involved in optimizing the TLD1433 and based on the encouraging results, has partnered with JSS Medical Research Inc. to commence a FDA/Health Canada Phase I/II clinical trial to validate the effects of its PDT technology employing PDCs for treatment of Non Muscle Invasive Bladder Cancer (NMIBC) in humans.

TLC-2000 Roll-out: The TLC-2000 biofeedback therapeutic laser system possesses patented Cell SensingTM technology, which allows the TLC-2000 to deliver exact doses of light energy to precise depths of target tissue. Having completed the development of the alpha, beta and pre-production level prototypes of this device from 2010 to 2014, Theralase has currently successfully completed the design of the TLC-2000, and has filed for Health Canada approval via a Class 3 Medical Device Licence application, the approval of which is expected within approximately 75 days of submission, which would indicate final approval to be expected around April 2015. We anticipate the Food and Drug Administration ("FDA") and Conformite Europeene ("CE") approval of the TLC-2000 to be submitted in March 2015. We suspect this process might take several months to play out, but by the second half of 2015 we expect to see the device roll-out into the market.

Based on management's prior guidance we expected revenue to ramp up from Q4 2014 from the sales of TLC-2000 device. However, due to the aforementioned reasons initial roll out of the TLC-2000 is taking longer. Revenue has remained soft in the past year, and has been primarily from the sales of the TLC-1000 device. We suspect this trend to continue until the TLC-2000 rolls out. Based on management's guidance we anticipate an improvement in top line revenues in 2H 2015.

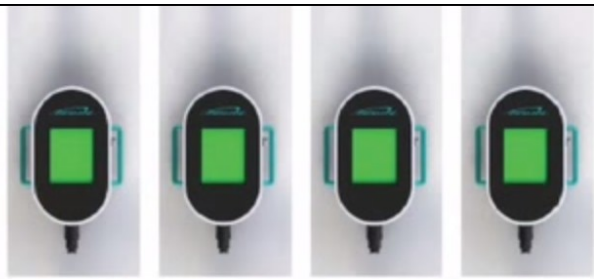
Maintain Outperform Rating: 2015 seems to be an exciting year for Theralase. The near term catalysts include the clinical trials for bladder cancer treatment in humans commencing in mid-2015 as well as TLC-2000 roll-out in Q3 2015.

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. We expect sales to improve through the second half of 2015 and generate significant revenue by fiscal year end. The TLC-2000 product launch in the U.S. and Europe could facilitate the growth in revenue. Based on the recent successful clinical achievements, our outlook is still intact and we maintain Outperform rating on Theralase.

In the third quarter of 2014, Theralase had been busy in advancing their cancer therapy technology and in getting ready to launch their therapeutic laser technology, the TLC-2000.



Tablet



Up to 4 Bio-Feedback Probes



Medical Power Supply



Battery Pack

TLC-2000
The TLC-2000 Biofeedback Laser System is a fully automated wireless technology driven by a tablet. Up to 4 laser probes can be run off of a single system. All of the specifications pertaining to the patient are entered on the computer and the system pulls up the corresponding protocol, sends it wirelessly to the probe to commence treatment. The LED screen on the probe displays the treatment time remaining. The instrument offers ease of use as the practitioner only needs to select the patient and the appropriate treatment. There is an option to over-ride the presets on the protocol and set the values manually. We believe that this device with its unique tissue sensing technology has the scientific backing to displace competitive devices.

The TLC-2000 device offers live tracking capability thereby allowing Theralase to track the use of the device. Theralase has also obtained a unique CPT code for reimbursement purposes in the U.S. market. Theralase plans to use third party contractors to manufacture the device as demand increases. Since management wants to maintain quality control over their device, they would supply two key components, the laser diodes and the test software to the manufacturer. The company plans to install the final product software onto the device before launch. As a part of the lease model, Theralase plans to lease the device through a third party contractor. They offer warranty, marketing as well as updates to the software for the lease term. The device is projected to have 75% gross margin. Cost of device, including the stand, power supply and computer, is priced at $7,500 with one probe and $25,000 with all four probes. The lease cost on the single probe system amounts to $150/month (5 year lease, 10% buyout) and $500/month with all four probes. The TLC-2000 is being offered as a trade-in to the customers who already own the TLC-1000 device.

Theralase still maintains an objective of displacing 100 of their legacy device in Canada by end of Q4, 2014. We expect about $500,000 in expenses related to the launch of TLC-2000. The TLC-2000 is expected to be launched in the U.S. by 3Q 2015 and internationally in 2016. Even though management is awaiting marketing approval for the device in Canada (2 weeks) and in the U.S. (1 month) they do not anticipate any hiccups with launch times. Currently the devices are ready for deployment pending approval in Canada.

TLC-3000
In early September 2014, Global News in Canada reported that there has been a problem at manufacturing plants operated by Merck and Sanofi Pasteur that manufactures BCG. This drug has been routinely used to prevent the recurrence of non-invasive bladder cancer (cancer that has not invaded muscle tissue), following surgical removal of the tumor. The drug is believed to work by stimulating the body's natural immune response that helps in destroying the cancer cells within the bladder. The unavailability of drug has serious implications in patients who suffer from bladder cancer as they may have to resort to surgical removal of the bladder.

