

# **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 interim consolidated financial statements for the nine-month period ended September 30<sup>th</sup>, 2023.

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

This MD&A is prepared as of November 29<sup>th</sup>, 2023.

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

## **Forward Looking Statements:**

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

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

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

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

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

## **Company Profile:**

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

## **Leadership Change**

On May 24, 2023, Roger DuMoulin-White, B.Sc., P.Eng., Pro. Dir. was appointed President and Chief Executive Officer (“CEO”) of the Company.

Dr. Arkady Mandel, M.D., Ph.D., D.Sc. tendered his resignation as Interim CEO and continues to serve as Chief Scientific Officer (“CSO”) and as a member of Theralase®’s Board.

Mr. DuMoulin-White is the founder of Theralase® and its former President and CEO. He stepped down as President and CEO in 2018 and has since served in a non-executive business development role. Mr. DuMoulin-White was the subject of a voluntary Settlement Agreement with the Ontario Securities Commission (“OSC”) dated February 16<sup>th</sup>, 2018 and an OSC Order dated February 26<sup>th</sup>, 2018 which required, among other things, that he resign as a director and officer of Theralase® and refrain from holding those positions for a period of five years. That period has expired and Theralase® obtained the approval of the Toronto Stock Venture Exchange (“TSXV”) to appoint Mr. DuMoulin-White as President and CEO of the Company and to nominate him for election to the Company’s Board of Directors at the Company’s Annual Meeting on June 29<sup>th</sup>, 2023.

On June 6<sup>th</sup>, 2023, Ms. Kaouther Lbiati, M.D., M.Sc. was appointed a director of the Company. Dr. Lbiati is an internationally trained medical doctor, who utilizes her extensive clinical and business background to assist biopharmaceutical organizations to achieve their strategic objectives through: systematic achievement of their value inflection milestones, partnering of their promising drug candidates with large international pharmaceutical companies and ultimately increasing shareholder value.

On June 29<sup>th</sup>, 2023, Mr. DuMoulin-White was appointed a director of the Company.

## **TSX Venture 50™**

Theralase® was named to the Toronto Stock Exchange Venture (“TSXV”) “2023 Venture 50™”. The Venture 50™ is an annual ranking of the top-performing companies from five industry sectors; specifically: Clean Technology and Life Sciences, Diversified Industries, Energy, Mining and Technology. Theralase® was recognized in the Clean Technology and Life Sciences category. Theralase® was previously named a 2015, 2019 and 2020 Venture 50™ company making this the fourth year Theralase® has been recognized as a top performer in the Clean Technology and Life Sciences sector in the last 8 years.

## **Non-Brokered Private Placement**

On June 30<sup>th</sup>, 2023, the Company completed a financing by way of a non-brokered private placement, where 4,800,000 units were issued at a price of \$CAN 0.25 per unit for gross proceeds of \$CAN 1,200,000. Each unit consisted of one common share and one non-transferable common share purchase warrant. Each whole warrant entitles the holder thereof to acquire one common share at a price of \$CAN 0.35, expiring on June 30<sup>th</sup>, 2025. An aggregate of 1,110,000 Units, representing gross proceeds of \$CAN 277,500, were issued to certain insiders of the Corporation.

On September 7, 2023, the Company completed a financing by way of a non-brokered private placement, where 1,840,000 units were issued at a price of \$0.25 per unit for gross proceeds of \$CAN 460,000. Each unit consisted of 1 common share and 1 non-transferable common share purchase warrant. Each whole warrant entitles the holder thereof to acquire 1 common share at a price of \$0.35, expiring on September 7, 2025. An aggregate of 424,000 Units, representing gross proceeds of \$CAN 106,000, were issued to certain insiders of the Corporation.

On November 29, 2023, the Company closed a non-brokered private placement of units. On closing, the Company issued an aggregate of 5,318,183 units at a price of \$0.22 per Unit for aggregate gross proceeds of approximately \$CAN 1,170,000 of which 461,282 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 \$0.28 for a period of 5 years following the date of issuance.

## **Warrant Extension**

On January 5<sup>th</sup>, 2023, the Company extended the expiry date of 4,095,157 share purchase warrants, all of which are exercisable at \$CAN 0.50 per share. The share purchase warrants were issued on January 9<sup>th</sup>, 2019 pursuant to a private placement involving the issuance of 4,095,157 units of the Company. The new expiry date of the warrants is January 9<sup>th</sup>, 2024.

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

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

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

The trade name Ruvidar™ was selected by the Company for its lead PDC, TLD-1433; where, Ru is the elemental symbol for Ruthenium (a rare transitional metal in Group 8 belonging to the platinum group, which the Theralase® PDC is based upon), vita is Latin for "life" and dar is Russian for "gift"; hence, roughly translated, "Ruthenium, the gift of life".

Iron, Ruthenium and Osmium are all transitional metals in Group 8, so named as they possess eight electrons in their outer shell, giving them similar characteristics.

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

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

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

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

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

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

Study II was designed to enroll and treat patients in up to 15 Clinical Study Sites ("CSSs") located in Canada and the US. To date, Theralase® has successfully launched 12 CSSs ; specifically, 5 CSSs in Canada and 7 CSSs in the US, with 1 US CSS terminating patient enrollment in Study II, leaving 5 active CSSs in Canada and 6 active 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 II Treatment.

### **Study II objectives:**

**Primary:** Efficacy, evaluated by Complete Response ("CR") at any point in time in patients confirmed to have CIS (with or without resected papillary disease (Ta / T1)) during the screening process.

CR is defined by at least one of the following:

- Negative cystoscopy and negative (including atypical) urine cytology

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

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

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

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

The Study II Treatment consists of a Study II Drug (Ruvidar™) at the Therapeutic Dose (0.70 mg/cm<sup>2</sup>) (equivalent to 0.65 mg/cm<sup>2</sup> of active drug moiety) instilled into the patient’s bladder intravesically for approximately 60 minutes and subsequently activated by the Study II 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 II Drug (Ruvidar™) and an Investigational Testing Authorization (“ITA”) for the Study II Device (TLC-3200) to allow commencement of enrolling and treating patients in Study II.

On October 23, 2023, Theralase® announced that it has been 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”).

The Study II optimization consists of:

1. **Post Study II Monitoring of Response** - Patients, who achieved a Complete Response (“CR”) or Indeterminate Response (“IR”), demonstrated a duration of that response at 450 days and remained in Study II will be monitored by the Company past 450 days, to help define the long-term duration of the Study II Treatment.
2. **Optional Maintenance Study II Treatment** -Patients currently receive a mandatory maintenance Study II Treatment at 180 days; however, this has been optimized to allow optional maintenance Study II Treatments, 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 maintenance Study II Treatments would be administered; however, if the patient recurs at any scheduled assessment visit (i.e.: 90, 180, 270, 360 or 450 days), then that patient would be eligible to receive up to 2 maintenance Study II Treatments 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.

**Note:**

IR is defined as:

- Negative cystoscopy and positive urine cytology, without confirmatory negative bladder cancer biopsies

As of November 29<sup>th</sup>, 2023, the following CSSs have enrolled and/or treated patients:

Clinical Study Sites	Location	Commenced	Status
University Health Network (“UHN”)	Toronto, Ontario, Canada	April 25, 2019	Enrolling
McGill University Health Centre (“MUHC”)	Montreal, Quebec, Canada	July 30, 2019	Enrolling
London Health Sciences Centre (“LHSC”)	London, Ontario, Canada	October 7, 2019	Enrolling
Nova Scotia Health Authority (“NSHA”)	Halifax, Nova Scotia, Canada	February 25, 2020	Enrolling
University of British Columbia (“UBC”)	Vancouver, British Columbia, Canada	December 7, 2020	Enrolling
Virginia Urology (“VU”)	Richmond, Virginia, United States	January 19, 2021	Closed to Enrollment
Urology Associates P.C. (“UAPC”)	Nashville, Tennessee, United States	January 20, 2021	Enrolling
MidLantic Urology (“MLU”)	Bala Cynwyd, Pennsylvania, United States	January 25, 2021	Enrolling
Carolina Urologic Research Center (“CURC”)	Myrtle Beach, South Carolina, United States	January 27, 2021	Enrolling
University of Wisconsin-Madison (“UWM”)	Madison, Wisconsin, United States	February 24, 2021	Enrolling
Urology San Antonio P. A. (“USAPA”)	San Antonio, Texas, United States	March 25, 2021	Enrolling
University of Chicago (“UC”)	Chicago, Illinois, United States	June 11, 2021	Enrolling

In 2020, the Company received FDA Investigational New Drug (“IND”) authorization (Study II Drug and Study II Device) to commence enrolling and treating patients in Study II in the United States. Theralase® has received Study II level approval through a central Institutional Review Board (“IRB”) to launch Study II in 7 US CSSs, subject to site level IRB approval, with 1 US CSS terminating patient enrollment in Study II, leaving 5 active CSSs in Canada and 6 active CSSs in the US.

