

QUARTERLY NEWSLETTER

COVID-19 PANDEMIC UPDATE

Due to the continued uncertainty associated with the COVID-19 pandemic, the impact on the Company's business, operations and financial performance cannot be fully quantified at this time. Theralase continues to closely monitor the situation, in conjunction with municipal, provincial and federal guidelines, in order to best manage its business in compliance with health and safety best practices.

UPDATE ON STUDY II

Three out of four Canadian clinical study sites have re-commenced new patient enrollment and treatment in Study II, specifically:

Study Site	Location	Site Status
University Health Network ("UHN")	Toronto, Ontario	Enrolling
London Health Sciences Centre ("LHSC")	London, Ontario	Enrolling
Nova Scotia Health Authority ("NSHA")	Halifax, Nova Scotia	Enrolling
McGill University Health Centre ("MUHC")	Montreal, Quebec	COVID-19 Hold

MUHC currently remains closed due to COVID-19, for new patient enrollment and treatment; however, patients who have already been enrolled, treated and are eligible for second treatment will receive a second treatment. The Company is preparing to launch a fifth Canadian clinical study site later in the year.

Theralase® is in advanced discussions to launch a number of US based clinical study sites later in the year, subject to the United States economy recovering from the COVID-19 pandemic.

The US based Trial Management Organization ("TMO") could potentially launch 4 clinical study sites in 4Q2020 and commence Study II patient enrollment and treatment as early as 1Q2021.

FINANCIAL STATEMENTS

Theralase® continues to experience reduced sales due to the ongoing COVID-19 pandemic and has taken actions to reduce expenses by eliminating non-essential personnel and imposing a temporary hiring freeze, to be lifted, subject to the Canadian and United States economies demonstrating recovery from COVID-19.

[2019 Financial Statements - April 29, 2020](#)

[Q1 2020 Financial Statements - May 29, 2020](#)

ANNUAL GENERAL MEETING ("AGM") UPDATE

The Company will be holding its AGM virtually on **September 24th, 2020 at 4:30 pm**. Details to attend the AGM virtually will be provided in due course to registered shareholders.