Theralase has been involved in developing an alternative therapy for treatment of bladder cancer; the Photo Dynamic Therapy ((PDT)). From the recent research completed in November 2014 involving Theralase's patented Photo Dynamic Compounds ((PDC)) technology, it was scientifically proven that the PDCs have the ability to destroy the tumor cells and offer short-term immune-mediated "memory response". Additionally, the PDT can be personalized for cancer patients to destroy their cancer permanently and prevent its recurrence in a single treatment.

At the beginning of September 2014, Theralase dispatched the TLC-3000 multi-wavelength laser system to Princess Margaret Cancer Centre, University Health Network ((UHN)) and to the University of Toledo to test the safety and efficacy of the PDCs in the preclinical environment. Tests to study the optimization between the combinations of wavelength of light used as well as the amount of light delivered to the cancer cells are due to be conducted. This will help determine the specific PDC that is most effective in the treatment for a particular type of cancer. The TLC-3000 laser system is designed to allow the user to adjust both the wavelength of laser light emitted as well as the amount of light energy delivered to a specific set of cancer cells. Beginning 2015, the company hopes to test their TLC-3000 device using various PDCs (patent issued and pending) in treating bladder cancer in humans.

Theralase would require clinical data from trials employing PDT to support a regulatory pre-market submission; need to drive its product adoption initially in the Canadian market and subsequently in international territories, and a medical reimbursement for its product. It is known that a Contract Research Organization ((CRO)) helps shorten the development time of the product thereby speeding the "time-to-market" phase. Many companies in the biotech sector have employed a CRO to alleviate the increase in pressure in terms of cost, time and regulatory hurdles. Theralase has partnered with JSS, a Montreal based CRO to provide expert guidance on the clinical development of TLC-3000 employing PDC technology. JSS is known to have an integrated expertise and approach to cover the entire spectrum of clinical research projects from conception, design, execution, data analysis, and announcing the results. The Medical Device Excise Tax and Obamacare are not yet clearly defined. This in turn puts Theralase on a high alert for ways to reduce costs, increase development efficiency and accelerate the time-to-market. Therefore, it is a strategic move by Theralase to partner with JSS in order to leverage their expertise to bring this technology to market.

Effect of research results on TLT.V's stocks:
If additional research proves that the PDCs activated by laser light has anti-cancer effects in humans, it would be an opportunity to buy TLT.V stock. Currently, the research is in the animal models. If the experiments are successful and the research progresses towards human trials with positive results, Theralase's stock might show positive reaction. It might be worthwhile to keep a lookout on the significant developments this company has to offer.

Financial Condition:
Theralase has shown minimal revenues with increase in selling and marketing expenses representing about 35% of sales, compared to 28% in 2013 for the 9 month period ending September 2014. Management has invested on advertising and travel in anticipation of increase in revenues in subsequent quarters. Administrative expenses increased due to spending on investor relations activities. The expenses related to the commercialization of the TLC-2000 therapeutic laser technology and scientific and preclinical research towards the development of the TLC-3000 anti-cancer technology, amounted to about $1M and were expensed as gross research and development costs. We expect the selling expenses to continue to increase in the future as Theralase expands its base in Canada, the U.S. and international markets. We anticipate a pop in revenue once the TLC-2000 is launched end of Q4 2014. Currently the company has cash of about $2M which should help cover expenses in the near-term.

Don't overlook these catalysts…

Anticipate launch of TLC-2000 in Q4 2014: We anticipate the launch of the TLC-2000 in Q4 2014. This next generation device is critical for Theralase to turn cash flow positive and will serve as the primary source of revenue until the launch of TLC-3000.

Products in pipeline: Theralase is currently completing preclinical research to validate its PDC technology (TLC-3000) in animal cancer model to support an Investigational New Drug (IND) application to be submitted to the FDA in 1Q2015. This IND application will allow Theralase to commence a Phase 1/2a human clinical trial to prove the safety and efficacy of its PDC technology on a 30 subject population with commencement in early 2015 and scheduled completion in late 2015 / early 2016.

Expect products to capitalize on biotech growth: The biotech sector continues to grow through the second and third quarter of 2014. The iShares NASDAQ index and the SPDR SNP Biotech ETF have shown a phenomenal return of more than 21% YTD. Although the market was spooked by comments by the Fed Chair Janet Yelen it appears to have shrugged off comments and is on the upswing again.

Ask the question "When will it happen?" and not "What will happen?": It is a given that we expect a huge pop in revenue from the TLC-2000 device and subsequently from TLC-3000 device. However, much of the value for Theralase will be derived from launching the devices into market as per schedule.

