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

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, 2025.

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 <u>www.sedar.com</u>.

This MD&A is prepared as of May 29<sup>th</sup>, 2025.

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

#### 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 or 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 or their timing; the competitive environment; business strategic objectives; research, development or commercialization plans, acquisition or disposition of assets; preclinical or clinical studies: status, timing or strategies; the supply or demand of products or services; the ability to meet current or future financial obligations; the ability to execute on business or growth strategies; management's assessment of business strategies or operations; the intention 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 or unknown, risks or uncertainties, both general or specific, that contribute to the possibility that the predictions, forecasts, projections or 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 or those discussed elsewhere in this MD&A. Some of the assumptions made by Theralase<sup>®</sup>, 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<sup>®</sup> to maintain reasonably stable operating or general administrative expenses; current or future success of research, development or commercialization initiatives; the ability to achieve development or commercialization milestones; market competition; the ability to secure all required regulatory, government or certification approvals; geographic protection over the intellectual property in the markets in which Theralase<sup>®</sup> does business; market acceptance or revenue generation of products under development; the stability of current economic or business conditions, international tariffs, reciprocal tariffs or the threat of them, the strength and/or stability of the economy in Canada, the United States or elsewhere; currency, exchange or interest rates or commodity prices being reasonably stable at current rates.

FLS reflect current expectations of management regarding future events or operating performance as of the date of this MD&A. Such information: involves significant risks or uncertainties; should not be read as guarantees of future performance or results; or 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 or 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 or 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 UNDUE 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 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<sup>®</sup> is a clinical stage pharmaceutical company dedicated to the research, development and commercialization of small molecules and their associated drug formulations that are able to be activated by light, radiation, sound and/or other drugs, for the safe and effective destruction of various cancers, bacteria and viruses. The Company in its Drug Division conducts preclinical research and clinical development of these small molecules, 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**") systems indicated and cleared by Health Canada and the Food and Drug Administration ("**FDA**") for the treatment of chronic knee pain and in off-label use for treating numerous nerve, muscle and joint conditions.

### **Non-Brokered Private Placement**

On March 11, 2025, the Company closed a non-brokered private placement of units. On closing, the Company issued an aggregate of 1,034,002 units at a price of \$0.30 per Unit for aggregate gross proceeds of approximately \$303,472 of which 251,668 units were purchased by certain insiders of the Corporation. 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 \$0.45 for a period of 5 years following the date of issuance.

On April 22, 2025, the Company closed a non-brokered private placement of units. On closing, the Company issued an aggregate of 1,995,829 units at a price of \$0.21 per Unit for aggregate gross proceeds of approximately \$419,124. 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 \$0.32 for a period of 5 years following the date of issuance.

The Company has raised approximately \$CAN 6.3 million over the last 2 years through non-brokered private placements in support of it research and development programs. It is currently investigating the use of a full-service investment bank in the United States to advise on potential financings and US listing opportunities. Information on any future financings will be released once available in accordance with applicable securities laws.

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

Theralase<sup>®</sup> 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<sup>®</sup> CLT can be used as a treatment for Parkinson's Disease, a brain disorder that causes unintended or uncontrollable movements, such as shaking, stiffness and difficulty with balance and coordination. Theralase<sup>®</sup>'s CLT, with its super-pulsed laser technology, is one of the few technologies in the world able to make an impact on this disease and improve the outcomes of Parkinson's Disease.

## Advancing the Theralase® Technology Platform

The Company's primary focus is the Drug Division, with strategic objectives of: preclinical research, clinical development and commercialization of small molecules and the light, radiation, sound and/or other drugs that activate them, intended primarily for the destruction of various cancers, bacteria and viruses.

Theralase<sup>®</sup>'s patented lead study drug, Ruvidar<sup>®</sup> (TLD-1433), 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**") (with or without resected  $T_a / T_1$ ).

The trade name Ruvidar<sup>®</sup> was selected by the Company for its lead small molecule, Ruvidar<sup>™</sup>; where, Ru is the elemental symbol for Ruthenium (a rare transitional metal in Group 8 belonging to the platinum group, which the Theralase<sup>®</sup> small

molecule 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<sup>™</sup>, has been demonstrated preclinically to bind with transferrin, a human glycoprotein, forming the compound named, Rutherrin<sup>®</sup>. 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<sup>®</sup> payload inside the cancer cell, versus a healthy cell, through endocytosis. When light or radiation activated, Ruvidar<sup>®</sup> 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**"). ICD has been shown to activate the innate and adaptive immune system, as a secondary response to the destruction of cancer cells.

The Drug Division is in the preclinical research and development of:

- Rutherrin<sup>®</sup> as an injectable form of Ruvidar<sup>®</sup>, for the treatment of Glio Blastoma Multiforme ("GBM"), a deadly form of brain cancer, Non-Small Cell Lung Cancer ("NSCLC"), pancreatic cancer, colorectal cancer, and Muscle Invasive Bladder Cancer ("MIBC").
- Ruvidar<sup>®</sup> as a topical treatment for Herpes Simplex Virus ("**HSV**") lesions.
- Ruvidar<sup>®</sup> as an extracorporeal treatment for Lymphoma, Leukemia and Multiple Myeloma.

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<sup>®</sup> 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<sup>®</sup> designed Study II to utilize the Therapeutic Dose (0.70 mg/cm<sup>2</sup>) of Ruvidar<sup>®</sup> and focus on the treatment of approximately 90 BCG-Unresponsive NMIBC patients presenting with persistent or recurrent CIS with or without resected  $T_a/T_1$  (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 was designed to enroll and treat patients in up to 15 Clinical Study Sites ("**CSSs**") located in Canada and the US. To date, Theralase<sup>®</sup> has successfully launched 16 CSSs; specifically: 6 CSSs in Canada and 10 CSSs in the US, with 2 US CSSs terminating patient enrollment in Study II, 1 US CSS closed out and 1 Canadian CSS in the process of being closed out, leaving 12 CSSs, 5 CSSs in Canada and 7 CSSs in the US.