Study II commenced in April 2019 with an estimated completion time of approximately 7 years and an estimated cost of approximately \$CAN 25 million. The timing and cost may vary significantly depending on numerous factors, including; number of CSSs enrolling and treating patients, patient enrollment rates in total and at each CSS, patient compliance, successful achievement of Study II primary, secondary and tertiary objectives and the ability of participating CSSs to enroll and treat patients considering challenges caused by current COVID-19 pandemic restrictions.

#### **Study II Clinical Study Site Update:**

As previously mentioned, patient enrollment and treatment rates were significantly delayed due to the COVID-19 pandemic restrictions in place at various CSSs; however, they have improved as Canada and the US recover from the COVID-19 pandemic. Canadian CSSs placed themselves on temporary hold commencing March 20<sup>th</sup>, 2020 and resumed normal operations between August 12<sup>th</sup>, 2020 and September 24<sup>th</sup>, 2020, respectively. Although Canadian CSSs recruiting activities were re-commenced in 4Q2020; patient recruitment and treatment activities have been significantly limited due to repeated waves of COVID-19.

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

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

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

To date, Theralase® has enrolled and treated 63 patients in Study II, who have been provided the primary Study II Treatment.

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

In 2020, the FDA granted Theralase® Fast Track Designation (“FTD”) for Study II. As a Fast Track designee, Theralase® has access to early and frequent communications with the FDA to discuss Theralase®’s development plans and ensure the timely collection of clinical data to support the approval process. The accelerated communication with the FDA potentially allows, the Study II Treatment, to be the first intravesical, patient-specific, light-activated, Ruthenium-based PDC for the treatment of patients diagnosed with BCG-

Unresponsive NMIBC CIS, (with or without recurrent / resected papillary T<sub>a</sub>/T<sub>1</sub> tumours). FTD can also lead to Break Through Designation (“**BTD**”), Accelerated Approval (“**AA**”) and/or Priority Review, if certain criteria are met, which the FDA has previously defined to the Company for BTD as clinical data on approximately 20 to 25 patients enrolled and provided the primary Study II Treatment, who demonstrate significant safety and efficacy clinical outcomes.

In 2021, Theralase<sup>®</sup> completed its first significant milestone of Study II by enrolling and treating (primary Study Treatment) 25 patients.

In 2022, Theralase<sup>®</sup> completed its second significant milestone of Study II by enrolling and treating (primary Study Treatment) 50 patients.

The Company has submitted a pre-BTD submission to the FDA and based on the FDA’s feedback, the Company is currently working with the CSSs, a biostatistics organization and a regulatory organization to update the pre-BTD with clinical data clarifications identified by the FDA. The Company plans to resubmit the pre-BTD submission to the FDA in early 1Q2024 for FDA review of these clarifications. Once the pre-BTD submission has been accepted by the FDA, the Company plans to compile a BTD submission for review by the FDA in support of the grant of a BTD approval in 1Q2024.

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

To date, Study II has provided the primary study treatment for 63 patients.

In recent discussions with the MSAB for Study II, the MSAB advised the Company to review the FDA Guidance to Industry<sup>1</sup> on how to best classify Indeterminate Response (“**IR**”) patients (patients assessed with negative cystoscopy and positive urine cytology), where the source of the positive urine cytology has not been determined.

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

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

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

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

Theralase<sup>®</sup>'s Study II treats patients with an intravesical Study II Drug activated by an intravesical Study II Device. In accordance with the FDA Guidance to Industry<sup>1</sup>, patients enrolled and provided the primary Study II Treatment, where the source of the positive urine cytology has not been identified (i.e.: upper tract or prostatic urethra Urothelial Cell Carcinoma (“**UCC**”)) and confirmatory bladder biopsies are negative, Theralase<sup>®</sup> has reclassified these patients from IR to CR.

For patients, who have been enrolled and provided the primary Study II Treatment in Study II, that have been diagnosed as IR and do not have confirmatory negative bladder biopsies (confirming that the source of the UCC is not from the bladder wall), then these patients have remained classified as IR, until additional clinical assessments can be completed by the respective Principal Investigator (“**PI**”) to prove or disprove a diagnosis of CR.

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

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

In 2016, Kamat et al. stated in the Journal of Clinical Oncology that the International Bladder Cancer Group (“**IBCG**”) recommended that, “*Single-arm designs may be relevant for the BCG-unresponsive population. Here, a clinically meaningful initial complete response*

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

rate (for carcinoma in situ) or recurrence-free rate (for papillary tumors) of at least 50% at 6 months, 30% at 12 months, and 25% at 18 months is recommended.”<sup>2</sup>

The interim clinical data presented below meets or exceeds these IBCG guidelines.

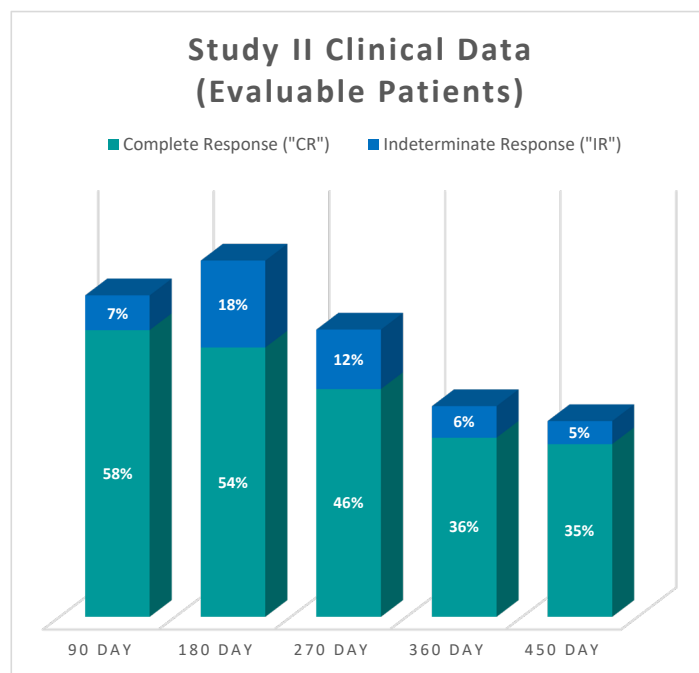
**Performance to Primary, Secondary and Tertiary Objectives:**

Assessment	Achieved		Achieved		Achieved	
	#	%	#	%	#	#
Complete Response ("CR")	38	67%	15	35%	57	100%
Indeterminate Response ("IR")	5	9%	2	5%	-	-
Total Responders (CR and IR)	43	75%	17	40%	57	100%
<b>Evaluable Patients</b>	<b>57</b>		<b>43</b>		<b>57</b>	

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

Assessment	Patient Assessment Visit									
	90 Days		180 Days		270 Days		360 Days		450 Days	
	#	%	#	%	#	%	#	%	#	%
Complete Response ("CR")	33	58%	31	54%	23	46%	17	36%	15	35%
Indeterminate Response ("IR")	4	7%	10	18%	6	12%	3	6%	2	5%
Total Responders (CR and IR)	37	65%	41	72%	29	58%	20	43%	17	40%
<b>Evaluable Patients</b>	<b>57</b>		<b>57</b>		<b>50</b>		<b>47</b>		<b>43</b>	

The interim clinical data demonstrates that at the 90 Day Assessment 58% of Evaluable Patients (achieved a CR and 65% achieved a Total Response (CR + IR) post primary Study II Treatment and at 450 days 35% achieved a CR and 40% achieved a TR.

