

# **Business Review and Update**

Fourth Annual and Special Meeting of Shareholders
October 28, 2010



## **Forward Looking Statements**

When used anywhere in this presentation, the words expects, believes, anticipates, estimates, and similar expressions are intended to identify forward-looking statements. Forward-looking statements herein may include statements addressing future financial and operating results for Critical Outcome Technologies Inc., (COTI).

COTI has based these forward-looking statements on its current expectations about future events. Such statements are subject to risks and uncertainties including, but not limited to, the successful implementation of COTI's strategic plans, the acceptance of new products, the obsolescence of existing products, the resolution of existing and potential future patent issues, additional competition, changes in economic conditions, and other risks described in documents COTI has filed with the Toronto Stock Exchange and Ontario Securities Commission.

All forward-looking statements in this document are qualified entirely by the cautionary statements included in this document and such filings. These risks and uncertainties could cause actual results to differ materially from results expressed or implied by forward-looking statements contained in this document. These forward-looking statements speak only as of the date of this document.



# Product Development Progress



#### **COTI-2: Our Lead Oncology Asset**

- Novel small molecule potential first-in-class and best-in-class mechanism of action
- Preclinical data demonstrates greater selectivity, improved safety profile and pharmacokinetics compared to other AKT inhibitors
- Potential biomarker high levels of AKT expression

- Initial clinical targets include: ovarian, endometrial and pancreatic cancers; estimated > \$4.65 billion market by 2018
- Other cancer indications: breast, lung, brain, colon and leukemia
- Novel intellectual property multiple patents filed including composition of matter through 2028
- Dr. Daniel Von Hoff agreed to lead IND enabling studies & Phase 1 clinical trial



# **COTI-2: Fiscal 2010 Developments**

Month	Announcement	
Oct '09	Effective as single agent with low toxicity in animal models of seven human cancers	
Oct '09	Update on COTI-2's novel mechanism of action as a potential first in class allosteric AKT inhibitor	
Dec '09	Equally effective as a single agent compared with gemcitabine and more effective in combination with gemcitabine in an animal model of human pancreatic cancer	
Jan '10	Translational Genomic/TD2 (Dr. Daniel Von Hoff) agrees to lead Pre-IND studies, IND filing and Phase 1 clinical trial for COTI-2 as a novel anti-cancer drug	
Jan '10	Oral COTI-2 effective as a single agent and in combination with abraxane in a second animal model of human pancreatic cancer	
Mar '10	Presented preclinical data on COTI-2 at US Oncology TOP Summit in Houston, TX	
Mar '10	Oral COTI-2 effective as a single agent in an animal model of aggressive triple negative human breast cancer; represents $^{\sim}$ 20% of all breast cancer with currently no effective therapy	



# **COTI-2: Fiscal 2011 Developments**

Month	Announcement	
May '10	Received a favourable independent pre-investigational new drug (IND) GAP analysis report	
	<ul> <li>No scientific or regulatory deficiencies identified in the preclinical program</li> </ul>	
	<ul> <li>Ready for FDA pre-IND meeting: to be scheduled</li> </ul>	



# **COTI-2: Work In Progress**

Activity	Status
Continue final intravenous (IV) formulation	In Progress
Continue development of sensitive detection method for in animal plasma	In Progress
Continue development of oral formulation	In Progress
Intravenous single dose and multiple dose maximum tolerated dose (MTD) experiments	In Progress; completion Oct 31/10
Confirmatory xenograft model of human ovarian cancer using final IV formulation once MTD determined including a direct head to head comparison with MK-2206 (Merck's Phase 2 asset)	To be completed Jan 2011
IND enabling studies	TBD (2011)
Phase 1 Clinical trial	To follow IND filing



#### **Adult Acute Leukemia Program**

- Continues to progress following notice of patents granted in the USA in F'2009 and F'2010 thus providing patents on three compounds as tyrosine kinase inhibitors in Canada, US and Europe.
- June 29, 2010: announced the approval of a funding contribution from NRC-IRAP for further development
- Oct 28, 2010: optimized drug candidates ready for synthesis
- Actively seeking the necessary financing to continue development including licensing or co-development



#### **HIV Integrase Inhibitor Program**

Month	Announced	
Apr '10	Provided update that 3 novel scaffolds successfully synthesized and delivered to its major pharma collaborator	
May '10	Announced all three scaffold demonstrated good inhibitory activity in a biochemical HIV Integrase assay at nanomolar concentrations	
	Next phase underway – optimize final candidates from these scaffolds for antiviral activity and ADME/Tox properties	