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<br/>or without resected papillary disease  $(T_a / T_1)$ ) 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 positive 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.

TertiarySafety, evaluated by the incidence and severity of Adverse Events ("AEs"), Grade 4 or higher that do not<br/>resolve within 450 days post treatment (Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4<br/>= 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 Procedure consists of a Study Drug (Ruvidar<sup>®</sup>) 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<sup>®</sup>) 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<sup>®</sup> 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<sup>®</sup> 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 CR or Indeterminate Response ("**IR**") (collectively a Total Response ("**TR**")), 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 prescribed; 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>, 2025, the following CSSs are eligible to enroll patients into Study II and provide 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
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
University of Chicago (" <b>UC</b> ")	Chicago, Illinois, United States	June 11, 2021
St. Joseph's Healthcare Hamilton ("SJHH")	Hamilton, Ontario, Canada	December 5, 2024
Associated Medical Professionals of NY ("AMPNY")	Syracuse, New York, United States	December 9, 2024
Urology of Indiana (" <b>UI</b> ")	Greenwood, Indiana, United States	December 9, 2024
Central Ohio Urology Group ("COUG")	Gahanna, Ohio, United States	December 9, 2024

#### Table 1.0: Study II Clinical Study Sites

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, patient compliance and successful achievement of Study II primary, secondary and tertiary objectives.

## Study II Interim Clinical Data

Theralase<sup>®</sup> has made steady progress on the completion of Study II by enrolling and providing the primary Study Procedure for 82 patients out of a target of 90 patients (91% enrollment).

According to the clinical study design, a patient is considered to have completed Study II, if they receive the Study Procedure (Study Drug activated by Study Device) and have been assessed by the PI for up to 15 months or they have been prematurely removed from the clinical study by the PI for failure to respond or failure to comply with the clinical study design. According to this definition, 69 patients have completed Study II (with 13 patients on study with pending clinical data) resulting in the following interim clinical data in support of the Study II endpoints.

Theralase<sup>®</sup> is on track to complete enrollment in Study II by the summer of 2025.

This will allow the Company to report on 75 patients who have completed Study II in December 2025 and to report on all 90 patients by September 2026.

Upon follow-up of all patients, the Company plans to submit a New Drug Application ("**NDA**") to Health Canada and the FDA in 4Q2026, with a decision expected by the respective regulatory authorities on a marketing approval by 1Q2027.

As Theralase<sup>®</sup> completes enrollment in Study II, it is actively searching for commercialization partners for international marketing and sales of Ruvidar<sup>®</sup>.

To this end, Theralase<sup>®</sup> is in various stages of initial and advanced discussions with international pharmaceutical companies for various geographical territories concerning:

- Licensing of the light-activated Ruvidar<sup>®</sup> for BCG-Unresponsive NMIBC CIS
- Collaborative research focused on investigating light-activated Ruvidar® in the treatment of NMIBC
- Collaborative research focused on combining Ruvidar<sup>®</sup> with other FDA approved drugs

In recent discussions with the FDA, the Company has decided that since Study II is 91% complete, the best course of action is not to pursue Break Through Designation, but to complete Study II and submit the clinical data to the FDA in a formal NDA. At the end of the meeting, the FDA made a comment that they were impressed that the interim clinical data obtained to date was able to be achieved with only one clinical treatment, in the majority of cases.

Ruvidar<sup>®</sup> has demonstrated 10 years of shelf life, strongly supporting the stability of the molecule and the ability of clinics to store the small molecule for extended periods of time.

## Performance to Primary Objective

For the primary endpoint of Study II (CR at any point in time) 62.3% (43/69) [43.7, 80.9] of patients provided the Study Procedure (Study Drug activated by the Study Device) demonstrated a CR. Including patients, who demonstrated an IR (negative cystoscopy and positive or suspicious urine cytology), the TR increases to 69.6% (48/69) [49.9, 89.2].

This represents that approximately 2 out of 3 BCG-Unresponsive NMIBC CIS patients treated with Theralase<sup>®</sup>'s unique Study Procedure are demonstrating complete destruction of their bladder cancer.

Primary Endpoint Performance (CR at any Point in Time)					
	#	%	Confidence Interval (95%)		
Complete Response ("CR")	43/69	62.3%	[43.7, 80.9]		
Total Response (CR and IR)	48/69	69.6%	[49.9, 89.2]		

## Performance to Secondary Objective

Table 2.0: Primary Endpoint Performance

For the secondary endpoint of Study II (duration of CR) 41.9% (18/43) [22.5, 61.2] of treated patients who achieved a CR, maintained their CR response for at least 12 months (450 days from date of Study Procedure).

Secondary Endpoint Performance (Duration of CR) (450 Days)					
	# % Confidence Interval (95				
Complete Response ("CR")	18/43	41.9%	[22.5, 61.2]		

Table 3.0: Secondary Endpoint Performance

## Performance to Tertiary Objective

For the tertiary endpoint of Study II (safety of Study Procedure) 100% (69/69) experienced no Serious Adverse Events ("**SAEs**") directly related to the Study Drug or Study Device.

Tertiary Endpoint Performance (Safety) (15 months)				
# %				
Safety	69/69	100.0%		

#### Table 4.0: Tertiary Endpoint Performance

**Note:** For patients to be included in the statistical clinical analysis for efficacy, they must be enrolled in Study II, provided the primary Study Procedure and evaluated by a PI at the 90 days assessment through to 450 days assessment (cystoscopy and urine cytology) or have been removed from Study II, after the 90 day assessment. There are 69 patients that have completed Study II and have been statistically analyzed for efficacy. The data analysis presented above should be read with caution, as the clinical data is interim in its presentation. Study II is ongoing and new clinical data collected may or may not continue to support the current trends, with clinical data pending.

