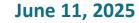


# Destroying Cancer at the Speed of Light<sup>®</sup> Healing at the Speed of Light<sup>®</sup>



TSXV:TLT | OTCQB:TLTFF

# **Forward-Looking Statements**

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

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

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

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

The material contained in this document is strictly confidential and the sole property of Theralase<sup>®</sup>. This presentation does not, and shall not, in any circumstances, constitute an offer to sell or solicitation of an offer to buy any securities of Theralase<sup>®</sup>, in any jurisdiction.



### Research



#### Cutting Edge Scientific and Preclinical Research

Small molecules researched and developed over the last 22 years

Formulated to destroy various cancers, bacteria and viruses, while sparing healthy cells<sup>1</sup>

Preclinical research supports high safety and efficacy in the destruction of:

Herpes lesions <sup>3</sup> GlioBlastoma Multiforme<sup>4</sup> Non-Small Cell Lung Cancer<sup>5</sup> Leukemia, Lymphoma, Myeloma<sup>6</sup>



Pipeline

Primary Indication

Non-Muscle Invasive Bladder Cancer<sup>2</sup>

#### Secondary Indications

Herpes Simplex Virus GlioBlastoma Multiforme Non-Small Cell Lung Cancer Muscle Invasive Bladder Cancer Pancreatic Cancer Colorectal Cancer

Leukemia, Lymphoma, Myeloma

#### **Clinical Studies**

Phase II NMIBC registration clinical study interim clinical data nearing completion with 82 patients enrolled and 69 patients have completed the study<sup>7</sup>

#### **Primary Endpoint**

62.3% Complete Response ("**CR**") 69.6% Total Response (CR + IR)

Secondary Endpoint: 41.9% CR at 15 months

Tertiary Endpoint: 100% safe

FDA Fast Track Designation Granted<sup>8</sup>



#### **Management Team**

Extensive experience in:1

Drug Discovery

Preclinical Research

**Clinical Development** 

Laser Design, Manufacturing and Commercialization

#### Partners

Conducting clinical development with leading scientific and clinical researchers from renowned research hospitals<sup>1</sup>



29 issued patents and 17 patents pending for small molecules and their formulations in the United States, Canada and internationally<sup>1</sup>

Composition of matter patent expires in US in 2033 (Potentially 2038 with extension)



1) Annual Information Form – September 20, 2023

2) Press Release - Theralase Commences Phase II NMIBC Clinical Study – April 25, 2019

- 4) Press Release Theralase\* Demonstrates Significant Advantage in Treatment of Brain Tumours June 11, 2018
- 5) Press Release Theralase\* Advances Anti-Cancer Technology in Destruction of Human Lung Cancer– March 5, 2018
- 6) Press Release February 25, 2025 Theralase® Demonstrates Efficacy of Rutherrin® in Destruction of Non-Hodgkin's Lymphoma

7) Press Release - Theralase<sup>®</sup> Provides Corporate Update- May 20, 2025

8) Press Release - Theralase<sup>®</sup> Granted FDA Fast Track Designation for NMIBC Phase II Clinical Study – November 23, 2020

<sup>3)</sup> Press Release – April 10, 2025 – Ruvidar More Effective in the Treatment of Herpes than FDA-Approved Treatments

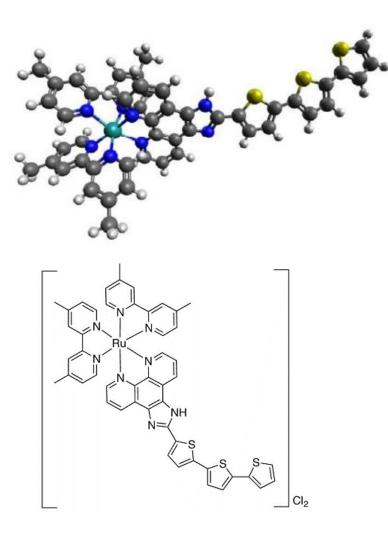
# **Intellectual Property<sup>1</sup>**

Expiry	Patent	Description
April 2033	Metal-Based Thiophene Photodynamic Compounds and Their Use	Protects Ruvidar <sup>®</sup> and all associated molecules in the USA, Canada, Russia, China, Europe, Brazil and India
March 2034	Metal-Based Coordination Complexes as Photodynamic Compounds and their Use	Protects Ruvidar <sup>®</sup> and all associated molecules in the USA, Canada, Russia, China, Europe, Brazil and India
April 2035	Apparatus and Method for Multiwavelength Photodynamic Therapy	Protects multiwavelength photodynamic therapy in the USA, Canada, Russia, China, Brazil and India
January 2036	Metal-Glycoprotein Complexes and Their Use as Chemotherapeutic Compounds	Protects Rutherrin <sup>®</sup> and all associated molecules in the USA, Canada, Russia, China, Europe, Brazil and India
July 2036	Photodynamic Compounds and Methods for Activating Them Using Ionizing Radiation and/or Other Electromagnetic Radiation for Therapy and/or Diagnostics	Protects radiation activation of Rutherrin <sup>®</sup> in the USA
July 2036	Vaccine Containing Cancer Cells Inactivated by Photodynamic Treatment with Metal-Based Coordination Complexes, and Immunotherapy Method Using Same	Protects Ruvidar <sup>®</sup> and all associated molecules as a vaccine platform in the USA, Canada, and Europe
October 2036	Fiber Optic Light Delivery, Monitoring and Apparatus Therefore	Protects Study Device in the USA and Canada

1) The listed patents (partial list) do not include the patent extensions afforded in the United States by "The Drug Price Competition and Patent Term Restoration Act" (Hatch-Waxman Act) of 1984 that provides patent holders on approved patented products with an extended term of protection under the patent to compensate for the delay in obtaining Food and Drug Administration ("FDA") approval.