- In Oct 2010 reviewed major pharma collaborator's test results and updated the criteria for developing successful final candidates
- Key criteria included: optimal virus killing activity and activity against known resistant viral mutations
- COTI is seeking additional funding to move the compounds forward to the next testing phase of the major pharma collaborator



# Pharmaceutical Industry Market Conditions



#### **Industry Market Conditions 2007-2009**

- Characterized by:
  - Flight from risk with financial markets meltdown
  - Large Pharmaceuticals facing a number of challenges:
    - Experiencing low productivity from R&D pipelines reflected in FDA approvals:

		New Molecular	NME from
Year	<sup>(1)</sup> Drug Approvals	Entities (NME)	Major Pharma
2007	92	17	8
2008	98	21	4
2009	102	19	7

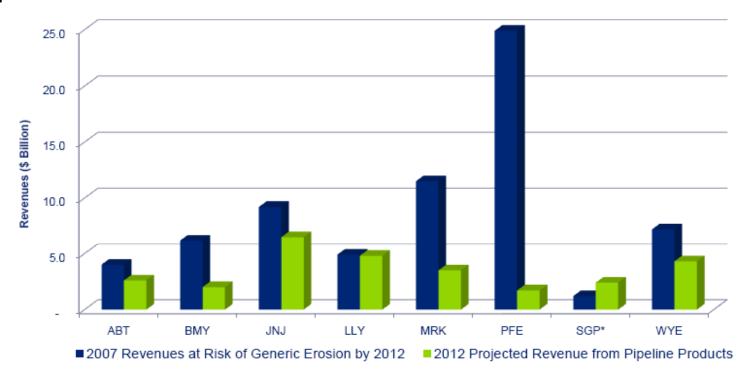
<sup>(1)</sup> Drugs@FDA

- New drug approvals will not make up the lost revenue/profits for drugs coming off patent
- Loss of patent protection for a large number of blockbuster drugs (patent cliff) during 2010-2013 period
- Competition from generic manufacturers sales volume and margin squeeze
- Uncertainty surrounding health care reform



#### **Patent Cliff & Pharmaceutical Pipelines**

• By 2012 drugs representing over \$74 billion in sales will lose patent protection



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Pharmaceutical companies re-evaluating their business development strategies

#### **Industry Market Conditions 2007-2009**

#### Resulted in:

- Striking increase in mergers of major pharma to improve earnings i.e. (Nov '08 to Oct '09) Lilly-ImClone, Pfizer-Wyeth, Merck-Schering Plough, Roche-Genentech, Abbott-Solvay
- Focus on late stage compounds (Phase 2 or 3 ready) for inlicensing activities - less risk and faster time to market and thus revenue/profits



### **Risks of Late Stage Deals**

- Lower scientific risk than early stage deals
- Much greater financial risk:
  - Higher deal valuations
  - Integration risks
  - Missteps very costly
    - Including delay of product launches
    - Compromising entire program
  - o ~ 30% of clinical candidates fail in Phase 3



#### **Merger Objectives**

#### Intended to:

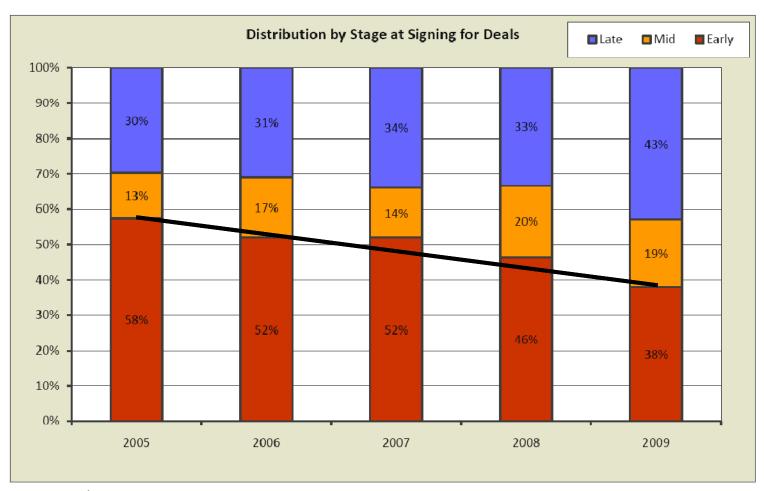
- Increase revenues and profits by:
  - Reducing SG&A costs by eliminating corporate overhead
  - Rationalizing the R&D programs to reduce costs
- Bolster R&D pipelines by focusing on best opportunities

#### Results:

- Merger requires focus on integration issues
- In-licensing focus on highest priorities being fastest to market deals
- 2010 NMEs approved by FDA to Oct 15/10 = 11 with 4 from major pharmas
- Will take time for results to be realized