Outside of the defined endpoints of Study II, Theralase<sup>®</sup> has demonstrated a duration of CR at extended time points, as follows:

Duration of CR						
Time	#	%	Confidence Interval (95%)			
2 Years	10/43	23.3%	[8.8, 37.7]			
3 Years	9/43	20.9%	[7.3, 34.6]			
7 Years	1/43	2.3%	[0.0, 6.9]			

Table 5.0:	Duration	of CR	Extended	Time	Points	Performance
		•••••				

**Note:** Not all patients have been assessed at these extended time points. As more clinical data is collected, the duration of CR at 2 and 3 years may increase.

## Serious Adverse Events

For 82 patients treated in Study II, there have been 21 Serious Adverse Events ("SAEs") reported:

- 1 Grade 1 (resolved within 9 days)
- 3 Grade 2 (resolved within 1, 1 and 33 days, respectively)
- 12 Grade 3 (resolved within 1, 1, 1, 2, 3, 4, 4, 5, 43, 48, 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 <u>unrelated</u> to the Study II Drug or Study II Device.

**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.

If approved by the regulatory authorities, the clinical data obtained could significantly benefit patients who are faced with a radical cystectomy (removal of their bladder), as the Theralase<sup>®</sup> treatment provides a strong initial CR and an equally strong duration of that CR over time. It is made even more impressive by the fact that this clinical data was achieved with only one study procedure in the majority of cases.

## Additional Oncology Targets

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

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

- Increase the resistance of Ruvidar<sup>®</sup>, the lead drug candidate, to photobleaching (loss of potency of the small molecule 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<sup>®</sup> (Ruvidar<sup>®</sup> + transferrin) the ability 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 small molecules, in pursuit of this goal.

Due to the limitations of using laser light to activate Rutherrin<sup>®</sup> in deep oncological targets, Theralase<sup>®</sup>'s research strongly suggests that Rutherrin<sup>®</sup> may be activated with radiation therapy, which is able to increase the "tumour's damage zone" and the effectiveness of Theralase<sup>®</sup>'s small molecule beyond the reach of light in the body.

Radio Therapy ("**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<sup>®</sup> is a unique drug 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 or even radio synergist. Several preclinical strategies have been investigated by Theralase<sup>®</sup>'s research scientists to research, develop, optimize and advance highly selective and effective radio sensitizing properties of Rutherrin<sup>®</sup>.

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<sup>®</sup>, its multidisciplinary applications, delivery methodologies, safety and efficacy.

Once Rutherrin<sup>®</sup>'s Maximum Tolerated Dose ("**MTD**") and hence Human Equivalent Dose ("**HED**") limits have been determined through Good Laboratory Practices ("**GLP**") toxicology studies, Theralase<sup>®</sup>, subject to regulatory approvals, plans to intravenously inject Rutherrin<sup>®</sup> into patients via a Phase O/I/II adaptive clinical study design, to first determine localization to various cancer cells, including Glio Blastoma Multiforme ("**GBM**"), Non-Small Cell Lung Cancer ("**NSCLC**"), pancreatic cancer, colorectal cancer and Muscle Invasive Bladder Cancer ("**MIBC**") and then in an adaptive design activate Rutherrin<sup>®</sup>, in single and multiple doses, with radiation with the intent of safely and effectively destroying the cancer of interest.

Rutherrin<sup>®</sup>, <u>if proven successful</u>, 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.

The Company expects to complete Good Laboratory Practice ("**GLP**") toxicology in 4Q2025 to allow commencement of a Phase 0/I/II adaptive clinical study in 1Q2026 for the following indications:

- 1) Glio Blastoma Multiforme ("GBM") Brain Cancer Treatment
- 2) Non-Small Cell Lung Cancer ("NSCLC") Treatment
- 3) Pancreatic Cncer
- 4) Colorectal Cancer
- 5) Muscle Invasive Bladder Cancer ("MIBC") Treatment
- 6) Herpes Simplex Virus ("HSV-1") Topical Treatment for Cold Sore Lesions

## **GlioBlastoma Multiforme**

Theralase<sup>®</sup> has successfully completed pre-clinical research to develop Ruvidar<sup>®</sup> for the destruction of GBM.

As an example of the effectiveness of Rutherrin<sup>®</sup> (Intra Venous ("**IV**") formulation of Ruvidar<sup>®</sup>) activated by radiation in the destruction of brain cancer, refer to Figure 1.



Figure 1: Destruction of Human Glioma Cells Treated with Radiation-Activated Rutherrin® Versus Radiation Alone

As shown in Figure 2, transferrin in the Rutherrin<sup>®</sup> formulation significantly increased both the total drug uptake and the specificity (> 10 times) compared to normal brain samples, while Ruvidar<sup>®</sup> alone does not show any selectivity. The selective uptake remains for at least 24 hours after injection, and the drug is gradually cleared overtime, which suggests for the requirement of a second Rutherrin<sup>®</sup> injection after 48 to 72 hours



Figure 2: Rat Glioma Orthotopic Model Rutherrin® Localization

As shown in Figure 3, tumour growth was slowed by radiation; however, the addition of Rutherrin<sup>®</sup> to radio therapy significantly inhibited tumour growth. None of the radiation alone treated mice showed CR; however, the combination of Rutherrin<sup>®</sup> with radiation treatment significantly delayed tumour progression and improved overall survival compared to radiation alone, with 25% of Rutherrin<sup>®</sup> activated by radiation demonstrating CR. Mice with CR were re-challenged with fresh tumour cells and none developed tumours, which suggests an immunity rate of 100%. In addition, strong efficacy was observed with a 3 mg/kg Rutherrin<sup>®</sup> dose, suggesting that radio-enhancement can be achieved with lower drug doses and lower uptake.



