



**Clinical Stage Pharmaceutical Company** 

Research, development and commercialization of light activated Photo Dynamic Compounds ("**PDCs**") to safely and effectively destroy various cancers, bacteria and viruses

February 7, 2022

#### Forward Looking Statements



Forward Looking Statements ("FLS") contained in this presentation, which deal with the future revenue potential, business opportunities and/or strategic initiatives of Theralase<sup>®</sup> Technologies Inc. ("Theralase<sup>®</sup>" or the "Company"); including: information, analyses and/or projections as to future corporate developments reflect the current expectations of Company's management.

Such FLS, refer to the Company's ongoing technologically complex preclinical, clinical and/or medical device research and development efforts; including, but not limited to assumptions about Theralase<sup>®</sup>'s: business operations, continued performance on a basis consistent with prior years; ability to access financing from time to time on favourable terms or at all; ability to retain executive management, senior management, key personnel and/or key consultants or the non-disruptive replacement of them on reasonable terms; reasonably stable operating and/or general administrative expenses; future success of current research and development initiatives, achievement of commercialization activities and/or milestones; market success of its products over its competition; successful and timely achievement of regulatory and/or certification approvals; uncontested protection over its intellectual property in the markets in which it does business; market acceptance and/or revenue generation of it's products; operation in stable economic environments (Canada, the United States and elsewhere); ability to access currency, exchange rates, interest rates and/or commodity prices at reasonable rates.

No conclusions as to the successful outcome of the ongoing and planned research and development initiatives in which the Company is involved are intended or implied; nor can they be foreseen or predicted prior to definitive corporate announcements as to their outcome. Any statements that refer to expectations, projections, future events or achievement of strategic initiatives are FLS. Although Theralase<sup>®</sup>'s management believes that the expectations reflected in any FLS made in this presentation are reasonable, such statements are based on a number of assumptions, which may prove to be incorrect; including, but not limited to assumptions related to the risks and factors set out in the Company's current Annual Information Form ("AIF") and documentation available on SEDAR under the Company's profile at www.sedar.com. Accordingly, no assurances can be given that any of the events or circumstances contemplated by such FLS will transpire or occur or, if any of them transpire or occur, what impact they will have on Theralase<sup>®</sup>'s results of operations or financial condition. Furthermore, the FLS contained in this presentation are made as of the date hereof for the purpose of providing, investors with information regarding the Company's future plans for its business and expected milestones. The Company does not undertake any obligation to update publicly or to revise any of the included FLS, whether as a result of new information, future events, or otherwise, unless required by applicable laws. The FLS contained in this presentation are expressly qualified by this cautionary statement.

The Company's financial disclosure includes non-International Financial Reporting Standards ("**IFRS**") financial measures as supplemental indicators of the Company's financial and operating performance. The Company believes these supplemental financial measures reflect the Company's on-going business in a manner that allows for meaningful period-to-period comparisons and analyses of trends in its business. Accordingly, the Company believes that such financial measures may also be useful to prospective investors in enhancing their understanding of the Company's operating or future performance. These non-IFRS measures are not recognized under IFRS and do not have standardized meanings prescribed by IFRS; therefore, it is unlikely that these measures will be comparable to similarly titled measures reported by other issuers. Non-IFRS financial measures should be considered in the context of the Company's IFRS results. The Company cautions readers to consider these non-IFRS financial measures, in addition to, and not as an alternative for, measures calculated in accordance with IFRS. The financial statements of the Company are prepared in accordance with IFRS and are reported in Canadian dollars. All currency amounts in this presentation and all references incorporated are expressed in Canadian dollars, unless otherwise indicated.

