

QUARTERLY NEWSLETTER

Theralase®.Technologies Inc. ("Theralase") is a clinical stage pharmaceutical company focused on the research and development of light activated Photo Dynamic Compounds ("PDCs") and their associated drug formulations with a primary objective of efficacy and a secondary objective of safety in the destruction of various cancers, bacteria and viruses.



LEADERSHIP RE-ORGANIZATION

Effective October 25, 2021, Vera Madzarevic, Ph.D. assumed the role of Director of Clinical Development and Quality Assurance. Dr. Madzarevic holds a Ph.D. in both clinical pharmacology and biochemistry and brings over 25 years of global experience in clinical research and quality assurance in the biopharmaceutical and medical device industry to Theralase®.

Effective, November 15, 2021, Mr. John Trikola agreed to resign from his positions as the Chief Operating Officer ("COO") and interim Chief Executive Officer ("CEO") of the Company, as a result of certain facts that came to the Company's attention concerning Mr. Trikola's background that the Company's vetting process failed to detect. The Company has taken steps to improve its vetting process for incoming officers and directors.

Effective November 15, 2021, Dr. Arkady Mandel, M.D., Ph.D., D.Sc., who is currently the Chief Scientific Officer ("CSO") of the Company, assumed the role of interim CEO, replacing Mr. Trikola.

“It is a pleasure to join the Theralase® clinical research team, reporting to Dr. Mandel. I feel my extensive global experience in clinical research and quality assurance will support the Company's primary objective of successfully developing with the objective of commercializing its Anti-Cancer Therapy ("ACT") technology.”

Dr. Vera Madzarevic
Director Clinical Development & Quality Assurance, Theralase®

"I am honored to return as the Interim CEO for the Company, as the Company realigns its executive management team to focus on the Company's primary objective of commercialization of its ACT technology, which, if successful, will ultimately deliver shareholder value."

Dr Arkady Mandel
Interim CEO & CSO, Theralase®



Strategic Objectives

1. Successful completion of Study II for Bacillus Calmette Guérin (“BCG”)-Unresponsive Carcinoma In-Situ (“CIS”)
2. Successful completion of non-Good Laboratory Practices (“GLP”) and GLP toxicology studies to allow regulatory approval and commencement of a Phase Ib clinical study for Glio Blastoma Multiforme (“GBM”) and Non-Small Cell Lung Cancer (“NSCLC”)
3. Preclinical research and clinical development of a Coronavirus (BSL-3) (“COVID-19”) vaccine.
4. Revenue generation in the Cool Laser Therapy (“CLT”) division

Q221 Financial Statement Highlights

For the 9 months ended September 30th, 2021

Unaudited Condensed Consolidated Statements of Operations	2021	2020	Change
In Canadian Dollars	\$	\$	%
Revenue			
Canada	501,523	449,359	12%
United States	52,100	52,074	0%
International	13,189	26,041	-49%
Total Revenue	566,812	527,474	7%
Cost of Sales	317,397	383,990	-17%
Gross Margin	249,415	143,484	74%
Gross Margin as a percentage of sales	44%	27%	
Operating Expenses			
Selling Expenses	271,708	333,863	-19%
Administrative Expenses	1,211,834	1,522,179	-20%
Research and Development Expenses – CLT Division	254,228	259,507	-2%
Research and Development Expenses – ACT Division	1,782,187	2,830,417	-37%
Other ⁽¹⁾	(140,810)	(86,711)	62%
Total Operating Expenses	3,379,146	4,859,255	-30%
Net Loss	(3,129,731)	(4,715,771)	-34%

(1) Other represents (Gain) from legal settlement, (Gain) Loss on foreign exchange, interest accretion on lease liabilities and interest income

Patient enrolment and treatment rates in Study II have been significantly delayed due to the COVID-19 pandemic restrictions in place at various Clinical Study Sites (“CSSs”); however, they are improving as Canada and the US recover from the COVID-19 pandemic.

Theralase® has experienced a significant reduction in revenue generation due to the ongoing COVID-19 pandemic and strategically reduced overhead expenses by eliminating non-essential personnel and imposing a temporary hiring freeze, commencing March 2020 which has since been lifted now that the Canadian and United States economies have started to demonstrate a sustainable business and economic recovery from the COVID-19 pandemic.