Figure 3: Efficacy of Rutherrin® and Comparison of Radiation Sources with Subcutaneous Mouse Model

#### **Non-Small Cell Lung Cancer**

Theralase<sup>®</sup> has completed pre-clinical research to develop Ruvidar<sup>®</sup> for the destruction of NSCLC, using a Lewis Lung Cancer ("**LLC1**") orthotopic model. In this model, mouse lungs are subjected to lung cancer cells, which induces these mice to develop very aggressive, fast growing and metastatic lung tumours.

As shown in Figure 4, lung tumours retained Rutherrin<sup>®</sup> longer than normal lung tissues (p>0.01), leading to a substantially improved selectivity of Rutherrin<sup>®</sup> to target lung cancer.



Figure 4: Rutherrin® Concentration in Normal and Tumour Lung After Single 3 Mg/Kg Intra Venous ("IV") Injection

As shown in Figure 5, the mice treated with x-ray activated Rutherrin<sup>®</sup> have demonstrated up to a 4-fold slower tumour progression, based on the Magnetic Resonance Imaging ("**MRI**") assessment of tumour volumes.

Mouse Orthotopic LLC1 Lung Cancer



Figure 5: Tumour Volume Analysis in Mice After Tumour Inoculation and Treatment with Either Radiation Only or Combined Treatment of Rutherrin<sup>®</sup> and Radiation Treatment

As shown in Figure 5, there is a significant delay in tumour progression in mice treated with X-ray activated Rutherrin<sup>®</sup> versus with radiation alone (p> 0.001). In fact, in mice treated with X-ray activated Rutherrin<sup>®</sup>, the tumour is notably regressing / being destroyed over time.

As shown in Figure 6, the Kaplan-Meier Curve representing animal survival demonstrates a significant increase in Overall Survival ("**OS**") of mice treated with X-ray activated Rutherrin<sup>®</sup> versus radiation only.



Figure 6: Kaplan-Meier Survival Analysis of Mice After Tumor Inoculation and Treatment with Radiation Only or Combined Treatment of Rutherrin<sup>®</sup> and Radiation Treatment

These results demonstrate that animals treated with a combination of Rutherrin<sup>®</sup> and radiation therapy demonstrated an increase in median survival from 26 to 35 days, versus radiation only. In scientific publications, mouse survival of 9 days has been equated to the equivalent of 1 year survival in humans, but more importantly, is that one animal treated with X-ray activated Rutherrin<sup>®</sup> (which had a positive lung tumour verified by CT scan) demonstrated a complete response and is now considered cancer free.

#### Muscle Invasive Bladder Cancer ("MIBC") Treatment

Theralase<sup>®</sup> is conducting pre-clinical research to develop Ruvidar<sup>®</sup> for the destruction of MIBC as an intravenous treatment for patients that are inflicted with this disease. The Company expects to complete GLP toxicology in 4Q2025 to allow commencement of a Phase I/II adaptive clinical study in 1Q2026.



Figure 7: Full Depth Tumour Necrosis Also Occurs in Muscle Invasive Bladder Tumours, with No Damage to Healthy Muscle Tissue (Light-Activated Ruvidar®)

## Leukemia, Lymphoma and Myeloma Treatment

Theralase<sup>®</sup> is conducting pre-clinical research to develop Ruvidar<sup>®</sup> for the destruction of Leukemia, Lymphoma and Myeloma as an extracorporeal treatment for patients that are inflicted with these diseases. Theralase<sup>®</sup> plans to develop this technology in 2026.

In the latest research, Figure 8 and 9, mice were inoculated with A20 mouse lymphoma cells subcutaneously ("SQ") on day 0. At day 10, tumours reached 3 to 5 mm in size.

To simulate proposed human treatments, mice were treated for 3 weeks with:

- Rutherrin<sup>®</sup> IV (3 times per week)
- Metformin intraperitoneally (daily)
- Radiation (5 times per week)

All treatments were stopped after 3 weeks of treatment and tumour volumes were assessed.

The results support the use of Rutherrin<sup>®</sup>, activated by both Metformin and radiation, in the effective treatment of NHL in a SQ mouse model.



Figure 8: Treatment without Radiation



Figure 9: Treatment with Radiation

## **Drug Combination Preclinical Research**

Ruvidar<sup>®</sup> and Rutherrin<sup>®</sup> have demonstrated an ability to "hunt" and localize to various cancer cells, viruses and bacteria and when activated by light and/or radiation safely and effectively destroy the target of interest.

Theralase<sup>®</sup> has expanded its research and development to include the evaluation of Ruvidar<sup>®</sup> and Rutherrin<sup>®</sup> in its ability to increase the safety and/or efficacy of currently marketed drugs; including: oncology drugs (i.e.: bacteria-based, chemotherapy and immunotherapy) and non-oncological drugs.

## <u>Ruvidar<sup>®</sup> + BCG</u>

In preclinical cell-based experiments, Ruvidar<sup>™</sup> combined with BCG creating a new compound, nicknamed RuBCG, that was able to significantly increase the efficacy of BCG in cancer cell kill versus BCG or Ruvidar<sup>®</sup> alone, when non-light activated. The Mechanism Of Action ("**MOA**") is believed to be through a reversal of the cell wall charge of the BCG bacteria and in return a significant enhancement of bladder cancer cell kill by RuBCG.

As shown in Figure 10, when Ruvidar<sup>™</sup> was combined with BCG, it was able to reverse the negative charge of BCG to a positive charge, thus allowing potentially greater BCG uptake by NMIBC cells and a corresponding higher kill rate.



Figure 10: Inversion of BCG Surface Charge by Ruvidar<sup>™</sup> in RuBCG Formulation

As shown in Figure 11, RuBCG was able to increase the immunogenicity (ability to produce an immune response) in bladder cancer cells, by significantly decreasing the immune checkpoint inhibitor, Programmed Death Ligand-1 ("**PD-L1**").