# Ruvidar<sup>®</sup> (TLD-1433)



- Ruthenium-based small molecule
- Designed to destroy solid core tumours (i.e.: bladder, brain, lung and breast) when absorbed by the cancer cell
- Highly effective in the destruction of viruses (i.e.: Influenza, Zika, coronaviruses, HSV)
- Activity is significantly enhanced when energy activated <sup>1</sup>
- Commercially manufactured in kilogram batches with high yield and high purity (98%)
- < 0.5 grams used for NMIBC treatment</li>
- Micrograms used for HSV treatment



# **Theralase<sup>®</sup> Device Division Pipeline**

Product	Indication	Concept	Prototype Stage	Safety Testing	Phase III Clinical Study	Health Canada / FDA Approved	Commercial
TLC-2000 Cool Laser Therapy (Professional Use)	Pain Management						$\rightarrow$
TLC-3200 Medical Laser System (Professional Use)	Non-Muscle Invasive Bladder Cancer						
TLC-900 Cool Laser Therapy (Conversion to Personal Use)	Pain Management			Not Required	Not Required		
TLC-2500 Cool Laser Therapy (Professional Use)	Pain Management				Not Required		
TLC-3000 Medical Laser System (Professional Use)	Leukemia / Lymphoma / Multiple Myeloma						



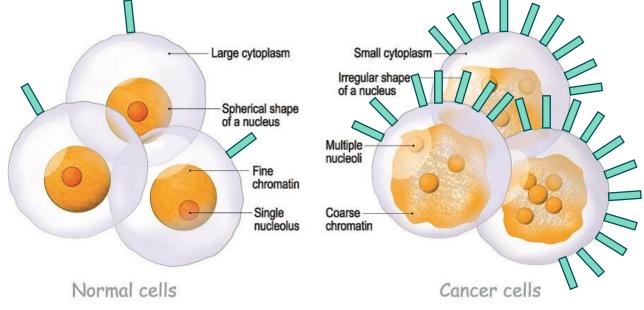
# **Theralase<sup>®</sup> Drug Division Pipeline**

Indication	Candidate	Pre- Clinical	GLP Toxicology	Phase 0	Phase I	Phase II	Phase III	FDA Approved
Non-Muscle Invasive Bladder Cancer (" <b>NMIBC</b> ")	Ruvidar <sup>™</sup> + TLC-3200						Not Required	
Herpes Simplex Virus (" <b>HSV</b> ")-1	Ruvidar™	$\rightarrow$						
Glio Blastoma Multiforme (" <b>GBM</b> ")	Rutherrin <sup>®</sup> + X-ray							
Non-Small Cell Lung Cancer ("NSCLC")	Rutherrin <sup>®</sup> + X-ray	$\rightarrow$						
Pancreatic Cancer	Rutherrin <sup>®</sup> + X-ray	$\rightarrow$						
Muscle Invasive Bladder Cancer (" <b>MIBC</b> ")	Rutherrin <sup>®</sup> + X-ray	$\rightarrow$						
Colorectal Cancer	Rutherrin <sup>®</sup> + X-ray	$\rightarrow$						
Non-Hodgkin's Lymphoma	Ruvidar <sup>™</sup> + TLC-3000	$\rightarrow$						
Leukemia / Multiple Myeloma	Ruvidar <sup>™</sup> + TLC-3000	$\rightarrow$						



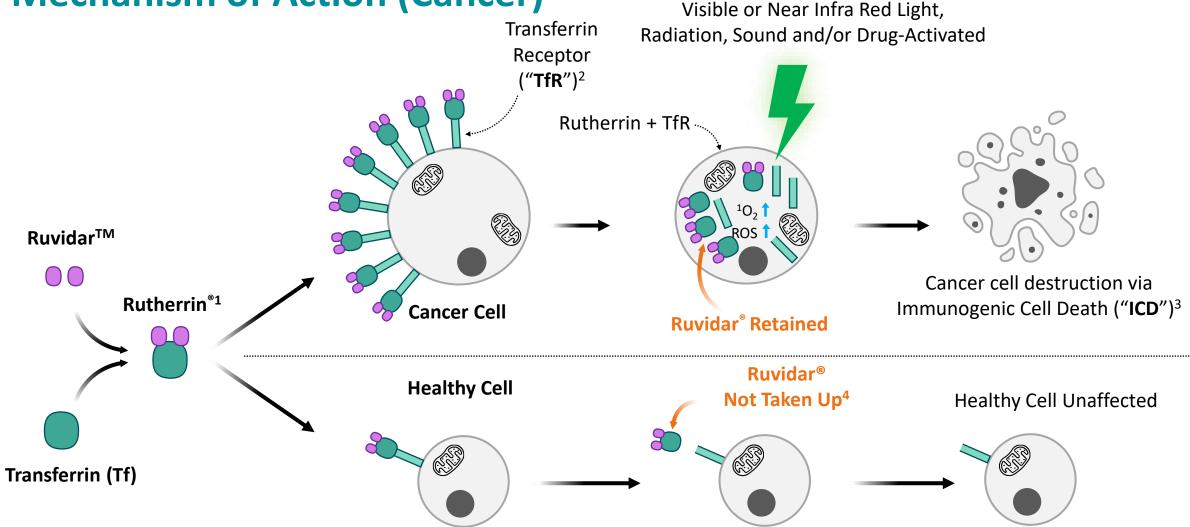
# What is Cancer?