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#### Company





Patented light-activated Photo Dynamic Compounds ("PDCs") have been scientifically and preclinically researched for 10+ years to optimize their ability to destroy cancer, bacteria and viruses <sup>1</sup>

Over 10+ peer reviewed published research publications



Theralase<sup>®</sup>'s patented lead PDC (TLD-1433) has successfully completed a Phase Ib Non-Muscle Invasive Bladder Cancer ("**NMIBC**") clinical study demonstrating strong safety and a 67% Complete Response ("**CR**") rate for patients treated at the therapeutic dose. <sup>2</sup>

In-progress pivotal Phase II NMIBC clinical study <sup>3</sup>



Vaccine for various enveloped viruses <sup>5</sup>

Granted FDA Fast Track Designation in November 2020 for Phase II Clinical Study<sup>6</sup>



destroy cancer and eliminate

pain<sup>7</sup>

Intellectual Property

24 issued patents for its PDC technology in the United States, Canada, China, Russia, Brazil, India and Europe <sup>8</sup>

28 patents pending <sup>8</sup>

<sup>1</sup> Annual Information Form – June 3, 2021

- <sup>3</sup> Press Release Theralase Commences Phase II NMIBC Clinical Study April 25, 2019
- <sup>4</sup> Press Release Theralase<sup>®</sup> Advances Anti-Cancer Technology in Destruction of Human Lung Cancer– March 5, 2018
- <sup>5</sup> Press Release Theralase Technology Demonstrates High Kill Rate of Coronavirus (BSL-2) November 13, 2020
- <sup>6</sup> Press Release Theralase Granted FDA Fast Track Designation for NMIBC Phase II Clinical Study November 23, 2020
- <sup>7</sup> Annual Information Form June 3, 2021
- <sup>8</sup> Annual Information Form June 3, 2021 + Press Release Theralase Expands Intellectual Property Portfolio December 9, 2021

<sup>&</sup>lt;sup>2</sup> Press Release - Patient Six Cancer-Free Twelve Months After Single Anti-Cancer Treatment, Results of Phase Ib Non-Muscle Invasive Bladder Cancer ("NMIBC") Clinical Study Demonstrate a 66% Complete Response ("CR") - April 2, 2019

## Lead Drug Candidate – TLD-1433

- TLD-1433 activated by a wide range of laser wavelengths and optical powers, regardless of the oxygenation level present in the tissue under treatment (Leads to an ability to destroy hypoxic tumours (low oxygenated tissues), such as solid core tumours (i.e.: brain, breast, lung, bladder cancer) <sup>9</sup>
- Scientifically researched and proven clinically to be preferentially absorbed into bladder cancer cells, leaving healthy urothelial cells intact <sup>10</sup>
- In-progress pivotal phase II NMIBC clinical study for patients with BCG-Unresponsive Carcinoma In-Situ ("CIS") in Canada and the United States (1/3 patients enrolled and provided primary study treatment) <sup>3</sup>
- Currently in development of an injectable form of TLD-1433 (TLD-1433 + Transferrin = Rutherrin<sup>®</sup>) for additional cancer indications; specifically, Non-Small Cell Lung Cancer ("NSCLC")<sup>4</sup>
- TLD-1433 manufactured according to Good Manufacturing Practices ("GMP") standards in preparation for commercialization <sup>11</sup>





<sup>&</sup>lt;sup>9</sup> Annual Information Form – June 3, 2021

<sup>&</sup>lt;sup>10</sup> Press Release - Patient Six Cancer-Free Twelve Months After Single Anti-Cancer Treatment, Results of Phase Ib Non-Muscle Invasive Bladder Cancer ("**NMIBC**") Clinical Study Demonstrate a 66% Complete Response ("**CR**") - April 2, 2019 <sup>11</sup> Press Release -Theralase Completes GMP Manufacture of Second Batch of Lead Drug – October 1, 2015

## Study Drug TLD-1433 Mechanism Of Action <sup>14</sup>





<sup>12</sup> Kaspler P, Lazic S, Forward S, Arenas Y, Mandel A, Lilge L. A ruthenium(ii)based photosensitizer and transferrin complexes enhance photo-physical properties, cell uptake, and photodynamic therapy safety and efficacy. Photochem Photobiol Sci. 2016 Apr;15(4):481-95. doi: 10.1039/c5pp00450k. Epub 2016 Mar 7. PubMed PMID: 26947517.