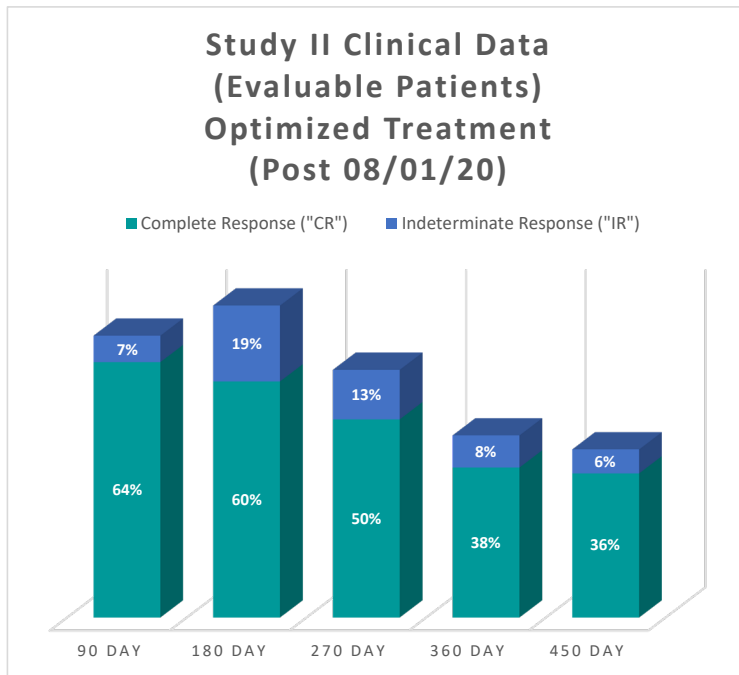


<sup>2</sup> Kamat AM et al. J Clin Oncol. 2016; 34: 1935-1944

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

Assessment	Patient Assessment Visit (Optimized Treatment - Post August 1, 2020)									
	90 Days		180 Days		270 Days		360 Days		450 Days	
	#	%	#	%	#	%	#	%	#	%
Complete Response ("CR")	29	64%	28	60%	20	50%	14	38%	12	36%
Indeterminate Response ("IR")	3	7%	9	19%	5	13%	3	8%	2	6%
Total Responders (CR and IR)	32	71%	37	79%	25	63%	17	46%	14	42%
<b>Evaluable Patients</b>	<b>45</b>		<b>47</b>		<b>40</b>		<b>37</b>		<b>33</b>	

The interim clinical data demonstrates that at the 90 Day Assessment 64% of Evaluable Patients achieved a CR and 71% achieved a Total Response (CR + IR) post primary Study II Treatment with the Optimized Study II Treatment and at 450 days 36% achieved a CR and 42% achieved a TR.



**Note:**

- For patients to be included in the statistical clinical analysis they must be enrolled in Study II, provided the primary Study II Treatment and evaluated by a PI at the 90 day assessment visit (cystoscopy and urine cytology)
- One patient passed away prior to their 90 day assessment and is therefore not included in the statistical analysis; therefore, there are 63 patients that have been statistically analyzed.
- Evaluable Patients are defined as patients who have been evaluated by a PI and thus excludes a patient’s clinical data at specific assessment days, if that clinical data is pending.
- Three patients have been enrolled and provided the primary Study II Treatment, but have not been evaluated at their 90 day assessment; therefore, 57 patients are considered Evaluable Patients at 90 days, with 43 patients considered Evaluable Patients at 450 days.
- The data analysis presented above, should be read with caution, as the clinical data is interim in its presentation, as Study II is ongoing and new clinical data collected may or may not continue to support the current trends, with significant data still pending.

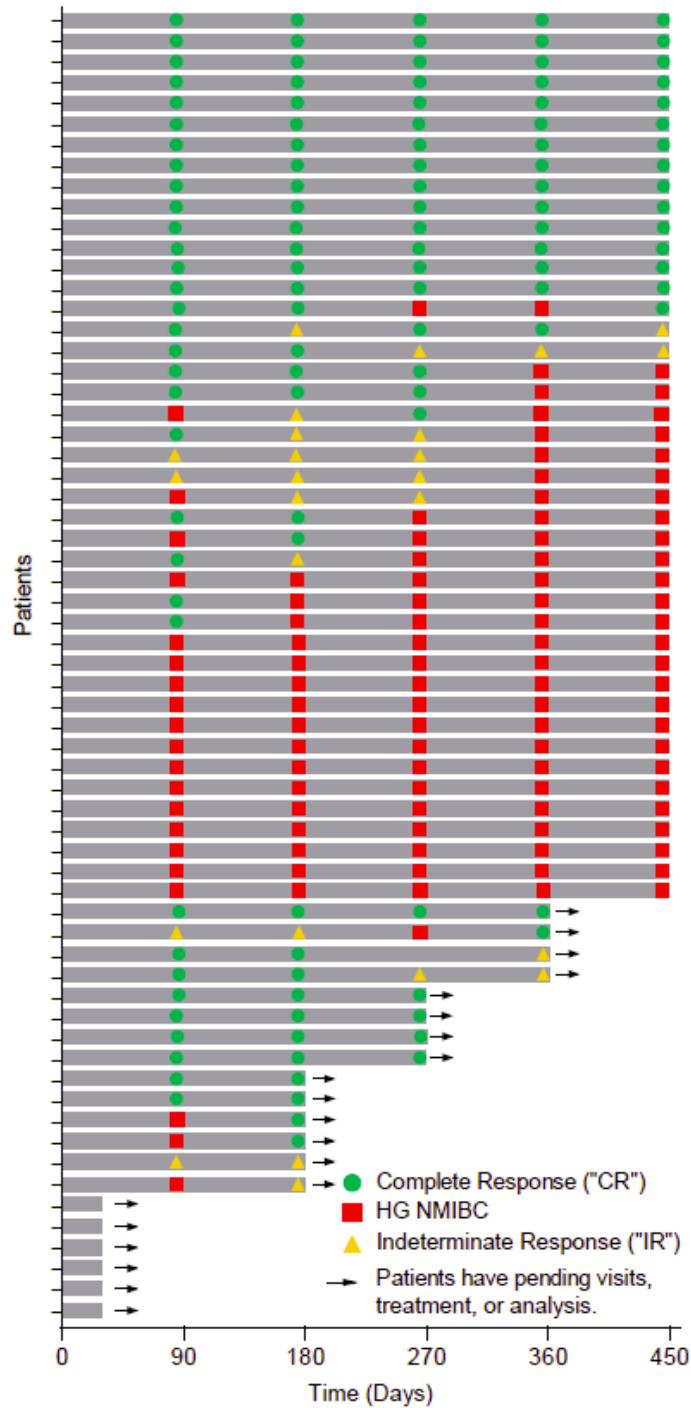


- For patients who have been removed from the study by the PI or have elected to discontinue from the clinical study their Last Observation Carried Forward ("LOCF") has been used in this statistical analysis.

**Patient Response Chart:**

The Swimmer's plot below is a graphical representation of the interim clinical results (n=63) graphically demonstrating a patient's response to a treatment over time. As can be seen in the plot, clinical data is still pending for patients, who have demonstrated an initial CR at 90 days and continue to demonstrate a duration of that response.