- Cancer = Cells that sustain DNA damage and become immortal
- Normal cells grow then die
- Cancer cells ignore these signals and continue to multiply, leading to tumours and eventually death, if not destroyed
- Each human has approximately 30 trillion cells in our bodies (200 different types, leading to over 100 known types of cancer)
- All cells require iron to grow. Cancer cells grow at a much higher rate than healthy cells; therefore, they require significantly more iron, which is absorbed through their greater number of transferrin receptor sites (
  )
- Theralase<sup>®</sup> exploits this mechanism to target cancer cells for destruction versus healthy cells





# **Mechanism of Action (Cancer)**



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

2) Jeong SM, Hwang S, Seong RH. Transferrin receptor regulates pancreatic cancer growth by modulating mitochondrial respiration and ROS generation. https://doi.org/10.1016/j.bbrc.2016.02.023

3) Kawamoto M., Horibe T., Kohno M., Kawakami K. A novel transferrin receptor-targeted hybrid peptide disintegrates cancer cell membrane to induce rapid killing of cancer cells. BMC Cancer. 2011; 11: 359

4) Seymour GJ, Walsh MD, Lavin MF, Strutton G, Gardiner RA. Transferrin receptor expression by human bladder transitional cell carcinomas. Urol Res. 1987;15(6):341-4. doi: 10.1007/BF00265663. PMID: 3324443.



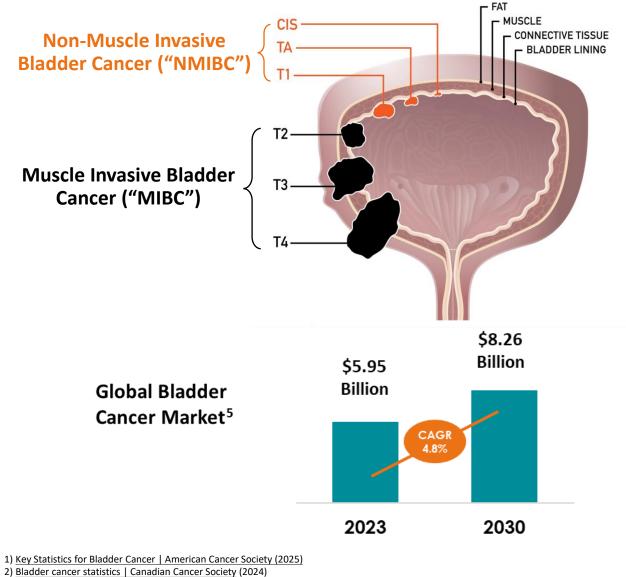
## **Non-Muscle Invasive Bladder Cancer**



#### **Bladder Cancer**

9<sup>th</sup> Most Common Cancer Worldwide 4<sup>th</sup> leading cancer in men<sup>1</sup> 84,870 in US<sup>1</sup> 12,300 in Canada<sup>2</sup> 200,000 in Europe<sup>3</sup>

614,298 in World<sup>4</sup>



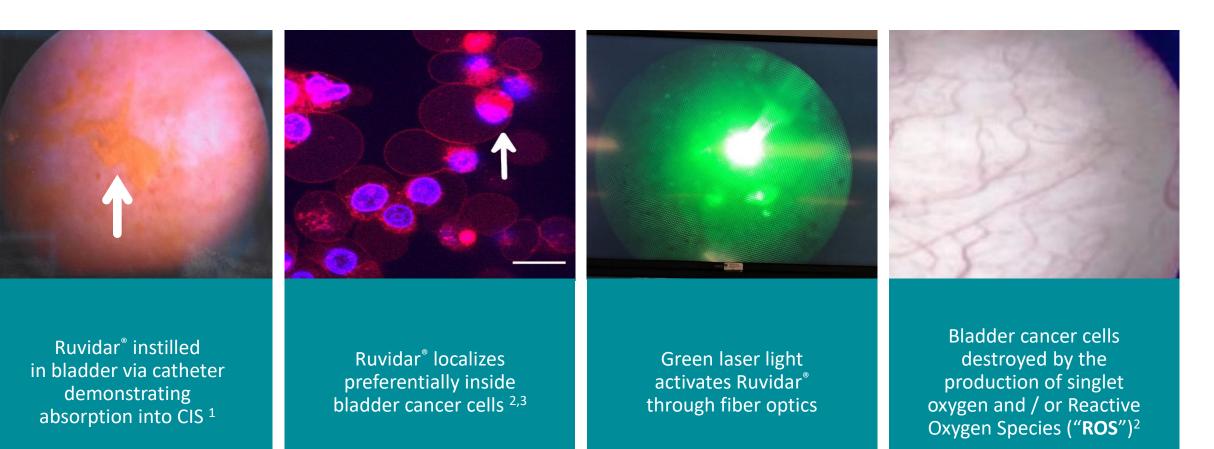
3) Bladder Cancer: The Forgotten Cancer.2022. Bladder Cancer: The Forgotten Cancer - Uroweb

4) International Agency for Research on Cancer (IARC). Globocan2022. GLOBOCAN 2022: Bladder cancer 9th most common worldwide - World Bladder Cancer Patient Coalition

5) Bladder Cancer Market: Global Industry Analysis and Forecast (2024 - 2030). Maximize Market Research. March 2024



### **Study Treatment**



Kalinina S, Breymayer J, Reeß K, Lilge L, Mandel A, Rück A. Correlation of intracellular oxygen and cell metabolism by simultaneous PLIM of phosphorescent TLD1433 and FLIM of NAD(P)H. J Biophotonics. 2018 Oct;11(10):e201800085. doi:10.1002/jbio.201800085. Epub 2018 Jul 9. PubMed PMID: 29877627.
 Seymour GJ, Walsh MD, Lavin MF, Strutton G, Gardiner RA. Transferrin receptor expression by human bladder transitional cell carcinomas. Urol Res. 1987;15(6):341-4



12

# Phase II NMIBC Interim Clinical Data<sup>1</sup>

**PREVIOUS BCG THERAPY TREATMENTS** AGE RACE SEX STAGE CIS + Ta < 7 **Non-White** Female ≤ 65 5% CIS + T1 6% 17% 20% 19% 14% 65 White CIS > 7 Male 80% 83% 80% 81% 95%

Ruvidar<sup>®</sup> has been demonstrated to achieve complete responses in patients, previously treated with and who failed therapy with: BCG, systemic PD-L1 immunotherapy, chemotherapy, intravesical oncolytic viruses and intravesical chemotherapies (gemcitabine with or without docetaxel).