<sup>13</sup> Transferrin receptor regulates pancreatic cancer growth by modulating mitochondrial respiration and ROS generation. Jeong SM, Hwang S, Seong RH

<sup>14</sup> A novel transferrin receptor-targeted hybrid peptide disintegrates cancer cell membrane to induce rapid killing of cancer cells. Megumi Kawamoto<sup>,</sup> Tomohisa Horibe<sup>,</sup> Masayuki Kohno<sup>,</sup> Koji Kawakami

## Lead Cancer Indication - NMIBC







70%

#### 243,000

New patients diagnosed with bladder cancer each year (United States, Canada and Europe)<sup>15</sup>

#### 170,000

Patients diagnosed with NMIBC <sup>16</sup> and treated with intravesical Bacillus Calmette-Guérin ("**BCG**") standard of care treatment

#### 51,000

Patients recur within 1 year of BCG therapy and become BCG-Unresponsive <sup>17</sup>



30%

Patients that fail BCG therapy are recommended to have their bladder and associated tissue removed via a radical cystectomy to prevent recurrence and/or progression <sup>19</sup>

#### Estimated 80,470 new cases in US, and 11,838 new cases in Canada, 151,000 new cases of bladder cancer in Europe in 2019<sup>(1)</sup>

<sup>15</sup> Key Statistics for Bladder Cancer – American Cancer Society (2018); Canadian Cancer Society (2019) and Bladder Cancer – European Cancer Patient Coalition

 $^{16} {\rm https://www.uptodate.com/contents/bladder-cancer-treatment-non-muscle-invasive-superficial-cancer-beyond-the-basics \# [10,10]{\rm https://www.uptodate.com/contents/bladder-cancer-beyond-the-basics \# [10,10]{\rm https://www.uptodate.com/contents/bladder-cancer-basics \# [10,10]{\rm https://www.uptodate.com/contents/bladder-cancer-basics \# [10,10]{\rm https://www.uptod$ 

<sup>17</sup> The management of BCG failure in non-muscle-invasive bladder cancer: an update (2009)

<sup>18</sup> European Organization for Research and Treatment of Cancer (EORTC) - (Veeratterapillay R, Heer R, Johnson MI, Persad R, Bach C. High-risk non-muscle-invasive bladder cancer-therapy options during intravesical BCG Shortage. Curr Urol Rep. 2016;17:68) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5769243/

<sup>19</sup> NCCN Guidelines Insights: Bladder Cancer, Version 5.2018, J Natl Compr Canc Netw 2018;16(9):1041–1053

## NMIBC Market Opportunity



Social Demand

Market

Opportunity

Patients wish to retain their bladder function and are willing to pay between \$USD 50,000 to \$USD 150,000 per Quality Adjusted Life Year ("**QALY**") for treatment <sup>20</sup>

**Innovation Demand** Bladder cancer patients face low Quality Of Life ("QOL") after radical cystectomy <sup>21</sup>

From diagnosis to death, it is estimated to cost between \$USD 89,000 to \$200,000 to treat a bladder cancer patient <sup>22</sup>

Bladder cancer has the highest lifetime treatment costs per patient of all cancers <sup>22</sup>



<sup>20</sup> Willingness to pay per Quality Adjusted Life Year ("QALY") for competitor drug, Pembrolizumab. Source: Cost-effectiveness of Pembrolizumab in Second-line Advanced Bladder Cancer, July 2018

<sup>21</sup> Tyson MD 2nd, Barocas DA. Quality of Life After Radical Cystectomy. Urol Clin North Am. 2018 May;45(2):249-256. doi: 10.1016/j.ucl.2017.12.008. Epub 2018 Feb 21. PMID: 29650140.

<sup>22</sup> Sievert KD, Amend B, Nagele U, et al. Economic aspects of bladder cancer: what are the benefits and costs?. World J Urol. 2009;27(3):295–300. doi:10.1007/s00345-009-0395-z

<sup>23</sup> 2025 estimated bladder cancer market (US, France, Germany, Italy, Spain, UK & Japan). Source: Global Data: Bladder cancer market size to more than triple to over \$1.1 billion by 2025, April 2017

<sup>24</sup> Ida K, Miyake M, Murakami K et al. Bacillus Calmette-Guérin-unresponsive non-muscle invasive bladder cancer outcomes in patients without radical cystectomy. Int J Clin Oncol. 2021 Nov;26(11):2104-2112. doi: 10.1007/s10147-021-01988-8. Epub 2021 Jul 27. PMID: 34313904.