Figure 11: Increase in Immunogenicity of T24 cells (Human Bladder Cancer) Upon Incubation with RuBCG

As shown in Figure 12, RuBCG increased cell kill of T24 (human bladder cancer cells) versus the individual toxicities of Ruvidar<sup>™</sup> or BCG alone, when non-light activated.



Figure 12: Increase in Cytotoxicity of T24 (Human Bladder Cancer Cells) Upon Incubation with RuBCG

## Rutherrin<sup>®</sup> + Chemotherapy

Rutherrin<sup>®</sup> has been proven preclinically to be effective in increasing the efficacy of chemotherapy and reducing multidrug resistance.

Chemotherapy is currently one of the principal treatment methods for cancer, along with radiation and surgery. Clinically, many tumours undergo a satisfactory response, when first exposed to chemotherapeutic drugs; however, despite the initial success of these treatments, growing resistance to treatment with these drugs becomes a common occurrence. This results in the steady loss of therapeutic response over time for cancer patients, despite the wide spectrum of drugs and treatments available. This phenomenon is termed Multi-Drug Resistance ("MDR").

In order to determine the effect of Rutherrin<sup>®</sup> on MDR in cancer cells, cells were treated with Rutherrin<sup>®</sup>, before addition of one of the following drugs:

- 1. Hoechst 33342 (nuclear dye commonly used to study ABC transporter drug efflux)
- 2. Temozolomide (chemotherapy used to treat brain cancer)
- 3. Gemcitabine (chemotherapy used to treat various cancers)
- 4. Cisplatin (platinum-based chemotherapy used to treat various cancers)

Following incubation, cells were washed and the amount of intracellular drug was quantified using High-Performance Liquid Chromatography ("HPLC") coupled with Mass Spectrometry.

The amount of drug was normalized to cells, which were not treated with Rutherrin<sup>®</sup>, as a control.

As shown in Figure 13, treatment with Rutherrin<sup>®</sup> significantly enhanced the retention of all tested chemotherapeutic drugs, presumably through the inhibition of the ABC transporter efflux pump, resulting in higher intracellular drug accumulation, which would increase exposure of the cancer cells to the respective chemotherapy and consequently improve overall treatment efficacy.



Figure 13: Relative Chemotherapeutic Drug Retention in Rutherrin® Treated Cells Normalized to Drug-Only Treated Cells

To further investigate this phenomenon and to demonstrate cancer cell kill, *in vitro* cells were treated with Rutherrin<sup>®</sup>, before addition of various chemotherapeutic drugs to analyze cell survival.

These chemotherapeutic drugs include:

- 1. Vandetanib (chemotherapy used to treat thyroid cancer)
- 2. Vemurafenib (chemotherapy used to treat melanoma)
- 3. Vinblatine (chemotherapy used to treat lymphoma, breast cancer and testicular cancer)
- 4. Cisplatin (platinum-based chemotherapy used to treat various cancers)
- 5. Temozolomide (chemotherapy used to treat brain cancer)
- 6. Gemcitabine (chemotherapy used to treat various cancers)

As shown in Figure 14, the addition of Rutherrin<sup>®</sup> significantly increased the cancer cell kill for all tested chemotherapeutic drugs, suggesting a universal effect of Rutherrin<sup>®</sup> on chemotherapeutic drugs in their destruction of cancer cells, rendering the cancer cells more susceptible to chemotherapy.



Figure 14: Cell Kill Percent After Treatment with Chemotherapeutic Drugs (Listed on X-axis) (+/- Rutherrin® Treatment)

To further validate the research, a mouse animal model was utilized, where the mice were injected subcutaneously with mouse colorectal cancer cells and divided into four treatment groups; specifically: Untreated Control, Rutherrin<sup>®</sup> only, Vinblastine only and Rutherrin<sup>®</sup> combined with Vinblastine.

As shown above, the combination of Rutherrin<sup>®</sup> and Vinblastine significantly delayed tumor volume progression and enhanced overall animal survival, compared to control or either treatment alone. This research was completed using Rutherrin<sup>®</sup> with no light or radiational activation.



Figure 15: Kaplan-Meier Survival Curve and Tumor Volume Analysis in Mice After Subcutaneous Tumour Inoculation and Treatment With Either: Control, Rutherrin<sup>®</sup> Only, Vinblastine Only or Combined Rutherrin<sup>®</sup>, Plus Vinblastine Treatment

#### Rutherrin<sup>®</sup> + Immunotherapy

Rutherrin<sup>®</sup> has been preclinically proven effective in increasing the efficacy of immunotherapy. Immunotherapy, the latest technology in the war on cancer, can come in various forms; including: checkpoint inhibitors, Chimeric Antigen Receptor ("**CAR**") T-Cell therapy, cytokines, immunomodulators, cancer vaccines, monoclonal antibodies and oncolytic viruses, but the fundamental MOA of all of these immunogenic drugs is to stimulate the immune system to destroy cancer cells.

Cancer cells hide from the immune system by overexpressing proteins on their cellular surface, known as checkpoint proteins, that prevent the immune system from recognizing and subsequently destroying them. They thus remain incognito to the one failsafe that can protect the human body, the immune system.

Theralase<sup>®</sup>'s research demonstrates that Rutherrin<sup>®</sup> enhances the MOA of immunotherapy by not only killing cancer cells directly, but also significantly reducing the amount of PD-L1 proteins expressed by cancer cells; hence, reducing the number of target checkpoint proteins that need to be blocked by checkpoint inhibitors.

This results in an elegant one-two-three punch on the destruction of cancer cells; where, Rutherrin<sup>®</sup> delivers the first punch, targeting and destroying cancer cells directly, as well as the second punch, by reducing the number of PD-L1 proteins expressed. This allows immunotherapeutic drugs to deliver the third and final punch, blocking the PD-L1 proteins remaining, allowing the immune system to significantly increase their recognition of cancer cells and hence their destruction. As a result, this technological advance increases both the safety and efficacy of immunotherapy, as less treatments would be required to induce the same clinical effect.