**Patient Demographics** 

# **Study Procedure**

- 90 patients with BCG-Unresponsive NMIBC CIS (82 patients treated to date, 8 patients to be completed by July 2025)
- 12 clinical study sites currently enrolling patients in Canada and the United States
- Patient provided primary Study Procedure on Day 0 (1 hour of drug instillation, 1 hour of light activation)
- Outpatient procedure
- Surgeon has the option to deliver up to 2 more re-induction Study Procedures, if the patient recurs
- Patient followed up quarterly for 2 years and then semi-annually for 1 additional year (3 years in total)



# Phase II NMIBC Interim Clinical Data<sup>1</sup>

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

#### **Primary Endpoint**

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

		Tertiary Endpo	pint Performance (Safety) (450 Days)
Tertiary Endpoint		#	%
	Safety	69/69	100.0%

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

#### Note: Indeterminate Response ("IR") is defined as negative cystoscopy (no evidence of Urothelial Cell Carcinoma ("UCC") in the bladder) and positive / suspicious urine cytology (detection of cancer in the urine, without a negative confirmatory bladder biopsy, suggesting UCC in the renal system other than the bladder).

**Note:** Theralase<sup>®</sup> believes all SAEs reported to date are <u>unrelated</u> to the Study Drug or Study Device.



# **NMIBC FDA Approved Drugs**

Company/ FDA Approved Drug (Date of Approval)	Number of Patients	Initial Complete Response ("CR")		Duration of Response (24 months)	(36 months)	Pros	Cons	Annual Cost (\$USD 000s)	Market Capitalization (\$USD Billion)
IBCG Guidelines (extrapolated)	92	60.0%	30.0%	20.0%	15.0%				
Immunity Bio BCG + N803 <sup>1</sup> (Intravesical SL-15 agonist) (2024)	77	62.3%	58.3%	39.6%	22.9%	High initial efficacy and duration of efficacy.	Combinational product, combined with standard of care BCG. BCG contributes efficacy in the patient population.	\$215 (Once a week for 6 weeks) (\$35.8 per dose + BCG)	\$1.9
Ferring Adstiladrin <sup>2</sup> (2023)	98	53.4%	45.5%	34.5%	25.5%	First intravesical oncologic virus approved for BCG- Unresponsive NMIBC CIS.	Median Duration Of Response (" <b>DOR</b> ") of 9.7 months. <b>Contraindicated for patients,</b> <b>who are immunosuppressed or immune-</b> <b>deficient.</b> Associated with increased glucose levels and increased serum creatinine.	\$211 (Once every 3 months) (\$60 per installation)	\$2.2 (Annual Revenue)
Merck Pembrolizumab (Keytruda*) <sup>3,4</sup> (2020)	96	40.6%	18.8%	9.4%	0%	First immunotherapy drug approved for BCG- Unresponsive NMIBC CIS.	Patients must have PD-L1 expression to generate a response. Only applicable to 20 to 40% of patient population. Associated with serious adverse events. Not uro-oncologist recommended.	\$150 (Every 3 weeks for up to 24 months)	\$319
Endo Pharmaceuticals Valrubicin (Valstar) <sup>5,6,7</sup> (1981)	90	21%	16.4%	Not Reported	Not Reported	First intravesical drug approved by the FDA for NMIBC.	Not a BCG-Unresponsive population. Not uro-oncologist recommended.	\$55 (Once a week for 6 weeks)	\$0.00014

1) Press Release – ImmunityBio Announces FDA Approval of ANKTIVA®, First-in-Class IL-15 Receptor Agonist for BCG-Unresponsive Non-Muscle Invasive Bladder Cancer – April 22, 2024

2) FDA Press Announcement. FDA Approves First Gene Therapy for the Treatment of High-Risk, Non-Muscle-Invasive Bladder Cancer.

3) Balar, A.V., et al., Pembrolizumab monotherapy for the treatment of high-risk non-muscle-invasive bladder cancer unresponsive to BCG (KEYNOTE-057): an open-label, single-arm, multicentre, phase 2 study. Lancet Oncol, 2021. 22(7): p. 919-930. 4) Press Release – Merck's KEYTRUDA<sup>®</sup> (pembrolizumab) Showed a Complete Response Rate of Nearly 40 Percent in Patients with High-Risk Non-Muscle Invasive Bladder Cancer (NMIBC) Unresponsive to Standard of Care – October 20, 2018

5) Steinberg G, Bahnson R, Brosman S, Middleton R, Wajsman Z, Wehle M. Efficacy and safety of valrubicin for the treatment of Bacillus Calmette-Guerin refractory carcinoma in situ of the bladder. The Valrubicin Study Group. J Urol. 2000 Mar;163(3):761-7. Erratum in: J Urol. 2008 Jan;179(1):386. PMID: 10687972.

6) Dinney CPN et al. Intravesical valrubicin in patients with bladder carcinoma in situ and contraindication to or failure after bacillus Calmette-Guérin. Urol Oncol. 2013 Nov;31(8):1635-42

7) Kim HS, Seo HK. Emerging treatments for bacillus Calmette-Guérin-unresponsive non-muscle-invasive bladder cancer. Investig Clin Urol. 2021 Jul;62(4):361-377. doi: 10.4111/icu.20200602. Epub 2021 May 27. PMID: 34085791; PMCID: PMC8246016.

