

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

Fiscal 2013 – First Quarter for the three months ended July 31, 2012

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### Overview

The following discussion and analysis by management (MD&A) is a review of the financial condition and results of operations of Critical Outcome Technologies Inc. (COTI or the Company) for the quarter ended July 31, 2012, and has been prepared with all information available up to and including <u>September 20, 2012</u>. This MD&A is intended to assist in understanding the dynamics of the Company's business and the key factors underlying its financial results.

The unaudited condensed interim financial statements (interim financial statements) have been prepared in accordance with International Accounting Standard (IAS) 34: Interim Financial Reporting, and with International Financial Reporting Standards (IFRS).

All dollar amounts are expressed in Canadian dollars. Historic quarterly interim reports, the Company's Annual Information Form (AIF) and annual audited financial statements as well as additional supplementary information concerning the Company can be found on SEDAR at www.sedar.com.

### **Forward-looking Statements**

This MD&A contains certain statements based upon forward-looking information (forward-looking statements or FLS) concerning the Company's plans for its operations and other matters within the meaning of applicable Canadian provincial securities laws. FLS are necessarily based on estimates and assumptions that are inherently subject to significant business, economic and competitive uncertainties and contingencies. All statements that address activities, events or developments that the Company believes, expects or anticipates will or may occur in the future are FLS. FLS are subject to a variety of risks and uncertainties that may cause the actual events or results of the Company to differ materially from those discussed in the FLS, and even if such actual events or results are realized or substantially realized, there can be no assurance that they will have the expected consequences to, or effects on, the Company.

Any statements that express or involve discussion with respect to predictions, expectations, beliefs, plans, projections, objectives, or assumptions of future events or performance (often, but not always, using words or phrases such as "expects" or "does not expect", "is expected", "anticipates" or "does not anticipate", "plans", "estimates" or "intends", or stating that certain actions, events or results "may", "could", "would", "might" or "will" be taken, occur or be achieved) are not statements of historical fact and may be FLS. The major FLS included in this MD&A are set out in Table 1.



Table 1: Forward-looking Statements

MD&A Section Heading	Nature of Forward-looking Information Disclosed
Our Business	<ul> <li>Intends to license its targeted molecules</li> <li>Plans for further testing of COTI-2 leading to an IND filing and readiness for a Phase 1 clinical trial</li> <li>Plans for future application of the CHEMSAS® technology on a collaboration basis</li> <li>The Company's commercialization strategy for collaborations</li> </ul>
Liquidity and Capital Resources	<ul> <li>Expectations of future expenditures on patents and computer software</li> <li>Plans to amend warrants issued in March-April 2011</li> <li>Plans for continued research and development spending and additional financing</li> </ul>
Financial and Operational Progress and Outlook	<ul> <li>Scientific experiments for COTI-2 progressing to optimize the licensing value of the drug candidate</li> <li>In vitro testing progressing for the AML program</li> <li>Collaboration project with Western University progressing</li> </ul>
Industry and Economic Factors Affecting Performance	<ul> <li>The expected continuation of losses until a revenue transaction is secured</li> <li>Plans to negotiate future licensing agreements</li> <li>Plans to raise additional financing through different venues and mechanisms available to the Company</li> </ul>
Changes in Accounting Policies including Initial Adoption	The adoption of new accounting standards issued by the Accounting Standards Board to occur in fiscal 2014

The basis for the FLS is management's current expectations, estimates, projections and assumptions. By their nature, they are not guarantees of future performance as they involve significant risks and uncertainties.

The main assumptions used by management to develop the forward-looking information include the following:

- An ability to obtain sufficient financing to support working capital requirements and fund further research and development initiatives over the long term
- An ability to further enhance and add features to the CHEMSAS® technology to incorporate advances in the state-of-the-art for internal and collaborative purposes
- A continuation of favourable preclinical test results from the COTI-2 program and an ability to meet the requirements for regulatory approval
- Obtaining patent protection for the Company's compounds and other intellectual property



 An ability to attract and retain skilled and experienced personnel and to maintain relationships with third party clinical research organizations

Management of COTI considers the assumptions on which the FLS are based to be reasonable. However, management cautions the reader that because of the many risk factors as set out in the Company's AIF, including those specifically described below which are of particular importance to the assumptions above, actual results could differ materially from those expressed or implied in the FLS. These assumptions may prove to be wrong, and as such, undue reliance should not be placed on any individual FLS.