### Study Treatment





Study Drug (TLD-1433) instilled in bladder via catheter <sup>25</sup>



TLD-1433 localizes preferentially inside bladder cancer cells <sup>26, 27</sup>



Green laser light activates TLD-1433 through fiber optics











<sup>25</sup> Phase Ib NMIBC clinical study patient cystoscopy photograph, after instillation of Study Drug, prior to TLC-3200 Light Activation, showing TLD-1433 localization to bladder cancer tumours

<sup>26</sup> Kalinina S, Breymayer J, Reeß K, Lilge L, Mandel A, Rück A. Correlation of intracellular oxygen and cell metabolism by simultaneous PLIM of phosphorescent TLD1433 and FLIM of NAD(P)H. J Biophotonics. 2018 Oct;11(10):e201800085. doi:10.1002/jbio.201800085.

<sup>27</sup> Reference: Urol Res. 1987;15(6):341-4.Transferrin receptor expression by human bladder transitional cell carcinomas, Seymour GJ, Walsh MD, Lavin MF, Strutton G, Gardiner RA



Primary Objective	Secondary Objective	Tertiary Objective			
Safety Safety and tolerability measured by Adverse Events ("AEs") not resolved within 180 days Strong safety profile, minimal to no side effects (95% of AEs fully resolved within 180 days)	Pharmacokinetics Pharmacokinetics (movement and exit of drug from the body), measured using plasma and urine samples Intravesical instillation leads to nanograms in urine and picograms in plasma. Exits body within 72 hours <sup>29</sup>	Efficacy Efficacy (evaluated primarily at 90 days, secondarily at 180 days), measured by Complete Response ("CR") 67% CR (2 out of 3 patients) treated at the therapeutic dose of TLD-1433 are CR 450 days post primary study treatment			

<sup>28</sup> Theralase Press Release "Patient Six Cancer-Free Twelve Months After Single Anti-Cancer Treatment, Results of Phase Ib Non-Muscle Invasive Bladder Cancer ("**NMIBC**") Clinical Study Demonstrate a 66% Complete Response ("**CR**") at the Therapeutic Dose (0.70 mg/cm2) 360 Days Post Treatment", Dated: April 2, 2019

## Phase II NMIBC Clinical Study (Design) <sup>25</sup>



Multi-center (Up to 15) Single-arm open-label Phase II pivotal clinical study for BCG-Unresponsive Carcinoma In-Situ ("**CIS**") NMIBC

100 to 125 patients to be treated with TLD-1433 (0.70 mg/cm<sup>2</sup>) light activated by the TLC-3200 (90 J/cm<sup>2</sup>)

All patients receive two Study Treatments (Primary - Day 0 and Maintenance - Day 180) <sup>30</sup>

FDA Guidelines state that "In BCG-Unresponsive NMIBC, a single-arm clinical trial with Complete Response ("**CR**") rate and duration of response as the primary endpoint can provide primary evidence of effectiveness to support a marketing application" <sup>31</sup>

#### Primary Objective

#### **Initial Efficacy**

CR achieved at any point in time (Negative cystoscopy and negative cytology)

(Positive cystoscopy (low grade) and negative cytology)

(Negative cystoscopy and positive cytology if Upper Tract Urothelial Cell Carcinoma ("**UTUCC**") is confirmed)

# **Duration of Efficacy**

Secondary Objective

12 months duration of CR after initial CR

(If CR detected at 3 months, then CR must be maintained for up to 15 months post primary study treatment)

#### Safety

**Tertiary Objective** 

Incidence and severity of Adverse Events ("**AEs**") > Grade 3 that do not resolve within 450 days post primary study treatment

Grade 1 = Mild

Grade 2 = Moderate

Grade 3 = Severe

Grade 4 = Life-threatening

Grade 5 = Death

<sup>30</sup> Clinical Protocol TLD-1433-2 (Version 8.0) Dated: April 16, 2019

<sup>31</sup> "BCG-Unresponsive Nonmuscle Invasive Bladder Cancer: Developing Drugs and Biologics for Treatment – Guidance for Industry" Dated: February 2018

# Phase II NMIBC Preliminary Clinical Data

![](_page_10_Picture_1.jpeg)

30 patients treated to date in the Phase II NMIBC clinical study <sup>32</sup>

3 patients treated in the Phase Ib NMIBC clinical study

### Total population of 33 patients

5 clinical study sites open in Canada and 7 in United States

All patients treated with TLD-1433 (0.70 mg/cm<sup>2</sup>) light activated by the TLC-3200 (90 J/cm<sup>2</sup>)

All patients received at least one Study Treatment (Primary - Day 0)

![](_page_10_Figure_8.jpeg)

![](_page_10_Figure_9.jpeg)

The data analysis is only a representation of the data accrued to date and does not intend to represent a tendency or portray any conclusion as to the effectiveness, duration or safety of the investigational treatment.

