theraLASE® Destroying Cancer at the Speed of Light™ | 1Q2020

QUARTERLY NEWSLETTER

OVERVIEW:

Phase II NMIBC Clinical Study Status

In 4Q2019, Theralase filed an Investigational New Drug ("**IND**") application to the Food and Drug Administration ("**FDA**") for a pivotal Phase II Non-Muscle Invasive Bladder Cancer ("**NMIBC**") clinical study. The IND is currently on Full Clinical Hold pending a response by Theralase, which is expected in 1Q2020. Pending FDA acceptance of Theralase's response, Theralase will commence onboarding clincial study sites in the United States. In the mean time, Theralase is proceeding with patient enrollment and study site onboarding in Canada.

The Phase II NMIBC clinical study ("**Study II**") has successfully launched in Canada, with 3 Canadian centres open for enrollment and treatment of patients.

1. University Health Network ("**UHN**") (Toronto, ON) - 5 patients treated
2. McGill University Health Centre ("**MUHC**") (Montreal, QC) - 1 patient treated
3. London Health Sciences Centre ("**LHSC**") (London, ON) - 0 patient treated

To date, 6 patients have been treated.

Moving Forward in 2020

The Company's primary objective is to advance the Anti-Cancer Technology ("**ACT**") platform for the destruction of various cancers. Study II is expected to treat approximately 100 patients at 20 clinical study sites in Canada and the US (subject to regulatory approval). Moreover, Theralase is currently conducting pre-clinical studies to determine Theralase's next cancer indication for a Phase Ib clinical study.

Patent Protection

In 4Q2019, Theralase was granted a European Patent for “Metal-Based Thiophene Photodynamic Compounds and Their Use”, strengthening the intellectual patent portfolio around the ACT platform. *Read more...*

Peer Reviewed Recognition

"These publications support the robustness of Theralase’s technology and the clear advantages...." *Read more...*

Analyst coverage

1. André Uddin, Ph.D, Managing Director Healthcare at Mackie Research Capital Corp.
2. Douglas Loe, Healthcare and Biotechnology Analyst at Echelon Wealth Partners Inc.

Financial Highlights

As of November 29, 2019, Theralase has $14.98M in cash and zero debt, except for trade payables. The Company is fully financed to finish Study II. The ACT division represents 58% of net loss due to increased research & development. *Read more...*

CEO Spotlight

From Shawn Shirazi, MSc., Ph.D

"We are happy with the progress of the pivotal Study II. Our objective is clear and in line with the FDA guidelines for BCG-Unresponsive NMIBC. The estimated timing of completion of Study II is approximately 3 years.

Theralase plans to expand the advanced ACT platform with additional indications, with a focus of delivering safe and effective cancer treatments. Our goal is to save more lives and keep patients cancer free."

(TSXV/TLT.V - OTCQB/TLTFF)