The main risk factors that will influence the Company's ability to realize on its FLS include:

- The ability to raise sufficient financing for continuing operations and development including maintaining the Company's workforce
- The ability to establish customer relationships leading to licensing agreements for the Company's compounds
- The ability to generate customer demand for outputs from the CHEMSAS® technology
- The ability to continue favourable preclinical test results from the Company's lead oncology compound, COTI-2
- The ability to meet future regulatory requirements to commercialize compounds, in particular COTI-2
- The ability to obtain patent protection for the Company's compounds

The forward-looking information is provided as of the date of this MD&A and the Company does not undertake any obligation to publicly update or revise any forward-looking information, whether because of new information, future events, or otherwise, except as required by securities laws.

### The Company

COTI is a London, Ontario based company resulting from the amalgamation on October 13, 2006 of Aviator Petroleum Corp. (Aviator), a public company listed on the TSX Venture Exchange (TSXV), and Critical Outcome Technologies Inc., a private company under the provisions of the *Business Corporations Act* (Ontario). The amalgamation constituted the qualifying transaction for Aviator pursuant to the policies of the TSXV. The amalgamated company adopted the name Critical Outcome Technologies Inc. and its common shares were listed and posted for trading on the TSXV under the symbol COT on October 30, 2006.

On November 27, 2007, the Company completed an acquisition of all the outstanding common shares in the capital of 3015402 Ontario Inc. operating as DDP Therapeutics (DDP), in which the Company had, up to the date of the acquisition, a 10% ownership interest. DDP was formed in



early 2005 to develop a library of small cell lung cancer molecules discovered by the Company using its drug discovery technology.

On May 1, 2008, the Company amalgamated with this wholly owned subsidiary under the laws of the Province of Ontario.

### **Our Business**

COTI is a biotechnology company focused on applying its proprietary computer-based technology, CHEMSAS®, to identify, profile, optimize and select potential new drug candidates at the discovery stage of preclinical drug development and thereby reduce the timeline and cost of getting new drug therapies to market. The Company's long-term business model is to license its targeted molecules following synthesis and completion of confirmatory preclinical testing to the investigational new drug (IND) ready stage in order to address the pipeline needs of pharmaceutical and biotechnology companies.

The Company is developing focused portfolios of novel, proprietary and optimized small molecules as potential drug candidates for specific therapeutic targets in diseases that have high morbidity and mortality rates and currently have either poor or no effective therapies. COTI has concentrated on developing drug candidates for the treatment of various cancers, human immunodeficiency virus (HIV), Alzheimer's disease and multiple sclerosis. Cancer types specifically targeted include small cell lung, adult myelogenous leukemia (AML), ovarian, endometrial, pancreatic, brain, breast and colon.

The Company is currently taking an oncology molecule, COTI-2, forward through various preclinical tests to Phase 1 clinical trials as commercial validation of both the compounds viability as a clinical drug candidate and the underlying CHEMSAS® technology used to discover it. In this regard, COTI is focused on preparing for an IND clinical trial submission based on the positive preclinical test results achieved for COTI-2, its lead cancer molecule, against a number of cancer indications. Current testing initiatives and planning would enable an IND filing in calendar 2013. Upon acceptance of an IND filing, COTI-2 would be available for licensing or codevelopment as a Phase 1 ready compound.

The Company also seeks to leverage CHEMSAS® to identify targeted lead candidates of commercial interest to pharmaceutical, biotechnology, research and academic organizations on a collaborative basis. The Company's commercialization strategy for collaborations involves an upfront fee and a shared risk/reward revenue model delivered through a series of milestone payments based on preclinical and clinical test results. This service offering provides prospective customers with an efficient and cost effective approach for generating targeted discovery stage compounds while enhancing value to COTI and its shareholders from the underlying CHEMSAS® technology. This collaboration approach resulted in two engagements



with multinational pharmaceutical companies in the past few years, one for a cancer target and the other for an HIV target and two collaborations announced in September 2012.

