

# Management's Discussion and Analysis of Financial Condition and Operations

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The following Management's Discussion and Analysis ("MD&A"), of Theralase® Technologies Inc. ("Theralase®" or the "Company") should be read in conjunction with the unaudited condensed consolidated interim financial statements for the three-month period ended March 31, 2024.

This MD&A has been filed in accordance with the provisions of National Instrument 51-102 (*Continuous Disclosure Obligations*). Additional information relating to the Company can be found on Sedar at [www.sedar.com](http://www.sedar.com).

This MD&A is prepared as of May 29th, 2024.

The Company's common shares are listed for trading on the TSX Venture Exchange (**Symbol: TLT**) and trade on the OTCQB marketplace (**Symbol: TLTF**).

## **Forward Looking Statements:**

*The information provided herein is intended to provide a general outline of the operations of the Company. This document contains certain forward-looking statements and information (collectively, "Forward-Looking Statements" or "FLS") within the meaning of applicable securities laws. FLS are statements and information that are not historical facts, but instead include financial projections and estimates; statements regarding plans, goals, objectives, intentions and expectations with respect to Theralase®'s future business, operations, research and development; including: anticipated timelines for the commencement or completion of certain activities, enrolment of patients in clinical studies or other information in future periods. FLS, which may be identified by words including, without limitation, "believe", "anticipate", "should", "could", "would", "estimate", "expect", "plan", "will", "intend", "may", "pending", "objective", "exploring", "potential", "project", "possible" and other similar expressions, and the negative of such expressions, are intended to provide information about management's current plans and expectations regarding future operations.*

*FLS in this MD&A include, but are not limited to, statements with respect to: future revenue projections, business initiatives and their timing; the competitive environment; business strategic objectives; research, development and/or commercialization plans, acquisition and disposition of assets; preclinical and/or clinical studies: status, timing and/or strategies; the supply and demand of products or services; the ability to meet current and future financial obligations; the ability to execute on business and/or growth strategies; management's assessment of business strategies and/or operations; the intention and/or ability to pay dividends on the common shares of the Company.*

*Readers are cautioned not to place undue reliance on FLS since there can be no assurance that the plans, intentions or expectations, upon which they are based will occur. By their nature, FLS involve numerous assumptions, known and unknown, risks and uncertainties, both general and specific, that contribute to the possibility that the predictions, forecasts, projections and other things contemplated by the FLS will not occur. Such FLS or information are based on a number of assumptions, which may prove to be incorrect; including, those assumptions listed below and those discussed elsewhere in this MD&A. Some of the assumptions made by Theralase®, upon which such FLS are based, include; but are not limited to, assumptions about: the ability to continue as a going concern, the business operations continuing on a basis consistent with prior years; the ability to access financing from time to time on favourable terms, or at all; the continuation of executive management, operating management, key personnel or key consultants or the non-disruptive replacement of them on reasonable terms; the ability of Theralase® to maintain reasonably stable operating and general administrative expenses; current and future success of research, development, and/or commercialization initiatives; the ability to achieve development and/or commercialization milestones; market competition; the ability to secure all required regulatory, government and/or certification approvals; geographic protection over the intellectual property in the markets in which Theralase® does business; market acceptance and/or revenue generation of products under development; the stability of current economic and business conditions, the strength of the economy in Canada, the United States and elsewhere; currency, exchange and/or interest rates and commodity prices being reasonably stable at current rates.*

*FLS reflect current expectations of management regarding future events and operating performance as of the date of this MD&A. Such information: involves significant risks and uncertainties; should not be read as guarantees of future performance and/or results; and will not necessarily be accurate indications of whether or not such results will be achieved. A number of factors could cause actual results to differ materially from the results discussed in the FLS; including, but not limited to, the risks related to: limited operating history; working capital and capital resources; ability to retain key personnel; protection of intellectual property; competition; implementation delays; strategic alliances; trade secret protection; product deficiencies; dependence on third party suppliers; volatility of share price; regulatory risks; early stage of product development; reliance on third parties; clinical study risk; clinical study timing delays; patient enrolment; failure to achieve milestones; currency risk; material weakness in internal controls over financial reporting; credit risk; product liability and clinical study liability. See "Risk and Uncertainties".*

**ALTHOUGH THE FLS CONTAINED IN THIS MD&A ARE BASED UPON WHAT THERALASE®'S MANAGEMENT BELIEVES TO BE REASONABLE ASSUMPTIONS, THERALASE® CANNOT ASSURE READERS THAT ACTUAL RESULTS WILL BE CONSISTENT WITH SUCH INFORMATION. FLS REFLECT MANAGEMENT'S CURRENT BELIEFS AND ARE BASED ON INFORMATION CURRENTLY AVAILABLE TO THERALASE®. READERS OF THIS MD&A ARE CAUTIONED NOT TO PLACE UNDUPLICATE RELIANCE ON THERALASE®'S FLS BECAUSE A NUMBER OF FACTORS, SUCH AS THOSE REFERRED TO IN THE PARAGRAPHS ABOVE, COULD CAUSE ACTUAL FUTURE RESULTS, CONDITIONS, ACTIONS OR EVENTS TO DIFFER MATERIALLY FROM THE TARGETS, EXPECTATIONS, ESTIMATES AND/OR INTENTIONS EXPRESSED IN THE FLS CONTAINED IN THIS MD&A. THE FLS ARE MADE AS OF THE DATE OF THIS MD&A AND THERALASE® ASSUMES NO OBLIGATION TO UPDATE OR REVISE SUCH INFORMATION TO REFLECT NEW EVENTS OR CIRCUMSTANCES, EXCEPT AS MAY BE REQUIRED BY APPLICABLE LAW.**

## **Company Profile:**

Theralase® is a clinical stage pharmaceutical company dedicated to the research and development of light activated Photo Dynamic Compounds ("PDCs") and their associated drug formulations with a primary objective of efficacy and a secondary objective of safety in the destruction of various cancers, bacteria and viruses. The Company in its Drug Division conducts preclinical research and clinical development of the PDCs, primarily in the treatment of cancer, with assistance from its Device Division to develop medical lasers to activate them. The Company in its Device Division designs, develops, manufactures and markets proprietary super-pulsed Cool Laser Therapy ("CLT") technology indicated and cleared by Health Canada and the Food and Drug Administration ("FDA") for the treatment of chronic knee pain and has been used off-label for treating numerous nerve, muscle and joint conditions.

## **Non-Brokered Private Placement**

On February 5, 2024, the Company closed a non-brokered private placement of units. On closing, the Company issued an aggregate of 6,666,670 units at a price of \$CAN 0.18 per Unit for aggregate gross proceeds of approximately \$CAN 1,200,000 of which 1,310,502 units were purchased by certain insiders of the Corporation. Each Unit consists of one common share of the Company and one non-transferable warrant. Each Warrant entitles the holder to acquire an additional Common Share at a price of \$CAN 0.25 for a period of 5 years following the date of issuance.

On April 24, 2024, the Company closed a non-brokered private placement of units. On closing, the Company issued an aggregate of 4,167,778 units at a price of \$0.18 per Unit for aggregate gross proceeds of approximately \$750,200. Each Unit consists of one common share of the Company and one non-transferable common share purchase warrant. Each Warrant entitles the holder to acquire an additional Common Share at a price of \$0.25 for a period of 5 years following the date of issuance.

## **Research Collaboration for Treatment for Parkinson's Disease**

Theralase® is working in collaboration with researchers at the University of Windsor, Faculty of Human Kinetics and a Windsor based chiropractor to conduct a groundbreaking clinical study into how Theralase® CLT can be used as a treatment for Parkinson's. Theralase®'s CLT, with its super-pulsed laser technology, is one of the few technologies in the world able to non-invasively penetrate the human skull, promoting anti-inflammatory responses and stimulating neurons to promote healing from this deadly disease.

## **Advancing the Theralase® Technology Platform:**

The Company's primary focus is the Drug Division, with strategic objectives of: preclinical research and clinical development of PDCs and the light and radiation systems that activate them, intended primarily for the destruction of various cancers, bacteria and viruses.

Theralase®'s patented lead study drug, TLD-1433 (Trade Name: Ruvidar™), is currently under late-stage clinical investigation in a Phase II clinical study for the treatment of Bacillus Calmette Guérin ("BCG")- Unresponsive Non-Muscle Invasive Bladder Cancer ("NMIBC") Carcinoma In-Situ ("CIS").

The trade name Ruvidar™ was selected by the Company for its lead PDC, TLD-1433; where, Ru is the elemental symbol for Ruthenium (a rare transitional metal in Group 8 belonging to the platinum group, which the Theralase® PDC is based upon), vita is Latin for "life" and dar is Russian for "gift"; hence, roughly translated, "Ruthenium, the gift of life". Iron, Ruthenium and Osmium are all transitional metals in Group 8, so named as they possess eight electrons in their outer shell, giving them similar chemical characteristics.

Ruvidar™, has been demonstrated preclinically to bind with transferrin, a human glycoprotein, forming the compound named, Rutherrin®. Transferrin is utilized by the human body to transport molecular iron to every cell in the body. Various cancer cells, in peer-reviewed publications, have demonstrated significantly more transferrin receptors versus healthy cells, allowing the preferential deposition of the Ruvidar® payload inside the cancer cell, versus a healthy cell, through endocytosis. When light or radiation activated, Ruvidar® has been demonstrated to destroy cancer cells through the production of singlet oxygen and/or Reactive Oxygen Species ("ROS"), from the inside out, inducing oxidative stress, leading to Immunogenic Cell Death ("ICD").

The Drug Division is in the preclinical research and development of Rutherrin® intended to be utilized as an injectable form of Ruvidar™, for the treatment of Glio Blastoma Multiforme ("GBM") and Non-Small Cell Lung Cancer ("NSCLC").

There are no commercial and/or financial benefits of the Drug Division for the Company at the present time, resulting in zero revenue, sales or commercial distribution of this technology.

Theralase® conducts its own research and development in the Drug Division, as well as enlisting the support of external scientific, research, regulatory and Clinical Research Organizations ("CROs").

## **Phase II NMIBC Clinical Study ("Study II")**

Theralase® designed Study II to utilize the Therapeutic Dose (0.70 mg/cm<sup>2</sup>) of Ruvidar® and focus on the treatment of approximately 100 BCG-Unresponsive NMIBC patients presenting with persistent or recurrent CIS with or without resected T<sub>a</sub>/T<sub>1</sub> (non-invasive/resected papillary disease/tumour that invades the subepithelial connective tissue) disease diagnosed within 12 months of completion of adequate BCG therapy (BCG-Unresponsive) or who are intolerant to BCG therapy ("Study II").

Study II was designed to enroll and treat patients in up to 15 Clinical Study Sites (“**CSSs**”) located in Canada and the US. To date, Theralase® has successfully launched 12 CSSs ; specifically, 5 CSSs in Canada and 7 CSSs in the US, with 2 US CSSs terminating patient enrollment in Study II, leaving 5 active CSSs in Canada and 5 active CSSs in the US.

Theralase® plans to launch up to 5 new CSSs in Canada and the US in 2024.

Study II (NCT03945162) is an ongoing, Phase II, open-label, single-arm, multi-center study conducted in Canada and the US evaluating the safety and efficacy of the Company’s Study Drug activated by the Study Device (collectively the “**Study Procedure**”).

### **Study II Objectives:**

**Primary:** Efficacy, evaluated by Complete Response (“**CR**”) at any point in time in patients confirmed to have CIS (with or without resected papillary disease (T<sub>a</sub> / T<sub>1</sub>)) during the screening process.

CR is defined by at least one of the following:

- Negative cystoscopy and negative (including atypical) urine cytology
- Positive cystoscopy with biopsy-proven benign or low-grade NMIBC and negative cytology
- Negative cystoscopy with malignant urine cytology, if urothelial cancer is suspected in the upper tract or prostatic urethra and random bladder biopsies are negative

**Secondary:** Duration of CR at 12 months post initial CR.

**Tertiary:** Safety, evaluated by the incidence and severity of Adverse Events (“**AEs**”), Grade 4 or higher that do not resolve within 450 days post treatment (Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life-threatening or disabling, Grade 5 = Death).