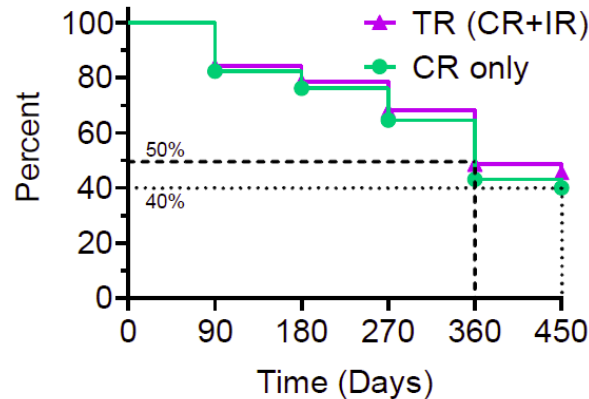
**Swimmer's Plot:**



The Swimmer's Plot illustrates:

- 15 Evaluable Patients that achieved CR at each assessment date (with one patient under PI review with a NR at the 270 and 360 assessment dates) and thus achieved the primary and secondary objectives of Study II for all patients assessed up to 450 days (15/43 = 35%).
- 38 Evaluable Patients that achieved CR on at least one assessment date and thus achieved the primary objective of Study II (38/57 = 67%)

Kaplan-Meier Curve:



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

According to the interim clinical data in the KM curve:

- > 80% of patients remained in Study II after 90 days, following the initial Study II Treatment.
- 46% of Total Response patients have a duration of response ≥ 450 days.
- 40% of Complete Response patients have a duration of response ≥ 450 days.

Serious Adverse Events

For 63 patients treated in Study II, there have been 11 Serious Adverse Events (“SAEs”) reported:

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

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

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

Study II Interim Data Presentations:

Study II (Interim) clinical data was presented at the American Society of Clinical Oncology (“ASCO”) Genito Urinary (“GU”) Cancer Symposium on February 17<sup>th</sup>, 2023 in San Francisco, California with the poster presented for general viewing and discussion within Poster Session B: Prostate Cancer and Urothelial Carcinoma. The poster presented at the ASCO GU Cancer Symposium can be found on the Company’s website at [www.theralase.com/ASCO\\_Poster](http://www.theralase.com/ASCO_Poster).

Study II (Interim) clinical data was presented at the 2023 American Urology Association (“AUA”) Annual Meeting on May 1<sup>st</sup>, 2023 in Chicago, Illinois with the poster presented for general viewing and discussion at a moderated poster session, within the AUA Annual Meeting. The poster presented at the AUA Annual Meeting can be found on the Company’s website at [www.thermalase.com/AUA\\_Poster](http://www.thermalase.com/AUA_Poster).

**Additional Oncology Targets:**

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

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

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

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

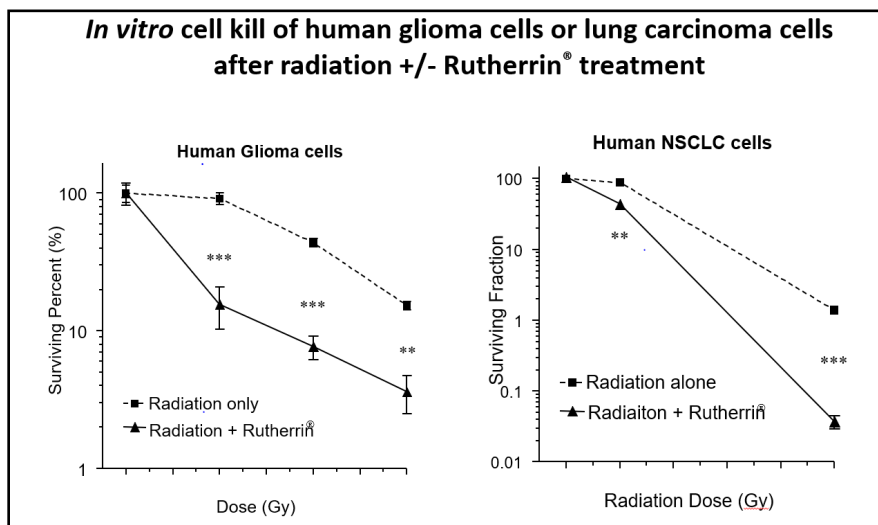
Due to the limitations of using laser light to activate Rutherrin® in deep oncological targets, Theralase®’s research strongly suggests that Rutherrin® may be activated with radiation therapy, which is able to increase the “tumour’s damage zone” and the effectiveness of Theralase®’s PDT beyond the reach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

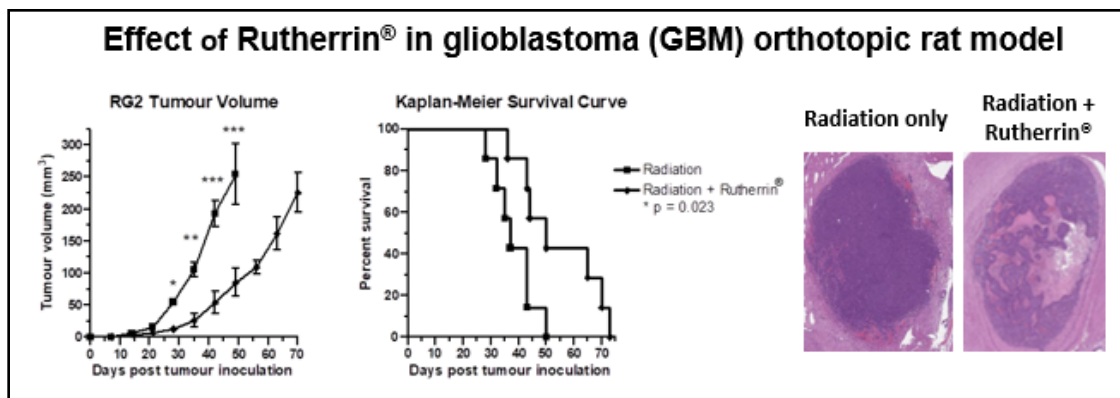
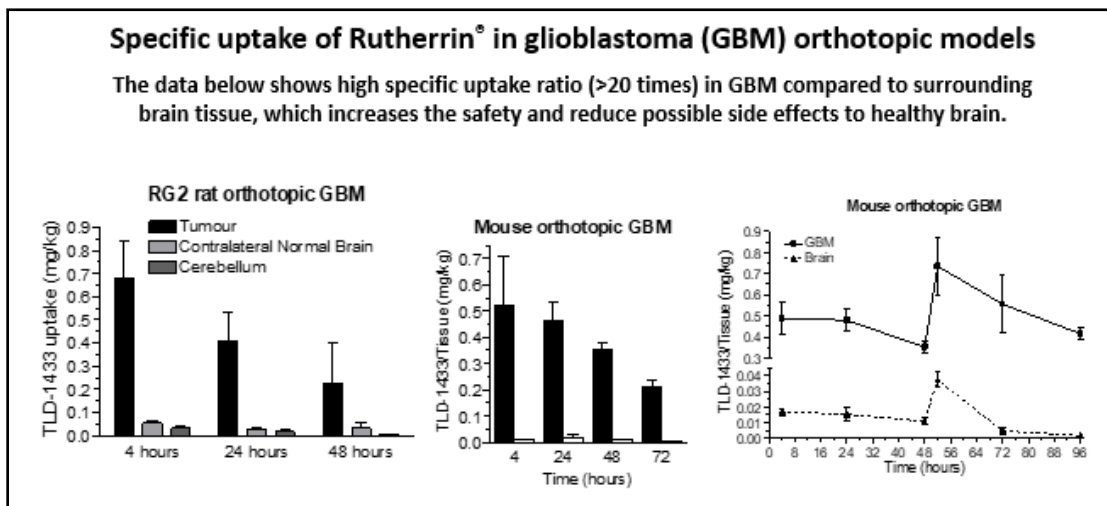
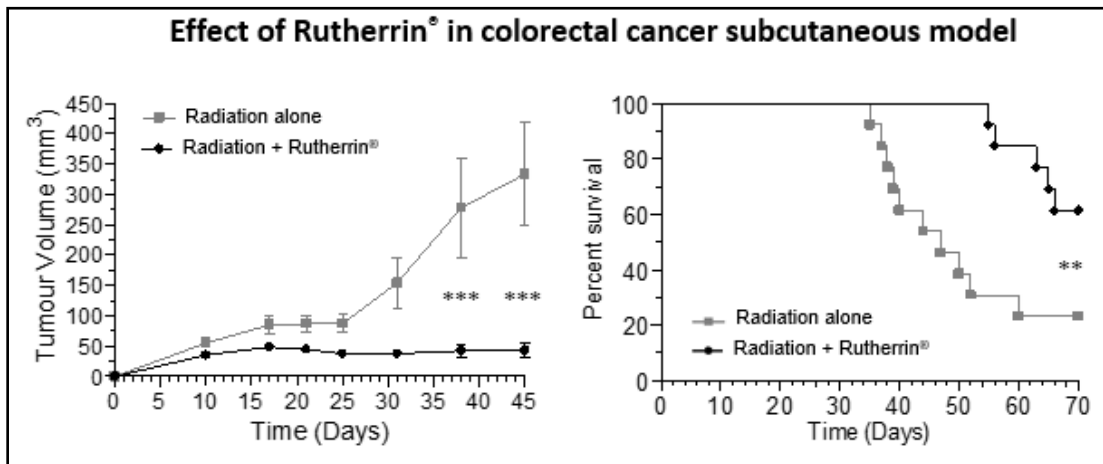
Radiotherapy (“RT”) is one of the primary treatment methodologies for many types of cancer, although it is currently a challenge to enhance radiation damage to tumour tissue, while reducing side effects to healthy tissue.