Study II Status:

Theralase® has enrolled and treated 30 patients in a Phase II Non-Muscle Invasive Bladder Cancer ("NMIBC") Clinical Study ("Study II") (including three patients from the Phase Ib NMIBC clinical study ("Study") treated at the Therapeutic Dose) for a total of 33 patients.

Theralase® has completed its first significant milestone of Study II by enrolling and treating 20 to 25 patients, in support of a Food and Drug Administration ("FDA") Break Through Designation ("BTD")

Theralase® plans to compile progressive interim clinical data reports at various assessment dates (urine cytology and cystoscopy) for submission to the FDA in support of the grant of a BTD approval, when indicated.

Study II Preliminary Clinical Data

As of November 29, 2021, Study II has provided the following interim results:

Significant clinical data is still pending and drawing conclusions from this clinical data should be done with caution.

Assessment Day	90 Days		180 Days		270 Days		360 Days		450 Days	
	#	%	#	%	#	%	#	%	#	%
Complete Response ("CR")	14	42%	7	21%	7	21%	4	12%	4	12%
Partial Response ("PR")	4	12%	5	15%	2	6%	4	12%	2	6%
Pending	7	21%	13	39%	15	45%	16	48%	17	52%
No Response ("NR")	8	24%	8	24%	9	27%	9	27%	10	30%
Total Treated*	33	100%	33	100%	33	100%	33	100%	33	100%

*Includes three patients treated at the Therapeutic Dose from the Phase Ib NMIBC Clinical Study (2 - CR and 1 - NR at 90, 180, 270, 360 and 450 days)

Patients that received the Optimized Study Treatment (July 30, 2020 Press Release) on or after August 20, 2020 has provided the following interim results:

Significant clinical data is still pending and drawing conclusions from this clinical data should be done with caution.

Assessment Day - Optimized Treatment (Post August 1, 2020)	90 Days		180 Days		270 Days		360 Days		450 Days	
	#	%	#	%	#	%	#	%	#	%
Complete Response ("CR")	8	44%	2	11%	1	6%	0	0%	0	0%
Partial Response ("PR")	2	11%	2	11%	1	6%	1	6%	0	0%
Pending	7	39%	13	72%	15	83%	16	89%	17	94%
No Response ("NR")	1	6%	1	6%	1	6%	1	6%	1	6%
Total Treated*	18	100%	18	100%	18	100%	18	100%	18	100%

*Preliminary clinical data on 18 patients who received the primary and/or maintenance Study II Treatment on or after August 1, 2020.

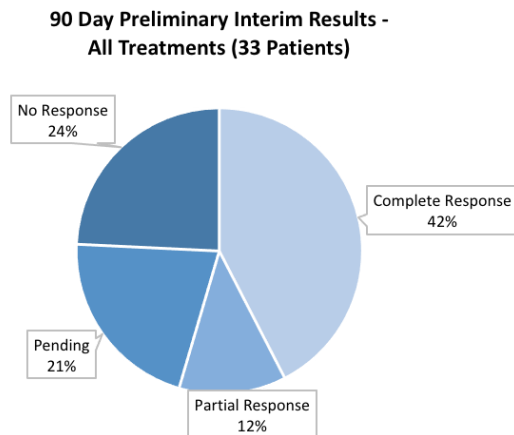
Note: There are 2 patients that received an unoptimized primary Study II Treatment and were diagnosed as non-responsive; however, they then received an optimized maintenance Study II Treatment.

Analyzing these 2 patients, 1 remained non-responsive and 1 achieved a CR at 270 days and PR at 360 and 450 days, respectively.

Study II Summary:

An analysis of the Study II clinical data (with 3 patients from Study Ib) provides the following interim assessments:

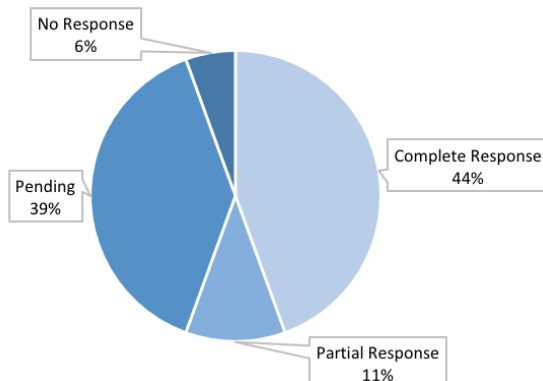
- 1.) 7/10 patients (70.0%), who achieved a CR at 90 days continue to demonstrate CR at 180 days
- 2.) In the total population of 33 patients (90 days):