# **Financial Review of Operations**

### Revenues

### Operating:

Service fee revenue of \$3,404 was recognized in the quarter ended July 31, 2012 (Q1-F'13) compared to no operating revenues in the quarter ended July 31, 2011 (Q1-F'12). The Company entered into a collaboration agreement on July 16, 2012 wherein it was eligible to receive an upfront payment of \$25,000 as a fee for the identification of lead candidates under the agreement as discussed more fully under Collaborations and Co-development Projects below. Revenue is being recognized on a percentage of completion basis over a period of three months based upon management's estimate of the length of time necessary for the Company to complete the identification of the lead candidates.

### Non-operating:

Investment tax credit (ITC) income of \$35,733 was recognized in Q1-F'13 compared to \$29,890 in Q1-F'12, related to scientific research and development tax credits earned on eligible expenditures in the respective quarters.

The Company earned \$3,959 in interest income on its cash, cash equivalents and short-term investments in Q1-F'13 compared to \$4,503 in Q1-F'12.

### **Operating Expenses**

Operating expenses increased from \$649,094 in Q1-F'12 to \$732,684 in Q1-F'13, an increase of \$83,590. Two major functional expense areas accounted for this comparable quarterly increase; research and product development (R&D) expenses increased by \$61,054 from \$205,941 in Q1-F'12 to \$266,995 in Q1-F'13; and general and administration (G&A) expenses increased by \$25,404 from \$415,325 in Q1-F'12 to \$440,729 in Q1-F'13.

Quarterly R&D expenditures increased year over year due to increased *in vivo* and *in vitro* testing for COTI-2. Table 2 provides a breakdown of R&D costs by major expense types for the comparable three month fiscal periods ended July 31.



Table 2: R&D Expenses - Comparative Periods Ended July 31

	Q1-F'13	Q1-F'12	Change
R&D testing, consulting and materials	\$ 164,318 \$	17,032 \$	147,286
Synthesis	9,469	103,909	(94,440)
	173,787	120,941	52,846
Labour including benefits	87,308	78,942	8,366
Other	5,900	6,058	(158)
Total	\$ 266,995 \$	205,941 \$	61,054

R&D testing, consulting and materials increased \$147,286 for Q1-F'13 compared to Q1-F'12 due to increased *in vitro* and *in vivo* testing of the Company's lead oncology asset, COTI-2. This increase was partially offset by a decrease in synthesis costs of \$94,440 year over year. The higher synthesis costs in Q1-F'12 related to the work being done in finding an oral formulation for COTI-2 that could be used in the final preclinical two species toxicity experiments and for use in the human clinical trial submission.

The modest increase in R&D labour costs year over year primarily related to the allocation of the Chief Scientific Officer's (CSO) salary costs between two functional expense areas; G&A and R&D. The allocation is based on time commitments to activities in these two areas. The Company also recovered \$2,155 in salary costs in Q1-F'13 from government assistance received for its acute myelogenous leukemia (AML) project compared to \$3,693 from government assistance in Q1-F'12. There were no changes in R&D staff levels during the comparable periods.

Table 3 provides a breakdown of G&A costs by major expense types for the comparable three month fiscal periods ended July 31.

Table 3: G&A Expenses – Comparative Periods Ended July 31

	Q1-F'13	Q1-F'12	Change
Salaries and benefits	\$ 100,684 \$	111,754 \$	(11,070)
Amortization	130,189	119,274	10,915
Corporate governance	20,288	17,085	3,203
Promotion and travel	12,731	9,488	3,243
Professional fees	99,875	86,798	13,077
Rent	9,346	9,346	-
Insurance	14,467	14,967	(500)
Other	10,764	5,431	5,333
	398,344	374,143	24,201
Share-based compensation	42,385	41,182	1,203
Total	\$ 440,729 \$	415,325 \$	25,404



Two expense items accounted for the majority of the increase. First, Q1-F'13 amortization costs increased by \$10,915 resulting from the grant of a patent for COTI-2 by the United States (U.S.) Patent Office in October 2011, which triggered the commencement of amortization starting in November 2012 on the accumulated patent costs incurred related to the U.S. filing. Second, professional fees increased year over year by \$13,077 primarily due to consulting contracts related to higher fiscal 2012 year end audit costs for the audit of the IFRS changes in the initial year of implementation, and executive consulting services for a full quarter compared to two months in Q1-F'12.