<sup>32</sup> Theralase® Press Release - Theralase Releases 3Q21 Financial Statements and Newsletter – November 29, 2021

### Phase II NMIBC Clinical Study Timeline (Projected)

![](_page_11_Picture_1.jpeg)

First patient treated in Canada August 2019 <sup>34</sup>	First patient United S May 20	nt treated in d States 2021 <sup>35</sup>		Provide study treatment and follow- up to 100 to 125 patients in Canada and United States March 2025 (Projected)		Commercialization Phase January 2023 to December 2025 (Projected)			
Milestone		2019	202	20	2021	2022	2023	2024	2025
100 to 125 Patients Treated (Projected)									
Fast Track Designation <sup>6</sup>									
Breakthrough Designation (Projected)									
Patient Follow Up (Projected)									
Data Lock / Clinical Study Report Submi	ission (Projected)								
Health Canada and FDA Marketing App	roval (Projected)								
Commercialization Phase (Projected)									

<sup>34</sup> Press Release - Theralase Announces First Patient Treated in Phase II Non-Muscle Invasive Bladder Cancer Clinical Study – September 4, 2019
<sup>35</sup>Theralase Launches Seventh US-Based Clinical Study Site and Treats First Patient in the US – June 11, 2021

### Secondary Indication: Non-Small Cell Lung Cancer ("NSCLC")

Non-Small Cell Lung Cancer - Rutherrin® + X-Ray Activation

A549 - Human NSCLC cells

![](_page_12_Figure_3.jpeg)

Rutherrin<sup>®</sup> + X-Ray Activation leads to a 3 log kill of human NSCLC cells in-vitro

<sup>36</sup> Kaspler, P, Roufaiel, M, Mandel, A. Theralase Research Paper June 20, 2021

thera

# Tertiary Indication: Virus Vaccine Research and

![](_page_13_Picture_1.jpeg)

#### Primary:

Investigate the ability of light activated TLD-1433 to inactivate enveloped viruses by up to 6 log kill invitro to create a vaccine (H1N1 Influenza, Zika, Herpes Simplex and Corona viruses - Biological Safety Level ("**BSL**") 2 and 3) <sup>37</sup>

#### Secondary:

Investigate the use of the vaccine to build antibodies in animals via assays and to protect animals from contacting the virus via challenge models (Pending)

![](_page_13_Figure_6.jpeg)

**Note:** Theralase<sup>®</sup> does not claim or profess that they have the ability to treat, cure or prevent the contraction of the SARS-CoV-2 coronavirus (COVID-19).

<sup>37</sup> Press Release – February 7, 2022 – Theralase® Demonstrates Proof-of-Concept for Canadian-Made COVID-19 Vaccine

#### Management Team

![](_page_14_Picture_1.jpeg)

![](_page_14_Picture_2.jpeg)

Arkady Mandel M.D., Ph.D., D.Sc. Interim Chief Executive Officer and Chief Scientific Officer

30+ years of scientific, preclinical and clinical experience in technology creation and innovation. A key founder of the therapeutic use of medical lasers in dermatological treatments and other areas of clinical medicine.

![](_page_14_Picture_5.jpeg)

Kristina Hachey CPA Chief Financial Officer

20+ years of financial and financing experience for public and private companies. Experienced in corporate governance and compliance.

![](_page_14_Picture_8.jpeg)

Vera Madzarevic Ph.D. Director of Clinical Development and Quality Assurance 20+ years of experience in

Phase I to IV clinical development, training, product development, strategic planning and implementing, monitoring and managing clinical and scientific activities.