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

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

Below, Theralase® highlights recent progress on the current research and development initiatives utilizing Rutherrin®, in several *in vitro* and *in vivo* models.





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

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

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

### Additional Virus Targets:

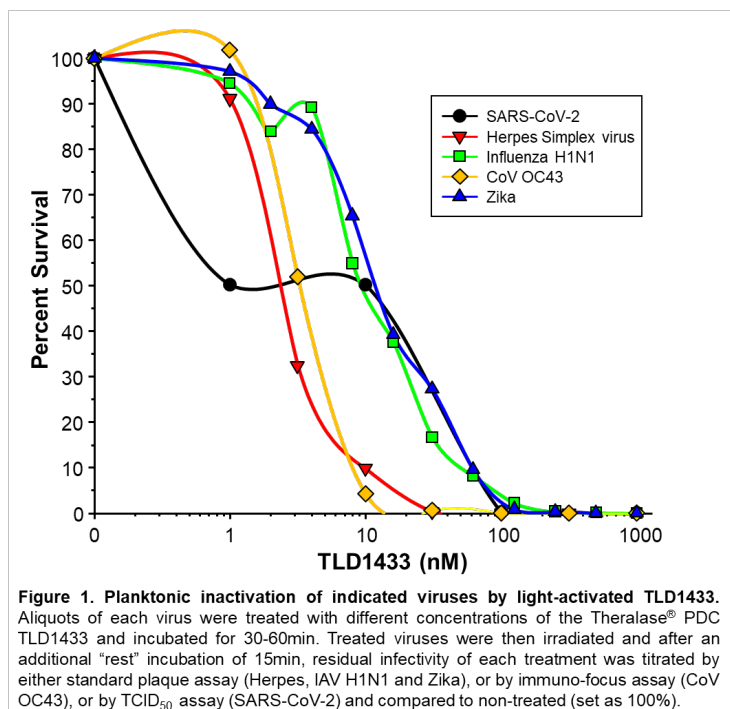
Theralase® executed a Sponsored Research Agreement (“SRA”) with the University of Manitoba (“UM”) Medical Microbiology department in July 2020, which has been subsequently extended to June 2023, to commence development of a coronavirus vaccine utilizing Theralase®’s patented and proprietary PDCs. The primary objective of the SRA was to investigate the efficacy of Theralase®’s lead PDC to destroy a variety of viruses; including: H1N1 Influenza, Zika and coronaviruses (Biological Safety Level (“BSL”) 2). The secondary objective was to optimize the concentration of PDC required, the activation methodology and how to potentially administer the treatment to humans to be used as a vaccine (prevention of a patient from contracting COVID-19) (BSL-3).

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

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

A rapid test was established to measure coronavirus destruction and using this new assay the Theralase® PDC technology was able to destroy coronavirus (BSL-2) with drug doses 5 times lower than what was used to kill H1N1 Influenza and Zika viruses. These drug doses are significantly lower than those used by the Company to treat cancers and are therefore considered safe for human use.

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



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

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

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



**Figure 2. Antigenicity and location of Spike (S) protein on TLD1433-treated coronaviruses.** Aliquots of CoV OC43 were either treated with 250 nM TLD1433 as described in the legend to Fig. 1, or not treated. Virions were pelleted at 40,000xg for 90min and supernatants (S) and virion pellets (P) resolved in SDS-PAGE, then transferred to nitrocellulose and probed with an antibody that recognizes S protein.

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

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

These results have now laid the groundwork for the next phase of the CRA, which is evaluating the Theralase® COVID-19 vaccine in the ability to prevent animals from contracting COVID-19, when exposed to the virus, which is expected to commence in 4Q2023 and be completed by 2Q2024.

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

### **Intellectual Property Portfolio Growth**

Theralase® received the following decisions to grant a patent in 2023:

Country	Patent Title
USA	Sonodynamic Therapy using Sonodynamically Activated Coordination Complexes of Transition Metals as Sensitizing Agents
Brazil	Metal-Based Thiophene Photodynamic Compounds and Their Use

### **Sonodynamic Therapy using Sonodynamically Activated Coordination Complexes of Transition Metals as Sensitizing Agents**

This invention relates to sonodynamic therapy and more particularly to Sono Dynamic Therapy (“SDT”) using sensitizing agents activated by sonic waves.

### **Metal-Based Thiophene Photodynamic Compounds and Their Use**

The Mechanism of Action (“MOA”) of the patented Theralase® PDCs involves selective localization of the PDC inside the cancer cells of interest and then activating it by laser light to produce effective free radicals, singlet oxygen and ROS, temporally and spatially to destroy the cancer cells, with minimum impact on healthy cells. Compositions of the invention include tunable metal-based thiophene photodynamic compounds useful as therapeutic agents and as in vivo diagnostic agents for treating or preventing diseases that involve hyperproliferating cell etiology including cancer and diseases associated with hyperproliferating cells. The compositions are also useful for treating infectious diseases and for pathogen disinfection.

## Overview of Financial Performance:

During the nine-month period ended September 30<sup>th</sup>, 2023, the Company's financial performance and its operating results reflect the continued investment by the Company into its future prosperity through the research, development, preclinical and clinical initiatives culminating in the successful completion of the Phase Ib NMIBC clinical study and the launch of Study II.

## Summary of Selected Audited Annual Information:

(Canadian Dollars)

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

	<b>2022</b>	<b>2021</b>
Total revenues	\$ 706,695	\$ 812,998
Net loss	(3,579,855)	(4,352,100)
Basic and diluted loss per share	\$ (0.016)	\$ (0.021)
Total assets	\$ 3,000,125	\$ 4,160,904
Total liabilities	1,368,257	1,068,336
Deficit	(62,248,981)	(58,451,686)
Shareholders' Equity	\$ 1,631,868	\$ 3,092,568

## Summary of Quarterly Results:

(Canadian Dollars)

	<b>2023</b>			
	<b>March 31</b>	<b>June 30</b>	<b>September 30</b>	
<b>For the period ending:</b>				
Total revenues	\$ 207,161	218,926	\$ 280,608	
Net loss	(1,408,953)	(1,155,234)	(1,015,668)	
Basic and diluted loss per share	(0.007)	(0.005)	(0.005)	
<b>As at:</b>	<b>March 31</b>	<b>June 30</b>	<b>September 30</b>	
Total assets	\$ 3,200,969	3,380,338	3,000,125	
Total liabilities	1,350,759	1,342,906	1,368,257	
Deficit	(60,078,080)	(61,233,313)	(62,248,981)	
Shareholders' Equity	\$ 1,850,210	2,037,432	1,631,868	
	<b>2022</b>			
	<b>March 31</b>	<b>June 30</b>	<b>September 30</b>	<b>December 31</b>
<b>For the period ending:</b>				
Total revenues	\$ 211,662	\$ 340,780	\$ 260,556	\$ 325,571
Net loss	(1,701,490)	(1,245,677)	(1,404,933)	(883,202)
Basic and diluted loss per share	\$ (0.008)	\$ (0.006)	\$ (0.007)	\$ (0.004)
<b>As at:</b>	<b>March 31</b>	<b>June 30</b>	<b>September 30</b>	<b>December 31</b>
Total assets	\$ 4,791,752	\$ 3,972,089	\$ 4,913,416	\$ 4,160,904
Total liabilities	1,334,760	987,778	1,257,010	1,068,336
Deficit	(54,793,787)	(56,039,466)	(57,563,626)	(58,451,686)
Shareholders' Equity	\$ 3,456,992	\$ 2,558,955	\$ 3,656,406	\$ 3,092,568

### **Liquidity and Capital Resources:**

As of September 30<sup>th</sup>, 2023, total current assets aggregated \$1,226,722 compared with total current liabilities of \$1,050,525 netting working capital of \$226,197 and a current ratio (current assets versus current liabilities) of approximately 1.2:1.