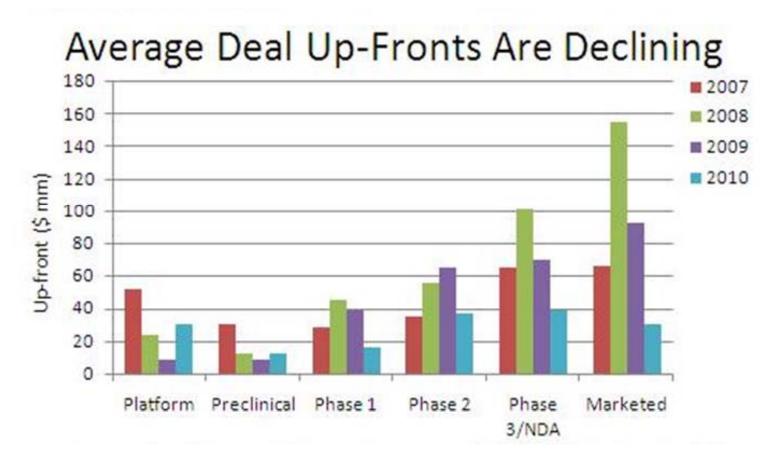
#### **Trends in Big Pharma In-licensing Deals**



Source: Deloitte Recap LLC



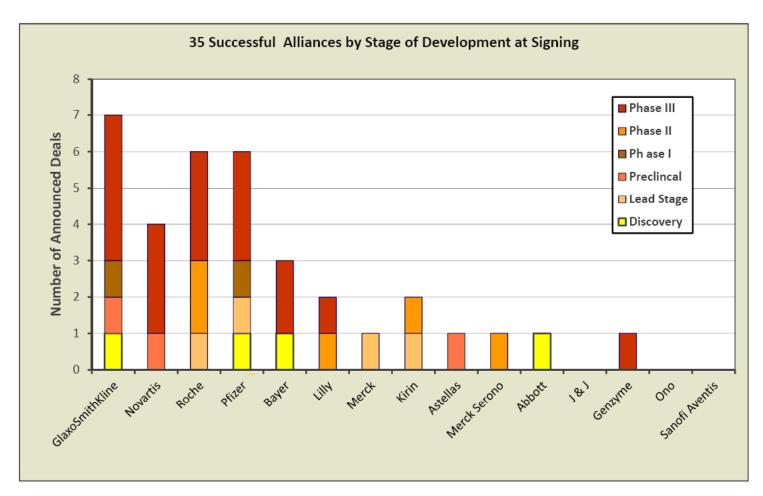
#### **In-Licensing Upfront Payment Trend**



Source: Elsevier's *Strategic Transactions*. Data set includes 277 alliances for which up-fronts were disclosed, signed between 1/01/2007 and 8/31/2010 by major pharmas, mid-sized European companies, top Japanese companies and large biotechs.



#### **Leading Deal Makers in 2009**



Source: Deloitte Recap LLC, www.recap.com



### **2010 Improving Market Conditions**

- 2007-2009 failed to address fundamental R&D productivity
- High quality late stage compounds either picked over or companies taking to market themselves
- Need to move downstream to find high potential promising assets
- 2010 has seen an increase in Phase 1 and pre-clinical deals
- Appears big Pharma focusing on strengths in late stage clinical trials, manufacturing, marketing and distribution
- Expect trend to continue into the future



# **COTI-2 Licensing**



# **COTI-2: Market Perspective**

Key Attributes	Licensing Challenges
Novel small molecule - potential first-in-class and best-in-class mechanism of action	Completion of IND enabling studies and receipt of IND viewed as a significant risk reduction point
Preclinical data demonstrates greater selectivity, improved safety profile and pharmacokinetics compared to other AKT inhibitors	Lack of human clinical data
Potential biomarker – high levels of AKT expression	
Initial clinical targets include: ovarian, endometrial and pancreatic cancers; estimated > \$4.65 billion market by 2018	
Other cancer indications: breast, lung, brain, colon and leukemia	
Novel intellectual property – multiple patents filed including composition of matter through 2028	
Dr. Daniel Von Hoff agreed to lead IND enabling studies and Phase 1 clinical trial	



### **Customer In-licensing Process**

	Process Step	Assessment	Time Line (mths)
1	Business Development	Assess fit for indication, target & stage of development	1
2	Preliminary Scientific Review	Assess non-confidential scientific data	1
3	Execution of Confidentiality Agreement	Indicates a commitment to allocate resources to review additional information	0.5
4	Extensive Scientific Review	Involves senior staff from various preclinical departments and clinical development	1-5
5	Intellectual Property Review	Review of freedom to operate	1
6	Term Sheet	Deal terms and timelines are discussed	2 – 6
7	Material Transfer Agreement	To validate experiment results	2 – 6
8	Due Diligence	On-site/data room review of all data and clinical development plan	1-3
9	Licensing Agreement	Legal contracts	4 – 9
	Process Time Line Range		13.5 - 32.5