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, which is focused on the development and commercialization of laser-based non-invasive pain management devices and the Photo Dynamic Therapy (PDT) division, which is focused on discovery of small, light-activated molecules and 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 Q42014, 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 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 China. Theralase plans to phase-out the TLC-1000 system 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 Photo Dynamic Therapy (PDT) division focuses on discovery of small, light-activated molecules and 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 visible light and become cytotoxic 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 cancers, bacteria and viruses. 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.

Bladder cancer 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 is currently pursuing destruction of bladder cancer in an orthotopic animal model. Preclinical trials using different PDCs are currently underway and expected to be completed in late 2014. Theralase plans to commence a Phase 1/2a clinical trial in bladder cancer in first quarter 2015. 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.

The commercial launch of the TLC-3000 PDC / Laser Technology Platform is likely to be at least a couple of years away. Between now and then, the company hopes to raise $10 to $20 million dollars of operating capital to complete Phase 1/2a clinical trials and then plans to pursue partnering arrangements in order to commercialize 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 (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 the fourth quarter of 2014.

Biodestructive 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, bacteria and viruses. In 2006, Virginia Polytechnic had developed three 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, et cetera) 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 600-970nm) 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 deep layers of tissue.

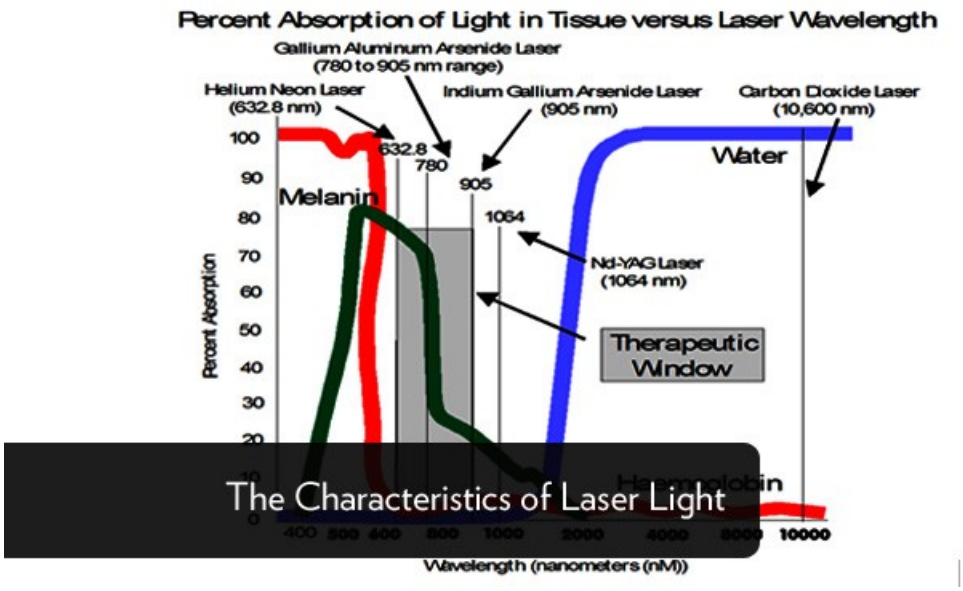


Figure 1 Therapeutic window (Source: www.theralase.com)

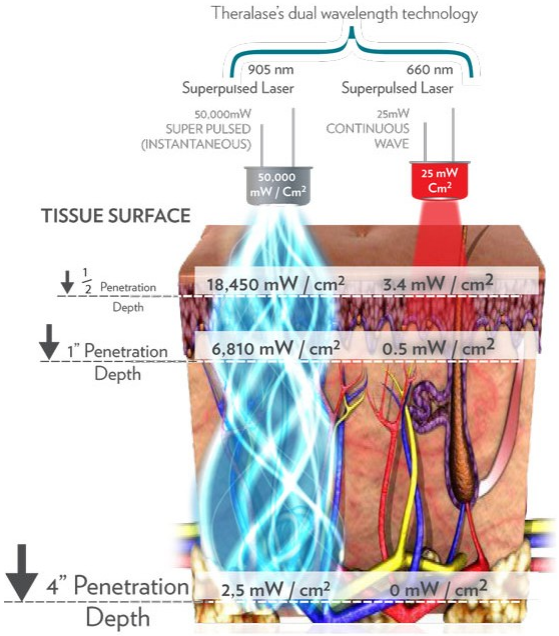


Figure 2 Tissue penetration depth at different laser strengths (Source: www.theralase.com)

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. 905nm super-pulsed light increases nitric oxide levels by 700% compared to other wavelengths and technologies. As a result, it rearranges downstream signaling effects such as increasing Adenosine Triphosphate (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.