Indeterminate Response (“**IR**”) is defined as patients who present with a negative cystoscopy and positive urine cytology, but do not have a confirmatory bladder biopsy at that assessment visit.

IR patients can be re-classified to CR patients, if they have a confirmatory bladder biopsy or subsequent assessments of CR can be carried back.

Patients who achieve CR or IR at 90 days and continue to demonstrate a CR or IR response at 450 days will be followed to assess the duration of their CR up to 1080 days.

The Study Treatment consists of a Study Drug (Ruvidar™) at the Therapeutic Dose (0.70 mg/cm<sup>2</sup>) (equivalent to 0.65 mg/cm<sup>2</sup> of active drug moiety) instilled into the patient’s bladder intravesically for approximately sixty (60) minutes and subsequently activated by the Study Device (“**TLC-3200 Medical Laser System**” or “**TLC-3200**”) to deliver an intended energy density of 90 J/cm<sup>2</sup> (approximately 60 to 180 minutes depending on bladder volume).

In 2018, Health Canada granted the Company both a Clinical Trial Application (“**CTA**”) for the Study Drug (Ruvidar™) and an Investigational Testing Authorization (“**ITA**”) for the Study Device (TLC-3200) to allow commencement of enrolling and treating patients in Study II.

On October 23, 2023, Theralase® was granted a Clinical Trial Application Amendment (“**CTA-A**”) by Health Canada through receipt of a No Objection Letter (“**NOL**”) for the optimization of the Phase II Non-Muscle Invasive Bladder Cancer (“**NMIBC**”) clinical study (“**Study II**”).

On February 9, 2024, Theralase® was granted an Investigational New Drug (“**IND**”) by the FDA for the optimization of the Study II.

The Study II optimization consisted of:

1. **Post Study II Monitoring of Response** - Patients, who achieved a Complete Response ("CR") or Indeterminate Response ("IR"), demonstrated a duration of that response at 450 days and remained in Study II will be monitored by the Company up to 1080 days, to help define the long-term duration of the Study Procedure.
2. **Optional Maintenance Study II Treatment** -Patients originally received a mandatory maintenance Study Procedure at 180 days; however, this has been optimized to allow optional re-induction Study Procedures, at the discretion of the Principal Investigator ("PI") based on the patient's response. For patients who have achieved a CR or IR at any point in time and have demonstrated a duration of that CR or IR, no further re-induction Study Procedures would be administered; however, if the patient recurs at any scheduled assessment visit (i.e.: 90, 180, 270, 360 or 450 days), then that patient would be eligible to receive up to two (2) re-induction Study Procedures at the discretion of the PI to assist the patient in achieving a CR.
3. **Central Pathology Laboratory Review** - Use of a central pathology laboratory to validate local pathology laboratory results.

As of May 29<sup>th</sup>, 2024, the following CSSs are continuing to accrue patients to Study II by enrolling and providing the primary Study Procedure to patients:

| Clinical Study Sites                       | Location                                    | Commenced         |
|--|---|-------------------|
| University Health Network ("UHN")          | Toronto, Ontario, Canada                    | April 25, 2019    |
| McGill University Health Centre ("MUHC")   | Montreal, Quebec, Canada                    | July 30, 2019     |
| London Health Sciences Centre ("LHSC")     | London, Ontario, Canada                     | October 7, 2019   |
| Nova Scotia Health Authority ("NSHA")      | Halifax, Nova Scotia, Canada                | February 25, 2020 |
| University of British Columbia ("UBC")     | Vancouver, British Columbia, Canada         | December 7, 2020  |
| Urology Associates P.C. ("UAPC")           | Nashville, Tennessee, United States         | January 20, 2021  |
| Carolina Urologic Research Center ("CURC") | Myrtle Beach, South Carolina, United States | January 27, 2021  |
| University of Wisconsin-Madison ("UWM")    | Madison, Wisconsin, United States           | February 24, 2021 |
| Urology San Antonio P. A. ("USAPA")        | San Antonio, Texas, United States           | March 25, 2021    |
| University of Chicago ("UC")               | Chicago, Illinois, United States            | June 11, 2021     |

On February 8<sup>th</sup>, 2024, Dr. Michael Jewett joined the Company in the role of an independent consultant, to assist the Company in the completion of enrollment of patients in Study II. Under the terms of the consulting agreement, Dr. Jewett will be responsible for working with existing clinical study sites and helping to onboard new clinical study sites to allow Theralase® to complete enrollment and provide the primary study treatment to all 100 patients in Study II, preferably by December 31, 2024.

Study II commenced in April 2019 with an estimated completion time of approximately 8 years and an estimated cost of approximately \$CAN 100 million. The timing and cost may vary significantly depending on numerous factors, including; number of CSSs enrolling and treating patients, patient enrollment rates in total and at each CSS, patient compliance, successful achievement of Study II primary, secondary and tertiary objectives.

**Study II Clinical Study Site Update:**

The Company implemented a Study Procedure optimization, as communicated via press release on July 30<sup>th</sup>, 2020, specifically, optimization in the:

- a) Bladder volume calculation
- b) Study Drug volume calculation
- c) Study Device volume calculation
- d) Study Device treatment time

which was implemented in patients enrolled and treated by the CSSs, for either the primary or re-induction Study Procedure on or after August 1<sup>st</sup>, 2020.

To date, Theralase® has enrolled and treated 68 patients in Study II, who have been provided the primary Study II Procedure.

Theralase® is working to add up to 5 new CSSs in 2024, as well as increase enrollment at the existing 10 CSSs to complete Study II accrual by the end of 2024.

All patients received the primary Study Procedure (n=68).

Approximately 50% of the patients received the maintenance Study Procedure (n=33)

Of the 33 patients who received the maintenance Study Procedure, 25 were CR prior to treatment, 4 were IR and 4 were No Response ("NR") (positive cystoscopy and positive urine cytology).

In conclusion, the primary Study Procedure provides a 58% opportunity for CR at the 90 day assessment.

### **Break Through Designation Update:**

In 2020, the FDA granted Theralase® Fast Track Designation ("FTD") for Study II. As a Fast Track designee, Theralase® has access to early and frequent communications with the FDA to discuss Theralase®'s development plans and ensure the timely collection of clinical data to support the approval process. The accelerated communication with the FDA potentially allows, the Study Procedure, to be the first intravesical, patient-specific, light-activated, Ruthenium-based PDC for the treatment of patients diagnosed with BCG-Unresponsive NMIBC CIS, (with or without recurrent / resected papillary T<sub>a</sub>/T<sub>1</sub> tumours). FTD can also lead to Break Through Designation ("BTD"), Accelerated Approval ("AA") and/or Priority Review, if certain criteria are met, which the FDA previously defined to the Company for BTD as clinical data on approximately 20 to 25 patients enrolled and provided the primary Study Procedure, who demonstrate significant safety and efficacy clinical outcomes.

To this list, the FDA has added: Post Study II Monitoring of Response and Central Pathology Laboratory Review, as further defined above.

The Company is currently working with the CSSs, a biostatistics organization and a regulatory organization to update the pre-BTD submission with clinical data clarifications identified by the FDA. The Company plans to resubmit the pre-BTD submission to the FDA in 2Q2024 / 3Q2024 for FDA review of these clarifications. Once the pre-BTD submission has been accepted by the FDA, the Company plans to compile a BTD submission for review by the FDA in support of the grant of a BTD approval.

Theralase® has commenced receiving clinical data from the CSSs with a number of patients showing a duration of their CR beyond 450 days, with some patients demonstrating CR for up to 3 years post the primary Study Procedure.

Additional clinical data is required, prior to a pre-BTD submission to the FDA.

### **Study II Preliminary Clinical Data:**

To date, Study II has provided the primary study treatment for 68 patients.

In recent discussions with the MSAB for Study II, the MSAB advised the Company to review the FDA Guidance to Industry<sup>1</sup> on how to best classify Indeterminate Response ("IR") patients (patients assessed with negative cystoscopy and positive urine cytology, without confirmatory bladder biopsies), where the source of the positive urine cytology has not been determined.

The FDA Guidance to Industry<sup>1</sup> states as follow:

*"For single-arm trials of patients with BCG-unresponsive disease, the FDA defines a complete response as at least one of the following:*

- *Negative cystoscopy and negative (including atypical) urine cytology*
- *Positive cystoscopy with biopsy-proven benign or low-grade NMIBC and negative cytology*

*For intravesical therapies without systemic toxicity, the FDA includes, in the definition of a complete response, negative cystoscopy with malignant urine cytology if cancer is found in the upper tract or prostatic urethra and random bladder biopsies are negative.*

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<sup>1</sup> BCG-Unresponsive Nonmuscle Invasive Bladder Cancer: Developing Drugs and Biologics for Treatment – Guidance for Industry. February 2018; [www.fda.gov/media/101468/download](http://www.fda.gov/media/101468/download)

In accordance with the FDA Guidance to Industry<sup>1</sup>, patients enrolled and provided the primary Study Procedure, where the source of the positive urine cytology has not been identified (i.e.: upper tract or prostatic urethra Urothelial Cell Carcinoma ("UCC")) and confirmatory bladder biopsies are negative, Theralase® has reclassified these patients from IR to CR.

For patients, who have been enrolled and provided the primary Study Procedure in Study II, that have been diagnosed as IR and do not have confirmatory negative bladder biopsies (confirming that the source of the UCC is not from the bladder wall), then these patients have remained classified as IR, until additional clinical assessments are completed to prove or disprove a diagnosis of CR.

As a result, Theralase® updated its Study II's interim clinical study data analysis, where some patients have been reclassified from IR to CR on certain assessment days.

In accordance with the FDA Guidance to Industry<sup>1</sup>, Theralase® will conduct sensitivity analyses, in which IR patients both considered to have achieved CR and those not considered to have achieved a CR, as a part of the final clinical report.

In 2016, Kamat et al. stated in the Journal of Clinical Oncology that the International Bladder Cancer Group ("IBCG") recommended that, "Single-arm designs may be relevant for the BCG-unresponsive population. Here, a clinically meaningful initial complete response rate (for carcinoma in situ) or recurrence-free rate (for papillary tumors) of at least 50% at 6 months, 30% at 12 months, and 25% at 18 months is recommended."<sup>2</sup>

The interim clinical data presented below exceeds these IBCG guidelines.

**Performance to Primary, Secondary and Tertiary Objectives:**

| Assessment                    | Primary Objective Performance |     | Secondary Objective Performance |     | Tertiary Objective Performance |      |
|-------------------------------|-------------------------------|-----|---------------------------------|-----|--------------------------------|------|
|                               | #                             | %   | #                               | %   | #                              | %    |
| Complete Response ("CR")      | 39                            | 63% | 19                              | 33% | 57                             | 100% |
| Indeterminate Response ("IR") | 5                             | 8%  | 1                               | 2%  | 0                              | 0%   |
| Total Response (CR and IR)    | 44                            | 71% | 20                              | 35% | 57                             | 100% |
| Evaluable Patients            | 62                            |     | 57                              |     | 57                             |      |

The interim clinical data above demonstrates that:

For the primary objective, 63% of patients provided the Study Procedure (Study Drug activated by the Study Device) demonstrated a Complete Response ("CR") (negative cystoscopy and negative urine cytology). Including patients, who demonstrated an Indeterminate Response ("IR") (negative cystoscopy and positive or suspicious urine cytology), the Total Response ("TR") increases to 71%. This represents approximately 3 out of 4 Bacillus Calmette Guérin ("BCG")-Unresponsive Non-Muscle Invasive Bladder Cancer ("NMIBC") Carcinoma In-Situ ("CIS") patients treated with Theralase®'s unique Study Procedure are demonstrating complete destruction of their CIS bladder cancer within their bladders.

For the secondary objective, 33% (approximately 1 out of 3) patients demonstrated a duration of their CR for 15 months from date of first treatment with 35% of patients demonstrating a TR.

For the tertiary objective, no patients have been diagnosed with a Serious Adverse Event ("SAE") directly related to the Study Drug or Study Device.