# **COTI-2: Out-licensing Progress**

	Process Step	Incidences
1	Business Development	180-190
2	Preliminary Scientific Review	150
3	Execution of Confidentiality Agreement	28
4	Extensive Scientific Review	21
5	Intellectual Property Review	3
6	Term Sheet	4
7	Material Transfer Agreement	2
8	Due Diligence	1
9	Licensing Agreement	



### **Proximity to Licensing**

- Need to keep moving compound forward in development to enhance license potential
- License potential exists throughout development continuum as positive test results are socialized with interested parties
- Relationships with 13 of the top 15 licensee companies of biotech programs as part of the COTI-2 marketing program
- Relationships with many of the emerging drug development companies (Phase 1 and 2)



#### **COTI-2: Out-licensing On-going Efforts**

- Track media on a daily basis to identify:
  - Companies newly interested in COTI-2's MOA
  - New oncology drug development firms
  - Companies whose out-licensing deals have generated resources to invest in new oncology pipeline
- Attend 7 global industry conferences annually to stay in contact with prospective partners
- Dialogue with business development and scientific review team leads on a weekly basis



#### **Licensing Revenue Components**

- Deals typically reported publicly as a total figure from four pre-royalty revenue sources:
  - Upfront payment
  - Development milestones
    - Commencement of each clinical trial
  - Regulatory milestones
    - Per regional approval i.e. FDA
  - Commercial milestones
    - Launch of product sales and sales milestones achieved
  - R&D contributions
    - Scope focused on specific programs/targets of commercial interest
- Royalties disclosed but typically not included in deal figure



# **Customer Collaborations**



## **Collaboration Activity**

- Proposals in play with two organizations
  - Apply CHEMSAS® to a target defined by the failure of a Phase 3 asset and a significant unmet medical need
  - Apply CHEMSAS® to salvage a research project with commercial potential
- In both projects, CHEMSAS® would have identified problems with these compounds prior to synthesis and would have discarded them in favour of optimized compounds
- Financial terms negotiated on a deal by deal basis



# **Financial Update**



#### **Financing Status**

- End of first quarter F'11 Jul 31/10 cash ~ \$1.401m
- Sufficient cash to end of F'11 Apr 30/11 with current spending plan
- Timing of a licensing deal and cash therefrom is unknown
- Need financing to extend operations and advance COTI-2 until licensing revenue achieved



#### **Macro-economic Conditions**

- Equity markets in Canada and around world remain nervous
- Bears versus Bulls glass half empty or half full
- Weak economic environment data choppy
- US based consumer driven recovery slow to develop unemployment high, mortgage foreclosures continue
- Sovereign debt issues PIGS but US debt as well
- Global impact:
  - US, Europe and Asia even China
  - o growth rates constrained



### **Impact on Biotech Financing Efforts**

- Venture capitalists (VC), institutions and angels not cash flush
- VC trend in biotech to move upstream and fund later stage assets to improve risk profile
- Riskier investments have not rebounded like blue chip companies
- Risk sector of market is highly selective
- Biotech in Canada up against resource sector in particular oil
   & gas and gold
- COTI focus is on:
  - the compelling scientific and business case of COTI-2
  - o how we are different than traditional biotech



# A Different Biotech Investment Opportunity

	Description	Traditional Biotech	СОТІ
1	Molecules to develop and license	1-2	Pipeline of > 47 with other revenue stream potential from underlying platform technology
2	Revenue cycle	Long – 5 to 10 yrs	Shorter – concept to revenue 22 to 33 months
3	Development process	Wet lab infrastructure, in-house testing with some 3 <sup>rd</sup> parties	Virtual – computational in-house with all testing by 3 <sup>rd</sup> parties
4	Capital requirements	High – supporting only a few products and revenue events	High – supporting multiple products and revenue events
5	Cash burn rate	High – infrastructure and in-house approach	Lower – virtual and discretionary with 3 <sup>rd</sup> parties
6	Risk profile	High – multiple failure points	Lower – shorter cycle, more products, more revenue streams
7	Investment return	All or Nothing	Multiple opportunities for positive outcomes



#### **Summary**

- COTI-2 is a highly marketable asset both scientifically and commercially
- Term sheet interest
- CHEMSAS® is a novel robust technology
- Multiple revenue opportunities from CHEMSAS®
- COTI team committed to success

Thank you for your continued support!

