



**Critical Outcome**  
Technologies Inc.

***Advancing the Treatment of Cancer  
Through Targeted Therapeutics***

November 2015

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A clinical stage biopharmaceutical company with a promising new drug for ovarian and other cancers with p53 mutations

- TSX-V: COT
- OTCQB: COTQF

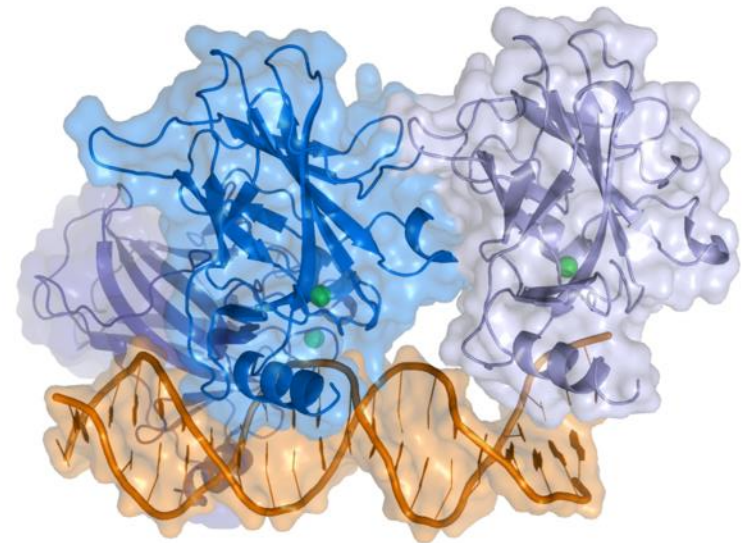


- 1** COTI-2: p53 activating drug entering Phase 1
  - > 95% of ovarian cancer patients have a p53 gene mutation
  - > \$1B market potential in U.S. alone
- 2** Strong pipeline of follow-on opportunities in oncology and other therapeutic areas
- 3** Approaching a critical inflection point

# COTI-2: A breakthrough for many cancers

- p53 is the single most important cancer causing gene mutation known
  - > 50% of all human cancers
- Novel mechanism of action reactivates p53 function
- Effective against many common cancers in preclinical animal models

**“a promising advance for many cancers with p53 mutations.”** – Dr. G.B. Mills, MDACC



# COTI-2: Strong market opportunity

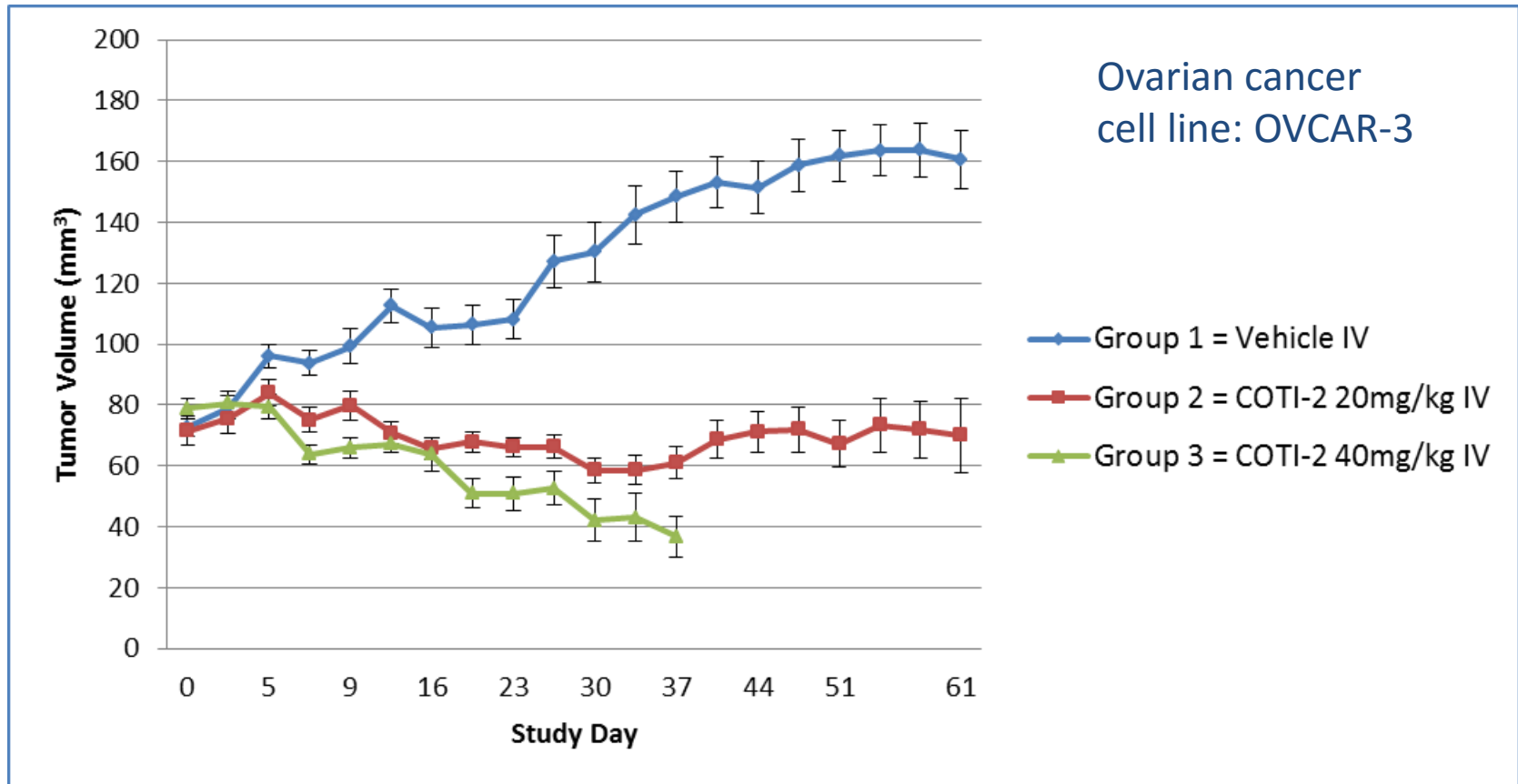
- ~ 12 million new cases of cancer annually worldwide
  - ~ 30% of all cancers would have susceptible p53 mutations
- Exploring clinical studies for multiple indications:
  - Head and neck (orphan) – next Phase 1 study in 2016
  - AML (orphan)
  - Li-Fraumeni syndrome (orphan)
- Preclinical models with COTI-2 demonstrate effectiveness when combined with many first-line therapies:
  - Chemotherapy and Immunotherapy