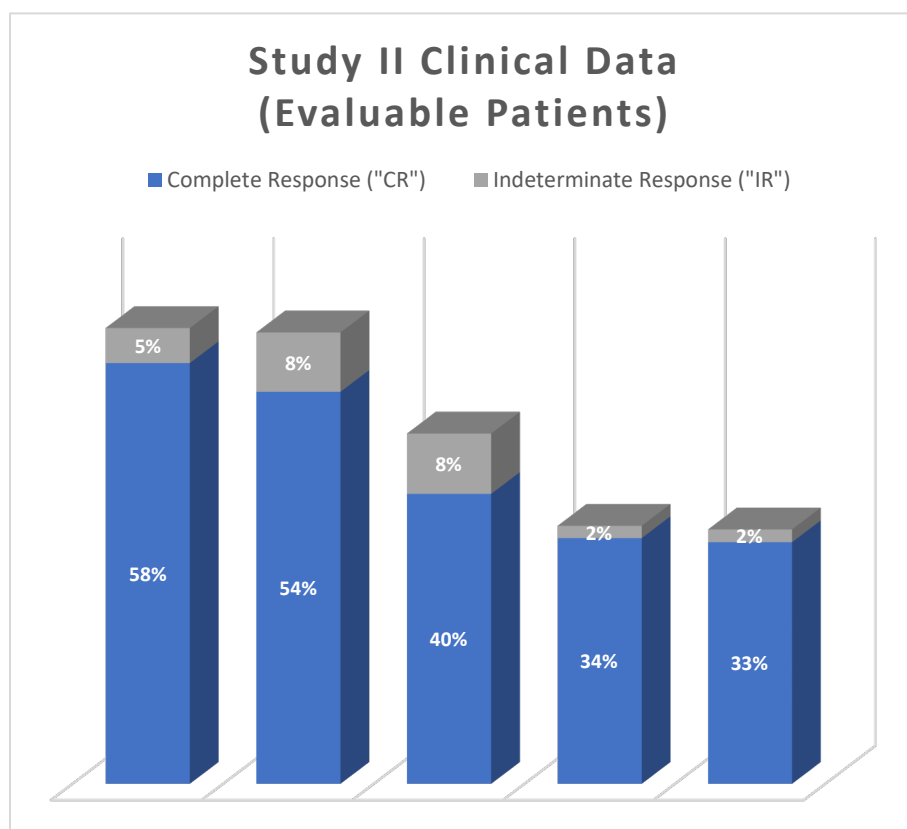
**Note:** One patient is currently under investigation for their secondary objective performance, as they demonstrated a CR, potentially recurred and demonstrated a CR once again.

<sup>2</sup> Kamat AM et al. J Clin Oncol. 2016; 34: 1935-1944

**Study II Clinical Data Based on Assessment Visit:**

| Assessment                    | Patient Assessment Visit |     |          |     |          |     |          |     |          |     |
|-------------------------------|--------------------------|-----|----------|-----|----------|-----|----------|-----|----------|-----|
|                               | 90 Days                  |     | 180 Days |     | 270 Days |     | 360 Days |     | 450 Days |     |
|                               | #                        | %   | #        | %   | #        | %   | #        | %   | #        | %   |
| Complete Response ("CR")      | 36                       | 58% | 33       | 54% | 24       | 40% | 20       | 34% | 19       | 33% |
| Indeterminate Response ("IR") | 3                        | 5%  | 5        | 8%  | 5        | 8%  | 1        | 2%  | 1        | 2%  |
| Total Response (CR and IR)    | 39                       | 63% | 38       | 62% | 29       | 48% | 21       | 36% | 20       | 35% |
| Evaluable Patients            | 62                       |     | 61       |     | 60       |     | 59       |     | 57       |     |

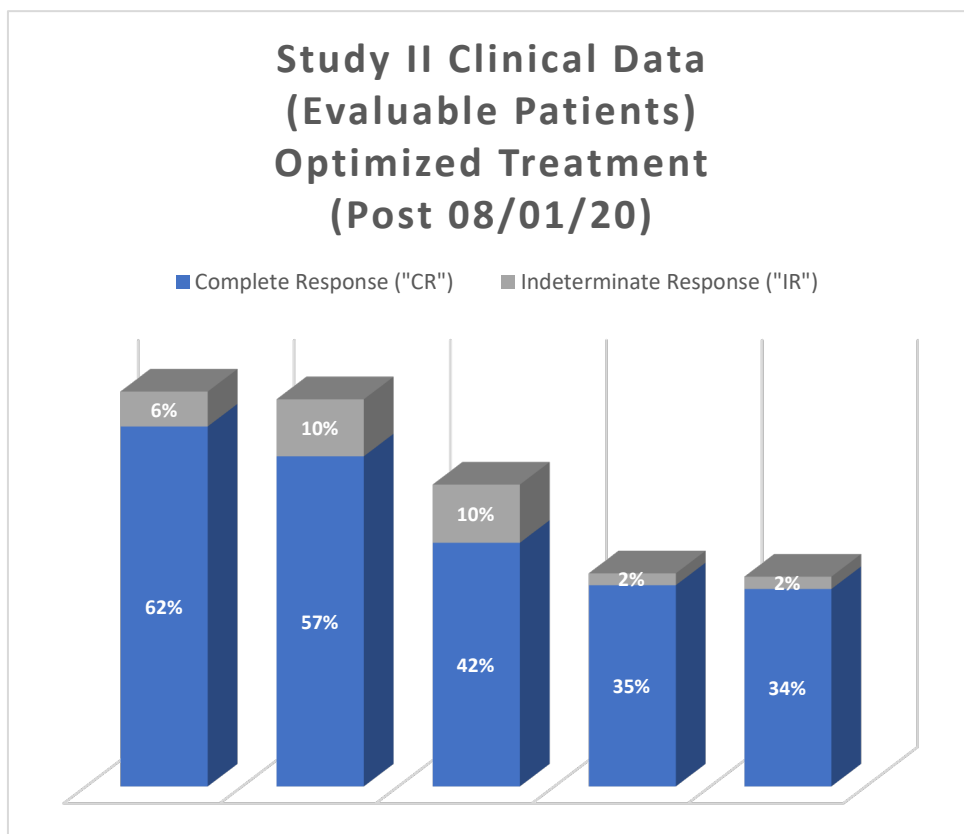
The interim clinical data demonstrates that at the 90 Day Assessment 58% of Evaluable Patients achieved a CR and 63% achieved a Total Response (CR + IR) post primary Study II Treatment and at 450 days 33% achieved a CR and 35% achieved a TR.



**Study II Clinical Data Based on Assessment Visit for Patients Treated with the Optimized Study Procedure (Post August 1, 2020):**

| Assessment                    | Patient Assessment Visit – Optimized Study Procedure |     |          |     |          |     |          |     |          |     |
|-------------------------------|--|-----|----------|-----|----------|-----|----------|-----|----------|-----|
|                               | 90 Days  |     | 180 Days |     | 270 Days |     | 360 Days |     | 450 Days |     |
|                               | #  | %   | #        | %   | #        | %   | #        | %   | #        | %   |
| Complete Response ("CR")      | 31   | 62% | 29       | 57% | 21       | 42% | 17       | 35% | 16       | 34% |
| Indeterminate Response ("IR") | 3  | 6%  | 5        | 10% | 5        | 10% | 1        | 2%  | 1        | 2%  |
| Total Response (CR and IR)    | 34   | 68% | 34       | 67% | 26       | 52% | 18       | 37% | 17       | 36% |
| Evaluable Patients            | 50   |     | 51       |     | 50       |     | 49       |     | 47       |     |

The above interim clinical data demonstrates that for patients who received the Optimized Study Procedure at the 90 Day assessment visit, 62% of Evaluable Patients achieved a CR and 68% achieved a Total Response (CR + IR) post the primary Study Procedure. At 450 days, 34% achieved a CR and 36% achieved a TR.

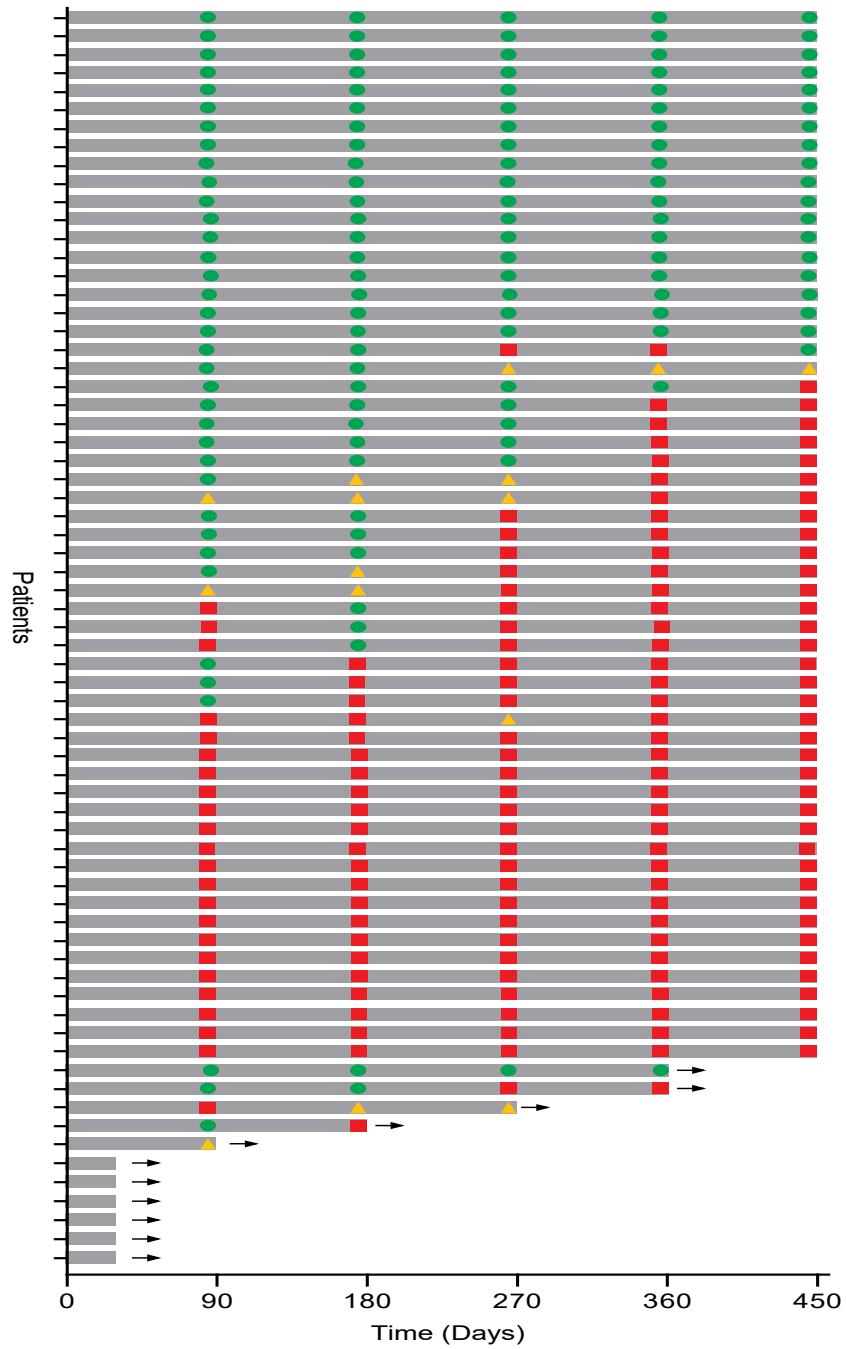


**Note:**

- For patients to be included in the statistical clinical analysis they must be enrolled in Study II, provided the primary Study Procedure and evaluated by a PI at the 90 day assessment visit (cystoscopy and urine cytology)
- One patient passed away prior to their 90 day assessment and is therefore not included in the efficacy statistical analysis, only in the safety statistical analysis; therefore, there are 68 patients that have been statistically analyzed for efficacy.
- Evaluable Patients are defined as patients who have been evaluated by a PI and thus excludes a patient's clinical data at specific assessment days, if that clinical data is pending.
- Six patients have been enrolled and provided the primary Study Procedure but, have not been evaluated at their 90 day assessment; therefore, 62 patients are considered Evaluable Patients at 90 days, with 57 patients considered Evaluable Patients at 450 days.
- The data analysis presented above, should be read with caution, as the clinical data is interim in its presentation, as Study II is ongoing and new clinical data collected may or may not continue to support the current trends, with clinical data still pending.
- For patients who have been removed from the study by the PI or have elected to discontinue from the clinical study their Last Observation Carried Forward ("**LOCF**") has been used in this statistical analysis.