As shown in Figure 16, treatment of human cancer cells; specifically, NMIBC and GBM with Rutherrin<sup>®</sup> significantly reduces the expression of PD-L1 checkpoint proteins on the surface of the cancer cells; hence, allowing immunogenic drugs a greater opportunity to block those remaining. This would allow the immune system a much better opportunity to identify them and target them for destruction.



Figure 16: Percentage Change in PD-L1 Expression in NMIBC and GBM Cancer Cells

#### **Herpes Simplex Virus**

In previous work, Dr. Kevin Coombs, a professor of virology at the University of Manitoba demonstrated that the small molecule, Ruvidar<sup>®</sup> could inhibit numerous pathogenic human viruses, when added to solutions of viruses, both with and without light-activation. In these experiments, Dr. Coombs evaluated the ability of Ruvidar<sup>™</sup> to restrict HSV-1 replication in Vero cells, both by itself and in combination with acyclovir in the absence of light-activation to mimic deep tissue application.

Light-activated Ruvidar<sup>®</sup> has been previously demonstrated to be even more effective in the inactivation of HSV versus non-light-activated Ruvidar<sup>®</sup>.

Ruvidar<sup>®</sup> successfully inhibited HSV-1 replication at significantly lower concentrations and more effectively than did the gold standard acyclovir alone. Dr. Coombs also discovered additive and synergistic, anti-HSV-1 effects, when combinational therapy was tested.



Figure 17: Effects of Ruvidar<sup>™</sup> versus Acyclovir on HSV-1 Yields When Added 24 Hours Post Infection ("HPI").

In Theralase<sup>®</sup> research, Balb/C mice were infected with human HSV-1 virus.

On day 6 post-infection, 1% Ruvidar<sup>®</sup> solution was applied topically over the area of well-developed lesions, once daily for 4 days.

Four days of Ruvidar<sup>®</sup> treatment resulted in complete healing of the HSV-1 cutaneous lesions.





Figure 18: Four days of Ruvidar<sup>®</sup> Treatment in Balb/C Mice with HSV-1 Infected Cutaneous Lesions

The results support the safety and efficacy of topically applied non-light activated Ruvidar<sup>®</sup> against cutaneous HSV-1 lesions in a mouse model.

An example of the efficacy of Ruvidar<sup>®</sup> versus standard of care therapies (i.e.: Acyclovir or Abreva) is demonstrated below:



Figure 19: Ruvidar<sup>™</sup> Versus Standard of Care Therapies

#### Intellectual Property Portfolio Growth

Theralase<sup>®</sup> received the following decisions to grant a patent in 2025:

Country	Patent Title
United States	Apparatus and Method for Irradiating Inside an Object

This patent protects Theralase<sup>®</sup>'s Emitter Detector Assembly, which is used in conjunction with the TLC-3200 to activate Ruvidar<sup>®</sup> in a patient's bladder for the destruction of BCG-Unresponsive NMIBC CIS.

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

During the year ended December 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>:

		2024		2023
Total revenues	\$	1,033,431	\$	1,070,307
Net loss		(4,256,114)		(4,570,879)
Basic and diluted loss per share	\$	(0.018)	\$	0.022
Total accosts	ć	2 246 040	ć	2 276 906
	Ş	3,240,949	Ş	3,270,800
		1,179,501		1,371,364
Deficit		(67,496,119)		(63,240,005)
Shareholders' Equity	\$	2,067,448	\$	1,905,442
<u>Summary of Quarterly Results</u> (Canadian Dollars)				
		2025		
For the period ending:		March 31		
Total revenues	\$	91,190		
Net loss		(1,471,250)		
Basic and diluted loss per share	\$	(0.006)		
As at:		March 31		
Total assets	\$	2,959,029		
Total liabilities		1,868,833		
Deficit		(68,967,369)		
Shareholders' Equity	\$	1,090,195		

	 	2024		
For the period ending:	 March 31	June 30	September 30	December 31
Total revenues	\$ 175,554 \$	100,847	\$ 346,583	\$ 410,447
Net loss	(1,266,711)	(1,133,750)	(937,534	) (918,119)
Basic and diluted loss per share	\$ (0.006) \$	(0.004)	\$ (0.004	) \$ (0.004)
As at:	March 31	June 30	September 30	December 31
Total assets	\$ 3,246,059 \$	3,384,859	\$ 3,222,164	\$ 3,246,949
Total liabilities	1,275,610	1,727,356	1,083,190	1,179,501
Deficit	(64,506,716)	(65,640,466)	(66,578,000	) (67,496,119)
Shareholders' Equity	\$ 1,970,449 \$	1,657,503	\$ 2,138,974	\$ 2,067,448

### Liquidity and Capital Resources

As of March 31, 2025, total current assets aggregated \$1,401,968 compared with total current liabilities of \$1,701,910 netting working capital of -\$299,942 and a current ratio (current assets versus current liabilities) of approximately .83:1.

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 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, 2025, the Company had a net loss of \$1,471,250 (2024 -\$1,266,711), an accumulated deficit of \$68,967,369 (December 31, 2024 - \$67,496,119) 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 are 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 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 2025. 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 be able to continue in operation for the foreseeable future and secure additional financing to satisfy its liabilities and commitments in the normal course of business. Accordingly, it is appropriate to prepare these consolidated financial statements on a going concern basis.

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.

## **Results of Operations**

### Sales:

For the three-month period ended March 31, 2025, total revenue decreased to \$91,190 from \$175,527 for the same period in 2024, a 48% decrease.