16

# **NMIBC Non-FDA Approved Drugs**

Competitive Drug (Non-FDA Approved)	Number of Patients	Response	(12 months)	Duration of Response (24 months)	(36 months)	Pros	Cons	Annual Cost (\$USD 000s)	Market Capitalization (\$USD Billion)
IBCG Guidelines (extrapolated)	92	60.0%	30.0%	20.0%	15.0%				
Theralase <sup>®</sup> Ruvidar <sup>®1</sup> (Estimated for 2026)	66/90	62.3% CR (Interim) (69.6% TR) (Interim)	41.9% CR (Interim)	23.3% (Interim)	20.9% (Interim)	High initial efficacy. 3/5 of patients achieve CR after only 1 study procedure. Demonstrated 9 years shelf life of Ruvidar <sup>™</sup>		\$Unknown (Single procedure)	\$.06
CG Oncology Cretostimogene grenadenorepvec <sup>2</sup> (Intravesical oncolytic immunotherapy) (Estimated for 2026)	110	75.5%	46.0%	36.1%	Not Reported	High initial efficacy	Biological drugs are prone to manufacturing issues. Gene therapy is not readily adopted by all uro- oncologists due to complexities. Only applicable to 25% of high-grade patient population, who exhibit retinoblastoma negative protein.	\$Unknown (6 weekly treatments, then 6 weekly treatments or 3 weekly treatments based on response, then 3 weekly treatments every 3 months for first 12 months, every 6 months for next 24 months)	\$2.2
Johnson and Johnson Slow-Release Gemcitabine <sup>3</sup> (Intravesical chemotherapy) (Estimated for 2026)	85	83.5%	57.4% (KM Curve estimated) 25.0%	Not Reported	Not Reported	High initial efficacy	Gemcitabine may result in little to no difference in the risk of disease progression compared to saline. Serious adverse events associated with chemotherapy. Median Duration Of Response ("DOR") of 30 weeks. 26.4% treatment related discontinuation.	\$Unknown (Dosed every 3 weeks for 24 weeks, followed by every 12 weeks through week 96)	\$372.3
enGene EG-70 (detalimogene voraplasmid) <sup>4</sup> (Non-viral gene therapy) (Estimated for 2027)	21/100	71% (Interim)	Not Reported	Not Reported	Not Reported	High initial efficacy	Phase II clinical study just commenced.	\$Unknown Unknown treatment schedule	\$0.3

Press Release - Theralase® Releases 2024 Annual Financial Statements - March 12, 2025

1) CG Oncology Website – December 5, 2024

2) TAR-200 monotherapy shows greater than 80% complete response rate in patients with high-risk non–muscle-invasive bladder cancer. September 15, 2024

3) Press Release – enGene Reports First Quarter 2024 Financial Results and Recent Corporate Progress – March 11, 2024



# **Herpes Simplex Virus**



# What is HSV?

There are hundreds of known types of herpes viruses, but only 8 routinely infect humans<sup>1</sup>

There are two main types of Herpes Simplex Virus ("HSV") that are most prevalent in humans:<sup>2</sup>

Туре	Symptoms	Global Prevalence (Billions)	% of Population (Under age 50)
HSV-1	Cold Sores	3.8	64%
HSV-2	Genital Herpes	0.52	13%

HSV infection is highly contagious, spreading via saliva (labial), vaginal secretion or semen (genital) and can be acquired unknowingly.<sup>3</sup>

50 to 80% of U.S. adults have oral herpes. According to the National Institutes of Health, about 90% of adults have been exposed to the virus by age 50.

Once infected, a person will have herpes simplex virus for the rest of their life.<sup>4</sup>

<sup>3</sup> Herpes Simplex Virus Treatment Market Size, Share & Trends Analysis Report By Type (HSV-1, HSV-2), By Drug (Acyclovir, Valacyclovir, Famciclovir), By Vaccine (Simplirix, Others), By Route of Administration, By End-use, By Region, And Segment Forecasts, 2024 – 2030
<sup>4</sup> Oral Herpes LJohns Hopkins Medicine



<sup>&</sup>lt;sup>1</sup> <u>Herpesviruses - Medical Microbiology - NCBI Bookshelf</u>

<sup>&</sup>lt;sup>2</sup> Herpes simplex virus

# **Mechanism of Action**

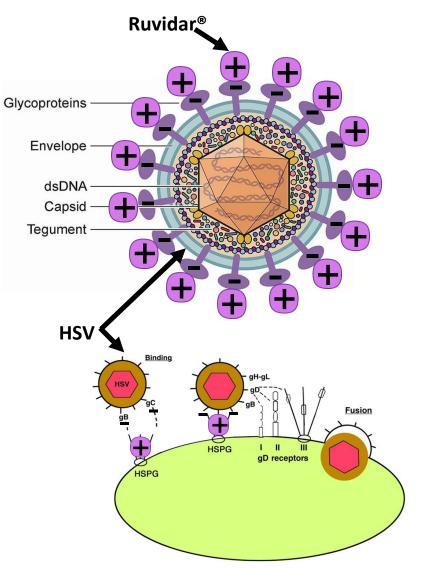
Glycoproteins (gB and gC) on HSV are negatively charged.<sup>1,2</sup>

They interact with Heparan Sulfate ("**HS**") on the cell surface, which is also negatively charged.<sup>3,4</sup>

This provides a novel mechanism (based on controlled electrostatic repulsion) that addresses how viruses balance between optimized viral attachment to target cells and efficient egress of progeny virus.<sup>1,2</sup>

Ruvidar<sup>®</sup> is positively charged.<sup>5</sup>

Ruvidar<sup>®</sup> blocks the glycoproteins on HSV preventing binding to host cells and on the cell surface preventing the efficient egress of progeny virus.