#### **Board of Directors**

![](_page_15_Picture_1.jpeg)

![](_page_15_Picture_2.jpeg)

Arkady Mandel M.D., Ph.D., D.Sc. Interim Chief Executive Officer & Chief Scientific Officer

30+ years of scientific, preclinical and clinical experience in technology creation and innovation. A key founder of the therapeutic use of medical lasers in dermatological treatments and other areas of clinical medicine.

![](_page_15_Picture_5.jpeg)

Kristina Hachey CPA Chief Financial Officer

20+ years of financial and financing experience for public and private companies. Experienced in corporate governance and compliance.

![](_page_15_Picture_8.jpeg)

Guy Anderson MDA, CFP®, CIM®

20+ years of financial experience, currently providing service to Aligned Capital Partners.

![](_page_15_Picture_11.jpeg)

Matthew Perraton PFP, FMA, FCSI

20+ years of financial experience, most recently as a Senior Investment Advisor for Jong Perraton Private Wealth Group.

![](_page_15_Picture_14.jpeg)

#### **Randy Bruder**

30+ years of senior management experience as owner and Chief Operation Officer of a Canadian wholesale/retail food processing organization.

## Capital Structure

![](_page_16_Picture_1.jpeg)

![](_page_16_Figure_2.jpeg)

## Why Invest?

![](_page_17_Picture_1.jpeg)

![](_page_17_Picture_2.jpeg)

#### Scientifically Researched

Patented light-activated Photo Dynamic Compounds ("**PDCs**") have been scientifically and preclinically researched for 10+ years to analyze and optimize their ability to destroy cancer, bacteria and viruses <sup>1</sup>

Over 10+ peer reviewed published research publications

![](_page_17_Figure_6.jpeg)

#### Clinically Proven

Theralase<sup>®</sup>'s patented TLD-1433 PDC has successfully completed a Phase Ib Non-Muscle Invasive Bladder Cancer ("**NMIBC**") clinical study demonstrating strong safety and a 67% Complete Response ("**CR**") rate for patients treated at the therapeutic dose. <sup>2</sup> In-progress on a pivotal Phase II NMIBC clinical study, expected to complete by 2025. <sup>3</sup>

![](_page_17_Picture_9.jpeg)

Extensive Pipeline

> **Lead** NMIBC

Under Development Non-Small Cell Lung Cancer ("NSCLC")<sup>4</sup>

Vaccine for various enveloped viruses <sup>5</sup>

Granted FDA Fast Track Designation in November 2020 for Phase II Clinical Study<sup>6</sup>

![](_page_17_Picture_15.jpeg)

Experienced Team

Experienced in clinical, pharmaceutical and medical device development. Partnered with leading scientific and clinical researchers from renowned research hospitals to develop cutting-edge technologies to destroy cancer and eliminate pain <sup>7</sup>

![](_page_17_Picture_18.jpeg)

#### Intellectual Property

24 issued patents for its PDC technology in the United States, Canada, China, Russia, India and Europe <sup>8</sup>

28 patents pending 8

<sup>3</sup> Press Release - Theralase Commences Phase II NMIBC Clinical Study - April 25, 2019

<sup>5</sup> Press Release - Theralase Technology Demonstrates High Kill Rate of Coronavirus (BSL-2) – November 13, 2020

<sup>7</sup> Annual Information Form – June 3, 2021

<sup>8</sup> Annual Information Form – June 3, 2021 + Press Release – Theralase Expands Intellectual Property Portfolio – December 9, 2021

<sup>&</sup>lt;sup>1</sup> Annual Information Form – June 3, 2021

<sup>&</sup>lt;sup>2</sup> Press Release - Patient Six Cancer-Free Twelve Months After Single Anti-Cancer Treatment, Results of Phase Ib Non-Muscle Invasive Bladder Cancer ("NMIBC") Clinical Study Demonstrate a 66% Complete Response ("CR") - April 2, 2019

<sup>&</sup>lt;sup>4</sup> Press Release - Theralase<sup>®</sup> Advances Anti-Cancer Technology in Destruction of Human Lung Cancer– March 5, 2018

<sup>&</sup>lt;sup>6</sup> Press Release - Theralase Granted FDA Fast Track Designation for NMIBC Phase II Clinical Study – November 23, 2020

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