**Patient Response Chart:**

The Swimmer's plot below is a graphical representation of the interim clinical results (n=68) graphically demonstrating a patient's response to a treatment over time. As can be seen in the plot, clinical data is still pending for patients, who have demonstrated an initial CR at 90 days and continue to demonstrate a duration of that response.



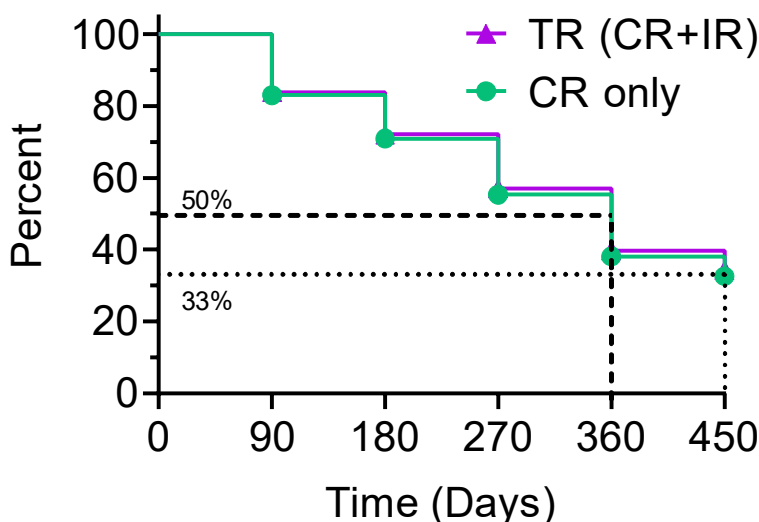
- Complete Response ("CR")
- HG NMIBC
- ▲ Indeterminate Response("IR")
- Patients have pending visits, treatment, or analysis.

### The Swimmer's Plot illustrates:

- 19 Evaluable Patients achieved CR initially and at the 450 day assessment visit and thus achieved the primary and secondary objectives of Study II for all patients assessed up to 450 days (19/57 = 33%).
- 39 Evaluable Patients that achieved CR on at least one assessment date and thus achieved the primary objective of Study II (39/62 = 63%)

### Kaplan-Meier Curve:

The Kaplan-Meier (“KM”) Curve represents the interim cumulative incidence of clinical events, including the treatment efficacy, occurring over prespecified time in Study II.



### According to the interim clinical data in the KM curve:

- > 80% of patients remained in Study II after 90 days, following the initial Study Procedure.
- 35% of Total Response patients have a duration of response  $\geq$  450 days.
- 33% of Complete Response patients have a duration of response  $\geq$  450 days.

### Serious Adverse Events

For 68 patients treated in Study II, there have been 13 Serious Adverse Events (“SAEs”) reported:

- 2 – Grade 2 (resolved within 1 and 1 days, respectively)
- 7 – Grade 3 (resolved within 1, 2, 3, 4, 4, 82 and unknown days, respectively)
- 3 – Grade 4 (resolved within 3, 6 and 8 days, respectively)
- 1 – Grade 5

Theralase® believes all SAEs reported to date are unrelated to the Study II Drug or Study II Device, as reviewed and confirmed by the independent Data Safety Monitoring Board (“DSMB”).

**Note:** A SAE is defined as any untoward medical occurrence that at any dose: Is serious or life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect or results in death.

### Study II Interim Data Presentations:

An advisory board meeting was completed on April 12, 2024 during the Canadian Urologic Association (“CUA”) Bladder Cancer Forum 2024 located in Toronto, Ontario and provided an update to all Canadian PIs of the Study II interim clinical data and an opportunity to discuss patient enrollment.

An advisory board meeting was completed on May 4<sup>th</sup>, 2024 during the 2024 American Urology Association (“**AUA**”) meeting in San Antonio, Texas and provided an update to all attendees of the Study II interim clinical data and an opportunity to discuss patient enrollment.

#### **Additional Oncology Targets:**

Theralase® has been granted international patents supporting a comprehensive Intellectual Property (“**IP**”) platform of its PDCs. The scientific and preclinical research and development of these PDCs has been optimized by fine-tuning the photophysical and photochemical properties of the PDCs, allowing them to demonstrate both Type I (oxygen limited) and Type II (oxygen dependent) photoreactions and activation in hypoxia.

By combining these PDCs with transferrin (human glycoprotein), as a delivery system it has been preclinically demonstrated that transferrin is able to significantly:

- Increase the resistance of Ruvidar™, the lead drug candidate, to photobleaching (loss of potency of the PDC over time)
- Increase Reactive Oxygen Species (“**ROS**”) production (ability to destroy cancer cells quickly and effectively)
- Increase selective tumour uptake (destruction of cancer cells, while sparing healthy cells) through the Transferrin Receptor (“**TfR**”)
- Increase anti-cancer efficacy (efficiency in cancer cell destruction)
- Decrease systemic toxicity (damage to healthy cells and/or organs)

This allows Rutherrin® (Ruvidar™ + transferrin) to be a strong candidate for the systemic treatment of recurrent, deep seated and/or progressive cancers. The Company continues to conduct extensive scientific and preclinical research and development towards new oncology indications and has developed significant expertise and IP assets regarding its patented PDCs, in pursuit of this goal.

Due to the limitations of using laser light to activate Rutherrin® in deep oncological targets, Theralase®’s research strongly suggests that Rutherrin® may be activated with radiation therapy, which is able to increase the “tumour’s damage zone” and the effectiveness of Theralase®’s PDT beyond the reach of light in the body.

Radiotherapy (“**RT**”) is one of the primary treatment methodologies for many types of cancer, although it is currently a challenge to enhance radiation damage to tumour tissue, while reducing side effects to healthy tissue.

Rutherrin® is a unique agent that offers the ability to enhance injury to tumor tissue by accelerating damage through the production of ROS and free radicals; thereby, acting as a radio enhancer. Several preclinical strategies have been investigated by Theralase®’s scientists to research, develop, optimize and advance highly selective and effective radio sensitizing properties of Rutherrin®.

Rutherrin® activation via RT is preferential to light activation due to the much deeper tissue penetration of RT.

Further research and development is currently underway into the mechanisms of action of Rutherrin®, its multidisciplinary applications, delivery methodologies, safety and efficacy.

Once Rutherrin®’s Maximum Tolerated Dose (“**MTD**”) and hence Human Equivalent Dose (“**HED**”) limits have been determined through Good Laboratory Practices (“**GLP**”) toxicology studies, Theralase®, subject to the required regulatory approvals, plans to intravenously inject Rutherrin® into patients via a Phase Ib/II adaptive clinical study design, to first determine localization to various cancer cells, including Glio Blastoma Multiforme (“**GBM**”) and Non-Small Cell Lung Cancer (“**NSCLC**”) and then in an adaptive design activate Rutherrin® with radiation with the intent of safely and effectively destroying the cancer of interest.

Rutherrin®, if proven successful, would thus be able to “hunt” and “localize” into cancer cells and when activated by radiation “destroy” them; wherever, they may reside in the body.

#### **Additional Virus Targets:**

Theralase® executed a Sponsored Research Agreement (“**SRA**”) with the University of Manitoba (“**UM**”) Medical Microbiology department in July 2020, which has been subsequently extended to June 2024, to commence development of a coronavirus vaccine utilizing Theralase®’s patented and proprietary PDCs. The primary objective of the SRA was to investigate the efficacy of Theralase®’s lead PDC to destroy a variety of viruses; including: H1N1 Influenza, Zika and coronaviruses (Biological Safety Level (“**BSL**”) 2). The

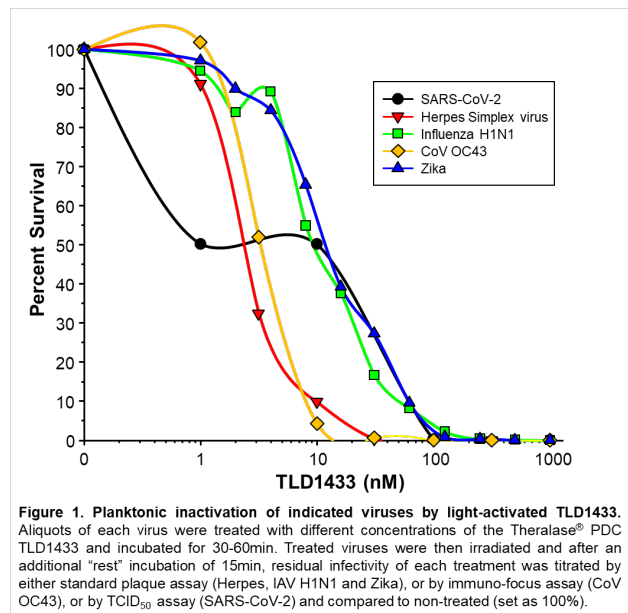
secondary objective was to optimize the concentration of PDC required, the activation methodology and how to potentially administer the treatment to humans to be used as a vaccine (prevention of a patient from contracting COVID-19) (BSL-3).

The Company's PDC technology was effective in the destruction of H1N1 Influenza and Zika viruses at low nanomolar concentrations and the research and development was expanded to include coronavirus (BSL-2).

**Note:** COVID-19 is caused by coronavirus (BSL-3), not coronavirus (BSL-2).

A rapid test 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 H1N1 Influenza and Zika viruses. These drug doses are significantly lower than those used by the Company to treat cancers and are therefore considered safe for human use.

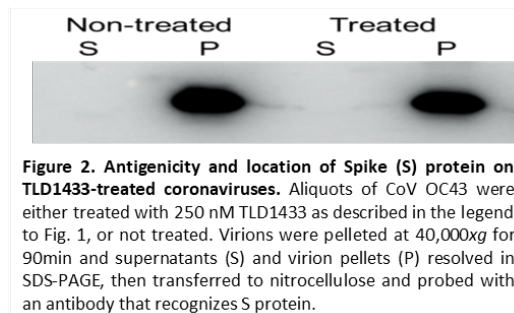
All coronaviruses are highly similar in their structure and these new results suggest that Theralase®'s proposed vaccine could be highly effective against the SARS-CoV-2 virus responsible for COVID-19. Further studies have shown that the human coronavirus ("CoV") appears to be much more sensitive to the action of the activated Theralase® PDC vaccine, with a dose as low of 3.3 nM required to inactivate 50%, whereas; 9.2 nM was required to inactivate the same amount of H1N1 Influenza virus and 12 nM was required to inactivate the same amount of Zika virus. The amount of PDC required to inactivate 99.9% of each virus are 61 nM for CoV, 322 nM for Zika virus and 497 nM for H1N1 Influenza virus, respectively; thus, the Theralase® PDC is 3 to 5 times more effective against CoV compared to the other tested viruses.



### Planktonic Inactivation of Indicated Viruses by Light-Activated TLD-1433

The Theralase® compound is also effective without activation, but on average, its activation results in a 4.2 fold increase in Zika virus inactivation, a 12 fold increase in H1N1 Influenza inactivation and an 18.7 fold increase in CoV inactivation.

Further research by UM also identified that the spike protein responsible for the transmission of a coronavirus into a host cell, remained intact after light-activated TLD-1433 inactivation, suggesting that the vaccine developed by this technology could potentially stimulate a protective antibody immune response in a mammalian host.