Hence, the potential for CR is up to 75.8% (assuming both PR and pending data are clinically determined to be CR at a later assessment date)

- 3.) In the total population of 18 patients (90 days), who received the optimized treatment:

90 Day Preliminary Interim Results - Optimized Treatments (18 patients)



Hence, the potential for CR is up to 94.4% (assuming both PR and pending data are clinically determined to be CR at a later assessment date)

“ The data accrued to date for the TLD 1433-2 open label study for the treatment of NMIBC, seems very encouraging, and Theralase may as well be heading towards fulfilling the necessary outcome requirements to apply for a “BTD from the FDA very soon.”

Dr. Vera Madzarevic
Director Clinical Development &
Quality Assurance, Theralase®

In accordance with the FDA's 2018 guidelines to industry, the patients who have achieved a Partial Response (“PR”) are being further assessed via Computerized Tomography (“CT”) scan and/or biopsy of the prostatic urethra to determine if upper tract Urothelial Cell Carcinoma (“UCC”) or prostatic urethra UCC can be detected to allow these patients to be re-categorized as CR.

In summary, for patients who received the primary optimized Study II Treatment versus the original Study II Treatment (90 days), there is a 5% increase in CR and a 75% decrease in NR.

Note: The current interim analysis presented above, should be read with caution, as the reported clinical data is extremely interim in its presentation, as Study II is still ongoing and new clinical data collected may or may not continue to support the current trends.

The data analysis is only a representation of the data accrued to date and does not intend to represent a tendency or portray any conclusion as to the effectiveness, duration or safety of the investigational treatment.

Additional Oncology Targets

Theralase® has diligently pursued the research and development of its Intellectual Property (“IP”) platform for PDCs, through scientific and preclinical research and development 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 it has been preclinically demonstrated that transferrin is able to significantly:

- Increase the resistance of TLD-1433, the lead drug candidate, to photobleaching (loss of potency of the PDC over time)
- Increase ROS production (ability to destroy cancer cells quickly and effectively)
- Increase selective tumour uptake (destruction of cancer cells, while sparing healthy cells) through the Transferrin Receptor (“TfR”)
- Increase anti-cancer efficacy (efficiency in cancer cell destruction)
- Decrease systemic toxicity (damage to healthy cells and/or organs)

This allows Rutherrin® (TLD-1433 + transferrin) to be a strong candidate for the systemic treatment of recurrent, deep seated and/or progressive cancers. The Company continues to conduct extensive scientific and preclinical research and development towards new oncology indications and has developed significant expertise and IP assets regarding its patented PDCs, in pursuit of this goal.

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 ‘tumor’s damage zone’ and the effectiveness of Theralase®’s ACT therapy beyond the reach of light in the body.

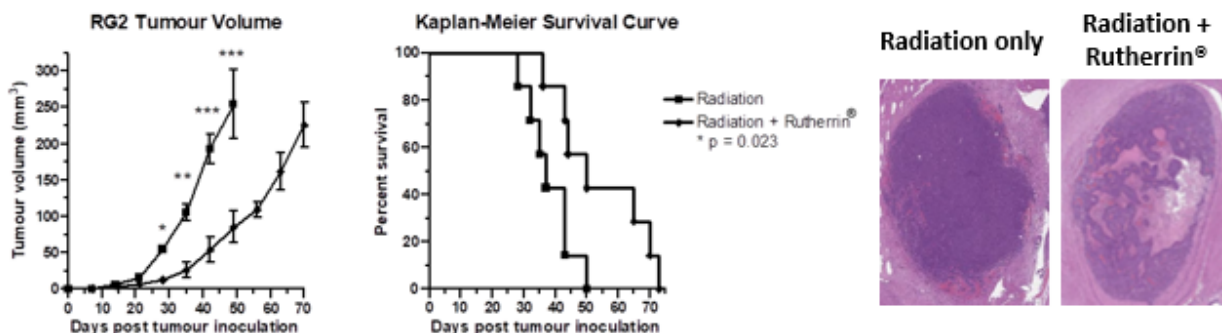
Radiotherapy (“RT”) is one of the primary treatment methodologies for many types of cancer, although it is currently a challenge to enhance radiation damage to tumor tissue, while reducing side effects to healthy tissue.