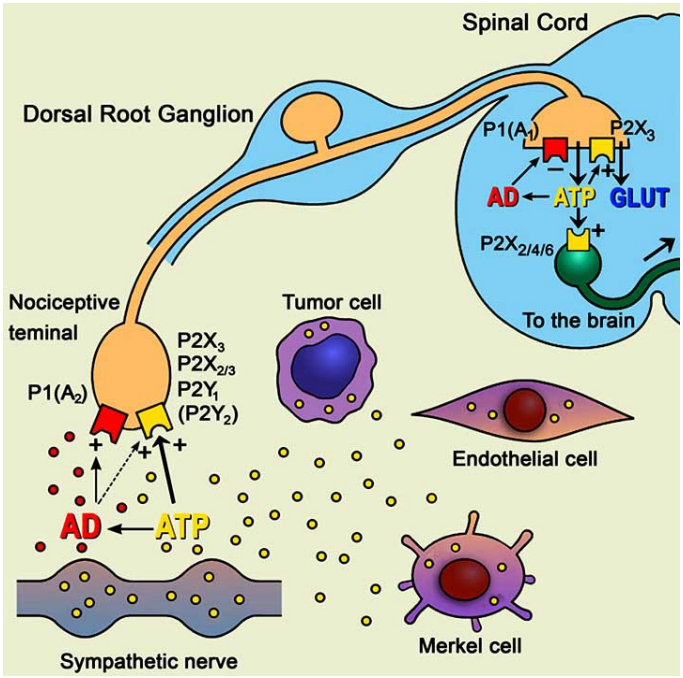


Figure 3 Hypothetical illustration of the initiation of nociception on primary afferent fibers in the periphery and purinergic relay pathways in the spinal cord[1]

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).

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

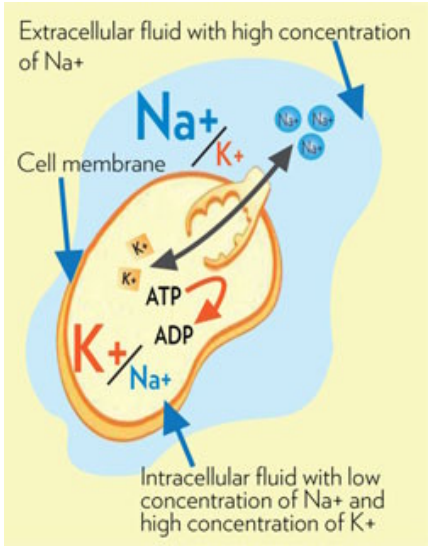


Figure 4 The energy to drive the sodium-potassium pump is released by hydrolysis of ATP. In order to decrease pain, the sodium ions need to repatriate into the cell and the potassium ions need to be released outside the cell through the sodium potassium pump or through the permeability of the bilipid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

PRODUCTS

TLC-1000: Therapeutic Laser Technology
The TLC-1000 Cold 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 2014 and introduce their next generation laser system, the TLC-2000 with a biofeedback technology in fourth quarter 2014.

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. Theralase has outsourced clinical studies to the University of Buffalo to demonstrate efficacy of the new biofeedback technology. 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
While a commercial roll out of the device is expected in Q4 2014, Theralase plans to place ten to fifteen TLC-2000 systems in the field with select healthcare practitioners, as Key Opinion Leaders (KOLs) for beta testing purposes in July 2014. 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 2014 and 2015. 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 new 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. Cold laser treatment 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 osteoarthritis (OA). An independent blinded, randomized, controlled clinical study was conducted to evaluate the Theralase laser system. Theralases' 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 osteoarthritis 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 near infrared and visible red light, treatments are designed to improve skin appearance and health through the production of collagen and elastin, both essential to 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. Photodynamic 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 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 actinic keratosis of the face and scalp. Methyl ester of ALA is activated with a red light. Porfimer sodium (Photofrin®) is the most widely used and studied photosensitizer. It's activated by red light from a laser. 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 never enter the blood stream, thus providing a very high safety profile and ultra-low toxicity versus ALA and Photofrin® which are 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.