<sup>1</sup> Transforms of Cell Surface Glycoproteins Charge Influences Tumor Cell Metastasis via Atypically Inhibiting Epithelial-Mesenchymal Transition Including Matrix Metalloproteinases and Cell Junctions. Mingzhe Wang et al. Bioconjugate Chemistry. Vol. 34. Issue 8. July 2023

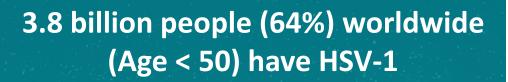
<sup>2</sup> Olofsson S, Bally M, Trybala E, Bergström T. Structure and Role of O-Linked Glycans in Viral Envelope Proteins. Annu Rev Virol. 2023 Sep 29;10(1):283-304. doi: 10.1146/annurev-virology-111821-121007. Epub 2023 Jul 6. PMID: 37285578.

<sup>3</sup> Agelidis AM, Shukla D. Cell entry mechanisms of HSV: what we have learned in recent years. Future Virol. 2015 Oct 1;10(10):1145-1154. doi: 10.2217/fvl.15.85. PMID: 27066105; PMCID: PMC4822157.

<sup>4</sup> Antoine TE, Park PJ, Shukla D. Glycoprotein targeted therapeutics: a new era of anti-herpes simplex virus-1 therapeutics. Rev Med Virol. 2013 May;23(3):194-208. doi: 10.1002/rmv.1740. Epub 2013 Feb 26. PMID: 23440920; PMCID: PMC3661299. <sup>5</sup> Ruvidar(TM) Enhances Efficacy of Cancer Drug



#### Herpes Simplex Virus<sup>1</sup>



0.5 billion people (13%) worldwide (Age 15 to 49) have HSV-2



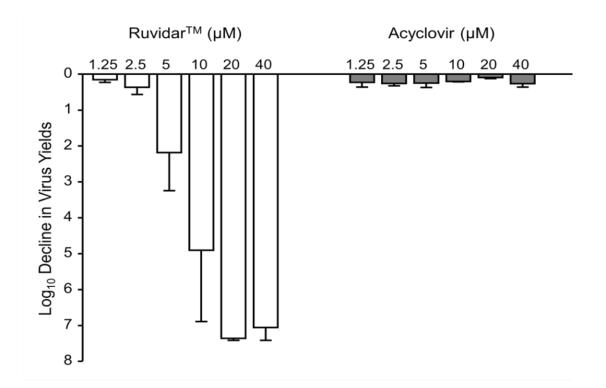


Global market size estimated at \$USD 2.8 billion in 2024 and is expected to grow to \$USD 4.7 billion by 2033.<sup>2</sup> North America has the largest market share at 37.1%.<sup>2</sup>

<sup>1</sup> <u>Herpes simplex virus</u>
 <sup>2</sup> <u>Herpes Simplex Virus Treatment Market Size, Top Share, Key Developments | By 2033</u>



# **Preclinical Research<sup>1</sup>**

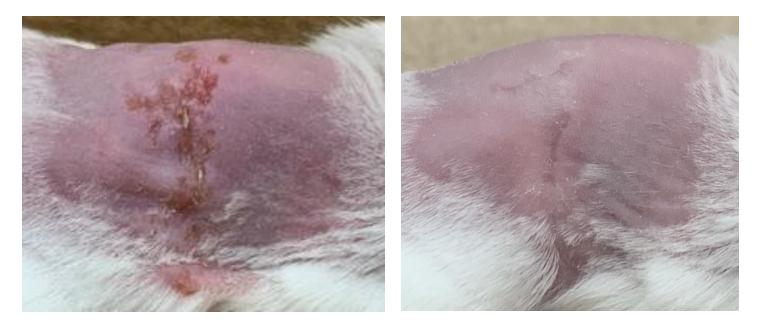


Effects of Ruvidar<sup>®</sup> Versus Acyclovir on HSV-1 Yields When Added 24 Hours Post Infection ("HPI").



# **Preclinical Research<sup>1</sup>**

Prior to Ruvidar<sup>™</sup> Treatment



After 4 days of Ruvidar<sup>™</sup> Treatment

Four days of daily Ruvidar<sup>®</sup> treatment in Balb/C mice with HSV-1 infected cutaneous lesions, 4 days post infection



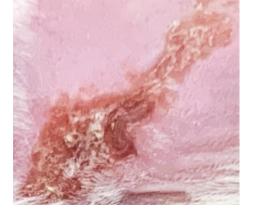
# **Preclinical Research<sup>1</sup>**

**No Treatment** 

#### Acyclovir (5%) (5 days of treatment / 5 times per day)

#### Abreva (10%) (6 days of treatment / 5 times per day)

**Ruvidar<sup>TM</sup> (1%)** (5 days of treatment / once per day)







Balb/C mice with HSV-1 infected cutaneous lesions, 1 day post-infection



# **HSV FDA Approved Drugs**

Drug <sup>1,2</sup>	Mode of Administration / Frequency	Drug Cost (\$USD) Per Treatment <sup>3</sup> / Manufacturer	Pros	Cons
Zovirax (5% Acyclovir cream)	Topical (5 to 6 times per day for 4 days)	\$62 (generic) to \$95 (Bausch / GlaxoSmith Kline) (4 gram tube)	Standard of care for labial and genital herpes	Prescription Use Only. Acyclovir resistance can occur in immunocompromised patients. 0.6 days healing versus placebo. 19.9% efficacy.
Valtrex (500 mg Valacyclovir tablets)	Oral (2 to 4 times daily for 7 days)	\$35 (generic) to \$159 (GlaxoSmith Kline) (30 tablets)	Prodrug converted to acyclovir in the body allowing for higher bioavailability than acyclovir. Lower frequency of treatments	Prescription Use Only. 0.7 days healing versus placebo.
Famvir (500 mg Famciclovir tablets)	Oral (Twice daily for 7 days)	\$59 (generic) to \$163 (Novartis) (21 to 30 tablets)	Higher bioavailability than acyclovir. Lower frequency of treatments	Prescription Use Only. 0.7 days healing versus placebo.
Denavir (1% Penciclovir cream)	Topical (6 times per day for 4 days)	\$33 to \$857 (Renaissance Pharma) (5 gram tube)		Prescription Use Only. 0.7 days healing versus placebo.
Abreva (Docosanol – 10%)	Topical (5 times per day for 10 days)	\$15 (GlaxoSmith Kline) (2 gram pump)	Over the Counter	Labial herpes lesions only. 0.7 days healing versus placebo.
Sitavig (Acyclovir - 50 mg tablet)	Buccal (1 tablet)	\$1,006 (2 tablets)		Prescription Use Only. 0.5 days healing versus placebo. Expensive.