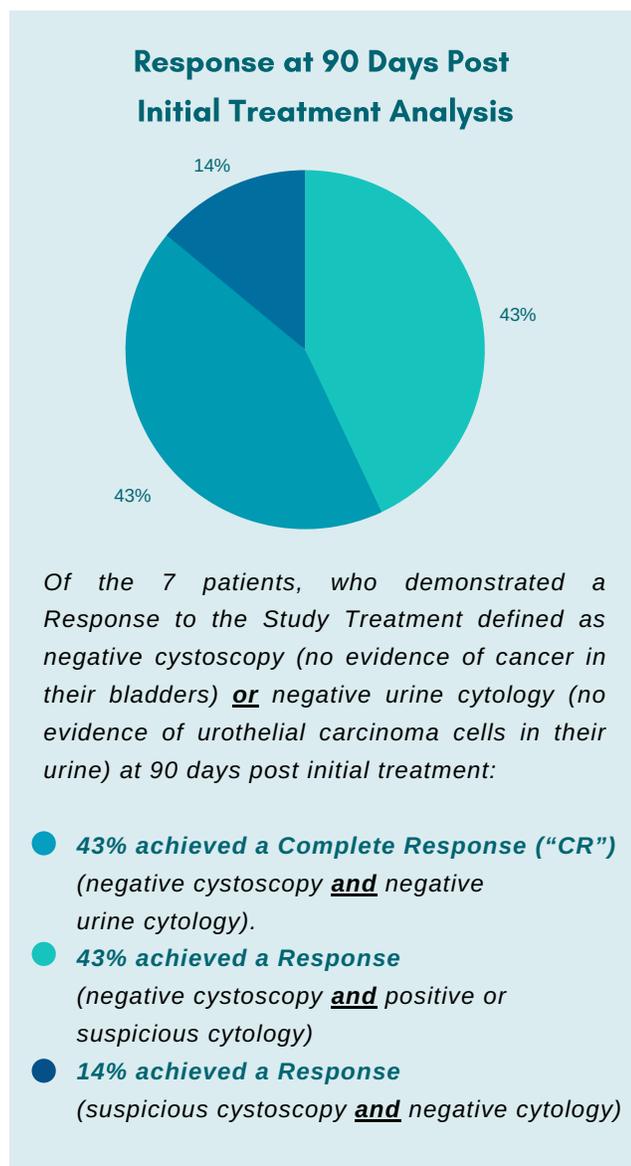
UPDATE ON STUDY II

On a go forward basis, all future and existing patients to be enrolled and treated (initial and second treatment) in Study II will be treated using the Study II treatment optimizations as communicated via press release on July 30, 2020, specifically:

- Bladder volume calculation
- Study drug volume calculation
- Study device volume calculation
- Study device treatment time

Study II enrolled and treated 12 patients, with the following results:

Patient Status	# of Patients	Percentage
First Treatment Provided	12	100.0%
Patients Eligible to Receive Second Treatment	8	66.7%
Second Treatment to be Provided	5	41.7%
Second Treatment Provided	3	25.0%
Response at 90 Days Post Initial Treatment	7	58.3%
Complete Response at 90 Days Post Initial Treatment	3	25.0%
Patients Removed from Study II	4	33.3%



The patients who responded to the Study Treatment are currently under medical review to assess the cause of the suspicious cystoscopy by directed bladder biopsy and the cause of the positive or suspicious cytology by repeating the urine cytology analysis. If found to be negative, these patients will be allocated to the CR column. If positive or suspicious again, then Computerized Tomography (“CT”) Scan imaging and/or prostatic biopsies will be conducted to rule out Upper Tract Urothelial Cell Carcinoma (“UTUCC”). If UTUCC is proven to exist, then according to FDA’s Bacillus Calmete Guérin (“BCG”)-Unresponsive Guidelines to Industry, issued in February 2018, these patients will be classified as CR, as only the bladder was treated by the Study Treatment and not non-addressable areas of the urinary system.

Of the 8 patients eligible to receive the second treatment in Study II, three patients have received their second treatment, four patients are awaiting second treatment, subject to clinical study site operating room availability, and one patient is undergoing additional assessments prior to proceeding to second treatment.

The four patients that were removed from Study II have been redirected to other treatment options available to them based on the principal investigator’s assessment.

The clinical data collected on the first twelve patients treated shows a favorable clinical response, which the Company expects will improve due to the implemented Study II treatment optimization.



FDA STATUS UPDATE:

On May 19th, 2020, Theralase was granted Food and Drug Administration (“**FDA**”) Investigational New Drug (“**IND**”) authorization to commence enrolling and treating patients in Study II in the United States. The Company is preparing to launch a number of US based clinical sites later in the year, subject to the United States economy demonstrating recovery from COVID-19; however, it is anticipated due to the severity of the COVID-19 pandemic in the United States, that these sites will not be open to commence enrollment and treatment of patients until 2021.

In a 3Q2019 conference call with the FDA, it was discussed between the FDA and the Company, that the Company would potentially be eligible for Fast Track Approval (“**FTA**”) post receipt of the FDA IND authorization, based on the clinical study data collected to date in the Phase Ib NMIBC clinical study. It was further discussed that Theralase would potentially be eligible for Breakthrough Therapy Designation (“**BTD**”) and / or Accelerated Approval (“**AA**”), if Theralase could demonstrate clinically significant results (high safety profile and high efficacy response), similar to the safety and efficacy results observed in the Phase Ib NMIBC clinical study (high safety profile and significant CR) at an interim analysis of approximately 20 to 25 patients enrolled and successfully treated.

Based on this guidance, Theralase® has submitted an application to the FDA for FTA and is currently awaiting their response.

