

# 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.

## OVERVIEW

The Company's main focus is the completion of:

1. Phase II Non-Muscle Invasive Bladder Cancer ("NMIBC") clinical study on BCG-Unresponsive patients ("Study II").
2. Glioblastoma Multiforme ("GBM") and Non-Small Cell Lung Cancer ("NSCLC") toxicology studies.
3. Coronavirus (BSL-3) vaccine research.

## NEW CORPORATE WEBSITE

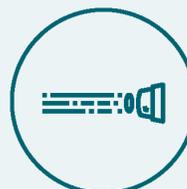
Theralase® has rebranded its two divisions.



DESTROYING CANCER AT THE SPEED OF LIGHT®

### Anti-Cancer Therapy ("ACT") Formerly PDT Division

Theralase®'s ACT uses patented light-activated Photo Dynamic Compounds ("PDCs") to safely and effectively destroy cancer, bacteria and viruses.



HEALING AT THE SPEED OF LIGHT®

### Cool Laser Therapy ("CLT") Formerly MLT Division

Theralase®'s CLT uses proprietary and patented medical laser systems to safely and effectively eliminate knee pain.

[Explore the updated website >](#)

## FINANCIAL STATEMENTS

Theralase® continues to experience reduced sales due to the ongoing COVID-19 pandemic and has taken actions to reduce expenses; specifically, terminating the positions of non essential personnel and instituting a temporary hiring freeze on full-time employees.

The hiring freeze will be lifted, subject to the Canadian and United States economies demonstrating recovery from COVID-19.

[Q2 2020 Financial Statement](#)

## ANNUAL GENERAL MEETING ("AGM") UPDATE

The Company held its AGM virtually on **September 24th, 2020**.

Presentations were conducted by:  
Dr. Shawn Shirazi – Corporate Overview  
Dr. Girish Kulkarni – Update on Study II  
Dr. Michael Jewett – Optimization of Study II



[Click here to view the recording.](#)

# UPDATE ON STUDY II

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All Canadian clinical study sites have re-commenced new patient enrollment and treatment in the Company's Phase II NMIBC clinical study ("Study II"). The clinical study sites placed themselves on temporary hold commencing March 20, 2020 due to the COVID-19 pandemic and resumed normal operations between August 12 and September 24, 2020. The Company is preparing to launch a fifth Canadian clinical study site later in 4Q2020.

Theralase® is in advanced discussions to launch a number of U.S. based clinical study sites in 4Q2020, subject to the United States economy recovering from the COVID-19 pandemic. The U.S. based Trial Management Organization ("TMO") plans to launch 4 to 5 clinical study sites in 4Q2020 and commence Study II patient enrollment and treatment as early as 1Q2021.

To date two of four clinical study sites in Canada have enrolled and treated 12 patients. Out of the 7 patients that are eligible to receive the second treatment, 6 have received the second treatment and 1 is pending in 4Q2020.

*Efficacy to date at the 90 day assessment includes:*

- 1. 3 out of 12 patients (25%) have demonstrated a Complete Response ("CR") (negative cystoscopy and negative (including atypical) urine cytology).*
- 2. In addition to CRs, there are two patients who are demonstrating Partial Responses ("PRs") (negative cystoscopy and positive urine cytology). If upper tract urothelial cell carcinoma or urothelial carcinoma of the prostatic urethra is confirmed, these patients have the potential to become CRs, in accordance with the FDA's guidance to industry.*



The estimated timing of Study II completion is approximately 3 years with an estimated cost of approximately \$9 to \$11 million; however, this timing and cost may vary significantly depending on numerous factors including: number of clinical study sites enrolling and treating patients, clinical study site patient enrollment rates, patient compliance, successful achievement of Study II primary, secondary and exploratory endpoints and the ability of participating clinical study sites to enroll and treat patients based on current COVID-19 pandemic restrictions.