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

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

### **Going Concern:**

The unaudited interim condensed consolidated financial statements have been prepared by management in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB") and including interpretations of the IFRS Interpretations Committee ("IFRIC") 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 nine-month period ended September 30, 2023, the Company had a net loss of \$3,579,855 (2022 - \$4,352,100), an accumulated deficit of \$62,248,981 (December 31<sup>st</sup>, 2022 -\$58,451,686) and has historically used net cash in operations.

These conditions indicate the existence of material uncertainties that casts 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's objective is to maintain a sufficient capital base to support future research, development and strategic business initiatives allowing the Company to invest in its future and maintain investor, creditor and market confidence. Sales of the TLC-2000, the Company's existing product line have not met expectations and have not been sufficient in and of themselves to enable the Company to fund all its continuing development and commercialization efforts and, accordingly the Company will require additional capital to continue to research and develop its Drug and Device Divisions and market its CLT products as it continues to develop sales opportunities. The Company is currently seeking new financing opportunities and intends to complete a financing round in Q4 2023. The Company has successfully raised capital through equity offerings in 2023, 2022 and 2019; however, there is no guarantee that the Company will be able to raise additional capital on terms and conditions agreeable to the Company. The Company continues to closely monitor its expenses. These material uncertainties may cast significant doubt about the Company's ability to continue as a going concern.

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

### **Results of Operations:**

For the nine-month period ended September 30<sup>th</sup>, 2023, total revenue decreased to \$706,694 from \$812,998 for the same period in 2022, a 13% decrease.

	<u>2023</u>	<u>2022</u>
Sales Revenue	\$ 563,640	\$ 628,139
Service Revenue	114,296	140,842
Other Revenue	28,758	44,017
	<u>\$ 706,694</u>	<u>\$ 812,998</u>

The TLC-2000 represented 88% of sales for the nine-month period September 30<sup>th</sup>, 2023 and 78% of sales for the same period in 2022.

In Canada, revenue decreased 19% to \$556,692 in 2023 from \$683,167 in 2022. In the US, revenue increased 33% to \$148,322 in 2023 from \$111,496 in 2022. Internationally, revenue decreased 91% to \$1,681 in 2023 from \$18,335 in 2022.



### Cost of Sales:

Cost of sales for the nine-month period ended September 30<sup>th</sup>, 2023 was \$363,882 or 51% of revenue resulting in a gross margin of \$342,813 or 49% of revenue. In comparison, the cost of sales for the same period in 2022 was \$389,232 or 48% of revenue resulting in a gross margin of \$423,766 or 52% of revenue. Cost of sales is represented by the following costs: raw materials, subcontracting, direct and indirect labour and the applicable share of manufacturing overhead.

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

### Operating Expenses:

For the nine-month period ended September 30<sup>th</sup>, 2023, selling expenses decreased to \$194,418, from \$238,904 for the same period in 2022, a 19% decrease and consisted of the following items:

		<b>2023</b>		2022
Sales salaries	\$	<b>115,772</b>	\$	154,086
Advertising		<b>13,786</b>		18,038
Commission		<b>32,118</b>		32,766
Travel		<b>22,627</b>		13,683
Stock based compensation		<b>58</b>		-
Amortization and depreciation allocation		<b>10,057</b>		20,331
<b>Total selling expenses</b>	<b>\$</b>	<b>194,418</b>	<b>\$</b>	<b>238,904</b>

The decrease in selling expenses is a result of reduced advertising (24%), and salaries (25%).

Administrative expenses for the nine-month period ended September 30<sup>th</sup>, 2023, increased to \$1,456,382 from \$1,060,980 for the same period in 2022, a 36% increase and consisted of the following items:

		<b>2023</b>		2022
Insurance	\$	<b>41,274</b>	\$	37,481
Professional fees		<b>268,729</b>		277,221
Rent		<b>30,914</b>		38,394
General and administrative expenses		<b>400,738</b>		220,651
Administrative salaries		<b>337,616</b>		353,911
Director and advisory fees		<b>63,724</b>		47,078
Stock based compensation		<b>288,245</b>		68,829
Amortization and depreciation allocation		<b>25,144</b>		25,414
<b>Total administrative expenses</b>	<b>\$</b>	<b>1,456,382</b>	<b>\$</b>	<b>1,068,980</b>

The increase in administrative expenses is primarily attributed to increased spending on general and administrative expenses (82%) and director and advisory fees (35%).

Stock based compensation expense increased 319% in 2022 due to an increase in stock options granted.

Net research and development expenses for the nine-month period ended September 30<sup>th</sup>, 2023, decreased to \$2,285,390 from \$3,464,664 for the same period in 2022, a 34% decrease, and consisted of the following items:

		<b>2023</b>		2022
Research and development (net of investment tax credit)	\$	<b>1,940,014</b>	\$	3,251,989
Stock based compensation		<b>188,162</b>		50,155
Amortization and depreciation allocation		<b>157,214</b>		162,520
<b>Total research and development expenses</b>	<b>\$</b>	<b>2,285,390</b>	<b>\$</b>	<b>3,464,664</b>

The decrease in research and development expenses is primarily attributed to the costs related to the manufacture of the Study II Drug. Research and development expenses represented 58% of the Company's operating expenses and represent investment into the research and development of the Company's Drug Division.

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

The net loss for the nine-month period ended September 30<sup>th</sup>, 2023, was \$3,579,855 which included \$714,020 of net non-cash expenses (i.e.: amortization, stock-based compensation expense and foreign exchange gain/loss). This compared to a net loss for the same period in 2022 of \$4,352,100 which included \$391,321 of net non-cash expenses. The Drug Division represented \$3,123,435 of this loss (87%) for the nine-month period ended September 30<sup>th</sup>, 2023.

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

### **Cash Flows:**

Funds used in operating activities, prior to net changes in other operating items, amounted to \$2,865,835 for the nine-month period ended September 30<sup>th</sup>, 2023, compared to funds used in operating activities of \$3,960,779 in 2022.

Funds used in operating activities, after taking into account net changes in other non-cash operating items were \$2,825,974 for the nine-month period ended September 30<sup>th</sup>, 2023, compared to funds used of \$4,030,677 for the same period in 2022. The decrease is primarily attributed to decreased spending in research and development expenses in Study II

Funds used in investing for the nine-month period ended September 30<sup>th</sup>, 2023, amounted to \$25,830 compared to \$7,089 for the same period in 2022. The increase is primarily attributed to increased spending on equipment related to Study II.

Funds received in financing activities amounted to \$1,578,203 for the nine-month period ended September 30<sup>th</sup>, 2023, compared to funds received of \$2,793,966 for the same period in 2022. The decrease is primarily attributed to the non-brokered private placement on September 22<sup>nd</sup>, 2022.

