

QUARTERLY NEWSLETTER

A clinical stage pharmaceutical company focused on the research and development of light activated compounds 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 TRANSITION

Effective August 20, 2021, Shawn Shirazi, Chief Executive Officer (“CEO”), left the employ of the Company.

Effective August 23, 2021, John Trikola assumed the role of Chief Operating Officer (“COO”) and Interim CEO for the Company. John brings over 25 years of technology experience working with companies ranging from startups to Global 500. Most recently, John was the president of Gardner Ross Corp., where he provided turnaround and restructuring engagements to various organizations in the technology, manufacturing, and retail sectors.

In addition to his senior management roles, John currently serves as a Board Director for Waypoint Centre for Mental Health Care and has served on the Board of Directors and as Chair of the Fundraising Committee for The Sandbox Project, the Board of Directors and Governance Committee for the Loughheed House Conservation Society.

Effective August 23, 2021, Arkady Mandel, M.D., Ph.D., D.Sc., Chief Scientific Officer, Theralase® has assumed the lead for the Phase II NonMuscle Invasive Bladder Cancer (“NMIBC”) clinical study (“Study II”), in addition to all current preclinical and future clinical research, development and commercialization initiatives of the Company.

“ I wanted to thank former Chief Executive Officer (“CEO”) Shawn Shirazi, for his contributions over the last few years and wish him the best in his future endeavours. Right now, I see Theralase at its most inventive ever, with Dr. Arkady Mandel spearheading the clinical and scientific research in the Anti-Cancer Division (“ACT”) and myself accelerating the Cool Laser Therapy (“CLT”) division. ”



JOHN TRIKOLA
INTERIM CEO & COO, THERALASE®

Strategic Objectives

1. Successful completion of Study II for Bacillus Calmette Guérin (“BCG”)-Unresponsive Carcinoma InSitu (“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 Glioblastoma Multiforme (“GBM”) and Non-Small Cell Lung Cancer (“NSCLC”)
3. Coronavirus (BSL-3) (“COVID-19”) vaccine through preclinical research and clinical development.
4. Revenue generation in the Cool Laser Therapy (“CLT”) division

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.

Q221 Financial Statement Highlights

For the 6 months ended June 30th, 2021

Unaudited Consolidated Statements of Operations	2021	2020	Change
In Canadian Dollars	\$	\$	%
Revenue			
Canada	384,154	255,146	51%
United States	32,656	12,267	166%
International	13,189	26,041	-49%
Total Revenue	429,999	293,453	47%
Cost of Sales	230,370	230,095	0.1%
Gross Margin	199,629	63,358	215%
Gross Margin as a percentage of sales	46%	22%	
Operating Expenses			
Selling Expenses	197,400	229,998	-14%
Administrative Expenses	802,271	965,824	-17%
Research and Development Expenses – CLT Division	88,141	209,154	-58%
Research and Development Expenses – ACT Division	1,305,437	2,009,903	-35%
Other ⁽¹⁾	(131,344)	(83,897)	57%
Total Operating Expenses	2,261,905	3,330,982	-32%
Net Loss	(2,062,276)	(3,267,624)	-37%

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

Study II Update:

Study II CSSs:

Theralase has successfully launched the following CSSs for patients enrollment and treatment:

Canada

Clinical Study Sites	Location	Commenced
University Health Network (“UHN”)	Toronto, Ontario	April 25, 2019
London Health Sciences Centre (“LHSC”)	London, Ontario	October 7, 2019
Nova Scotia Health Authority (“NSHA”)	Halifax, Nova Scotia	February 25, 2020
University of British Columbia (“UBC”)	Vancouver, British Columbia	December 7, 2020
McGill University Health Centre (“MUHC”)	Montreal, Quebec	July 30, 2019

United States

Clinical Study Sites	Location	Commenced
Virginia Urology (“VU”)	Richmond, Virginia	January 19, 2021
Urology Associates P.C. (“UA”)	Nashville, Tennessee	January 20, 2021
Mid Lantic Urology (“MU”)	Bala Cynwyd, Pennsylvania	January 25, 2021
Carolina Urologic Research Center (“CURC”)	Myrtle Beach, South Carolina	January 27, 2021
University of Wisconsin Health-Madison (“UWH”)	Madison, Wisconsin	February 24, 2021
Urology San Antonio (“USA”)	San Antonio, Texas	March 25, 2021
University of Chicago (“UChicago Medicine”)	Chicago, Illinois	June 11, 2021

Study II Objectives:

Primary:

Efficacy, evaluated by the Complete Response (“CR”) rate at any time point in patients with Carcinoma In-Situ (“CIS”) with completely resected papillary disease. CR is defined as at least one of the following:

- Negative cystoscopy and negative (including atypical) urine cytology
- Positive cystoscopy with biopsy-proven benign or low-grade NMIBC and negative cytology
- Negative cystoscopy with malignant urine cytology, if urothelial cancer is present in the upper tract or prostatic urethra and random bladder biopsies are negative

Secondary:

Duration of CR at 12 months post initial CR.