<sup>1</sup> Sharma D, Sharma S, Akojwar N, Dondulkar A, Yenorkar N, Pandita D, Prasad SK, Dhobi M. An Insight into Current Treatment Strategies, Their Limitations, and Ongoing Developments in Vaccine Technologies against Herpes Simplex Infections. Vaccines (Basel). 2023 Jan 17;11(2):206. doi: 10.3390/vaccines11020206. PMID: 36851084; PMCID: PMC9966607.

<sup>2</sup> Sadowski LA, Upadhyay R, Greeley ZW, Margulies BJ. Current Drugs to Treat Infections with Herpes Simplex Viruses-1 and -2. Viruses. 2021 Jun 25;13(7):1228. doi: 10.3390/v13071228. PMID: 34202050; PMCID: PMC8310346 <sup>3</sup> https://www.canadadrugsdirect.com/products



## **HSV Non-FDA Approved Drugs**

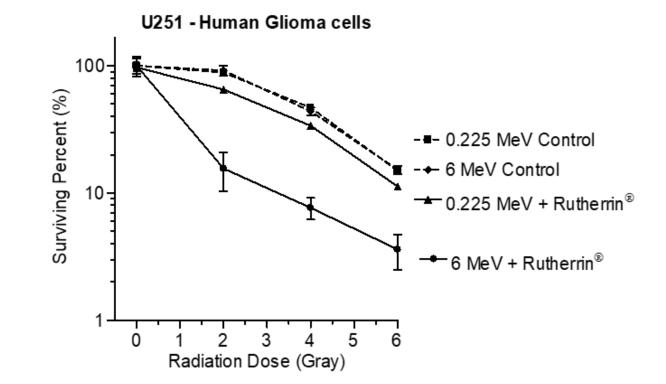
Drug <sup>1</sup>	Mode of Administration / Frequency	Drug Cost (\$USD) Per Treatment / Manufacturer	Pros	Cons
He-X (1% Ruvidar <sup>™</sup> )	Topical (1 time per day for 4 days)	TBD (Theralase®) (4 gram tube)	Over the Counter High safety and efficacy preclinically.	Not FDA approved. Phase I/II/III clinical study to be completed.
Pritelivir (5% AIC-316)	Topical (5 times per day for 4 days)	TBD (AiCuris Anti-infective Cures AG) (Tablets)		Not FDA approved. 21.8% efficacy.



## **New Cancer Indications**



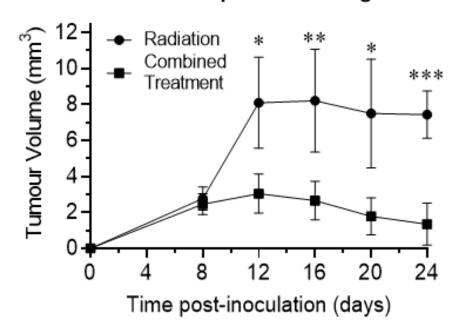
### **GBM Preclinical Research**



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



## **NSCLC Preclinical Research**

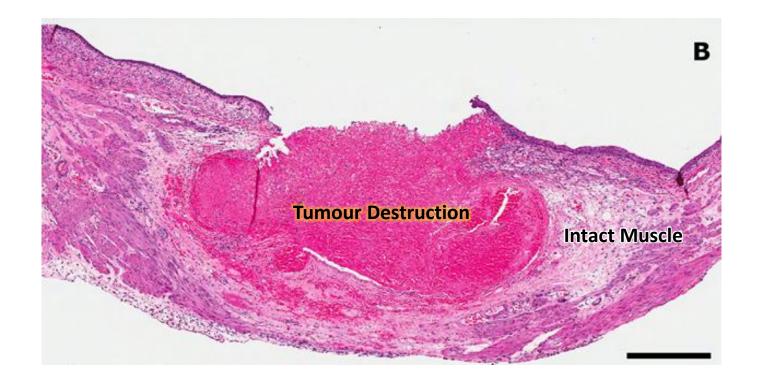


Mouse Orthotopic LLC1 Lung Cancer

Tumour Volume Analysis in Mice After Tumour Inoculation and Treatment with Either Radiation Alone or a Combined Treatment of Rutherrin<sup>®</sup> and Radiation Treatment



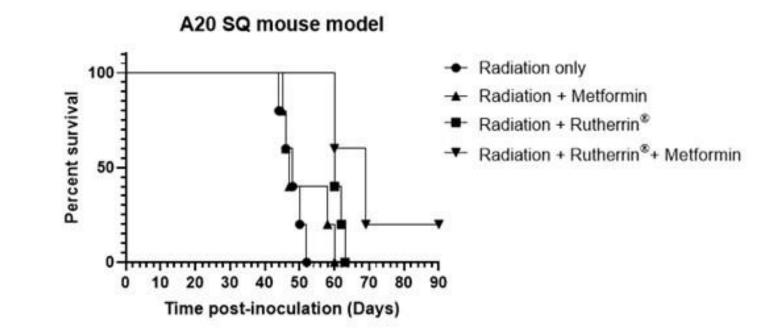
### **MIBC Preclinical Research**



Full Depth Tumour Necrosis in Muscle Invasive Bladder Tumours (No Damage to Healthy Muscle Tissue (Light-activated Ruvidar®))