In April 2021, Theralase® executed a Collaborative Research Agreement (“**CRA**”) with the National Microbiology Laboratory, Public Health Agency of Canada (“**PHAC**”) for the research and development of a Canadian-based SARS-CoV-2 (“**COVID-19**”) vaccine. Under the terms of the agreement, Theralase® and PHAC are collaborating on the development and optimization of a COVID-19 vaccine by treating the SARS-CoV-2 virus grown on cell lines with Theralase®’s patented PDC and then light activating it with Theralase®’s proprietary TLC-3000A light technology to inactivate the virus and create the fundamental building blocks of a COVID-19 vaccine. This inactivated virus could then be purified and used to inoculate naive animals, followed by challenge with the SARS-CoV-2 virus, to ascertain the efficacy of the vaccine. The project is entitled, “**Photo Dynamic Compound Inactivation of SARS-CoV-2 Vaccine**” and commenced in mid-April 2021.

In February 2022 Theralase® reported that PHAC had demonstrated that light-activated TLD-1433 (Trade Name: Ruvidar™), was effective in rapidly inactivating the SARS-CoV-2 virus by up to 99.99%, compared to control in an in vitro study. Further research is required to confirm these findings.

These results have now laid the groundwork for the next phase of the CRA, which is evaluating the Theralase® COVID-19 vaccine in the ability to prevent animals from contracting COVID-19, when exposed to the virus, which commenced in 4Q2023 and is expected to be completed by 4Q2024.

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

### **Intellectual Property Portfolio Growth**

Theralase® received the following decisions to grant a patent in 2024:

| Country | Patent Title  |
|---------|---|
| CAD     | Vaccine Containing Cancer Cells Inactivated by Photodynamic Treatment with Metal-Based Coordination Complexes and Immunotherapy Method Using Same |

The patent protects Theralase® PDC technology in the treatment of a patient with a cancer vaccine; specifically, programmed to destroy their cancer. This is fundamentally accomplished by obtaining a sample of their cancer and treating it extracorporeally with a Theralase® PDC and then activating the PDC with either light or radiation. This inactivated cancer is then injected back into the patient intravenously, programming the patient’s immune system to recognize, attack and destroy the particular cancer of interest.

### **Overview of Financial Performance:**

During the three-month period ended March 31<sup>st</sup>, 2024, the Company's financial performance and its operating results reflect the continued investment by the Company into its future prosperity through the research, development, preclinical and clinical initiatives culminating in the successful completion of the Phase Ib NMIBC clinical study and the launch of Study II.

### **Summary of Selected Audited Annual Information:**

(Canadian Dollars)

For the twelve-month periods ended December 31<sup>st</sup>:

|                                  | <b>2023</b>  | <b>2022</b>  |
|----------------------------------|--------------|--------------|
| Total revenues                   | \$ 1,070,307 | \$ 1,138,569 |
| Net loss                         | (4,570,879)  | (5,235,302)  |
| Basic and diluted loss per share | \$ 0.022     | \$ (0.025)   |
| <br>                             |              |              |
| Total assets                     | \$ 3,276,806 | \$ 4,160,904 |
| Total liabilities                | 1,371,364    | 1,068,336    |
| Deficit                          | (63,240,005) | (58,451,686) |
| Shareholders' Equity             | \$ 1,905,442 | \$ 3,092,568 |

**Summary of Quarterly Results:**

(Canadian Dollars)

|                                  | <b>2024</b>     |                |                     |                    |
|----------------------------------|-----------------|----------------|---------------------|--------------------|
|                                  | <b>March 31</b> |                |                     |                    |
| <b>For the period ending:</b>    |                 |                |                     |                    |
| Total revenues                   | \$              | 175,554        |                     |                    |
| Net loss                         |                 | (1,266,711)    |                     |                    |
| Basic and diluted loss per share | \$              | (0.006)        |                     |                    |
| <b>As at:</b>                    |                 |                |                     |                    |
| Total assets                     | \$              | 3,246,059      |                     |                    |
| Total liabilities                |                 | 1,275,610      |                     |                    |
| Deficit                          |                 | (64,506,716)   |                     |                    |
| Shareholders' Equity             | \$              | 1,970,449      |                     |                    |
|                                  |                 |                |                     |                    |
|                                  | <b>2023</b>     |                |                     |                    |
|                                  | <b>March 31</b> | <b>June 30</b> | <b>September 30</b> | <b>December 31</b> |
| <b>For the period ending:</b>    |                 |                |                     |                    |
| Total revenues                   | \$              | 207,161        | \$                  | 218,926            |
| Net loss                         |                 | (1,408,953)    |                     | (1,155,234)        |
| Basic and diluted loss per share | \$              | (0.007)        | \$                  | (0.005)            |
|                                  |                 |                | \$                  | 280,608            |
|                                  |                 |                | \$                  | 363,612            |
|                                  |                 |                |                     | (991,024)          |
|                                  |                 |                | \$                  | (0.005)            |
|                                  |                 |                | \$                  | (0.005)            |
| <b>As at:</b>                    |                 |                |                     |                    |
| Total assets                     | \$              | 3,200,969      | \$                  | 3,380,338          |
| Total liabilities                |                 | 1,350,759      |                     | 1,342,906          |
| Deficit                          |                 | (60,078,080)   |                     | (61,233,313)       |
| Shareholders' Equity             | \$              | 1,850,210      | \$                  | 2,037,432          |
|                                  |                 |                | \$                  | 1,631,868          |
|                                  |                 |                | \$                  | 1,905,442          |

**Liquidity and Capital Resources:**

As of March 31<sup>st</sup>, 2024, total current assets aggregated \$1,540,118 compared with total current liabilities of \$1,006,028 netting working capital of \$534,090 and a current ratio (current assets versus current liabilities) of approximately 1.5:1.

The Company's objective is to maintain a sufficient capital base to support future research, development and strategic business initiatives allowing the Company to invest in its future and maintain investor, creditor and market confidence. The capital structure of the Company consists of cash, cash equivalents and shareholders' equity.

The Company is not subject to any externally imposed capital requirements and the Company does not use financial ratios to manage capital. There were no changes in the Company's approach to capital management during the years presented.

**Going Concern:**

The unaudited interim condensed consolidated financial statements have been prepared by management in accordance with International Financial Reporting Standards ("**IFRS**") as issued by the International Accounting Standards Board ("**IASB**") and including interpretations of the IFRS Interpretations Committee ("**IFRSIC**") on a going concern basis, which contemplates the realization of assets and the discharge of liabilities in the normal course of business for the foreseeable future.

For the three-month period ended March 31, 2024, the Company had a net loss of \$1,266,711 (2023 - \$1,408,953), an accumulated deficit of \$64,506,716 (December 31, 2023 -\$63,240,005) and has historically used net cash in operations.

These conditions indicate the existence of material uncertainties that cast substantial doubt about the Company's ability to continue as a going concern, which is dependent upon achieving a profitable level of operations and obtaining additional financing, neither of which is assured.

The Company's objective is to maintain a sufficient capital base to support future research, development and strategic business initiatives allowing the Company to invest in its future and maintain investor, creditor and market confidence. Sales of the TLC-2000, the Company's existing product line have not met expectations and have not been sufficient in and of themselves to enable the Company to fund all its continuing development and commercialization efforts and, accordingly the Company will require additional capital to continue to research and develop its drug technology and market its device products as it continues to develop sales opportunities. The Company is currently seeking new financing opportunities and intends to complete a financing round in Q2 and Q3 2024. The Company has successfully raised capital through equity offerings in 2024, 2023 and 2022, however, there is no guarantee that the Company will be able to raise additional capital on terms and conditions agreeable to the Company. The Company continues to closely monitor its expenses to preserve cash resources until new financing is obtained. These material uncertainties may cast significant doubt about the Company's ability to continue as a going concern.

Management believes the Company will continue in operation for the foreseeable future and will be able to secure additional financing to satisfy its liabilities and commitments in the normal course of business, and accordingly, it is appropriate to prepare these consolidated financial statements on a going concern basis.

### **Results of Operations:**

#### **Sales:**

For the three-month period ended March 31, 2024, total revenue decreased to \$175,527 from \$207,161 for the same period in 2023, a 15% decrease.

|                 | <b>2024</b> |                | <b>2023</b> |         |
|-----------------|-------------|----------------|-------------|---------|
| Sales Revenue   | \$          | <b>154,772</b> | \$          | 145,084 |
| Service Revenue |             | <b>17,464</b>  |             | 51,134  |
| Other Revenue   |             | <b>3,291</b>   |             | 10,943  |
|                 | \$          | <b>175,527</b> | \$          | 207,161 |

The TLC-2000 represented 95% of sales for the three-month period ended March 31, 2024 and 77% of sales for the same period in 2023.

In Canada, revenue decreased 20% to \$122,098 from \$152,124. In the US, revenue decreased 42% to \$31,847 from \$55,037. International sales increased to \$21,609 from \$Nil.

#### **Cost of Sales:**

Cost of sales for the three-month period ended March 31, 2024 was \$113,440 or 65% of revenue resulting in a gross margin of \$62,114 or 35% of revenue. In comparison, the cost of sales for the same period in 2023 was \$114,638 or 55% of revenue resulting in a gross margin of \$92,523 or 45% of revenue. Cost of sales is represented by the following costs: raw materials, subcontracting, direct and indirect labour and the applicable share of manufacturing overhead.

The gross margin increase, as a percentage of sales, year over year, is attributed to an increase in material costs.

#### **Operating Expenses:**

For the three-month period ended March 31, 2024, selling expenses decreased to \$67,552, from \$74,671 for the same period in 2023, a 10% decrease and consisted of the following items:

|  | <b>2024</b>      | <b>2023</b>      |
|--|------------------|------------------|
| Sales salaries                           | \$ 49,074        | \$ 51,190        |
| Advertising                              | 5,849            | 3,464            |
| Commission                               | 5,996            | 8,108            |
| Travel                                   | 2,182            | 8,556            |
| Stock based compensation                 | 1,024            | -                |
| Amortization and depreciation allocation | 3,428            | 3,353            |
| <b>Total selling expenses</b>            | <b>\$ 67,552</b> | <b>\$ 74,671</b> |

The decrease in selling expenses is a result of reduced spending in commissions (26%), and travel (74%).

Administrative expenses for the three-month period ended March 31, 2024, decreased to \$511,495 from \$522,695 for the same period in 2023, a 2% decrease and consisted of the following items:

|  | <b>2024</b>       | <b>2023</b>       |
|--|-------------------|-------------------|
| Insurance                                | \$ 13,625         | \$ 14,802         |
| Professional fees                        | 117,939           | 104,871           |
| Rent                                     | 10,304            | 10,306            |
| General and administrative expenses      | 51,647            | 90,263            |
| Investor Relations                       | 69,422            | 54,550            |
| Administrative salaries                  | 128,592           | 121,388           |
| Director and advisory fees               | 21,856            | 16,946            |
| Stock based compensation                 | 91,255            | 101,187           |
| Amortization and depreciation allocation | 6,856             | 8,382             |
| <b>Total administrative expenses</b>     | <b>\$ 511,495</b> | <b>\$ 522,695</b> |

The decrease in administrative expenses is a result of reduced spending on general and administrative expenses (43%), insurance costs (8%) and stock based compensation (10%).

Stock based compensation expense decreased 10% in 2024, due to cumulative effect of accounting for vesting of stock options granted in the current and prior years.

Net research and development expenses for the three-month period ended March 31, 2024, decreased to \$756,380 from \$910,280 for the same period in 2023, a 17% decrease, and consisted of the following items:

|   | <b>2024</b>       | <b>2023</b>       |
|---|-------------------|-------------------|
| Research and development (net of investment tax credit) | \$ 654,033        | \$ 792,372        |
| Stock based compensation                                | 50,861            | 66,158            |
| Amortization and depreciation allocation                | 51,486            | 51,751            |
| <b>Total research and development expenses</b>          | <b>\$ 756,380</b> | <b>\$ 910,280</b> |

The decrease in research and development expenses is attributed to the decrease in costs for Study II patient enrollment and treatment. Research and development expenses represented 57% of the Company's operating expenses and represent investment into the research and development of the Company's Drug Division.

### **Net Profit (Loss):**

The net loss for the three month period ended March 31, 2024, was \$1,266,711, which included \$220,919 of net non-cash expenses (i.e.: amortization, stock-based compensation expense and foreign exchange gain/loss). This compared to a net loss in 2023 of \$1,408,953 which included \$244,787 of net non-cash expenses. The Drug Division represented \$1,011,762 of this loss (80%) in 2023.

