

Press Release



CORRECTION: Theralase Releases 3Q2020 Financial Statements

Correction of the press release published November 27, 2020. The release contained incorrect dates within the financial table. This has been corrected in the release below.

Toronto, Ontario – November 27, 2020, Theralase® Technologies Inc. (“Theralase” or the “Company”) (TSXV: TLT) (OTCQB: TLTF), a clinical stage pharmaceutical company dedicated to the research and development of light activated PhotoDynamic Compounds (“PDC”) and their associated drug formulations intended to safely and effectively destroy various cancers is issuing this corrected press release to revise the columns in the financial highlights. The 2019 column heading was changed to 2020 and should be the 2020 released its audited annual consolidated 3Q2020 financial statements.

Financial Highlights:

For the nine-month periods ended September 30:

Unaudited Condensed Consolidated Statements of Operations In Canadian Dollars	2020	2019	% Change
Revenue			
Canada	449,359	477,502	-6%
United States	52,074	23,926	+117%
International	26,041	13,463	+93%
Total Revenue	527,474	514,891	+2%
Cost of Sales	383,990	374,070	+3%
Gross Margin	143,484	140,851	+2%
Gross Margin as a percentage of sales	27%	27%	0%
Operating Expenses			
Selling Expenses	333,863	505,914	-34%
Administrative Expenses	1,522,179	1,798,682	-15%
Research and Development Expenses – CLT Division	259,507	401,511	-35%
Research and Development Expenses – ACT Division	2,830,417	1,829,543	+55%
Other ⁽¹⁾	(86,711)	4,246	+2,142%
Total Operating Expenses	4,859,255	4,539,896	+7%
Net Loss	(4,715,771)	(4,399,045)	+7%

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

Total revenue remained predominantly flat, year over year, and is primarily attributed to the COVID-19 pandemic as most health care practitioners elected to temporarily close their practices and place any purchasing decisions on temporary or permanent hold.

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Cost of sales for the nine-month period ended September 30, 2020 was \$383,990 which included a one-time provision for inventory of \$77,075 resulting in an adjusted cost of sales of \$306,915 or 58% of revenue with an adjusted gross margin of \$220,559 or 42% of revenue. The gross margin increase, as a percentage of sales, year over year, is attributed to eliminating non-essential personnel leading to decreased production salaries, attributed to the COVID-19 pandemic for the TLC-1000 and TLC-2000 product lines

The decrease in selling expenses year over year is primarily due to the restructuring of the Canadian and US sales and marketing departments, resulting in the resignation and/or termination of certain non-essential sales and marketing personnel and significantly reduced travel expenditures due to the COVID-19 pandemic.

The decrease in administrative expenses year over year is primarily attributed to decreased spending on general and administrative expenses, director and advisory fees and administrative salaries due to the COVID-19 pandemic, resulting in the termination of certain non-essential administrative personnel.

Net research and development expenses increased year over year primarily due to increased expenses for operating Study II. Research and development expenses represented 64% of the Company's operating expenses for the nine-month period ended September 30, 2020 and represent investment into the research and development of the Company's ACT technology.

The net loss for the nine-month period ended September 30, 2020 was \$4,715,771 which included \$921,448 of net non-cash expenses (i.e.: amortization, stock-based compensation expense and foreign exchange gain/loss). This compared to a net loss for the same period in 2019 of \$4,399,045 which included \$341,548 of net non-cash expenses. The ACT division represented \$3,641,470 of this loss (77%) for the nine-month period ended September 30, 2020.

The increase in net loss is primarily attributed to the following:

- 1) Increased investment in the clinical expense of conducting Study II.
- 2) Predominantly flat sales of the TLC-1000 and TLC-2000 due to market uncertainty directly attributable to the COVID-19 pandemic.

Operational Highlights:

1. **FDA Fast Track.** On November 23, 2020, the FDA granted Theralase® Fast Track Designation ("FTD") for Study II. As a Fast Track designee, Theralase® will have access to early and frequent communications with the FDA to discuss Theralase's development plans and ensure timely collection of the appropriate clinical data to support the approval process. The accelerated communication with the FDA potentially allows, TLD-1433, in combination with TLC-3200, to be the first intravesical patient-specific Ruthenium-based PDC for the treatment of patients with Bacillus Calmette-Guerin ("BCG") - Unresponsive Non- Muscle Invasive Bladder Cancer ("NMIBC") Carcinoma In-Situ ("CIS"), with or without papillary Ta or T1 tumors. FTD can lead to an Accelerated Approval ("AA"), Break Through Designation ("BTD") and/or Priority Review, if certain criteria are met, which the FDA has previously defined to the Company for BTD to

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represent approximately 20 to 25 patients enrolled and treated, who demonstrate significant safety and efficacy clinical outcomes.