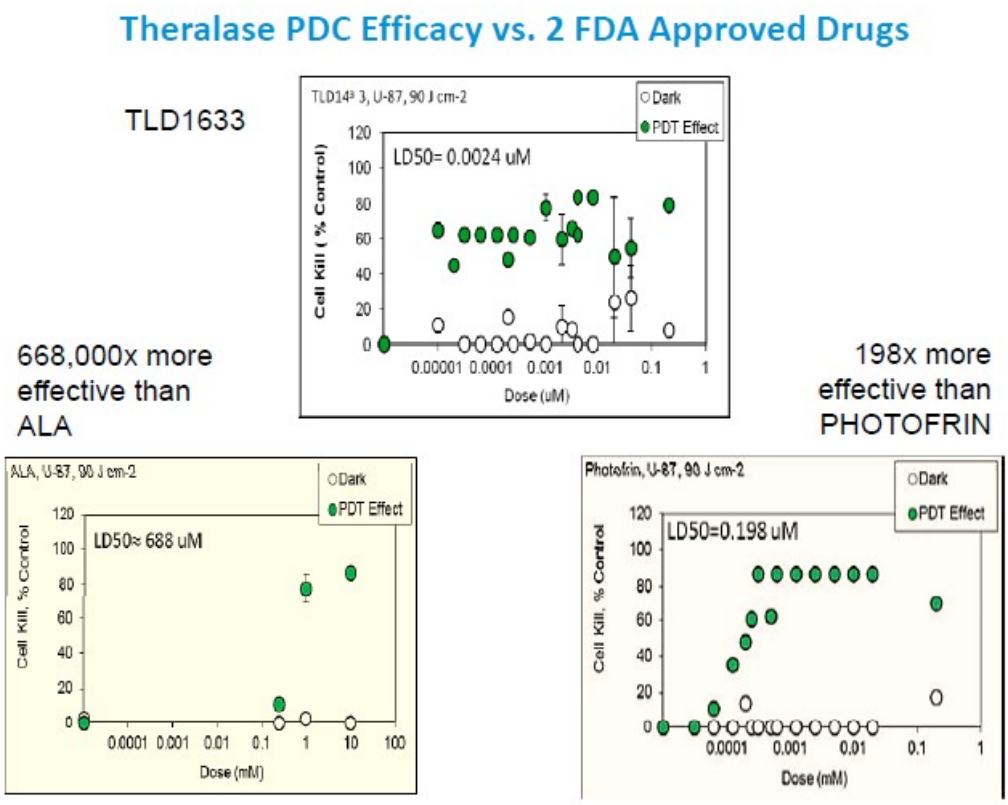


Figure 5 Theralase's PDC efficacy as compared to 2 FDA approved drugs (ALA and Photofrin)
(Source: www.theralase.com)

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.

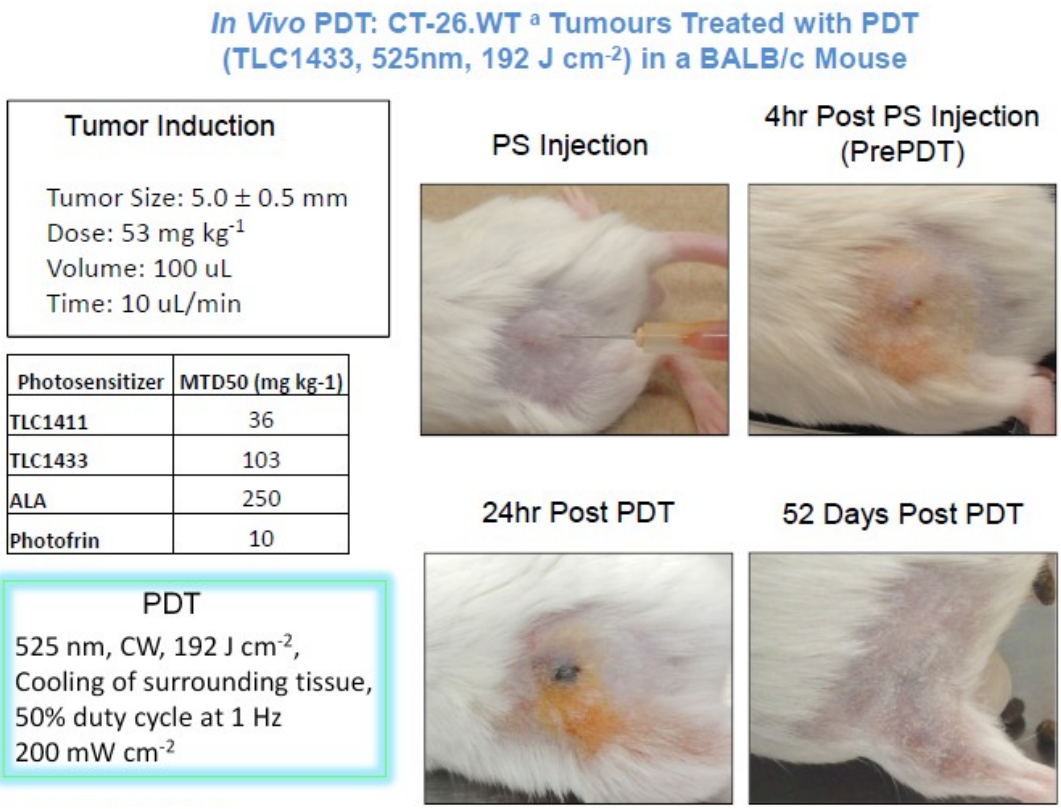


Figure 6 in-vivo Tumors Treated with PDT in a mouse (Source: www.theralase.com)

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 they enter the cancer cell and lock onto the cell nucleus. The compound 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 cleaved the DNA of the cancer cells and induced 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 are living 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.