	2025	2024
Sales Revenue	\$ 38,252	\$ 154,772
Service Revenue	47,929	17,464
Other Revenue	5,009	3,291
	\$ 91,190	\$ 175,527

The TLC-2000 represented 81% of sales for the three-month period ended March 31, 2025 and 95% of sales for the same period in 2024.

In Canada, revenue decreased 38% to \$76,238 from \$122,099. In the US, revenue decreased 53% to \$14,952 from \$31,847. International sales decreased to \$Nil from \$21,609.

### Cost of Sales

Cost of sales for the three-month period ended March 31, 2025 was \$77,896 (85% of revenue) resulting in a gross margin of \$13,294 (15% of revenue). In comparison, the cost of sales for the same period in 2024 was \$113,440 (65% of revenue) resulting in a gross margin of \$62,114 (35% 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.

#### **Operating Expenses**

For the year three-month period ended March 31, 2025, selling expenses increased to \$68,143, from \$67,552 for the same period in 2024, a 1% increase and consisted of the following items:

	2025	2024
Sales salaries	\$ <b>49,848</b> \$	49,074
Advertising	7,100	5,849
Commission	153	5,996
Travel	6,515	2,182
Stock based compensation	1,156	1,024
Amortization and depreciation allocation	3,371	3,428
Total selling expenses	\$ <b>68,143</b> \$	67,552

The increase in selling expenses is primarily a result of increased spending on advertising (21%) and travel (199%).

Administrative expenses for the three-month period ended March 31, 2025, increased to 555,074 from \$511,495 for the same period in 2024, a 9% increase and consisted of the following items:

	2025	2024
Insurance	\$ <b>17,295</b> \$	13,625
Professional fees	133,999	117,939
Rent	10,304	10,304
General and administrative expenses	65 <i>,</i> 800	51,647
Investor Relations	54,691	69,422
Administrative salaries	124,181	128,592
Director and advisory fees	22,246	21,856
Stock based compensation	119,814	91,255
Amortization and depreciation allocation	6,744	6,856
Total administrative expenses	\$ <b>555,074</b> \$	511,495

The increase in administrative expenses is primarily a result of increased spending on insurance (27%), general and administrative expenses (27%) and professional fees (14%).

Stock based compensation expense increased 31% in 2024, due to the 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, 2025, increased to \$877,670 from \$756,380 for the same period in 2025, a 16% increase, and consisted of the following items:

	2025	2024
Research and development (net of investment tax credit)	\$ 760,096	\$ 654,033
Stock based compensation	68,395	50,861
Amortization and depreciation allocation	49,179	51,486
Total research and development expenses	\$ 877,670	\$ 756,380

The increase in research and development expenses is attributed to an increase in costs for Study II patient enrollment and treatment. Research and development expenses represented 60% of the Company's operating expenses and represent investment into the research and development of the Company's Drug Division.

## <u>Net Profit (Loss)</u>

The net loss for the three-month period ended March 31, 2025, was \$1,471,250 which included \$256,199 of net non-cash expenses (i.e.: amortization, stock-based compensation expense and foreign exchange gain/loss). This compared to a net loss in the three-month period ended March 31, 2024 of \$1,266,711, which included \$220,919 of net non-cash expenses. The Drug Division represented \$1,154,380 (78%) of this loss in the first quarter 2024.

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

## Cash Flows

Cashflows for the three-month period's ended March 31<sup>st</sup> are as follows:

	2025	2024
Net loss and comprehensive loss	\$ <b>(1,471,250)</b> \$	(1,266,711)
Items not involving cash	256,199	220,919
Cash provided by operations	(1,215,050)	(1,045,792)
Net change in non-cash working capital	867,288	(46,062)
Cash (used in) provided by operating activities	(347,762)	(1,091,854)
Cash (used in) provided by investing activities	(64,577)	(3,576)
Cash (used in) provided by financing activities	275,346	1,165,930
Net change in cash and cash equivalents during the period	(136,993)	70,500
Cash and cash equivalents, beginning of year	268,757	43,911
Cash and cash equivalents, end of period	131,764	114,411

Funds used in operating activities, after taking into account net changes in other non-cash operating items, were \$347,762 for the three-month period ended March 31, 2025, compared to funds used of \$1,091,854 in 2024. The decrease is attributed to increase in liabilities.

Funds used in investing for the three-month period ended March 31, 2025, amounted to \$64,557 compared to \$3,576 in 2024. The decrease is attributed to increased spending on equipment.

Funds received in financing activities amounted to \$304,633 for the three-month period ended March 31, 2025, compared to funds received of \$1,188,578 in 2024. The decrease is attributed to the timing of various non-brokered private placements.

## 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.

	Ma	rch 31, 2025	Dec	ember 31, 2024
Lease beginning balance	\$	1,438,315	\$	1,193,604
New leases for the period		11,461		538,547
Interest charge for the period <sup>1</sup>		19,121		70,053
Lease payments for the period <sup>2</sup>		(133,160)		(363,888)
Total	\$	1,335,738	\$	1,438,315

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:

	Undiscou	nted Lease Receivable	Discounted Lease Receivable	Unearned Finance Income
2025	\$	345,375	284,758	60,616
2026		459,032	403,028	56,004
2027		367,532	339,415	28,118
2028		225,557	209,390	16,168
2029		94,557	91,698	2,859
2030		7,521	7,448	72
Total	\$	1,499,575	\$ 1,438,315	\$ 163,836

### <u>Commitments</u>

As of March 31, 2025, the Company's commitments consisted of the following:

	Total	2025	2026		2027		2028		2029		2030		2	031
Research Agreement (a)	\$ 29,327	\$ -	\$	29,327	\$	-	\$	-	\$	-	\$	-	\$	-
Research Agreement (b)	107,120	55,020		8,800		8,800		8,800		8,800	8	3,800		8,100
Total	\$ 136,447	\$ 55,020	\$	38,127	\$	8,800	\$	8,800	\$	8,800	\$ 8	3,800	\$	8,100

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 \$29,327 (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, 2031. The Company has paid \$371,530 relating to this commitment, of which \$107,170 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 premises for an additional 5 years until September 30<sup>th</sup>, 2027.