NEW ONCOLOGY TARGETS

Theralase® has worldwide exclusive licensing rights to the Theralase® ruthenium and osmium compounds and any improvements to the compounds listed in the Company’s issued and pending patents; therefore, Theralase® has full commercial control on these patented and patent pending Photo Dynamic Compounds (“**PDC**”), including TLD-1433.

Theralase® has steered the research and development of these PDCs through scientific and preclinical research to fine-tune the photophysical and photochemical properties of the PDCs, by the inventor, while demonstrating Type I and II photoreactions and activation in hypoxia, by combining these PDCs with transferrin, as a delivery system. Transferrin significantly increases the photobleaching resistance (loss of potency of the PDC over time), Reactive Oxygen Species (“**ROS**”) production (ability to destroy cancer cells quickly and effectively), selective tumour uptake (destruction of cancer cells, while sparing healthy cells), anti-cancer efficacy (efficiency in cancer cell destruction) and decreasing systemic toxicity (damage to healthy cells) of the PDCs. This makes Rutherrin® (TLD-1433 + transferrin) attractive for systemic treatment of recurrent, deep seated and/or progressive cancers.

The Company continues to conduct extensive scientific and preclinical research towards new oncology indications and has developed significant expertise and intellectual property regarding its patented PDCs, in pursuit of this goal.

Rutherrin® (patented formulation of the Company’s lead PDC (TLD-1433) combined with transferrin) enables a preferential and targeted delivery of TLD-1433 inside cancer cells, with a mandate of “hunting” and “destroying” cancer cells wherever they may reside in the body. The Company has demonstrated significant anti-cancer efficacy of Rutherrin®, when activated by laser light or radiation treatment across numerous preclinical models; including: Glioblastoma Multiforme (“**GBM**”) and Non-Small Cell Lung Cancer (“**NSCLC**”).

The Company is planning to commence toxicology studies with Rutherrin® to determine the maximum recommended human dose of the drug, when administered systemically into the human body, via intravenous injections.

Due to the limitations of using laser light to activate Rutherrin® in deep oncological targets, Theralase’s research strongly suggests that Rutherrin® may be activated with radiation therapy, which is able to increase the ‘tumour’s damage zone’ and the effectiveness of the anti-cancer therapy beyond the reach of light in the body.

(TSXV/TLT.V - OTCQB/TLTFF)



RESEARCH PUBLICATIONS

[Minimal Required PDT Light Dosimetry for Non-Muscle Invasive Bladder Cancer \(Peer reviewed and published in the Journal of Biomedical Optics \("JBO"\)\)](#)

JBO is an acclaimed peer reviewed scientific journal covering the landscape of optical technology and biomedical research.

Dosimetry data from Theralase's Phase Ib clinical study reinforces the advanced capabilities of Theralase's cutting-edge Anti-Cancer Therapy ("ACT") to safely and effectively destroy NMIBC without damaging healthy bladder tissue. Human bladders are unique and have different shapes, volumes and bladder wall reflectances. As a result, the irradiance (laser light energy delivered per square centimeter) will vary significantly depending on the physical properties of an individual patient's bladder. Despite the irregularity of bladders, Theralase's ACT can detect these bladder permutations to help prevent safety events from occurring, if the laser light energy is directed too close to a bladder wall.

[Anticancer Photodynamic Therapy Using Ruthenium\(II\) and Osmium\(II\)-Based Complexes as Photosensitizers \(Open access peer reviewed chapter published on IntechOpen\)](#)

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In-vitro and in-vivo results demonstrate that transition metal based complexes (Ruthenium(II) and Osmium(II)) PDCs (in-licensed by the Company) have enviable physical characteristics including, being able to: be activated at a wide range of wavelengths (allowing for activation at various tissue depths) and have a high singlet oxygen quantum yield (ability to efficiently convert photons of light into cancer killing Reactive Oxygen Species ("ROS")).