Tertiary:

Safety, evaluated by the incidence and severity of Adverse Events (“AEs”), Grade 4 or higher that do not resolve within 450 days post treatment (Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening or disabling, Grade 5 = Death).

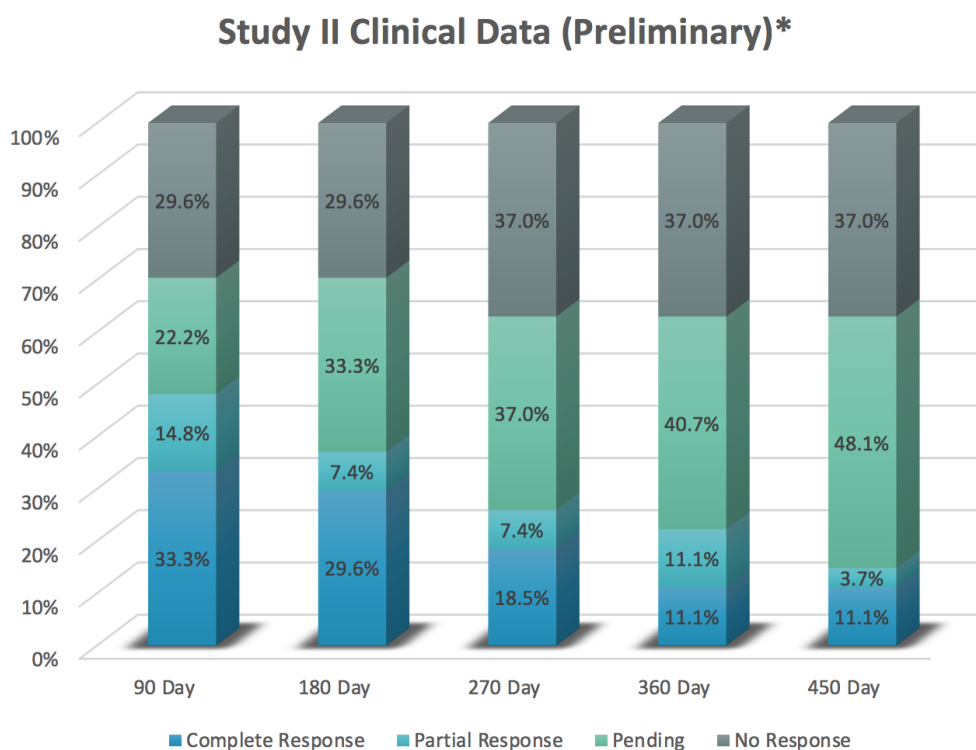
Study II Status:

Theralase® has enrolled and treated 24 patients in Study II (including three patients from the Phase Ib NMIBC clinical study (“Study”) treated at the Therapeutic Dose) for a total of 27 patients.

Theralase® plans to complete enrolling and treating 25 patients in Study II in 3Q2021 (28 in total), marking the first significant milestone of Study II.

Once achieved, Theralase® plans to compile progressive interim clinical data at the 90, 180, 270, 360 and 450 day assessment dates (urine cytology and cystoscopy) for submission to the Food and Drug Administration (“FDA”) for consideration of Breakthrough Designation (“BTD”) approval.

Interim clinical data for Study II (27 patients) ***:



*** 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)

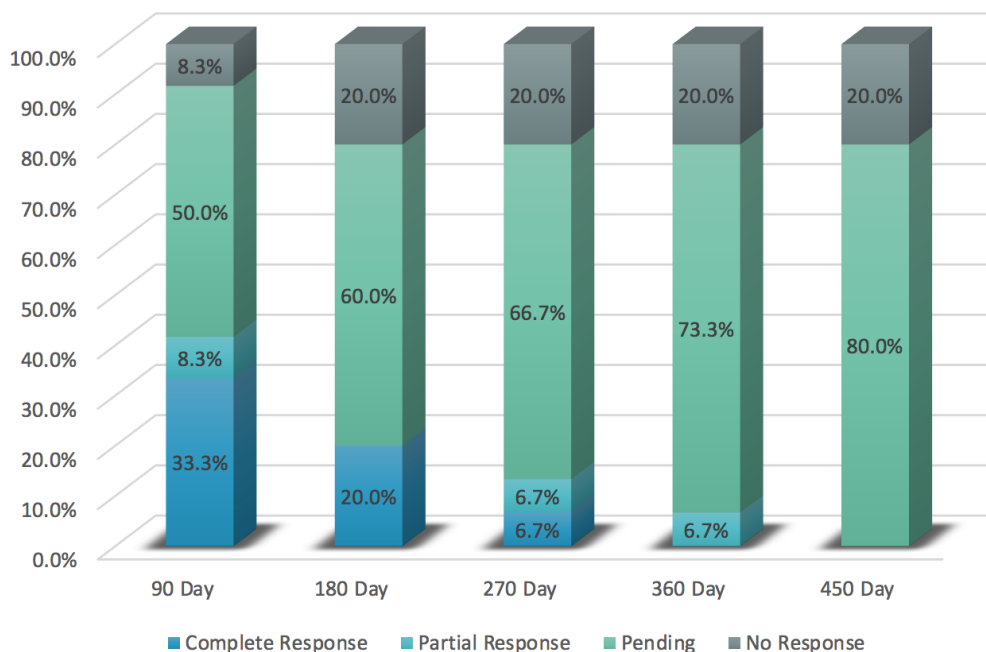
The Company implemented a Study Treatment optimization (Press release July 30, 2020), specifically:

- a) Bladder volume calculation
- b) Study drug volume calculation
- c) Study device volume calculation
- d) Study device treatment time

Study II Status:

Interim clinical data for Study II (15 patients) ***:

Study II Clinical Data (Preliminary)**
Optimized Treatment (Post 08/01/20)



**** Preliminary clinical data on 15 patients who received a primary or maintenance treatment on or after August 1, 2020.

Summary:

Objective	Interim clinical data for Study II (27 patients)	Interim clinical data for Study II (15 patients)
Primary	33.3%	33.3%
Secondary	11.1% (48.1% of data still pending - Insufficient data to analyze)	0.0% (80% of data still pending - Insufficient data to analyze)
Tertiary	All patients have experienced some transient grade 1 or grade 2 AEs (i.e.: bladder spasms, constipation, urge incontinence, fatigue, urinary frequency, hematuria, penile discomfort, urinary urgency, pain, urinary tract infections and other) where > 80% have completely resolved with 180 days. Out of 27 patients treated to date, one patient unfortunately passed away from causes unlikely related to the Study Drug, Study Device or Study Treatment	All patients have experienced some transient grade 1 or grade 2 AEs (i.e.: bladder spasms, constipation, urge incontinence, fatigue, urinary frequency, hematuria, penile discomfort, urinary urgency, pain, urinary tract infections and other) where > 80% have completely resolved with 180 days. Out of 15 patients treated to date, one patient unfortunately passed away from causes unlikely related to the Study Drug, Study Device or Study Treatment

The current interim analysis of the clinical data (with significant clinical data still pending and based on only 27 patients) demonstrates that Study II's primary (33.3%) and tertiary objectives (1 Severe AE) demonstrate a strong initial efficacy, strong durable efficacy and a high safety profile. There is insufficient data to comment on the Study II secondary objective.

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.

The Study Treatment optimization has shown a trend to higher primary and secondary objectives, as the incidence of No Response ("NR") has reduced from 37.0% of patients treated to 20.0%.

The interim clinical data is early in its analysis with significant clinical data still pending that may improve the reported status to the primary and secondary objectives.

Intellectual Property ("IP") Update:

Country	Patent Title
Europe	Metal-Glycoprotein Complexes and Their use as Chemotherapeutic Compounds
Canada	Metal-Based Coordination Complexes as Photodynamic Compounds and their Use.

Metal-Glycoprotein Complexes and Their use as Chemotherapeutic Compounds

Metal-based Photo Dynamic Compounds ("PDCs") that are used as light activated compounds to destroy various cancers, bacteria and viruses. They are able to be activated by various wavelengths of light.

Metal-Based Coordination Complexes as Photodynamic Compounds and their Use

Allows light activated compounds and their associated drug formulations to be intravenously injected to "hunt" and "localize" into various cancer cells, primarily GBM and NSCLC, then to safely and effectively "destroy" them when activated by laser light or radiation.