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

	Property	Office E	quipment
2025	74,510		1,519
2026	107,209		880
2027	85,464		-
	\$ 267,183	\$	2,399

## Share Capital Analysis

As of May 29, 2025:

- The share capital of the Company consisted of 250,810,200 common shares. Each common share entitles the holder to one vote per share.
- There were 19,620,000 options outstanding, of which 5,360,000 were vested and exercisable into an equivalent number of the Company's common shares.
- There were 45,306,591 warrants outstanding. Each whole warrant entitles the holder thereof to purchase one additional common share.

The warrants are exercisable as follows:

- 10,000,000 at a price of \$CAN 0.35 until September 22<sup>nd</sup>, 2027
- 1,000,000 at a price of \$CAN 0.35 until November 17<sup>th</sup>, 2027
- 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
- 4,167,778 at a price of \$CAN 0.25 until April 24, 2029
- 3,522,729 at a price of \$CAN 0.30 until July 8, 2029
- 2,730,500 at a price of \$CAN 0.30 until September 24, 2029
- 2,221,334 at a price of \$CAN 0.45 until November 15, 2029
- 1,034,002 at a price of \$CAN 0.45 until March 11, 2030
- 1,995,829 at a price of \$CAN 0.32 until April 22, 2030

As of May 29, 2025, there were 18,864 finder's units that were issued in connection with the November 29, 2023, nonbrokered 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.

## 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 small molecules 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 researches, 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:

	2025							2024			
		Device		Drug		Total	Device	Drug		Total	
Sales	\$	91,190	\$	-	\$	91,190	\$ 175,554	\$ -	\$	175,554	
Cost of sales	-	77,896		-		77,896	113,440	-		113,440	
Gross margin		13,294		-		13,294	 62,114	-		62,114	
Operating Expenses											
Selling expenses		68,143		-		68,143	67,552	-		67,552	
Administrative expenses		234,533		320,540		555,074	229,620	281,875		511,495	
Research and development expenses		44,669		833,001		877,670	31,363	725,017		756,380	
Loss on foreign exchange		(1,663)		(1,663)		(3,325)	1,550	1,550		3,100	
Interest accretion on lease liabilities		2,501		2,501		5,002	3,320	3,320		6,640	
Interest income		(18,020)		-		(18,020)	(16,341)	-		(16,341)	
		330,164		1,154,380		1,484,544	 317,064	1,011,762		1,328,825	
Loss for the period	\$	(316,870)	\$	(1,154,380)	\$	(1,471,250)	\$ (254,950)	\$ (1,011,762)	\$	(1,266,711)	
Total Assets	\$	2,282,815	\$	676,214	\$	2,959,029	\$ 2,361,142	\$ 884,917	\$	3,246,059	
Total Liabilities		448,682		1,420,151		1,868,833	 415,261	860,349		1,275,610	

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:

			2025			2024							
	Canada		USA	Inte	ernational	Canada			USA	International			
Sales by Product Line													
TLC-1000	\$	11,853	\$ 5,110	\$	-	\$	7,913	\$	388	\$	-		
TLC-2000		64,385	9,842		-		114,185		31,459		21,609		
		76,238	14,952		-		122,099		31,847		21,609		
Expenses													
Cost of Sales		65,123	12,773		-		78,897		20,580		13,963		
Selling Expenses		53,130	12,294		2,719		52,630		8,920		6,001		
		118,253	25,067		2,719		131,527		29,500		19,964		
	\$	(42,015)	\$ (10,115)	\$	(2,719)	\$	(9,428)	\$	2,347	\$	1,645		

As at March 31<sup>st</sup>, 2025 and December 31<sup>st</sup>, 2024, 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 condensed consolidated interim financial statements for the three-month period ended March 31<sup>st</sup>, 2025, 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>, 2024. Please refer to the Company's annual and quarterly financial statement filings, including material interim press releases, at <u>www.sedarplus.ca</u>.

## 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
- <u>Level 3:</u> inputs for the asset or liability that are not based upon observable market data.

Cash and cash equivalents, trade and other receivable and payables and accrued liabilities are valued at Level 1. These are stated at fair value due to the short-term maturities of these instruments.

The investment in leases is fair valued using Level 3. All future receipts have been discounted using the Bank prime rate of interest as at March 31<sup>st</sup>, 2025. No Level 3 adjustment was required. (See page 33 for reconciliation)

#### (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 receivable 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:

Cash and cash equivalents Financed trade receivables Short-term fixed and variable interest rate Long-term fixed interest rate (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 condensed consolidated interim financial statements as of March 31<sup>st</sup>, 2025 and audited consolidated financial statements as of December 31<sup>st</sup>, 2024, respectively, and for the three-month period ended March 31<sup>st</sup>, 2025 and 2024, respectively, have been prepared in accordance with IFRS. The policies applied are based on IFRS issued and outstanding as of May 29<sup>th</sup>, 2025 which is the date at which the Company's Board of Directors approved the audited 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 prepared. Here the audited consolidated financial statements are prepared.

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 consolidated financial statements can be found in note 2 to the audited consolidated financial statements of December 31<sup>st</sup>, 2024 and 2023.

## **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 consolidated 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 consolidated financial statements; and
- (ii) the consolidated 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 consolidated 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, 2024 and 2023, 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, 2025. 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 consolidated 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 or prevent fraud.

## **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 via private placements 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 small molecule 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 small molecules, all of which are subject to regulatory oversights, audits and controls by various national regulatory agencies (i.e.: FDA, Health Canada and 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 small molecules 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 than 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 / Review Ethics Boards ("IRBs / REBs") 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>, 2025

Kristina Hachey, CPA Chief Financial Officer