### **Assets (other than Cash):**

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

### **Commitments:**

As of September 30<sup>th</sup>, 2023, the Company's commitments consisted of the following:

	Total	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032
Research Agreement (a)	\$ 24,969	\$ -	\$ 24,969	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Research Agreement (b)	121,920	43,420	8,800	8,800	8,800	8,800	8,800	8,800	8,800	8,800	8,100
Research Agreement (c)	99,380	-	99,380	-	-	-	-	-	-	-	-
<b>Total</b>	<b>\$ 246,269</b>	<b>\$ 43,420</b>	<b>\$ 133,149</b>	<b>\$ 8,800</b>	<b>\$ 8,800</b>	<b>\$ 8,800</b>	<b>\$ 8,800</b>	<b>\$ 8,800</b>	<b>\$ 8,800</b>	<b>\$ 8,800</b>	<b>\$ 8,100</b>

- Research Commitments under a research agreement with a Trial Management Organization for the TLC-3000 cancer therapy project. Under the terms of this agreement, the Company is required to pay \$CAN 126,324 (\$USD 96,800) for the period from July 23, 2019 through to December 31, 2024. The Company has paid \$CAN 101,355 (\$USD 76,400) relating to this commitment, of which \$CAN 24,969 (\$USD 20,400) is the remaining commitment.
- Research Commitments under a research agreement with a Contract Manufacturer for the TLC-3000 cancer therapy project. Under the terms of this agreement, the Company is required to pay \$CAN 499,100 for the period from April 29, 2021 through to November 15, 2032. The Company has paid \$CAN 377,180 relating to this commitment, of which \$CAN 121,920 is the remaining commitment.
- Research Commitments under a research agreement with a Contract Manufacturer for the TLC-3000 cancer therapy project. Under the terms of this agreement, the Company is required to pay \$CAN 1,351,918 (\$USD 1,079,865) for the period from April 29, 2021 through to April 29, 2024. The Company has paid \$CAN 1,252,538 (\$USD 1,006,430) relating to this commitment, of which \$CAN 99,380 (\$USD 73,435) 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 on its premise for an additional 5 years until September 30<sup>th</sup>, 2027. A liability of \$CAN 476,240 was established, representing the lease payments of \$CAN 48,683 in 2022, \$CAN 115,000 in 2023, \$CAN 115,000 in 2024, \$ CAN 115,575 in 2025, \$ CAN 117,300 in 2026 and \$ CAN 87,975 in 2027, discounted using an incremental borrowing rate of 7.0%.

	Property		Office Equipment		Total
<b>Right-of-use Assets</b>					
Balance at January 1, 2022	\$	37,096	\$	1,643	\$ 38,739
Addition	\$	477,091	\$	6,577	\$ 483,668
Depreciation charge for the period		74,594		1,842	76,436
Balance at December 31, 2022	\$	439,593	\$	6,378	\$ 445,971
<b>Balance at January 1, 2023</b>	<b>\$</b>	<b>439,593</b>	<b>\$</b>	<b>6,378</b>	<b>\$ 445,971</b>
<b>Depreciation charge for the period</b>		<b>69,409</b>		<b>1,381</b>	<b>70,792</b>
<b>Balance at September 30, 2023</b>	<b>\$</b>	<b>370,184</b>	<b>\$</b>	<b>4,996</b>	<b>\$ 375,179</b>
<b>Lease Liabilities</b>					
Balance at January 1, 2022	\$	34,161	\$	1,563	\$ 35,724
Addition	\$	485,822	\$	6,576	\$ 492,398
Interest charge for the period		20,730		519	21,248
Lease payments for the period <sup>1</sup>		(73,600)		(2,148)	(75,748)
Balance at December 31, 2022	\$	467,113	\$	6,510	\$ 473,623
<b>Balance at January 1, 2023</b>	<b>\$</b>	<b>467,113</b>	<b>\$</b>	<b>6,510</b>	<b>\$ 473,623</b>
<b>Interest charge for the period</b>		<b>23,063</b>		<b>312</b>	<b>23,375</b>
<b>Lease payments for the period<sup>1</sup></b>		<b>(86,250)</b>		<b>(1,611)</b>	<b>(87,861)</b>
<b>Balance at September 30, 2023</b>	<b>\$</b>	<b>403,926</b>	<b>\$</b>	<b>5,211</b>	<b>\$ 409,137</b>

1) Lease payments are discounted using an incremental borrowing rate of 7% and does not include variable property lease payments of \$30,912 (2022 - \$38,394).

	As at September 30, 2023			As at December 31, 2022		
	Property	Office Equipment	Total	Property	Office Equipment	Total
Current portion of lease liabilities	\$ 89,564	\$ 1,841	\$ 91,405	\$ 107,188	\$ 6,510	\$ 113,698
Non-current portion of lease liabilities	314,363	3,370	317,732	359,925	-	359,925
	<b>\$ 403,926</b>	<b>\$ 5,211</b>	<b>\$ 409,137</b>	<b>\$ 467,113</b>	<b>\$ 6,510</b>	<b>\$ 473,623</b>

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

	Property	Office Equipment
2023	\$ 21,809	\$ 448
2024	91,139	1,874
2025	98,306	2,009
2026	107,209	880
2027	85,462	-
	<b>\$ 403,926</b>	<b>\$ 5,211</b>

## Share Capital Analysis:

As of November 29<sup>th</sup>, 2023, the share capital of the Company consisted of 228,460,858 common shares. Each common share entitles the holder to one vote per share.

As of November 29<sup>th</sup>, 2023, there were 18,510,000 options outstanding, of which 10,286,667 were vested and exercisable into an equivalent number of the Company's common shares.

As of November 29<sup>th</sup>, 2023, there were 84,619,714 warrants outstanding. Each whole warrant entitles the holder thereof to purchase one additional common share. The warrants are exercisable as follows: 4,095,157 at a price of \$0.50 until January 9<sup>th</sup>, 2023, 57,499,000 at a price of \$0.35 until August 22<sup>nd</sup>, 2024, 10,058,734 at a price of \$0.35 until September 22<sup>nd</sup>, 2024, 1,002,700 at a price of \$0.35 until November 17<sup>th</sup>, 2024, 4,805,400 at a price of \$0.35 until June 30<sup>th</sup>, 2025 and 5,318,183 at a price of \$0.28 until November 29, 2028.

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

As of November 29<sup>th</sup>, 2023, there were 2,023,077 broker compensation units that were issued in connection with the August 22<sup>nd</sup>, 2019 public offering. Each broker compensation unit entitles the holder thereof to acquire one common share and one common share purchase warrant at a price of \$0.35 per unit until August 22<sup>nd</sup>, 2024.

## Segmented Information:

For management purposes, the Company is organized into two separate reportable operating divisions; the Drug Division and the Device Division. The Drug Division is responsible for the research and development of PDCs primarily for the treatment of cancer with assistance from the Device division to develop medical lasers to activate them. The Device Division is also responsible for the Company's medical laser business, which researches, develops, manufactures and distributes Cool Laser Therapy ("CLT") 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 nine-month period ended September 30<sup>th</sup>:

	2023			2022		
	Device	Drug	Total	Device	Drug	Total
Sales	\$ 706,695	\$ -	\$ 706,695	\$ 812,998	\$ -	\$ 812,998
Cost of sales	363,882	-	363,882	389,232	-	389,232
<b>Gross margin</b>	<b>342,813</b>	<b>-</b>	<b>342,813</b>	<b>423,766</b>	<b>-</b>	<b>423,766</b>
<b>Operating Expenses</b>						
Selling expenses	194,418	-	194,418	238,904	-	238,904
Administrative expenses	595,092	861,290	1,456,382	588,613	480,366	1,068,979
Research and development expense:	34,844	2,250,546	2,285,390	133,959	3,330,705	3,464,664
(Gain) loss from legal settlement		-		(14,983)	-	(14,983)
Loss on foreign exchange	(88)	(88)	(176)	12,807	12,807	25,614
Interest accretion on lease liabilities	11,688	11,688	23,375	6,188	6,187	12,375
Interest income	(36,721)	-	(36,721)	(9,844)	(9,843)	(19,687)
	<b>799,233</b>	<b>3,123,435</b>	<b>3,922,668</b>	<b>955,644</b>	<b>3,820,222</b>	<b>4,775,866</b>
<b>Loss for the period</b>	<b>\$ (456,420)</b>	<b>\$ (3,123,435)</b>	<b>\$ (3,579,855)</b>	<b>\$ (531,878)</b>	<b>\$ (3,820,222)</b>	<b>\$ (4,352,100)</b>
Total Assets	\$ 2,157,427	\$ 842,698	\$ 3,000,125	\$ 2,146,126	\$ 2,767,290	\$ 4,913,416
Total Liabilities	496,044	872,213	1,368,257	587,276	669,734	1,257,010