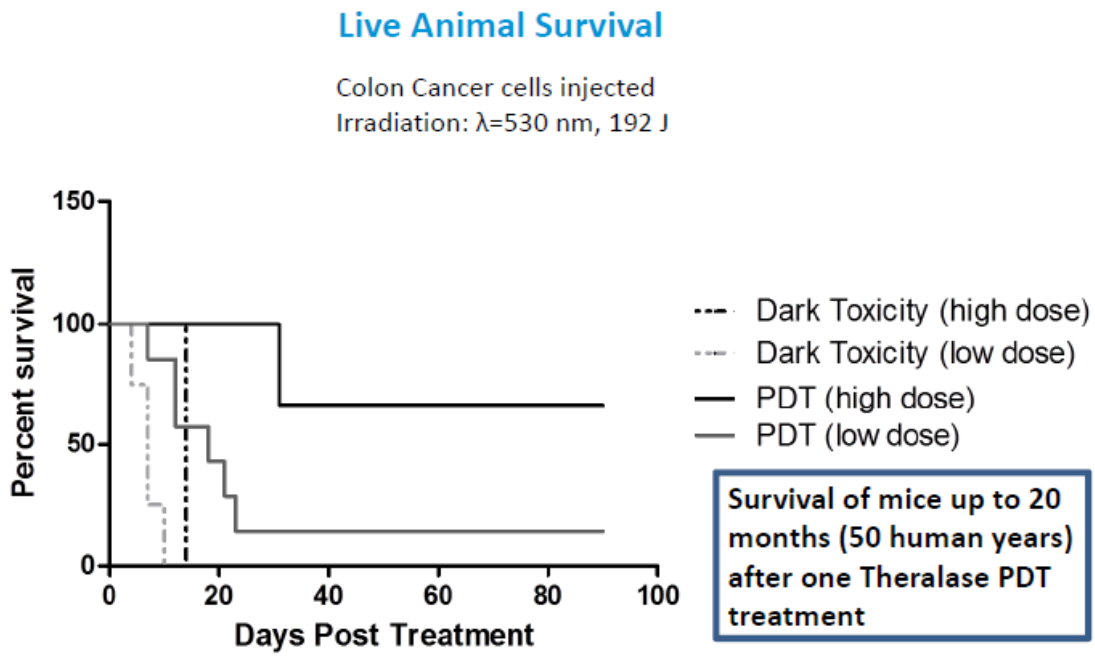


Figure 7 Survival period of mouse post treatment with PDC anti-cancer technology (Source: www.theralase.com)

In 2013, Theralase's proprietary PDC technology was approved for use in a live animal bladder cancer model by UHN Research Ethics Board. 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 1/2a human clinical trial to prove the safety and efficacy of its PDC technology in the first quarter 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 will be used by Theralase to commence toxicity analysis and manufacturing ramp up via Contract Manufacturing Organization (CMO); both mandatory prerequisites in the evolution towards an approved Investigational New Drug (IND) application from the FDA and Health Canada. With larger quantities of the PDCs in hand and an approved IND, Theralase would be in a position to commence a Phase 1/2a human clinical trial for the lead indication of bladder cancer, as early as Q1 2015.

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

The World Health Organization (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 2014 and 2015, 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 and is further evaluating augmenting its direct Canadian (2 largest provinces) and U.S. (5 largest states) sales force with additional direct representatives, manufacturing representatives and distributors, while growing its sales internationally through the strategic partnering with 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 high 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 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

Cold laser therapy is usually paid for in cash at clinics, as it has limited 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 4 (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%.

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. Starting in the fourth quarter of 2014, Theralase plans to begin phasing out the TLC-1000 product in Canada and the U.S. by converting existing customers currently using the TLC-1000 to trade-up to the TLC-2000 model. The sales effort will also target new customers with its TLC-2000 technology.

In the new revenue model, the practitioners enter into a 42-month lease structured payment plan (6 payments @ $99/month, followed by 36 months @ $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 42 month lease with the next generation smart laser system or return the device. The equipment will be billed through the internet; 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 course of two years, ending 2016. The short-term catalyst will be to successfully convince existing customers to upgrade to the new technology. A long term goal might 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 42 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. and Canada from 2016 and in the European and international markets by 2017. 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.

R&D expense for 2013 was down 40% when compared to R&D expense for 2012. This was attributable to a decrease in expenditures and investment related to the commercialization of the TLC-2000. We look for aggregate Selling, General and Administrative (SG&A) expenses to increase as additional sales personnel are recruited for targeting new customers in the initial years; however, expenses relating to sales will stabilize over time as the product becomes more established in the market.

Equity
Since 2011, Theralase has closed 4 non-brokered private placements raising a total of $5.08M. Theralase actively needs to pursue additional financing through a combination of the issuance of new equity or debt instruments, entering into joint venture arrangements and strategic alliances.

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 2014. Expansion in international markets, the 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 that will allow Theralase to commence a Phase 1/2a human clinical trial to prove the safety and efficacy of its PDC technology in 1Q 2015. The Company hopes to enter the cancer destruction market after having success in clinical trials using PDCs to destroy: breast, colon, brain and bladder cancer cells.

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 out-year 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
If management continues to execute as per plan, TLC 2000 could displace the company's prior product and we can see a rise in the company's top line. Theralase's stock is still under-valued compared to peers but the company has potential upside dues to the anticipated launch of their devices.