Table 4 provides a breakdown of sales and marketing costs (S&M) by major expense types for the comparable three month periods ended July 31. S&M expenses increased modestly from \$57,718 in Q1-F'12 to \$60,693 in Q1-F'13.

Table 4: S&M Expenses – Comparative Periods Ended July 31

	Q1-F'13	Q1-F'12	Change
Salaries and benefits	\$ 18,901 \$	44,668 \$	(25,767)
Marketing and travel	17,451	11,176	6,275
Other	24,341	1,874	22,467
Total	\$ 60,693 \$	57,718 \$	2,975

Salaries and benefits expense decreased from \$44,668 in Q1-F'12 to \$18,901 in Q1-F'13 due to a lower head count in Q1-F'13. This lower cost was offset by an increase of \$24,000 in consulting expense recorded in the Other category.

Marketing and travel expense increased from \$11,176 in Q1-F'12 to \$17,451 in Q1-F'13 and was related to an increased presence at the BIO International Convention held in Boston in June 2012 as the Company actively engaged with parties potentially interested in licensing COTI-2 and in collaborations.



# **Financial Results Summary by Quarter**

Table 5 summarizes the financial results of COTI by quarter for the past two fiscal years including the most recent quarter. All quarters are presented in compliance with IFRS.

Table 5: Summary of Quarterly Financial Results

FYE 2013		Q1	Q2	Q3	Q4	Year
		31-Jul	31-Oct	31-Jan	30-Apr	to Date
Revenue	\$	3,404	\$ -	\$ -	\$ -	\$ 3,404
Loss	(	722,769)	-	-	=	(722,769)
Loss per common share	\$	(0.01)	\$ -	\$ -	\$ -	\$ (0.01)
FYE 2012		Q1	Q2	Q3	Q4	Full Year
	3	31-Jul	31-Oct	31-Jan	30-Apr	
Revenue	\$	-	\$ -	\$ -	\$ =	\$ 
Loss	(	642,256)	(648,530)	(619,550)	(680,815)	(2,591,151)
Loss per common share	\$	(0.01)	\$ (0.01)	\$ (0.01)	\$ (0.01)	\$ (0.04)
FYE 2011		Q1	Q2	Q3	Q4	Full Year
	3	31-Jul	31-Oct	31-Jan	30-Apr	
Revenue	\$	-	\$ -	\$ -	\$ -	\$ -
Loss	(	558,950)	(334,498)	(634,345)	(473,585)	(2,001,378)
Loss per common share	\$	(0.01)	\$ (0.01)	\$ (0.01)	\$ (0.01)	\$ (0.04)

The majority of the variation by quarter across the years, and year over year, is explained by three expense categories as set out in Table 6.



Table 6: Selected Quarterly Expense Categories (1)

FYE 2013	Q1	Q2		Q3		Q4			Year
111 2013	-	-		-		Q+			i Cai
	31-Jul	31-Oct		31-Jan		30-Apr	•	1	o Date
General and administration	\$ 398,344	\$	-	\$	-	\$	-	\$	398,344
Research and product development	266,995		-		-		-		266,995
Investment tax credit recovery	(35,733)		-		-		-		(35,733)
Share-based compensation	42,385		-		-		-		42,385
Total of expense categories	671,991		-		-		-		671,991
Total expense for the quarter	\$ 732,684	\$	-	\$	-	\$	-	\$	732,684
Expense categories as a % of total expense	91.7%	0	.0%	(	0.0%		0.0%		91.7%

FYE 2012	Q1	Q2	Q3	Q4	
	31-Jul	31-Oct	31-Jan	30-Apr	Full Year
General and administration	\$ 374,144	\$ 424,332	\$ 361,305	\$ 406,956	\$ 1,566,737
Research and product development	205,941	120,008	163,640	223,134	712,723
Investment tax credit recovery	(29,890)	(19,887)	(33,669)	(50,326)	(133,772)
Share-based compensation	41,182	66,717	74,411	39,675	221,985
Total of expense categories	591,377	591,170	565,687	619,439	2,367,673
Total expense for the quarter	\$ 649,094	\$ 657,774	\$ 624,652	\$ 677,619	\$ 2,609,139
Expense categories as a % of total expense	91.1%	89.9%	90.6%	91.4%	90.7%