*Advancing the treatment of p53-dependent cancers*

# COTI-2: Best-in-class potential

- Novel p53-dependent mechanism of action
- Orally bio-available and effective at low dose
- Low toxicity in preclinical development
- Opportunity for single agent and combination therapy
- Strong IP protection in place
  - 6 U.S. patents issued
  - 1 Japanese, 1 Canadian and 1 EU patent issued
  - Additional patents pending

# COTI-2: Significant tumor reduction



Tumor volumes significantly reduced by COTI-2 in all treatment groups relative to vehicle control



# Competitor comparison to COTI-2

<b>DRUG</b>	<b>COTI-2</b>	<b>Kevetrin</b>	<b>APR-246 / PRIMA-1<sup>MET</sup></b>
<b>COMPANY</b>	Critical Outcome Technologies Inc.	Cellceutix Corp	Aprea
<b>MECHANISM OF ACTION</b>	Targets mutant p53 (restoration of wild-type p53 conformation and activity)	Targets wild-type and mutant p53 (MDM2-related mechanism)	Targets mutant p53 (restoration of wild-type p53 conformation and activity)
<b><i>IN VITRO</i> EFFICACY</b>	Most potent (nanomolar range of activity)	Least potent (activity >100 μM)	Much less potent than COTI-2 (activity in high micromolar range)
<b>CLINICAL PHASE OF DEVELOPMENT</b>	Phase 1	Phase 1	Phase 1/2
<b>INDICATIONS</b>	Gynecological malignancies (first patient in fall 2015)	Solid tumors (ongoing)	Hematological malignancies and prostate cancer (phase 1/2 completed)

# MD Anderson collaboration

- Key Opinion Leader, Dr. Gordon Mills, independently confirmed COTI-2's novel p53-dependent mechanism of action
- Confirmed COTI-2's selective & potent anti-cancer activity
- Identified effective dosage 60% lower than in prior animal experiments
- MDACC has committed financial support to a Phase 1

- *In vitro* and *in vivo* studies done with human cancer cell lines
- Toxicity studies show limited toxicity and dosing level relatively low for seeing results
- Dr. Mills has stated that based on his long experience results seen to date should translate to people
- Queen's University study – clinical success where there are 5 or more preclinical cancer indications

# COTI-2: Important milestones

## COMPLETED

- ✓ Granted orphan drug status for ovarian cancer by FDA in June 2014
- ✓ Signed LOI with MD Anderson for Phase 1 clinical trial in August 2014
- ✓ Appointed experienced Scientific Advisory Board (SAB)
- ✓ IND grant to proceed from FDA on May 22, 2015
- ✓ Obtained financing of ~ \$1.97 million CAD during summer 2015