TLT.V currently trades at $0.34, well below our calculated and targeted fair value. We utilized a risk-adjusted Net Present Value (NPV) analysis to determine our price target objective. Using a Discounted Cash Flow (DCF) analysis, we derive the total equity value of approximately $64 million, assuming 68.5 million fully-diluted shares outstanding and roughly $2.00 million in cash by end of 2015. This projection is based solely on projected sales of the TLC 2000 device. At this point we do not consider sales of the TLC-3000 device as it is in pre-clinical stage and not likely to reach commercialization in the near-term; however, we do acknowledge that the TLC-3000 could be a potential driver of revenue post 2017. Some risks such as delay in clinical trials pertaining to the PDC technology are evident and cannot be ruled out but the potential return may be quite significant. Company is still on a high cash burn but the company seems poised for long term growth when things turn positive after the launch of TLC-2000. We maintain our price target of $1.00 per share with an outperform rating.

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 from the current year 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.

FINANCIAL MODEL

Theralase Technologies Inc.

	2013 A	Q1 A	Q2 A	Q3 A	Q4 E	2014 E	2015 E	2016 E	2017 E	2018 E	2019 E
Revenue	$1,203,620.0	$361,179.0	$499,258.0	$134,036.0	$1,600,000.0	$2,555,342.0	$5,696,250.0	$10,027,500.0	$11,830,875.0	$9,677,430.0	$13,132,035.0
YOY Growth	*-34.0%*	*5.3%*	*-1.9%*	*-57.2%*	*311.9%*	*112.3%*	*122.9%*	*76.0%*	*18.0%*	*-18.2%*	*35.7%*
Cost of Goods Sold	$404,540.0	$121,546.0	$124,282.0	$65,627.0	$387,500.0	$749,328.0	$1,443,750.0	$2,425,500.0	$2,752,200.0	$2,193,550.8	$2,926,567.8
Gross Income	$799,080.0	$239,633.0	$374,976.0	$68,409.0	$1,212,500.0	$1,806,014.0	$4,252,500.0	$7,602,000.0	$9,078,675.0	$7,483,879.2	$10,205,467.2
Gross Margin	*66.4%*	*66.3%*	*75.1%*	*51.0%*	*75.8%*	*70.7%*	*74.7%*	*75.8%*	*76.7%*	*77.3%*	*77.7%*
SG&A	$1,441,018.0	$385,916.0	$476,774.00	$536,372.00	$850,072.7	$2,249,134.7	$3,078,452.5	$4,123,915.0	$4,696,754.5	$3,309,308.4	$4,103,086.8
%SG&A	*119.7%*	*106.8%*	*95.5%*	*400.2%*	*53.1%*	*88.0%*	*54.0%*	*41.1%*	*39.7%*	*34.2%*	*31.2%*
R&D	$527,233.0	$197,792.0	$243,855.0	$580,070.0	$200,000.0	$1,221,717.0	$1,221,717.0	$1,221,717.0	$1,221,717.0	$1,221,717.0	$1,221,717.0
%R&D	*43.8%*	*54.8%*	*48.8%*	*432.8%*	*12.5%*	*47.8%*	*21.4%*	*12.2%*	*10.3%*	*12.6%*	*9.3%*
Operating Income	($1,169,171.0)	($344,075.0)	($345,653.0)	($1,048,033.0)	$162,427.3	($1,664,837.7)	($47,669.5)	$2,256,368.0	$3,160,203.5	$2,952,853.8	$4,880,663.4
Operating Margin	-	-	-	-	-	-		*22.5%*	*26.7%*	*30.5%*	*37.2%*
Total Other Expense (Income) - Stock based compensation	$94,872.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($1,264,043.0)	($344,075.0)	($345,653.0)	($1,048,033.0)	$162,427.3	($1,664,837.7)	($47,669.5)	$2,256,368.0	$3,160,203.5	$2,952,853.8	$4,880,663.4
Taxes (benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$1,708,232.2
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	$0.0	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Net Income	($1,264,043.0)	($344,075.0)	($345,653.0)	($1,048,033.0)	$162,427.3	($1,664,837.7)	($47,669.5)	$2,256,368.0	$3,160,203.5	$2,952,853.8	$3,172,431.2
Net Margin	-	-	-	-	-	-		*22.5%*	*26.7%*	*30.5%*	*24.2%*
EPS	($0.02)	($0.01)	($0.01)	($0.02)	$0.00	($0.03)	($0.00)	$0.03	$0.03	$0.03	$0.03
YOY Growth	-	-	-	-	-	-	-				
Diluted Shares O/S	47,853,882	47,853,882	59,412,497	68,448,691	76,580,642	63,073,928	77,580,642	87,580,642	97,580,642	107,580,642	117,580,642

Anita Dushyanth

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MANAGEMENT TEAM

Roger Dumoulin-White
P. Eng., President & CEO
Mr. Dumoulin-White founded Theralase in 1995 and has over 25 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 cancers, bacteria and viruses 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
CGA, Chief Financial Officer
Ms. Hachey has over 17 years of experience in finance and financings in public and private companies.