The following table displays the revenue and direct expenses from the CLT systems sold in the Device Division by product line and geographic area for the nine-month period ended September 30<sup>th</sup>:

	2023			2022		
	Canada	USA	International	Canada	USA	International
<b>Sales by Product Line</b>						
TLC-1000	\$ 73,276	\$ 11,304	\$ -	\$ 115,363	\$ 66,500	\$ -
TLC-2000	483,416	137,018	1,681	567,804	44,996	18,335
	<b>556,692</b>	<b>148,322</b>	<b>1,681</b>	<b>683,167</b>	<b>111,496</b>	<b>18,335</b>
<b>Expenses</b>						
Cost of Sales	286,645	76,372	865	327,074	53,380	8,778
Selling Expenses	166,188	21,938	6,292	204,250	25,383	9,271
	<b>452,833</b>	<b>98,311</b>	<b>7,158</b>	<b>531,324</b>	<b>78,763</b>	<b>18,049</b>
	<b>\$ 103,859</b>	<b>\$ 50,011</b>	<b>\$ (5,477)</b>	<b>\$ 151,843</b>	<b>\$ 32,733</b>	<b>\$ 286</b>

As at September 30<sup>th</sup>, 2023 and December 31<sup>st</sup>, 2023, the Company's long-lived assets used in operations are all located in Canada. Timing of revenue is recognized at a point in time.

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

The unaudited consolidated interim condensed financial statements for the nine-month period ended September 30, 2023, 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>, 2022. Please refer to the Company's annual and quarterly financial statement filings, including material interim press releases, at [www.sedar.com](http://www.sedar.com).

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

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

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

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

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

Assets are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. As of September 30<sup>th</sup>, 2023 and December 31<sup>st</sup>, 2022, respectively, the Company's cash and cash equivalents are categorized as Level 1. There were no financial instruments categorized as Level 2 or 3.

(i) Credit risk:

Credit risk is the risk of financial loss to the Company if a customer or counterparty to a financial instrument fails to meet its contractual obligations and arises principally from the Company's trade and other receivable. The amounts reported in the

consolidated balance sheets are net of allowances for credit losses, estimated by the Company's management based on prior experience and its assessment of the current economic environment. The Company reviews its trade receivable accounts 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 represent the Company's maximum exposure to credit risk.

(ii) Liquidity risk:

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

(iii) Interest rate risk:

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

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

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Cash and cash equivalents	Short-term fixed and variable interest rate
Short-term investments	Short-term fixed interest rate
Financed trade receivables	Short-term and long-term fixed interest rate

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(iv) Foreign currency exchange risk:

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

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

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

As noted above, the Company's unaudited interim condensed consolidated financial statements as of September 30<sup>th</sup>, 2023 and December 31<sup>st</sup>, 2022, respectively, and for the nine-month period ended September 30<sup>th</sup>, 2023 and 2022, respectively, have been prepared in accordance with IFRS. The policies applied are based on IFRS issued and outstanding as of November 29<sup>th</sup>, 2023 which is the date at which the Company's Board of Directors approved the unaudited consolidated interim condensed financial statements.

Additionally, the preparation of the unaudited consolidated interim condensed 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 unaudited consolidated interim condensed 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 unaudited consolidated interim condensed financial statements are presented fairly and in accordance with IFRS.

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

## **Disclosure of Internal Controls:**

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

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

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

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

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

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

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

## **Risks and Uncertainties:**

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

### **Limited Operating History:**

The Company is still in the development and commercialization stages of its businesses and therefore will be subject to the risks associated with early-stage companies, including uncertainty of the success and acceptance of its products, uncertainty of revenues, markets and profitability and the continuing need to raise additional capital. The Company's business prospects must be considered in light of the risks, expenses and difficulties frequently encountered by companies in this stage of development. Such risks include the evolving and unpredictable nature of the Company's business, the Company's ability to anticipate and adapt to a developing market, acceptance by consumers of the Company's products, the ability to identify, attract and retain qualified personnel and the

ability to generate sufficient revenue or raise sufficient capital to carry out its business plans. There can be no assurance that the Company will be successful in adequately mitigating these risks.

**Working Capital and Capital Resources:**

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

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

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

**Key Personnel:**

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

**Protection of Intellectual Property:**

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

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

**Competition:**

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



**Implementation Delays:**

Many of the Company's products will be in development, testing or preliminary stage and there may be delays or other problems in the introduction of the Company's products. The Company cannot predict when customers that are in a testing or preliminary use phase of the Company's products will adopt a broader use of the products. The market for the Company's products is relatively new and continues to evolve. The Company's products will involve changes in the manner in which businesses have traditionally used such products. In some cases, the Company's customers will have little experience with products offered by the Company. The Company will have to spend considerable resources educating potential customers about the value of the Company's products. It is difficult to assess, or predict with any assurance, the present and future size of the potential market for the Company's products or its growth rate, if any. The Company cannot predict whether or not its products will achieve market acceptance.

**Strategic Alliances:**

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

**Trade Secret Protection:**

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

**Product Deficiencies:**

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

**Dependence on Third Party Suppliers:**

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

**Volatility of Share Price:**

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

**Regulatory Approvals:**

The Company is directly and indirectly engaged in the design, manufacture, sale and international marketing of therapeutic and medical laser equipment, as well as the research and development of light activated PDCs, all of which are subject to regulatory oversights, audits and controls by various national regulatory agencies (i.e.: FDA, Health Canada, CE) and authoritative quality standards bodies (i.e.: UL, CSA, ISO and TUV), which all possess strict quality certification procedures. The Company is in full compliance with all the governing regulatory and quality standards and approval requirements pertaining to the medical laser devices it currently designs, manufactures and markets and the PDCs it researches and develops. No assurance can be given that current regulations relating to regulatory approval will not change or become more stringent and product approvals may be withdrawn if compliance with regulatory standards is not maintained.

**Early Stage of Product Development:**

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

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

**Reliance on Third Parties:**

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

**Clinical Study Risk:**

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

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

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

The Company cannot predict whether any clinical studies will begin as planned, will need to be restructured, or will be completed on schedule, or at all. The Company's product development costs may increase significantly if the Company experiences delays in clinical testing. Significant clinical study delays could shorten any periods during which the Company may have the exclusive right to commercialize its product candidates or allow the Company's competitors to bring products to market before the Company, which would impair the Company's ability to successfully commercialize its product candidates and may harm the Company's financial condition, results of operations and / or prospects. The commencement and completion of clinical studies for the Company's products may be delayed for a number of reasons, including delays related, but not limited, to:

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

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

### **Patient Enrollment:**

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

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

**Failure to Achieve Milestones:**

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

**Currency Risk:**

The Company's primary risks are exposure to foreign currency exchange risk. These risks arise from the Company's holdings of US and Canadian dollar denominated cash, accounts receivable and accounts payable. Changes arising from these risks could impact the Company's reported foreign exchange gains or losses. The Company limits its exposure to foreign currency risk by holding US denominated cash in amounts of up to 100% of forecasted twelve-month US dollar expenditures; thereby, creating a natural hedge against foreign currency fluctuations and limiting foreign currency risk to translation of US dollar balances at the balance sheet date.

**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. 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 receivable 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 coverage in the aggregate of \$CAN 5,000,000. This coverage is limited, and 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 5,000,000. 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.

November 29<sup>th</sup>, 2023

Kristina Hachey, CPA  
Chief Financial Officer