## UPCOMING

- ✓ Phase 1 clinical trial initiated December 2015
- Increase value of COTI-2 by identifying new clinical indications and combination therapies
- Select next preclinical candidate for development
- Develop additional collaborations and partnerships with COTI-2 and CHEMSAS®
- COTI-2 publications 2016

# COTI-2: First of many opportunities

Therapy Library /Compound	Target	CHEMSAS	Lead Selection	Synthesis	Preclinical	Phase 1
Oncology						
COTI-2 (p53)	[Red bar]					
AML library	[Black bar]					
Colon library	[Blue bar]					
COTI-219	[Black bar]					
COTI-4	[Blue bar]					
COTI-58	[Black bar]					
Other programs *	[Blue bar]					

\* Other programs for MRSA, Multiple Sclerosis, Alzheimer's, and HIV Integrase

# Building a robust pipeline with CHEMSAS®

- Proprietary, machine learning (AI) based drug discovery platform technology
- Big data analysis solutions



Database driven  
computational  
replication of  
traditional  
'wet lab' drug  
discovery process

Costly failed attempts  
occur **quickly & cheaply**  
in computer simulations,  
not the 'wet lab'

**Increased probability** of  
clinical & commercial  
success

# Next clinical candidate options

- 1** COTI-219, a unique oncology drug candidate for CRC and melanoma
- 2** COTI-AML-01, a multi-kinase inhibitor for Acute Myelogenous Leukemia (AML)
- 3** COTI-HIV-II, second generation dual HIV Integrase inhibitor
- 4** COTI-MRSA1, highly novel antibiotic

**All pipeline candidates discovered by CHEMSAS®**



- Two R&D collaborations in progress:
  - Western University
  - Delmar Chemicals
- Third collaboration with a medium sized pharma in early discussions

Actively pursuing additional R&D collaboration opportunities with CHEMSAS®

## Management Team

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### **Wayne Danter, MD, FRCPC**

- Co-founder, President, CEO & CSO
- Former Associate Professor of Medicine at Western University

### **Gene Kelly**

- Chief Financial Officer
- Former VP Finance, Cuddy Farms
- Former VP Commodities & Industry Relations, Cuddy Foods
- Former VP Strategic Implementations, Cuddy Farms

### **Kowthar Salim, PhD, MBA**

- Program Director and Senior Scientist

### **Alison Silva, MS**

- Co-founder, EVP & COO, Synlogic

## Directors

### **John Drake, LLB, Chairman**

- Chairman, Whippoorwill Holdings Limited

### **Wayne Danter, MD, FRCPC**

### **Douglas Alexander, CPA, CA**

- Chairman, Hydrogenics Corporation

### **Bruno Maruzzo, MAsc, MBA**

- President, TechnoVenture Inc.

### **Dave Sanderson, LLB**

- President & CEO, KFL Investment Management Inc.

### **Alison Silva, MS**

- Co-founder, EVP & COO, Synlogic

### **John Yoo, MD FRCPC**

- Professor, Chairman and City-wide Chief of Otolaryngology – Head and Neck Surgery at Western University

# COTI-2 Scientific Advisory Board



**Dr. Gordon Mills** from the University of Texas MD Anderson Cancer Center, Houston, TX, Chairman

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**Dr. Douglas Levine** from the Memorial Sloan-Kettering Cancer Center in New York City, NY

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**Dr. David Parkinson** from New Enterprise Associates in Menlo Park, CA

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**Dr. Marshall Strome** from the Center for Head and Neck Oncology at Roosevelt St. Luke's Hospital in New York City, NY

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**Dr. Wayne R. Danter**, Chief Scientific Officer, Critical Outcome Technologies Inc, London, Canada

# Key Company Facts

<b>Trading</b>	
TSX Venture <sup>(2)</sup>	COT
Recent Closing Price <sup>(3)</sup>	\$0.295
52 Week Range <sup>(3)</sup>	\$0.195 - 0.375
Market Capitalization <sup>(3)</sup>	\$37,391,185
<b>Capital</b>	
Cash <sup>(4)</sup>	\$2,474,092
Basic Shares Outstanding <sup>(3)</sup>	126,749,781
Options Outstanding <sup>(3)</sup>	7,145,470
Warrants Outstanding <sup>(3)</sup>	45,539,152
Fully Diluted Shares Outstanding <sup>(3)</sup>	179,434,403
Board & management control <sup>(3) (5)</sup>	16.2%

(1) All \$ amounts in CAD

(2) COTI also trades on the OTCQB:COTQF but amounts presented are for the TSXV only

(3) As at Oct 31, 2015

(4) As at Oct 8, 2015 consisting of cash, cash equivalents and short-term investment

(5) On a fully diluted basis



# Critical Outcome

Technologies Inc.

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