Rhonda Mostyn
DC, Clinic Director
Dr. Mostyn is a chiropractor, and cold laser therapist. She has been in practice for over 15 years and for the past 5 years has been focused on care with cold laser therapy.

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.

Derek Small
Director of Sales & Marketing
Mr. Small has 15 years of professional sales and sales management experience in medical capital equipment sales in Canada and the US. In one of Mr. Small's previous positions he grew Canadian and US sales of an aesthetic laser company from $0 to $20 MM in 5 years managing a team of 12 sales professionals.

SCIENTIFIC AND MEDICAL ADVISORY BOARD (SMAB)
The SMAB is comprised of international key opinion leaders 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

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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 M. Kamat, MD
Dr. Kamat is an internationally recognized expert in urologic oncology and an authority in the management of urologic cancers. Dr. Kamat holds the Rank of Professor and Fellowship Program Director in the Department of Urology, Division of Surgery at the University of Texas MD Anderson Cancer Center located in Houston, Texas.

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

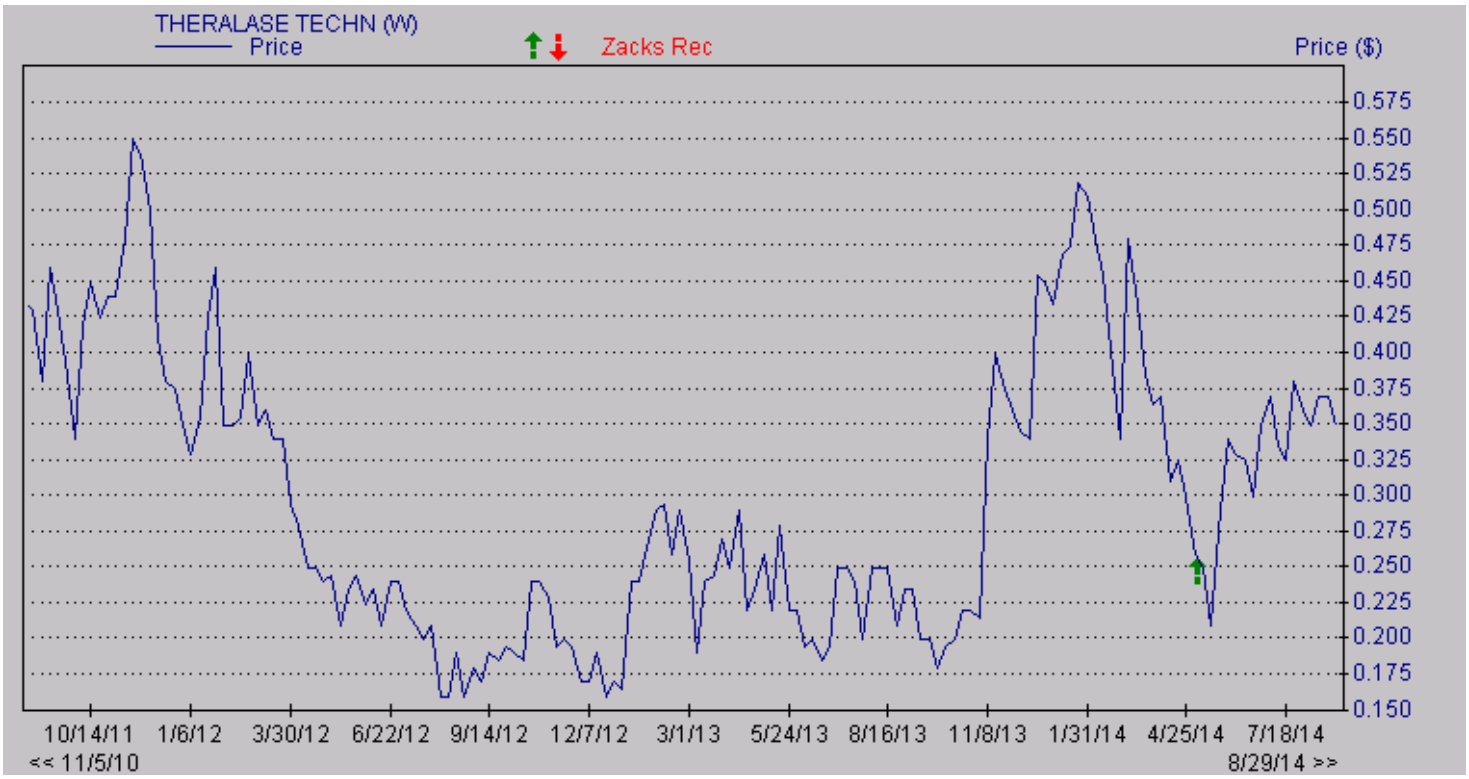
Founded in 1838, when Baptist leaders reached a breaking point in their ability to access higher education, they created their own university and removed barriers for themselves and others. Researchers at Acadia University are the Canadian inventors of a second platform of PDCs used by Theralase in its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

HISTORICAL ZACKS RECOMMENDATIONS



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Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters.
Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

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.