Ontario Securities Commission | Commission des valeurs mobilières de l'Ontario | 22nd Floor, 20 Queen Street West, Toronto ON M5H 3S8 | 22e étage, 20, rue queen ouest, Toronto ON M5H 3S8

IN THE MATTER OF
THERALASE TECHNOLOGIES INC. and ROGER DUMOULIN-WHITE

STATEMENT OF ALLEGATIONS

(Subsection 127(1) of the *Securities Act*, RSO 1990, c S.5)

A. ORDER SOUGHT:

Staff of the Enforcement Branch ("**Enforcement Staff**") of the Ontario Securities Commission (the "**Commission**") request that the Commission make an order pursuant to subsection 127(1) of the *Securities Act*, RSO 1990, c S.5 (the "**Act**") to approve the settlement agreement dated as of February 16, 2018 between Theralase Technologies Inc. ("**Theralase**" or the "**Company**"), Roger Dumoulin-White ("**Dumoulin-White**" and, together with Theralase, the "**Respondents**") and Enforcement Staff.

B. FACTS:

Enforcement Staff make the following allegations of fact:

(1) Overview

1. Requirements for timely, accurate and efficient disclosure of information, be it forward-looking or about historical events, are a primary means for achieving the purposes of the Act. This matter concerns failures by a TSX-Venture-listed issuer, Theralase, and its President and Chief Executive Officer, Dumoulin-White, to provide accurate and complete disclosure about the development of one of Theralase's lead products, the TLC-2000 therapeutic laser (the "**TLC-2000**"). The disclosure issues concern: (a) forward-looking information ("**FLI**") about anticipated milestones and expected revenues; (b) the absence of updates to that information, including why targets were not achieved; and (c) historical information about the status of the device's regulatory approvals.

2. The conduct at issue relates to Theralase's disclosure about the TLC-2000 between November 3, 2006 and August 29, 2017 (the "**Material Time**"). The Company disclosed expected launch dates, revenue projections and growth targets for the TLC-2000 in a manner contrary to National Instrument 51-102 *Continuous Disclosure Obligations* ("**NI 51-102**") and the public interest. The conduct at issue also relates to Theralase's disclosure regarding regulatory applications and approvals in respect of the TLC-2000's biofeedback or Cell Sensing technology from Health Canada and the U.S. Food and Drug Administration (the "**FDA**").

3. This matter does not concern the accuracy of Theralase's financial reporting in its quarterly and annual financial statements filed with the Canadian Securities Administrators on the System for Electronic Document Analysis and Retrieval ("**SEDAR**").

4. During the Material Time, Theralase did not have a Disclosure Committee and Dumoulin-White's wife acted as Theralase's Chief Financial Officer. The respondents in this matter are Theralase and Dumoulin-White.

(2) Respondents

5. Theralase is a medical devices company, the registered and head office of which is located in Toronto, Ontario. It is a reporting issuer in Ontario, the common shares ("**Shares**") of which are listed on the TSX Venture Exchange under the trading symbol "TLT". The Shares also trade on the OTCQX Best Market under the trading symbol "TLTFF". Share purchase warrants and stock options of Theralase are also outstanding.

6. Dumoulin-White is Theralase's founder, President, Chief Executive Officer and the Chair of its Board of Directors. He is resident in Toronto, Ontario.

(3) Theralase's Business

7. Theralase has two main divisions: the Photo Dynamic Therapy division (the "**PDT Division**") and the Therapeutic Laser Technology division (the "**TLT Division**"). According to a news release of Theralase dated November 29, 2017:

(a) the PDT Division researches and develops specially designed molecules called Photo Dynamic Compounds, which are able to localize to cancer cells and then when laser light activated, effectively destroy them; and

(b) the TLT Division designs, manufactures, markets and distributes patented super-pulsed laser technology indicated for the treatment of chronic knee pain, and in off-label use, the elimination of pain, reduction of inflammation and acceleration of tissue healing for numerous nerve, muscle, tendon, ligament, joint and wound conditions.

