

# **QUARTERLY NEWSLETTER**

## **QUARTERLY UPDATE**

As COVID-19 continues to affect businesses globally, Theralase elected to place the Company's head office on a temporary layoff from March 24th to April 6th, 2020. Theralase commenced a return to work for employees on April 6th, 2020 with all employees expected to return to work by early May 2020. Theralase will continue to monitor the COVID-19 pandemic, provincial and federal guidelines in order to manage its business in compliance with all health and safety best practices.

All clinical study sites remain on temporary hold pending resolution of the COVID-19 pandemic. The Company is in close contact with the clinical study sites and will continue to work in conjunction with them to monitor the situation to determine the best time to re-commence the enrollment and treatment of patients in Canada for the Phase II Non-Muscle Invasive ("NMIBC") Clinical Study ("Study").

The Company is conducting pre-clinical non-Good Laboratory Practices ("GLP") studies to determine the next cancer indication for Rutherrin, a proprietary formulation of the lead photo Dynamic Compound ("PDC"), TLD-1433 with transferrin. Once these non-GLP studies have been completed, confirmatory GLP studies will be undertaken, prior to human use.

The 2019 annual audited consolidate financial statements are expected to be completed on or about April 29, 2020.



# VENTURE **50**2020

Presented by the TSX Venture
Exchange, Theralase is ranked 8th in the Clean Technology & Life
Sciences sector. This award recognizes the top 10 performing companies from five industry sectors selected based on three equally weighted criteria: market capitalization growth, share price appreciation and trading volume amount.

(Learn More...)

### **UPDATE ON STUDY II**

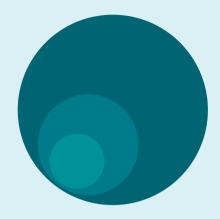
The Canadian clinical study sites are currently on hold for patient enrolment and treatment due to the current COVID-19 pandemic. No new patients will be enrolled or treated at any Canadian clinical study site, nor will any existing patient currently enrolled in the clinical study be treated a second time or be assessed by the Principal Investigator ("PI") for their follow up visits, until the clinical study sites re-commence operations. Theralase is in constant communication for any update on re-starting the recruitment and treatment activities.

12 patients have been treated to date representing approximately 50% of the interim milestone of treating 20 to 25 patients to submit analysis to the U.S. Food and Drug Administration ("FDA") in support of a Breakthrough Therapy Designation ("BTD") proposed from the FDA.

### **FDA STATUS**

Theralase has submitted it's Clinical Hold Complete Response to the FDA. The Company's response has addressed all deficiencies identified in the November 25, 2019 letter from the FDA that placed the Investigation New Drug ("IND") application on Full Clinical Hold pending resolution of specific deficiencies identified in the letter. A response is expected from the FDA on or about mid May 2020.

12% of patient enrolment and treatment is completed for Phase II NMIBC Study (assumes 100 patient population)



- Objective: treat approximately 100-125 patients
- Near-term objective: treat 20-25 patients
- 12 patients treated

<u>Canadian</u> <u>Clinical Sites</u>	Patients Treated
University Health Network	8 Patients
Toronto, Ontario	
McGill University Health Centre	4 Patients
Montreal, Quebec	
London Health Sciences	0 Patients
Centre London, Ontario	
Nova Scotia Health Authority	0 Patients
Halifax, Nova Scotia	

### **RECENT PUBLICATIONS**

Evaluation of a Ruthenium coordination complex as photosensitizer for PDT of bladder cancer:

Cellular response, tissue selectivity and in vivo response. (*Translational Biophotonics*. 2020; e201900032)

Metal-based photosensitizers for photodynamic therapy: the future of multimodal oncology? (*Current Opinion in Chemial Biology 2020, 56:23-27*)