The decrease in net loss is primarily attributed to decreased spending on research and development expenses in Study II.

## Cash Flows:

Cashflows for the years ended are as follows:

|   | 2024           | 2023           |
|---|----------------|----------------|
| Net loss and comprehensive loss                           | \$ (1,266,711) | \$ (1,408,953) |
| Items not involving cash                                  | 220,919        | 244,787        |
| Cash provided by operations                               | (1,045,792)    | (1,164,166)    |
| Net change in non-cash working capital                    | (46,062)       | 55,166         |
| Cash (used in) provided by operating activities           | (1,091,854)    | (1,109,000)    |
| Cash (used in) provided by investing activities           | (3,576)        | (11,870)       |
| Cash (used in) provided by financing activities           | 1,165,930      | (21,872)       |
| Net change in cash and cash equivalents during the period | 70,500         | (1,142,740)    |
| Cash and cash equivalents, beginning of year              | 43,911         | 1,508,617      |
| Cash and cash equivalents, end of period                  | 114,411        | 365,877        |

Funds used in operating activities, after taking into account net changes in other non-cash operating items were \$1,091,854 for the three-month period ended March 31, 2024, compared to funds used of \$1,109,000 in 2023. The decrease is attributed to decreased spending in research and development expenses in Study II.

Funds used in investing for the three-month period ended March 31, 2024, amounted to \$3,576 compared to \$11,870 in 2023. The decrease is attributed to decreased spending on equipment related to Study II.

Funds received in financing activities amounted to \$1,165,930 for the three-month period ended March 31, 2024, compared to funds used of \$21,872 in 2023. The increase is attributed to the February 5, 2024 non-brokered private placement.

## Assets (other than Cash):

The Company holds essential and valuable intellectual property rights and assets; including: patents, trademarks, development and other related costs.

## Net Investment in Leases:

Net investment in leases represents amounts owing from customers to whom the Company sold products under a finance lease with a payment term of 60 months.

|   | <u>As at March 31 2024</u> | <u>As at December 31, 2023</u> |
|---|----------------------------|--------------------------------|
| Lease beginning balance                     | \$ 1,193,604               | \$ 694,204                     |
| New leases for the period                   | 77,311                     | 694,149                        |
| Interest charge for the period <sup>1</sup> | 17,143                     | 44,230                         |
| Lease payments for the period <sup>2</sup>  | (80,017)                   | (238,979)                      |
| <b>Total</b>                                | <b>\$ 1,208,041</b>        | <b>\$ 1,193,604</b>            |

1) Lease investments are discounted using prime rate at time of inception.

2) Lease investments does not include any variable payments of \$0.50 per minute of use.

Principal receivables of the Company's investment in leases until maturity are as follows:

|              |           |                  |
|--------------|-----------|------------------|
| 2024         | \$        | 219,862          |
| 2025         |           | 307,627          |
| 2026         |           | 319,413          |
| 2027         |           | 247,555          |
| 2028         |           | 110,772          |
| 2029         |           | 2,812            |
| <b>Total</b> | <b>\$</b> | <b>1,208,041</b> |

### **Commitments:**

As of March 31<sup>st</sup>, 2024, the Company's commitments consisted of the following:

|                        | <b>Total</b>      | <b>2024</b>      | <b>2025</b>      | <b>2026</b>     | <b>2027</b>     | <b>2028</b>     | <b>2029</b>     | <b>2030</b>     | <b>2031</b>     | <b>2032</b>     |
|------------------------|-------------------|------------------|------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Research Agreement (a) | \$ 24,969         | \$ -             | \$ 24,969        | \$ -            | \$ -            | \$ -            | \$ -            | \$ -            | \$ -            | \$ -            |
| Research Agreement (b) | 142,320           | 72,620           | 8,800            | 8,800           | 8,800           | 8,800           | 8,800           | 8,800           | 8,800           | 8,800           |
| <b>Total</b>           | <b>\$ 167,289</b> | <b>\$ 72,620</b> | <b>\$ 33,769</b> | <b>\$ 8,800</b> | <b>\$ 8,800</b> | <b>\$ 8,800</b> | <b>\$ 8,800</b> | <b>\$ 8,800</b> | <b>\$ 8,800</b> | <b>\$ 8,800</b> |

- a) Research Commitments under a research agreement with a Clinical Research Organization for the TLC-3200 cancer therapy project. Under the terms of this agreement, the Company is required to pay \$126,324 (USD\$96,800) for the period from July 23, 2019 through to the end of the Phase II Clinical Study. The Company has paid \$101,355 (USD\$76,400) relating to this commitment, of which \$24,969 (USD\$20,400) is the remaining commitment.
- b) Research Commitments under a research agreement with a Contract Manufacturer for the TLC-3200 cancer therapy project. Under the terms of this agreement, the Company is required to pay \$478,700 for the period from April 29, 2021 through to November 15, 2032. The Company has paid \$336,380 relating to this commitment, of which \$142,320 is the remaining commitment.

The Company indemnifies its directors and officers against any and all costs, charges and expenses, including settlement of claims in respect of any civil, criminal or administrative action incurred in the performance of their service to the Company to the extent permitted by law. The Company maintains liability insurance for its officers and directors.

### **Lease Liabilities and Right-of-Use-Assets:**

The Company leases premises consisting of its office and manufacturing facilities. On May 20<sup>th</sup>, 2022, the Company extended the lease of its premise for an additional 5 years until September 30<sup>th</sup>, 2027.

Principal repayments of the Company's leased premises and office equipment until maturity are as follows:

|      | <b>Property</b>   | <b>Office Equipment</b> |
|------|-------------------|-------------------------|
| 2024 | 68,947            | 1,417                   |
| 2025 | 98,306            | 2,009                   |
| 2026 | 107,209           | 880                     |
| 2027 | 85,463            | -                       |
|      | <b>\$ 359,926</b> | <b>\$ 4,306</b>         |

### **Share Capital Analysis:**

As of May 29, 2024, the share capital of the Company consisted of 239,295,306 common shares. Each common share entitles the holder to one vote per share.

As of May 29, 2024, there were 18,500,000 options outstanding, of which 12,900,000 were vested and exercisable into an equivalent number of the Company's common shares.

As of May 29, 2024, there were 87,194,853 warrants outstanding. Each whole warrant entitles the holder thereof to purchase one additional common share. The warrants are exercisable as follows: 57,499,000 at a price of \$CAN 0.35 until August 22<sup>nd</sup>, 2024, 10,058,734 at a price of \$CAN 0.35 until September 22<sup>nd</sup>, 2024, 1,002,700 at a price of \$CAN 0.35 until November 17<sup>th</sup>, 2024, 4,805,400 at a price of \$CAN 0.35 until June 30<sup>th</sup>, 2025, 1,840,000 at a price of \$CAN 0.35 until September 7, 2025, 5,318,183 at a price of \$CAN 0.28 until November 29, 2028, 6,670,836 at a price of \$CAN 0.25 until February 5, 2029 and 4,167,778 at a price of \$CAN 0.25 until April 24, 2029.

As of May 29, 2024, there were 18,864 finder's units that were issued in connection with the November 29, 2023, non-brokered private placement. Each finder's unit entitles the holder thereof to acquire one common share and one common share purchase warrant at a price of \$CAN 0.22 per unit until November 29, 2028.

As of May 29, 2024, there were 2,023,077 broker compensation units that were issued in connection with the August 22<sup>nd</sup>, 2019 public offering. Each broker compensation unit entitles the holder thereof to acquire one common share and one common share purchase warrant at a price of \$CAN 0.35 per unit until August 22<sup>nd</sup>, 2024.

### **Segmented Information:**

For management purposes, the Company is organized into two separate reportable operating divisions; the Drug Division and the Device Division. The Drug Division is responsible for the research and development of PDCs primarily for the treatment of cancer with assistance from the Device Division to develop medical lasers to activate them. The Device Division is responsible for the Company's medical laser business, which research, develops, manufactures and distributes Cool Laser Therapy systems to healthcare practitioners predominantly for the healing of pain.

The following table displays revenue and direct expenses from the drug and device division for the three-month periods ended March 31:

|   | 2024                |                       |                       | 2023                |                       |                       |
|---|---------------------|-----------------------|-----------------------|---------------------|-----------------------|-----------------------|
|   | Device              | Drug                  | Total                 | Device              | Drug                  | Total                 |
| Sales                                   | \$ 175,554          | \$ -                  | \$ 175,554            | \$ 207,161          | \$ -                  | \$ 207,161            |
| Cost of sales                           | 113,440             | -                     | 113,440               | 114,638             | -                     | 114,638               |
| <b>Gross margin</b>                     | <b>62,114</b>       | <b>-</b>              | <b>62,114</b>         | <b>92,523</b>       | <b>-</b>              | <b>92,523</b>         |
| <b>Operating Expenses</b>               |                     |                       |                       |                     |                       |                       |
| Selling expenses                        | 67,552              | -                     | 67,552                | 74,671              | -                     | 74,671                |
| Administrative expenses                 | 229,620             | 281,875               | 511,495               | 271,630             | 251,065               | 522,695               |
| Research and development expense:       | 31,363              | 725,017               | 756,380               | 3,181               | 907,099               | 910,280               |
| Loss on foreign exchange                | 1,550               | 1,550                 | 3,100                 | (819)               | (819)                 | (1,638)               |
| Interest accretion on lease liabilities | 3,320               | 3,320                 | 6,639                 | 4,083               | 4,083                 | 8,166                 |
| Interest income                         | (16,341)            | -                     | (16,341)              | (12,698)            | -                     | (12,698)              |
|   | <b>317,063</b>      | <b>1,011,762</b>      | <b>1,328,825</b>      | <b>340,048</b>      | <b>1,161,428</b>      | <b>1,501,476</b>      |
| <b>Loss for the period</b>              | <b>\$ (254,949)</b> | <b>\$ (1,011,762)</b> | <b>\$ (1,266,711)</b> | <b>\$ (247,525)</b> | <b>\$ (1,161,428)</b> | <b>\$ (1,408,953)</b> |
| Total Assets                            | \$ 2,361,142        | \$ 884,917            | \$ 3,246,059          | \$ 2,062,256        | \$ 1,138,713          | \$ 3,200,969          |
| Total Liabilities                       | 415,261             | 860,349               | 1,275,610             | 682,261             | 668,498               | 1,350,759             |

The following table displays revenue and direct expenses from the device division product sales by product line and geographic area for three-month periods ended March 31:

|                              | 2024              |                 |                 | 2023      |           |               |
|------------------------------|-------------------|-----------------|-----------------|-----------|-----------|---------------|
|                              | Canada            | USA             | International   | Canada    | USA       | International |
| <b>Sales by Product Line</b> |                   |                 |                 |           |           |               |
| TLC-1000                     | \$ 7,913          | \$ 388          | \$ -            | \$ 25,024 | \$ 22,291 | \$ -          |
| TLC-2000                     | 114,185           | 31,459          | 21,609          | 127,099   | 32,746    | -             |
|                              | <b>122,098</b>    | <b>31,847</b>   | <b>21,609</b>   | 152,124   | 55,037    | -             |
| <b>Expenses</b>              |                   |                 |                 |           |           |               |
| Cost of Sales                | 78,897            | 20,580          | 13,963          | 84,182    | 30,456    | -             |
| Selling Expenses             | 52,630            | 8,921           | 6,001           | 63,290    | 8,654     | 2,727         |
|                              | <b>131,527</b>    | <b>29,500</b>   | <b>19,964</b>   | 147,472   | 39,110    | 2,727         |
|                              | <b>\$ (9,428)</b> | <b>\$ 2,345</b> | <b>\$ 1,645</b> | \$ 4,652  | \$ 15,927 | \$ (2,727)    |

As at March 31, 2024 and December 31, 2023, the Company's long-lived assets used in operations are all located in Canada. Timing of revenue is recognized at a point in time.