FYE 2011	Q1	Q2	Q3	Q4	
	31-Jul	31-Oct	31-Jan	30-Apr	Full Year
General and administration	\$ 360,708	\$ 351,097	\$ 367,233	\$ 307,468	\$ 1,386,506
Research and product development	196,374	137,220	125,255	133,893	592,742
Investment tax credit recovery	-	(122,244)	-	(72,185)	(194,429)
Stock-based compensation	(57,157)	(90,878)	71,069	45,287	(31,679)
Total of expense categories	499,925	275,195	563,557	414,463	1,753,140
Total expense for the quarter	\$ 562,452	\$ 335,758	\$ 635,959	\$ 469,924	\$ 2,004,093
Expense categories as a % of total expense	88.9%	82.0%	88.6%	88.2%	87.5%

<sup>(1)</sup> The presentation noted in this table does not conform to the IFRS functional presentation in the Company's interim financial statements. Share-based compensation included in General and Administration, and Research and Product Development in the financial statements has been removed from the functional disclosure and shown separately in this table.

The year over year first quarter comparison is relatively consistent except for the increase in R&D expense in Q1-F'13, which was explained above under Operating Expenses in the discussion of the Financial Review of Operations for the current quarter. The balance of the remaining expense categories remained relatively consistent.

# **Liquidity and Capital Resources**

At the end of Q1-F'13, the Company had cash, cash equivalents and short-term investments of \$1,028,629 compared to \$1,718,671 in cash, cash equivalents and short-term investments at the end of FYE 2012 reflecting a decrease of \$690,042. Table 7 summarizes the changes in cash resources for the comparable three month periods ending July 31 for Q1-F'13 and Q1-F'12. The difference in the year over year cash positions is \$529,568.



Table 7: Summary of Changes in Capital Resources (1)

	Q1-F'13	Q1-F'12
Increase (decrease) from:		
Operating activities	\$ (674,068) \$	(545,238)
Investing activities excluding changes in short-term investments	(35,281)	(12,454)
(Decrease) in capital resources before issuance of common shares		
and warrants	(709,349)	(557,692)
Proceeds from issuance of common shares and warrants	-	18,974
Financing activities not including proceeds from common shares issued	17,383	(151)
(Decrease) increase in capital resources	(691,967)	(538,869)
Less: unrealized foreign exchange loss on capital resources	1,925	2,149
Capital resources - beginning of period	1,718,671	2,094,917
Capital resources - end of period	\$ 1,028,629 \$	1,558,197

<sup>(1)</sup> See Use of Non-GAAP Financial Measures

Investing activities in Q1-F'13 and Q1-F'12 related to intangible asset expenditures for computer software and patents. Investment in such items will continue into the future as the Company relies heavily on computing technology to run its CHEMSAS® process, and investing in patents for the molecules identified from the process ensures that the licensing value of this intellectual property is protected.

There were no options exercised in Q1-F'13 compared to 116,279 options exercised for gross proceeds of \$19,186 in Q1-F'12. No warrants were exercised in either quarter. Financing activities in Q1-F'13 related primarily to the receipt of ITC of \$17,570 related to fiscal 2011 tax filings.

The Company's working capital at the end of Q1-F'13 was \$1,002,777 compared to \$1,588,254 at FYE 2012. Current assets continue to remain highly liquid, as there are no restrictions on the use of these assets. Cash equivalents are invested in instruments with maturities of three months or less. Short-term investments are held in a flexible guaranteed investment certificate, which became cashable without penalty after June 14, 2012. Current assets decreased to \$1,267,699 at Q1-F'13 from \$1,929,759 at FYE 2012 for a decrease of \$662,060, primarily due to the decrease in cash, cash equivalents and short-term investment. Current liabilities decreased \$76,583 to \$264,922 at Q1-F'13 from \$341,505 at FYE 2012 because of decreased project accruals and reduced trade payables related to professional fees offset by an increase in Unearned Revenue related to an upfront payment on a collaboration contract noted earlier in the MD&A.