8. The PDT Division is in early stages, is presently engaged in clinical trials in Toronto, Ontario and is not expected to produce revenues in the near future. Theralase's revenue-generating unit is the TLT Division, the principal products of which are the TLC-1000 and TLC-2000 therapeutic lasers. Theralase has indicated that it expects the TLC-2000 to displace the TLC-1000 as its lead product, once the former is successfully launched. While Theralase continues to work on successfully commercializing the TLC-2000, it is also actively developing its PDT Division.

(4) Launch Dates, Revenue Projections and Growth Targets

9. On November 3, 2006, Theralase disclosed the anticipated launch of laser biofeedback technology in 2007. In its subsequent Management's Discussion & Analysis ("**MD&A**"),[1] it specified that commercialization of the biofeedback technology was slated to commence in the first quarter of 2007. On March 6, 2007, Theralase indicated that the biofeedback technology had been housed in the TLC-2000.

10. Over the next eight and a half years, Theralase made various statements in its public disclosure (including news releases and MD&A filed on SEDAR and marketing materials posted on the Theralase website and elsewhere on the Internet) in which it rolled forward the launch date of the TLC-2000 in 30-day to five quarter increments (collectively, the "**Launch Date FLI**"). Sales of the TLC-2000 did not commence until December 15, 2015, following the issuance of regulatory approvals from Health Canada and the FDA.

11. Between 2006 and 2016, Theralase also disclosed revenue projections for the TLC-2000 (the "**Revenue Projections**"). The financial outlooks appeared in offering memoranda and other marketing materials provided to prospective investors and posted on the Internet, as well as in a post on Theralase's Twitter feed. They ranged from $2.5 million

[1] Dated November 20, 2006.

to $10 million in the first year of launch to $50 million to $60 million in the fifth year following launch of the TLC-2000.

12. Theralase also referred to five-year outlooks in its SEDAR filings (the "**Growth Targets**"). For example, in a news release dated August 16, 2012, Dumoulin-White stated that one aspect of the Company's mandate was to build the TLT Division into a "$50 million annual recurring revenue model within the next 5 to 7 years." Theralase's Annual Information Forms ("**AIF**") dated September 24, 2014 provided that "Theralase's corporate mandate is to capture at least 1% of the therapeutic laser market, thus achieving annual revenues of >$50 million . . . within five years of launch" of the TLC-2000.

13. The financial outlooks were not achieved. By way of example, Theralase's revenues in 2016 were approximately $1.9 million. On June 30, 2017, at the request of Staff of the Corporate Finance Branch of the Commission, Theralase issued a news release in which it stated that it did not expect to achieve any of the forward-looking targets with respect to revenues that it had previously provided.

14. When Theralase provided the Launch Date FLI, Revenue Projections and Growth Targets, it did not accompany them with the disclosure ("**FLI Required Disclosure**") required by NI 51-102. For example, while some of the FLI was accompanied by a general "boilerplate", forward-looking statement disclaimer, Theralase did not identify the material risk factors that could cause actual results to differ, such as the effect that the regulatory approval process could have on the Launch Date FLI, or the quantitative and qualitative assumptions underlying the Revenue Projections or Growth Targets.

15. Theralase also did not update the FLI in accordance with NI 51-102. For instance, while its news releases and MD&A disclosed new launch dates for the TLC-2000, they did not reference the previous ones or explain why they had not been met.

(5) Regulatory Approval of Biofeedback or Cell Sensing Technology

16. Since 2003, Theralase's SEDAR filings have referred to the development of its patented, biofeedback technology, which would eventually be housed in the TLC-2000. The purpose of the biofeedback technology is to sense and target the injured tissue at depth and calibrate the laser's energy dose accordingly. Theralase consistently described this biofeedback feature as an advance that distinguished the TLC-2000 from its competition. In 2015, Theralase trademarked the term "Cell Sensing" to refer to it.