### **Selected Financial Information and Accounting Policies:**

The unaudited consolidated interim condensed financial statements for the three-month period ended March 31, 2024, and all other financial statements referred to herein, have been prepared in accordance with International Financial Reporting Standards ("IFRS"), consistently applied, and all amounts and currencies reported therein, and in this MD&A, are in Canadian dollars, unless otherwise noted. The ongoing accounting policies are more particularly described in the Notes to the audited annual consolidated financial statements for the year ended December 31<sup>st</sup>, 2023. Please refer to the Company's annual and quarterly financial statement filings, including material interim press releases, at [www.sedarplus.ca](http://www.sedarplus.ca).

### **Use of Financial Instruments:**

The Company's financial instruments consists of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities. The fair value of cash, accounts receivable, accounts payable and accrued liabilities approximate carrying value because of the short-term nature of these instruments.

IFRS 7 Financial Instruments Disclosures establishes a fair value hierarchy that reflects the significance of inputs used in making fair value measurements as follows:

- Level 1: quoted prices in active markets for identical assets or liabilities;
- Level 2: inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly (i.e. as prices) or indirectly (i.e. from derived prices); and
- Level 3: inputs for the asset or liability that are not based upon observable market data.

The carrying amounts of cash and cash equivalents, accounts receivable and accounts payable and accrued liabilities approximate fair value due to the short-term maturities of these instruments.

The carrying amount of the investment in leases approximates fair value because lease contracts are based on bank prime rates of interest which approximate current rates.

(i) Credit risk:

Credit risk is the risk of financial loss to the Company if a customer or counterparty to a financial instrument fails to meet its contractual obligations and arises principally from the Company's trade and other receivable. The amounts reported in the consolidated balance sheets are net of allowances for credit losses, estimated by the Company's management based on prior experience and its assessment of the current economic environment. The Company reviews its trade receivable and investment in leases regularly and reduces amounts to their expected realizable values by adjusting the allowance for credit losses when management determines that the account may not be fully collectible. The Company has adopted credit policies

in an effort to minimize those risks. The carrying value of trade and other receivables and investment in leases represent the Company's maximum exposure to credit risk.

(ii) Liquidity risk:

Liquidity risk is the risk that the Company will not be able to meet its financial obligations as they come due. The Company manages its liquidity risk by continuously monitoring forecasted and actual cash flows, as well as anticipated investing and financing activities. The Company does not have material long-term financial liabilities.

(iii) Interest rate risk:

Interest rate risk is the risk that changes in interest rates will affect the Company's income or the value of the financial instruments held. Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market interest rates.

The Company's exposure to interest rate risk is as follows:

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|                            |   |
|----------------------------|---|
| Cash and cash equivalents  | Short-term fixed and variable interest rate |
| Financed trade receivables | Long-term fixed interest rate               |

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(iv) Foreign currency exchange risk:

The Company is exposed to foreign currency exchange risk. This risk arises from the Company's holdings of US dollar denominated cash, trade and other receivables and payables and accrued liabilities. Changes arising from this risk could impact the Company's reported foreign currency exchange gains or losses.

The Company has not entered into any conventional or other financial instruments designed to minimize its investment risk, currency risk or commodity risk. No off-balance sheet arrangements have been established nor are there any pending proposals or indicated business requirements to this effect.

**Critical Accounting Policies, Estimates and Judgments:**

As noted above, the Company's unaudited interim condensed consolidated financial statements as of March 31, 2024 and audited consolidated financial statements as of December 31, 2023, respectively, and for the three-month period ended March 31, 2024 and 2023, respectively, have been prepared in accordance with IFRS. The policies applied are based on IFRS issued and outstanding as of May 29, 2024 which is the date at which the Company's Board of Directors approved the unaudited interim condensed consolidated financial statements.

Additionally, the preparation of the audited consolidated financial statements in accordance with IFRS often requires management to make estimates about and apply assumptions or subjective judgment to future events and other matters that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures. Assumptions, estimates and judgments are based on historical experience, expectations, current trends and other factors that management believes to be relevant at the time at which the audited consolidated financial statements are prepared. Management reviews, on a regular basis, the Company's accounting policies, assumptions, estimates and judgments, in order to ensure that the audited consolidated financial statements are presented fairly and in accordance with IFRS.

Critical accounting estimates and judgments are those that have a significant risk of causing material adjustment and are often applied to matters or outcomes that are inherently uncertain and subject to change. As such, management cautions that future events often vary from forecasts and expectations and that estimates routinely require adjustment. A summary of those areas where the Company's management believe critical accounting policies affect the significant judgments and estimates used in the preparation of the financial statements can be found in note 2 to the audited consolidated financial statements of December 31, 2023 and 2022.

**Disclosure of Internal Controls:**

Management has established processes, which are in place to provide them sufficient knowledge to support management representations that they have exercised reasonable diligence that:

- (i) the financial statements do not contain any untrue statement of material fact or omit to state a material fact required to be stated or that is necessary to make a statement not misleading in light of the circumstances under which it is made, as of the date of and for the periods presented by the financial statements; and
- (ii) the financial statements fairly present in all material respects the financial condition, financial performance and cash flows of the Company, as of the date of and for the periods presented by the financial statements.

In contrast to the certificate required under National Instrument 52-109 *Certification of Disclosure in Issuers' Annual and Interim Filings* ("NI 52-109"), the Company utilizes the Venture Issuer Basic Certificate, which does not include representations relating to the establishment and maintenance of Disclosure Controls and Procedures ("DC&P") and Internal Control over Financial Reporting ("ICFR"), as defined in NI 52-109.

In particular, the certifying officers filing the Certificate are not making any representations relating to the establishment and maintenance of:

- (i) controls and other procedures designed to provide reasonable assurance that information required to be disclosed by the issuer in its annual filings, interim filings or other reports filed or submitted under securities legislation is recorded, processed, summarized and reported within the time periods specified in securities legislation; and
- (ii) a process to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with the issuer's GAAP. The Company's certifying officers are responsible for ensuring that processes are in place to provide them with sufficient knowledge to support the representations they are making in the certificate.

Investors should be aware that inherent limitations on the ability of certifying officers of a venture issuer to design and implement on a cost-effective basis DC&P and ICFR as defined in NI 52-109 may result in additional risks to the quality, reliability, transparency and timeliness of interim and annual filings and other reports provided under securities legislation.

In connection with the audits of the Company's consolidated financial statements for the years' ended December 31, 2023 and 2022, the Company's independent registered public accountants identified certain material weaknesses in the Company's internal control over financial reporting. Such material weaknesses continue to exist as of May 29, 2024. A "material weaknesses" is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses relate to not having a full segregation of duties within members of its accounting staff dedicated to financial reporting functions so that all journal entries and account reconciliations are reviewed by someone other than the preparer, heightening the risk of error or fraud. If the Company is unable to remediate the material weakness, or other control deficiencies are identified, the Company may not be able to report its financial results accurately, prevent fraud or file its periodic reports as a public company in a timely manner.

### **Risks and Uncertainties:**

The Company's operations involve certain risks and uncertainties that are inherent to the Company's industry. The most significant known risks and uncertainties faced by the Company are described below.

### **Limited Operating History:**

The Company is still in the development and commercialization stages of its businesses and therefore will be subject to the risks associated with early-stage companies, including uncertainty of the success and acceptance of its products, uncertainty of revenues, markets and profitability and the continuing need to raise additional capital. The Company's business prospects must be considered in light of the risks, expenses and difficulties frequently encountered by companies in this stage of development. Such risks include the evolving and unpredictable nature of the Company's business, the Company's ability to anticipate and adapt to a developing market, acceptance by consumers of the Company's products, the ability to identify, attract and retain qualified personnel and the ability to generate sufficient revenue or raise sufficient capital to carry out its business plans. There can be no assurance that the Company will be successful in adequately mitigating these risks.

**Working Capital and Capital Resources:**

The Company has not been able to consistently generate sufficient profits from its revenue to provide the financial resources necessary to continue to have sufficient working capital for the development of its products and marketing activities. There is no assurance that future revenues will be sufficient to generate the required funds to continue product development, business development and marketing activities or that additional funds required for such working capital will be available from financings.

These conditions indicate the existence of material uncertainties that cast substantial doubt about the Company's ability to continue as a going concern. The Company's ability to continue as a going concern is dependent upon achieving a profitable level of operations and obtaining additional financing, neither of which is assured. The Company has been able, to date, to raise capital to continue to market its products and continues to develop sales opportunities which could result in additional sales of its products in the future.

In order to achieve its long-term development and commercialization strategy for the Company's range of therapeutic laser systems and PDC anti-cancer technology, the Company may need to raise additional capital through the issuance of shares, collaboration agreements or strategic partnerships that would allow the Company to finance its activities. There is no assurance that additional funds will be available as required or that they may be available on acceptable terms and conditions. Additional financing may also result in dilution of shareholder value.

**Key Personnel:**

The Company's success is dependent upon its ability to attract and retain a highly qualified work force, and to establish and maintain close relationships with research centers. Competition is intense and the Company's success will depend, to a great extent, on its senior and executive managers, scientific personnel and academic partners. The loss of one or more of its key employees or the inability to attract and retain highly skilled personnel could have a material adverse effect on the Company's development of its products, operations or business prospects.

**Protection of Intellectual Property:**

The Company's success will depend in part on its ability to obtain patents, protect its trade secrets and operate without infringing the exclusive rights of other parties. There is no guarantee that any patent that will be granted to the Company will bring any competitive advantage to the Company, that its patent protection will not be contested by third parties, or that the patents of competitors will not be detrimental to the Company's commercial activities. It cannot be assured that competitors will not independently develop products similar to the Company's products, that they will not imitate the Company's products or that they will not circumvent or invalidate patents granted to the Company.

Although the Company does not believe that its products infringe the proprietary rights of any third parties, there can be no assurance that infringement or invalidity claims (or claims for indemnification resulting from infringement claims) will not be asserted or prosecuted against the Company or that any such assertions or prosecutions, valid or otherwise, will not materially adversely affect the Company's business, financial condition or results of operations. Irrespective of the validity of the successful assertion of such claims, the Company could incur significant costs and diversion of resources with respect to the defense thereof, which could have a material adverse effect on the Company. The Company's performance and ability to develop markets and compete effectively are dependent to a significant degree on its proprietary and patented technology. The Company relies on its patents and trade secrets, as well as confidentiality agreements and technical measures, to establish and protect its proprietary rights. While the Company will endeavor to protect its intellectual property, there can be no assurance that the steps taken will prevent misappropriation or that agreements entered into for that purpose will be enforceable. The laws of certain other countries may afford the Company little or no effective protection of its intellectual property.

**Competition:**

Many of the Company's current and potential competitors have longer operating histories, larger customer bases, greater name and brand recognition and significantly greater financial, sales, marketing, engineering, scientific, technical and other resources than the Company. These competitors have research and development capabilities that may allow them to develop new or improved products that may compete with the Company's products. New technologies and the expansion of existing technologies may also increase competitive pressures on the Company. Increased competition may result in reduced operating margins as well as loss of market share and could result in decreased usage in the Company's products and may have a material adverse effect on the Company.

**Implementation Delays:**

Many of the Company's products will be in development, testing or preliminary stage and there may be delays or other problems in the introduction of the Company's products. The Company cannot predict when customers that are in a testing or preliminary use phase of the Company's products will adopt a broader use of the products. The market for the Company's products is relatively new

and continues to evolve. The Company's products will involve changes in the manner in which businesses have traditionally used such products. In some cases, the Company's customers will have little experience with products offered by the Company. The Company will have to spend considerable resources educating potential customers about the value of the Company's products. It is difficult to assess, or predict with any assurance, the present and future size of the potential market for the Company's products or its growth rate, if any. The Company cannot predict whether or not its products will achieve market acceptance.

**Strategic Alliances:**

The Company's ability to successfully complete the research and development of its products and its growth and marketing strategies are based, in significant part, in the strategic alliances it has in place and the licenses and agreements securing those strategic alliances. The Company's success will depend upon the ability to seek out and establish new strategic alliances and working relationships. There can be no assurance that existing strategic alliances and working relationships will not be terminated or adversely modified in the future, nor can there be any assurance that new relationships, if any, will afford the Company the same benefits as those currently in place.