## Leukemia, Lymphoma and Myeloma Preclinical Research



**Evaluation of Lymphoma in a Mouse Model** 



# **Regulatory Timeline (NMIBC)**

Milestone	2019	2020	2021	2022	2023	2024	2025	2026	2027
90 Patients Enrolled and Provided Primary Study Treatment (Projected)									
FDA Fast Track Designation (Actual)									
Patient Follow Up (Projected)									
Premarket Approval (Study Device) (Projected)									
Data Lock / Clinical Study Report Submission (Projected)									
Health Canada and FDA Marketing Approval (Projected)									
Commercialization Phase (Projected)									

Regulatory Strategy: Study Drug (IND / NDA) - Study Device (PMA) – Drug / Device Combination



# **Regulatory Timeline (HSV-1)**

Milestone	2025	2026	2027	2028
Formulation of HSV topical cream (Projected)				
GLP Toxicology (Projected)				
Phase I /II Clinical Study (Projected)				
Phase III Clinical Study (Projected)				
Data Lock / Clinical Study Report Submission (Projected)				
Health Canada and FDA Marketing Approval (Projected)				
Commercialization Phase (Projected)				

Regulatory Strategy: Study Drug (IND / NDA)



# **Regulatory Timeline (GBM, NSCLC, Pancreatic, Colorectal)**

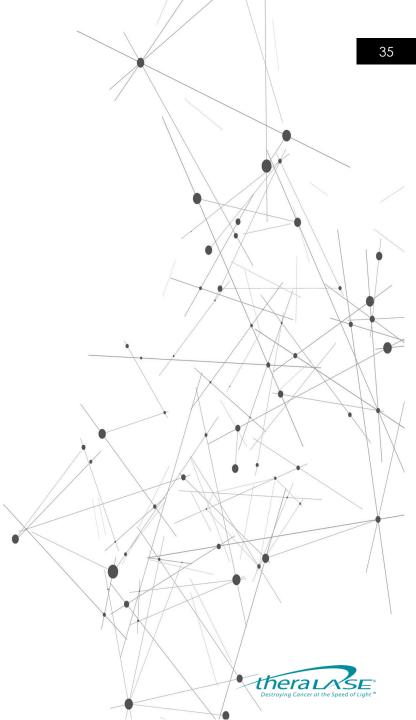
Milestone	2025	2026	2027	2028	2029	2030
Formulation of IV Rutherrin <sup>®</sup> (Completed)						
GLP Toxicology (Projected)						
Phase I /II Clinical Study (Projected)						
Phase III Clinical Study (Projected)						
Data Lock / Clinical Study Report Submission (Projected)						
Health Canada and FDA Marketing Approval (Projected)						
Commercialization Phase (Projected)						

Regulatory Strategy: Study Drug (IND / NDA)



# **NMIBC Investment Highlights**

- Next standard of care treatment for bladder cancer (9<sup>th</sup> most common cancer in the world (4<sup>th</sup> in men))
- Unique value proposition, combining a patented small molecule and proprietary laser system
- Able to directly destroy bladder cancer, leaving healthy bladder cells intact and providing a secondary response through activation of the immune system
- 82/90 patients enrolled and treated in an FDA Phase II registration clinical study
- Pending Health Canada and FDA approval in 2026, Theralase<sup>®</sup> will gain access to Canada, US and international bladder cancer markets estimated at up to \$USD 8 B annually
- Strong duration of response at 1, 2 and 3 years



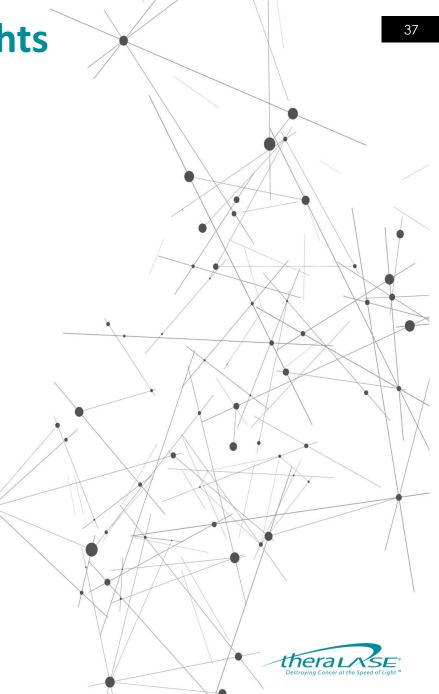
# **HSV Investment Highlights**

- Next standard of care treatment for HSV-1 lesions (cold sores)
- Ability to treat with a patented small molecule alone or increase efficacy with a proprietary laser system
- High safety and efficacy in preclinical models
- Pending Health Canada, FDA and international approval in 2027, Theralase<sup>®</sup> has a potential to gain access to Canada, US and international HSV markets estimated to be valued at up to \$USD 4.7 billion annually
- Best-in-class efficacy versus FDA approved drugs according to preclinical models
- Preclinical data support the safety and efficacy of topically applied non-light activated Ruvidar<sup>®</sup> against cutaneous HSV-1 lesions (mouse model) that could be further enhanced with light activation



# **Other Cancer Indications Investment Highlights**

- Minimally invasive treatment that provides IV installation of Rutherrin<sup>®</sup> activated by radiation therapy
- Patient centric treatment
- High safety and efficacy in preclinical models
- Pending Health Canada, FDA and international approval in 2030, Theralase<sup>®</sup> has a potential to gain access to Canada, US and international cancer markets estimated to be valued at up to \$USD 286 billion annually in 2030
- Best-in-class efficacy versus FDA approved drugs according to preclinical models



### **Capital Structure**

TSXV:TLT			06/04/2025
Common share price	\$CAN 0.185	Warrants	45,314,721
Market Capital	\$CAN 46.4 M	Options	19,620,000
Shares Outstanding	250,810,200	Finder Units	18,864
Fully Diluted	315,763,785	Insider Ownership	12.75% Fully Diluted







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