The Company's exposure to fluctuations in the recoverability of its financial assets is limited as cash not required for current purposes is held in interest bearing cash accounts. Miscellaneous receivables are of high credit quality. The short periods to maturity of these instruments and their capacity for prompt liquidation result in future settlement amounts that are consistent with carrying values. Given the nature of the Company's financial liabilities, there is also limited risk that future settlement amounts will differ from carrying values. The Company does not



have any derivative financial instruments, nor does it engage in hedging transactions, as risk exposure is limited.

The Company's long-term contractual obligations are summarized in Table 8. The last R&D contract commitment for \$3,900 expires on January 31, 2014.

**Table 8: Contractual Obligations** 

Obligation	Total	2013	2014
Premises rent <sup>(1)</sup>	\$ 9,345	\$ 9,345	\$ -
Research and development contracts	280,988	277,088	3,900
Total contractual obligations	\$ 290,333	\$ 286,433	\$ 3,900

<sup>(1)</sup> The premises lease agreement expired on May 31, 2009 and was extended on a month-to-month basis with a 90-day notice period.

### **Warrant Amendment**

Subsequent to the July 31, 2012 quarter end, the Company recognized that 12,500,000 common share purchase warrants (Warrants) issued pursuant to a private placement in March and April, 2011 would potentially expire on September 24, October 6, and October 20, 2012 as the Company's shares were trading in a range well below their exercise price of \$0.30. On September 10, 2012, the Company received the consent of the TSX Venture Exchange to extend the expiry date of these Warrants to October 31, 2013 conditional upon obtaining the necessary warrant holder consents and issuing a press release. There were no other changes in the terms of the Warrants.

### Future Plans Impact

The Company has formulated goals for the balance of fiscal 2013 to advance the testing of COTI-2 thereby enhancing its value to potential licensees and to move the AML project and other projects forward as resources permit. The Company has discretion in many of its budgeted activities and plans to manage these activities in a manner to sustain operations until the necessary financing is available to meet its goals for COTI-2. The Company expects to continue its efforts to obtain financing over the next year to accomplish its goals.

### **Off-Balance Sheet Arrangements**

The Company has not historically utilized, nor is it currently utilizing any off-balance sheet financial instruments.



### **Foreign Exchange Exposure**

During Q1-F'13, the Company recorded a foreign exchange gain of \$2,552 compared to a gain of \$2,336 in Q1-F'12. The gain recorded in Q1-F'13 reflects \$1,925 in unrealized gains resulting from holding foreign currency balances at the quarter end compared to \$2,149 in unrealized gains at quarter end Q1-F'12. The foreign currency exposure at the end of Q1-F'13 was immaterial and consistent with Q1-F'12.

### **Related Party Transactions**

Material transactions with related parties during the quarter were in the ordinary course of business. These were measured at the transaction amount, being the amount of consideration established and agreed to by the related parties and included:

- (a) a grant of 17,838 share options to a new director appointed on July 11, 2012; and,
- (b) consulting fees paid under a fee for service contract with a director in the amount of \$46,584. This contract expired on May 31, 2012, and was renewed with an expiry date of April 30, 2013. Payments under this contract in Q1-F'12 totaled \$35,625.



# **Outstanding Share Information**

Outstanding share information at the close of business on September 20, 2012 is set out in Table 9. For clarity, this table does not reflect the pending warrant amendment as described under Liquidity and Capital Resources above.

Table 9: Outstanding Share Information

	Outstanding	Expiry Date
Common shares		
Authorized - unlimited		
Issued	74,453,214	
Fully diluted <sup>(1)</sup>	104,756,685	
Weighted average outstanding (2)	74,453,214	
Common share warrants		
\$0.55 warrants	129,019	Jan 31/13
\$0.30 warrants	8,152,500	Sep 24/12
\$0.30 warrants	2,187,500	Oct 6/12
\$0.30 warrants	2,160,000	Oct 20/12
\$0.37 warrants	1,446,481	Jan 31/13
\$0.30 warrants	3,125,000	Sep 23/13
\$0.30 warrants	6,250,000	Oct 9/13
\$0.30 warrants	1,875,000	Oct 26/13
\$0.30 compensation warrants	385,500	Sep 24/12
\$0.30 compensation warrants	82,000	Oct 6/12
\$0.30 compensation warrants	40,000	Oct 20/12
\$0.30 compensation warrants	157,937	Sep 23/13
\$0.30 compensation warrants	371,874	Oct 9/13
\$0.30 compensation warrants	196,875	Oct 26/13
	26,559,686	
Common share stock options		
\$0.01 - \$0.50	3,122,601	Sep 9/14 - Oct 7/17
\$0.51 - \$1.00	521,184	Jun 9/13 - Feb 16/14
\$1.01 - \$2.00	100,000	Oct 8/12
	3,743,785	

 $<sup>^{</sup>m (1)}$  Assumes conversion of all outstanding common share stock options and warrants.