Rutherrin® is a unique agent that offers the ability to enhance injury to tumor tissue by accelerating damage through the production of free radicals; thereby, acting as a radio enhancer. Several preclinical strategies have been investigated by Theralase®’s scientists to research, develop, optimize and advance highly selective and effective radio sensitizing properties of Rutherrin®.

Below, recent progress on the current research and development initiatives utilizing Rutherrin®, in several in vitro and in vivo models is reported.

Rutherrin® activation via RT is preferential to light activation due to the much deeper tissue penetration of RT.

Effect of Rutherrin® in glioblastoma (GBM) orthotopic rat model



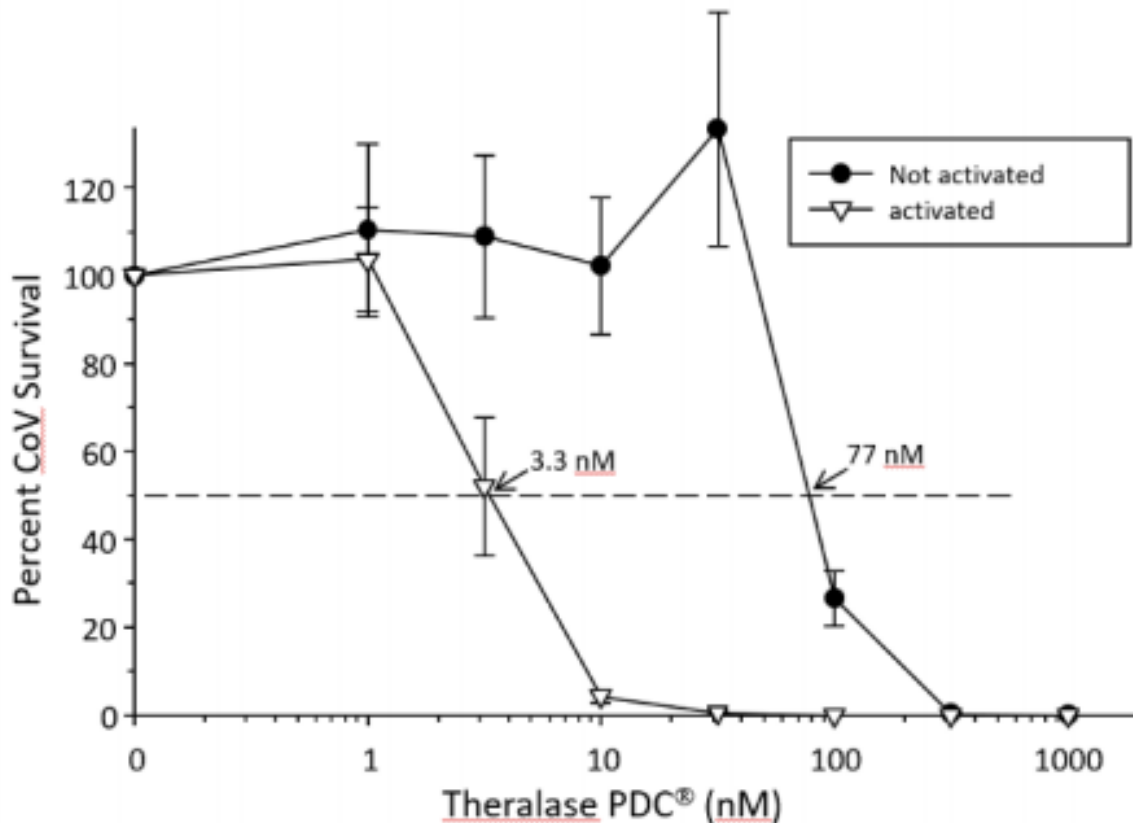
COVID-19 Vaccine Research



In April 2021, Theralase® executed a Collaborative Research Agreement (“**CRA**”) with the National Microbiology Laboratory, Public Health Agency of Canada (“**PHAC**”) for the research and development of a Canadian-based SARS-CoV-2 (“**COVID-19**”) vaccine. Under the terms of the agreement, Theralase® and PHAC are collaborating on the development and optimization of a COVID-19 vaccine. The project is entitled, “Photo Dynamic Compound Inactivation of SARS-CoV-2 Vaccine” and commenced in mid-April 2021.

This research and development is currently ongoing and no reportable data is available at this time.

Coronavirus Inactivation by Theralase PDC



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.