17. On February 9, 2015, Theralase announced that it had applied for Health Canada approval of the TLC-2000 and expected to do the same with respect to the FDA in March 2015. The news release described the TLC-2000 as a biofeedback therapeutic laser possessing Cell Sensing technology. Theralase had not applied to Health Canada for approval of the biofeedback or Cell Sensing technology and did not seek approval of it from the FDA until February 2017.

18. In its prospectus supplement to its base shelf prospectus dated February 25, 2015 (the "**2015 Prospectus**"), Theralase stated that it had filed for Health Canada approval of the TLC-2000. The two MD&A,[2] AIF and marketing materials incorporated by reference into the 2015 Prospectus described the TLC-2000 as having biofeedback or Cell Sensing technology.

19. In five subsequent news releases[3] and four MD&A,[4] Theralase indicated that it was awaiting Health Canada and/or the FDA approval to launch the TLC-2000. In the same news releases and MD&A, Theralase described the TLC-2000 as having biofeedback or Cell Sensing technology. For example, according to MD&A: "The TLC-2000 Biofeedback Therapeutic Laser System is currently being reviewed by . . . Health Canada and is expected to be approved for commercial distribution in Canada in early Q2 2015. Approval of the TLC-2000 Biofeedback Therapeutic Laser System by the Food and Drug Administration ("FDA") is expected in 4Q2015 for commercial distribution in the United States . . ."

20. On November 25, 2015 and December 14, 2015, respectively, Theralase announced that it had obtained regulatory approval for the TLC-2000 from the FDA and Health Canada. In nine subsequent MD&A[5] and its AIF dated November 7, 2016 (the "**2016 AIF**"), Theralase referred to approval or clearance by Health Canada or the FDA of the TLC-2000. It also described the TLC-2000 as having biofeedback or Cell Sensing technology. For example, according to Theralase's MD&A dated November 3, 2016 and the 2016 AIF: "The TLC-2000 Biofeedback Therapeutic Laser System . . . has a Health Canada approved Medical Device License (Class III)."

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[2] Dated April 29, 2014 and November 27, 2014.
[3] Dated May 1, 2015, May 29, 2015, June 10, 2015, June 11, 2015 and July 17, 2015.
[4] Dated April 30, 2015, May 29, 2015, August 28, 2015 and November 27, 2015.
[5] Dated November 27, 2015, April 29, 2016, May 27, 2016, August 29, 2016, November 3, 2016, November 29, 2016, May 1, 2017, May 30, 2017 and August 29, 2017.

21. Two of these MD&A[6] and the 2016 AIF were incorporated by reference into Theralase's prospectus supplement dated November 7, 2016.

C. NON-COMPLIANCE WITH ONTARIO SECURITIES LAW AND CONDUCT CONTRARY TO THE PUBLIC INTEREST

Enforcement Staff allege the following non-compliance with Ontario securities law and conduct contrary to the public interest:

(a) Theralase did not provide FLI Required Disclosure with, or update, its Launch Date FLI, Revenue Projections or Growth Targets, contrary to sections 4A.3, 4B.3 and 5.8 of NI 51-102 (with respect to FLI disclosed on or after December 31, 2007, when these provisions came into force) and contrary to the public interest (with respect to the other FLI at issue);

(b) Dumoulin-White, a director and officer of Theralase, authorized, permitted or acquiesced in Theralase's non-compliance with Ontario securities law, as set out in subparagraph (a) above, and is deemed not to have complied with Ontario securities law under section 129.2 of the Act;

(c) certain of Theralase's disclosure may have conveyed that the regulatory approvals obtained with respect to the TLC-2000 extended to the biofeedback or Cell Sensing technology, when they did not, contrary to the public interest; and

(d) as set out in subparagraphs (a) through (c) above, the Respondents engaged in conduct contrary to the public interest.

DATED this 21st day of February, 2018.

ONTARIO SECURITIES COMMISSION
20 Queen Street West, 22nd Floor
Toronto, ON M5H 3S8

Anna Huculak
Litigation Counsel, Enforcement Branch
Email: ahuculak@osc.gov.on.ca
Tel.: 416.593.8291

[6] Dated April 29, 2016 and November 3, 2016.