2. **COVID-19 Pandemic Update.** In the ACT division, all Canadian Clinical Study Sites (“CSS”) have recommenced new patient enrollment and treatment in Study II as of September 24, 2020. The CSSs placed themselves on temporary hold due to the COVID-19 between March 20, 2020 to August 12, 2020 and September 24, 2020. In the CLT division, the Company continues to experience variations in sales and the timing of these sales due to the ongoing COVID-19 pandemic and has taken actions to reduce expenses by eliminating non-essential personnel and imposing a temporary hiring freeze, to be lifted, subject to the Canadian and United States economies demonstrating recovery from COVID-19.
3. **Clinical study site status.** The Company has successfully launched four CSSs and is preparing to launch a fifth Canadian CSS later in the year. The Company is in advanced discussions to launch a number of U.S. based CSS, subject to the United States economy recovering from the COVID-19 pandemic. The U.S. based Trial Management Organization is supporting the of launch 4 to 5 CSSs in 4Q2020 with potential to commence Study II patient enrollment and treatment as early as 1Q2021.
4. **Additional cancer indications.** The Company has demonstrated significant anti-cancer efficacy of Rutherrin®, when activated by laser light or radiation treatment across numerous preclinical models; including: Glioblastoma Multiforme (“GBM”) and Non-Small Cell Lung Cancer (“NSCLC”). The Company has commenced Non - Good Laboratory Practices (“GLP”) toxicology studies with Rutherrin® in animals to help determine the maximum recommended human dose of the drug, when administered systemically into the human body, via intravenous injections. Theralase plans to commence GLP toxicology studies in animals in 2021.
5. **COVID-19 Research Update.** The Company’s PDC technology was proven to be effective in the destruction of Influenza H1N1 and Zika viruses at low nanomolar concentrations. These studies were expanded to include coronavirus Bio Safety Level (“BSL”) 2. As a note, COVID-19 is caused by coronavirus (BSL-3), not coronavirus (BSL-2). A new assay was established to measure coronavirus destruction and using this new assay the Theralase® PDC technology was able to destroy coronavirus (BSL-2) with drug doses 5 times lower than what was used to kill Influenza H1N1 and Zika viruses. These drug doses demonstrated a 99.995% destruction rate of the BSL-2 coronavirus and are significantly lower than those used by the Company to treat cancers; hence considered safe for human use. Coronaviruses are considered similar in their structure and these new results strongly suggest that Theralase®’s PDC will be highly effective against the SARS-CoV-2 (BSL-3) virus responsible for COVID-19. Theralase® plans to commence an in-vivo small animal study later this year at another facility equipped to handle SARS-CoV-2 viruses (BSL-3) and if successful commence human clinical studies in 2021, subject to the availability of suitable financing.*

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

About Study II

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Study II utilizes the Therapeutic Dose (0.70 mg/cm²) of TLD-1433 and is focused on the enrollment and treatment of approximately 100 BCG-Unresponsive NMIBC CIS patients in up to 20 clinical study sites located in Canada and the US.

Study II has a:

- 1) Primary endpoint of efficacy (defined by Complete Response ("CR") at any point in time
- 2) Secondary endpoint of duration of CR at 360 days post-initial CR (approximately 450 days post initial Study treatment, assuming CR is achieved at the 90 day assessment)
- 3) Tertiary endpoint of safety measured by incidence and severity of Adverse Events ("AEs") grade 4 or higher that do not resolve within 450 days post-initial treatment

The FDA, in its 2018 guidance to industry has stated that, "For single-arm trials of patients with BCG-unresponsive disease, the FDA defines a CR as at least one of the following:

- 1) Negative cystoscopy and negative (including atypical) urine cytology
- 2) Positive cystoscopy with biopsy-proven benign or low-grade NMIBC and negative cytology
- 3) For intravesical therapies without systemic toxicity, the FDA includes, in the definition of a CR, negative cystoscopy with malignant urine cytology, if cancer is found in the upper tract or prostatic urethra and random bladder biopsies are negative.

Intravesical instillation does not deliver the investigational drug to the upper tract or prostatic urethra; therefore, the development of disease in these areas cannot be attributed to a lack of activity of the investigational drug. Thus, sponsors can consider patients with new malignant lesions of the upper tract or prostatic urethra, who have received intravesical therapy to have achieved a CR in the primary analysis; however, sponsors should record these lesions and conduct sensitivity analyses in which these patients are not considered to have achieved a CR."¹

About Theralase® Technologies Inc.

Theralase® is a clinical stage pharmaceutical company dedicated to the research and development of light activated Photo Dynamic Compounds and their associated drug formulations intended to safely and effectively destroy various cancers, bacteria and viruses.

Additional information is available at www.theralase.com and www.sedar.com

This news release contains "forward-looking statements" which reflect the current expectations of Company's management for future growth, results of operations, performance and business prospects and opportunities. Such statements include, but are not limited to, statements regarding the Company's proposed development plans with respect to Photo Dynamic Compounds and their drug formulations. Wherever possible, words such as "may", "would", "could", "should", "will", "anticipate", "believe", "plan", "expect", "intend", "estimate", "potential for" and similar expressions have been used to identify these forward-looking statements. These statements reflect management's current beliefs with respect to future events and are based on information currently available to management. Forward-looking statements involve significant risks, uncertainties and assumptions including with respect to the ability of the Company to: adequately fund, secure the requisite regulatory approvals to commence and successfully complete a Phase II NMIBC clinical study in a timely fashion and implement its development plans. Many factors could cause the Company's actual results, performance or achievements to be materially different from any future results, performance or achievements that may be expressed or implied by such forward-looking statements; including, without limitation, those listed in the filings made by the Company with the Canadian securities regulatory authorities (which may be viewed at www.sedar.com). Should one or more of these risks or uncertainties materialize or should assumptions underlying the forward looking statements prove incorrect, actual results, performance or achievements may vary materially from those expressed or implied by the forward-looking statements contained in this news release. These factors should be considered carefully and prospective investors should not place undue reliance on the forward-looking statements. Although the forward-looking

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statements contained in the press release are based upon what management currently believes to be reasonable assumptions, the Company cannot assure prospective investors that actual results, performance or achievements will be consistent with these forward-looking statements. The Company disclaims any intention or obligation to revise forward-looking statements whether as a result of new information, future developments or otherwise except as required by law. All forward-looking statements are expressly qualified in their entirety by this cautionary statement.

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