**Trade Secret Protection:**

Because the Company relies on third parties to develop its products, the Company must share trade secrets with them. The Company seeks to protect its proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with its collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically restrict the ability of its collaborators, advisors, employees and consultants to publish data potentially relating to its trade secrets. The Company's academic collaborators typically have rights to publish data, provided that the Company is notified in advance and may delay publication for a specified time in order to secure its intellectual property rights arising from the collaboration. In other cases, publication rights are controlled exclusively by the Company, although in some cases the Company may share these rights with other parties. The Company also conducts joint research and development programs which may require the Company to share trade secrets under the terms of research and development collaboration or similar agreements. Despite the Company's efforts to protect its trade secrets, the Company's competitors may discover the Company's trade secrets, either through breach of these agreements, independent development or publication of information including the Company's trade secrets in cases where the Company does not have proprietary or otherwise protected rights at the time of publication. A competitor's discovery of the Company's trade secrets may impair the Company's competitive position and could have a material adverse effect on the Company's business and financial condition.

**Product Deficiencies:**

Given that the Company's products are either fairly new, or are in various stages of development, there may be difficulties in product design, performance and reliability which could result in lost revenue, delays in customer acceptance of the Company's products and legal claims against the Company, which would be detrimental, perhaps materially to the Company's market reputation and ability to generate further sales. Serious defects are frequently found during the period immediately following the introduction of new products or enhancements to existing products and undetected errors or performance problems may be discovered in the future. Product defects may expose the Company to liability claims, for which the Company may not have sufficient liability insurance.

**Dependence on Third Party Suppliers:**

The Company has established relationships with certain third-party suppliers upon whom it relies on to provide key materials and components for completion of its products. In the event of the inability of these third parties to supply such materials and components in a timely manner or to supply materials and components that continue to meet the Company's quality, quantity or cost requirements, the Company would be required to purchase these materials and components from other suppliers. There is no assurance that other suppliers can be found in such circumstances who can supply the materials and components in a timely manner or that meet the Company's quality, quantity or cost requirements.

**Volatility of Share Price:**

The market price of the Company's common shares is subject to volatility. General market conditions as well as differences between the Company's financial, scientific and clinical results, and the expectations of investors, as well as securities analysts can have a significant impact on the trading price of the Company's common shares.

**Regulatory Approvals:**

The Company is directly and indirectly engaged in the design, manufacture, sale and international marketing of therapeutic and medical laser equipment, as well as the research and development of light activated PDCs, all of which are subject to regulatory oversights, audits and controls by various national regulatory agencies (i.e.: FDA, Health Canada, CE) and authoritative quality

standards bodies (i.e.: UL, CSA, ISO and TUV), which all possess strict quality certification procedures. The Company is in full compliance with all the governing regulatory and quality standards and approval requirements pertaining to the medical laser devices it currently designs, manufactures and markets and the PDCs it researches and develops. No assurance can be given that current regulations relating to regulatory approval will not change or become more stringent and product approvals may be withdrawn if compliance with regulatory standards is not maintained.

#### **Early Stage of Product Development:**

Given the early stage of the Company's product development, the Company can make no assurance that its research and development programs will result in regulatory approval or commercially viable products. To achieve profitable operations, the Company alone or with others, must successfully develop, gain regulatory approval and market its future products. To obtain regulatory approvals for its product candidates being developed and to achieve commercial success, clinical studies must demonstrate that the product candidates are safe and tolerable for human use and that they demonstrate efficacy equal to or greater than standard of care.

Many product candidates never reach the stage of clinical testing and even those that do have only a small chance of successfully completing clinical development and gaining regulatory approval. Product candidates may fail for a number of reasons, including, but not limited to: being unsafe for human use or due to the failure to provide therapeutic benefits equal to or better than the standard of treatment at the time of testing. Unsatisfactory results obtained from a particular study relating to a research and development program may cause the Company or its collaborators to abandon commitments to that program. Positive results of early preclinical research may not be indicative of the results that may be obtained in later stages of preclinical or clinical research. Similarly, positive results from early-stage clinical studies may not be indicative of favorable outcomes in later-stage clinical studies. The Company can make no assurance that any future studies, if undertaken, will yield favorable results.

#### **Reliance on Third Parties:**

The Company relies and will continue to rely on third parties to conduct a significant portion of its preclinical and clinical development activities. Preclinical activities include: in-vivo studies providing access to specific disease models, pharmacology and toxicology studies and assay development. Clinical development activities include: trial design, regulatory submissions, clinical patient recruitment, clinical trial monitoring, clinical data management and analysis, safety monitoring and project management. If there is any dispute or disruption in the Company's relationship with third parties, or if they are unable to provide quality services in a timely manner and at a feasible cost, the Company's active development programs may face delays. Further, if any of these third parties fails to perform as the Company expects or if their work fails to meet regulatory requirements, the Company's testing could be delayed, cancelled or rendered ineffective.

#### **Clinical Study Risk:**

Before obtaining marketing approval from regulatory authorities for the sale of the Company's product candidates, the Company must conduct preclinical studies in animals and extensive clinical studies in humans to demonstrate the safety, tolerability and efficacy of the product candidates. Clinical testing is expensive and difficult to design and implement, can take many years to complete and has uncertain outcomes. The outcome of preclinical experiments and early clinical studies may not predict the success of later clinical studies, and interim results of a clinical study do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical studies due to lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier studies. The Company does not know whether the clinical studies it may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market any of the Company's product candidates in any jurisdiction. A product candidate may fail for safety, tolerability or efficacy reasons at any stage of the testing process. A major risk the Company faces is the possibility that none of the Company's product candidates under development will successfully gain market approval from Health Canada, the FDA or other regulatory authorities, resulting in the Company being unable to derive any commercial revenue from them after investing significant amounts of capital in multiple stages of preclinical and clinical testing.

From time to time, scientific studies or clinical studies on various aspects of biopharmaceutical products are conducted by academic researchers, competitors or others. The results of these studies, when published, may have a significant effect on the market for the biopharmaceutical product that is the subject of the study. The publication of negative results of scientific studies or clinical studies or adverse safety events related to the Company's product candidates, or the therapeutic areas in which the Company's product candidates compete, could adversely affect the Company's share price and the Company's ability to finance future development of its product candidates; hence, the Company's business and financial results could be materially and adversely affected.

#### **Clinical Study Timing Delays:**

The Company cannot predict whether any clinical studies will begin as planned, will need to be restructured, or will be completed on schedule, or at all. The Company's product development costs may increase significantly if the Company experiences delays in clinical

testing. Significant clinical study delays could shorten any periods during which the Company may have the exclusive right to commercialize its product candidates or allow the Company's competitors to bring products to market before the Company, which would impair the Company's ability to successfully commercialize its product candidates and may harm the Company's financial condition, results of operations and / or prospects. The commencement and completion of clinical studies for the Company's products may be delayed for a number of reasons, including delays related, but not limited, to:

- failure by regulatory authorities to grant permission to proceed or placing the clinical study on hold;
- patients failing to enroll or remain in the Company's studies at the rate the Company expects;
- suspension or termination of clinical studies by regulators for many reasons, including concerns about patient safety or tolerability
- any changes to the Company's manufacturing process that may be necessary or desired;
- delays or failure to obtain clinical supply from contract manufacturers of the Company's products necessary to conduct clinical studies;
- product candidates demonstrating a lack of safety, tolerability or efficacy during clinical studies;
- patients choosing an alternative treatment for the indications for which the Company is developing any of its product candidates or participating in competing clinical studies;
- patients failing to complete clinical studies due to dissatisfaction with the treatment, side effects or other reasons;
- reports of clinical testing on similar technologies and products raising safety, tolerability and/or efficacy concerns;
- competing clinical studies and scheduling conflicts with participating clinicians;
- clinical investigators not performing the Company's clinical studies on their anticipated schedule, dropping out of a study, or employing methods not consistent with the clinical study protocol, regulatory requirements or other third parties not performing data collection and analysis in a timely or accurate manner;
- failure of the Company's Contract Research Organizations, to satisfy their contractual duties or meet expected deadlines;
- inspections of clinical study sites by regulatory authorities, Review Ethics Boards ("REB"), or Institutional Review Boards ("IRBs") or ethics committees finding regulatory violations that require the Company to undertake corrective action, resulting in suspension or termination of one or more sites or the imposition of a clinical hold on the entire study;
- one or more IRBs or ethics committees rejecting, suspending or terminating the study at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the study; or
- failure to reach agreement on acceptable terms with prospective clinical study sites.

The Company's product development costs may increase if the Company experiences delays in testing or approval or if the Company needs to perform more or larger clinical studies than planned. Additionally, changes in regulatory requirements and policies may occur, and the Company may need to amend study protocols to reflect these changes. Amendments may require the Company to resubmit its study protocols to regulatory authorities or IRBs or ethics committees for re-examination, which may impact the cost, timing or successful completion of that study. Delays or increased product development costs may have a material adverse effect on the Company's business, financial condition and prospects.

#### **Patient Enrollment:**

As the Company's product candidates advance from preclinical testing to clinical testing, and then through progressively larger and more complex clinical studies, the Company may need to enroll an increasing number of patients that meet the Company's eligibility criteria. There is significant competition for recruiting cancer patients in clinical studies, and the Company may be unable to enroll the patients it needs to complete clinical studies on a timely basis or at all. The factors that affect the Company's ability to enroll patients are largely uncontrollable and include, but are not limited to, the following:

- size and nature of the patient population
- eligibility, inclusion and exclusion criteria for the study
- design of the clinical study protocol
- competition with other companies for clinical sites or patients
- the perceived risks and benefits of the product candidate under study
- the patient referral practices of physicians
- the number, availability, location and accessibility of clinical study sites

#### **Failure to Achieve Milestones:**

From time to time, the Company may announce the timing of certain events it expects to occur, such as the anticipated timing of results from the Company's clinical studies or product sales. These statements are forward-looking and are based on the best estimates of management at the time relating to the occurrence of such events; however, the actual timing of such events may differ from what

has been publicly disclosed. The timing of events such as initiation or completion of a clinical study, filing of an application to obtain regulatory approval or announcement of additional clinical studies for a product candidate or adoption / sales of the Company's products may ultimately vary from what is publicly disclosed. These variations in timing may occur as a result of different events, including the nature of the results obtained during a clinical study or during a research phase or any other event having the effect of delaying the publicly announced timeline. The Company undertakes no obligation to update or revise any forward-looking information, whether as a result of new information, future events or otherwise, except as otherwise required by law. Any variation in the timing of previously announced milestones could have a material adverse effect on the Company's business plan, financial condition or operating results and the trading price of common shares.

**Currency Risk:**

The Company's primary risks are exposure to foreign currency exchange risk. These risks arise from the Company's holdings of US and Canadian dollar denominated cash, accounts receivable and accounts payable. Changes arising from these risks could impact the Company's reported foreign exchange gains or losses.

**Credit Risk:**

Credit risk is the risk of financial loss to the Company, if a customer or counterparty to a financial instrument fails to meet its contractual obligations and arises principally from the Company's accounts receivable and investment in leases. The amounts reported in the balance sheet are net of allowances for bad debts, estimated by the Company's management based on prior experience and their assessment of the current economic environment. The Company reviews its trade receivables and investments in leases accounts regularly and reduces amounts to their expected realizable values by adjusting the allowance for doubtful accounts as soon as the account is determined not to be fully collectible. The Company has adopted credit policies in an effort to minimize these risks.

**Product Liability:**

The Company has obtained product liability insurance which covers each occurrence up to \$5 million with a cap of \$10 million. A product liability claim could potentially be greater than this coverage. The Company's profitability would be adversely affected by any successful product liability claim in excess of its insurance coverage.

**Clinical Trial Liability:**

The Company has obtained clinical trial liability insurance coverage in the aggregate of \$CAN 5 million. This coverage is limited, and a clinical trial liability claim could potentially be greater than this coverage. The Company's profitability would be adversely affected by any successful product liability claim in excess of its insurance coverage.

May 29<sup>th</sup>, 2024

Kristina Hachey, CPA  
Chief Financial Officer