# ADDITIONAL ONCOLOGY TARGETS

## ADDITIONAL VIRUS TARGETS

Theralase® executed a Sponsored Research Agreement (“SRA”) with the University of Manitoba (“UM”) Medical Microbiology department in 3Q2020 to commence development of a coronavirus vaccine utilizing Theralase’s patented and proprietary PDCs. According to the SRA, UM will conduct experiments in conjunction with Theralase® for the research and development of a coronavirus vaccine to be further evaluated at additional research centers in animal models, and if proven successful in human clinical studies as early as 2021.

The primary objective of the SRA is to investigate the efficacy of Theralase’s lead PDC to destroy a variety of viruses; including: H1N1 Influenza, Zika and coronaviruses (Biological Safety Level (“BSL”) 2). The secondary objective is to optimize the concentration of PDC required, the activation methodology and how to potentially administer the treatment to humans to be used as a vaccine (prevention of a patient from contracting COVID-19) (BSL-3). The research is primarily directed to in-vitro (cell lines) analysis, but based on these initial experiments, Theralase® plans to expand the work, in conjunction with Dr. Coombs, to in-vivo (small animal) analysis, toxicology (optimized doses for human delivery), at additional research centers, and if proven successful preclinically in human clinical testing through Phase I (safety), Phase II (efficacy) and Phase III (efficacy in a larger population) clinical studies. If successful through a Phase III clinical study, and with the successful regulatory approval of Health Canada, the technology could be commercialized across Canada for the benefit of all Canadians.

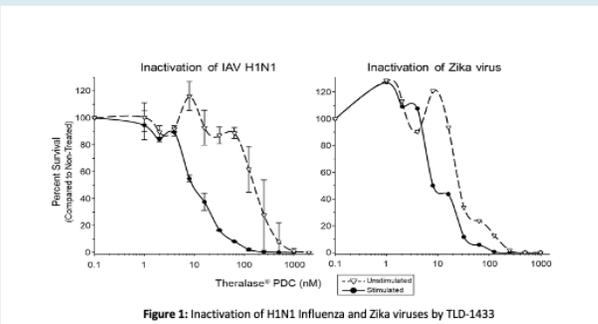
Theralase® has worldwide exclusive rights to the Theralase® Ruthenium and Osmium based Photo Dynamic Compounds (“PDCs”) and any improvements to the PDCs listed in the Company’s issued and pending patents; therefore, Theralase® exerts full commercial control on these patented and patent pending PDCs, including our lead study drug 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 (oxygen independent) and II (oxygen dependent) photoreactions and activation in hypoxia, by combining these PDCs with transferrin (human glycoprotein), as a delivery system. Transferrin significantly increases the resistance of TLD-1433, the lead drug candidate, to photobleaching (loss of PDC potency 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 and/or organs) of the PDC. This makes Rutherrin® (TLD-1433 +transferrin) attractive for systemic treatment of recurrent, deep seated and/or progressive cancers.

Rutherrin®, a systemic formulation of TLD-1433 suitable for intravenous (“IV”) injection is being investigated to be injected via IV into the body, with a mandate of “hunting” and “destroying” cancer cells; wherever, they may reside in the body. The Company has demonstrated the significant anti-cancer efficacy of Rutherrin®, when activated by laser light or radiation treatment across, numerous preclinical in-vitro (cell lines) and in-vivo (animal) models; including: GBM and NSCLC.

The Company is currently conducting non Good Laboratory Practice (“GLP”) toxicology studies with Rutherrin® to determine the maximum recommended human dose of Rutherrin®, when administered systemically into the human body, via IV injections. Theralase® has completed one animal model and is diligently working to complete the second animal model. If successful, Theralase® will commence GLP toxicology studies in 2Q2021 with an aim to commencing a Phase Ib clinical study in GBM and NSCLC in 4Q2021.

Due to the limitations of using laser light to activate Rutherrin® in deep seated 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.



Note: The Company does not claim or profess that they have the ability to treat, cure or prevent the contraction of the COVID-19 coronavirus.