 $<sup>^{(2)}</sup>$  Weighted average shares outstanding calculated from May 1, 2012 to September 20, 2012



# Financial and Operational Progress & Outlook

#### Financial Outlook for Remainder of F'2013

The Company remains focused on out-licensing COTI-2 not only for the monetary benefit to its shareholders but the opportunity COTI-2 presents for further development in the clinic and ultimately for the benefit of oncology patients. In this regard, the Company continued to meet with prospective licensing partners during Q1-F'13 and anticipates being positioned to negotiate an out-licensing deal for COTI-2 in the second half of fiscal 2013. In January 2012, the Company announced the identification of eight viable oral formulations to be evaluated in determining the best formulation to use in future two species toxicity studies and in Phase 1 human clinical trials. As discussed below, progress on this evaluation continued during Q1-F'13 and is expected to be completed in Q2-F'13. The two species toxicity studies will then commence in Q2-F'13 based upon the selection of the optimal oral formulation from the candidates identified. Expenditures on these major activities and related experiments are important investments in the development of the asset and should add value for prospective licensees and the Company during Q2 and Q3 of fiscal 2013.

R&D expenditures have historically been conducted with contract research organizations in the most cost effective manner considering the opportunity for refundable ITCs in identifying least cost, best value suppliers, and this is anticipated to continue as the Company works to finalize its plans for the two species toxicity studies and its IND submission documentation.

The Company's strategy to complement the development of COTI-2, and its ultimate licensing, by advancing other drug discovery projects along parallel tracks, continued during the quarter and is expected to continue for the balance of fiscal 2013 within the context of the Company's ability to finance such development. *In vitro* testing commenced in January 2012 and was completed during the first quarter of fiscal 2013 for the Company's AML program. Spending on the project is partially offset through funding of eligible expenditures under an NRC-IRAP grant. The funding commitment available for fiscal 2013 is \$100,000.

Expenditures on G&A and S&M activities for fiscal 2013 are expected to remain consistent with those budgeted for the year with actual results for the first quarter being lower than budget by approximately \$64,000.

### Product Development Progress – Q1-F'13 and Future Outlook

The Company continued to make progress in developing its drug candidate pipeline during Q1-F'13 with primary focus on COTI-2, the Company's lead oncology compound, and to a lesser extent its AML program. Because of limited financial resources, the Company has a number of drug compounds and programs whose further development remains on hold. The Company is



exploring a variety of ways to realize value on these compounds or further their development through co-development projects.

#### COTI-2

During the quarter, the Company continued development of COTI-2 by carrying out additional experiments and laboratory work in preparation for an IND clinical trial submission. A summary of key milestones in this development is set out below.

- Development of an oral formulation candidate for COTI-2 progressed during the quarter and subsequent to the quarter end on September 11, 2012, the Company announced that it had identified the oral formulation to be used in completing the two species toxicity testing for the COTI-2 clinical submission package and in the Phase 1 human clinical trial. The candidate was selected based upon a number of criteria including ease of manufacturing, efficacy, and its pharmacodynamic and pharmacokinetic profile, including bioavailability.
- Both Health Canada and the United States Food and Drug Administration require a validated detection method for measuring a drug's concentration in human plasma as part of the IND submission package. In Q4-F'12, the Company announced it had engaged Algorithme Pharma Inc. of Montreal, Canada, an internationally recognized contract research organization, to develop and validate the final method to be used for preclinical and Phase 1 studies for COTI-2. This work continued during Q1-F'13 and the completion of this work was announced subsequent to the quarter end on September 11, 2012.

### Acute Myelogenous Leukemia (AML)

Like many cancers, AML is the result of multiple gene mutations that affect multiple cell signaling kinase pathways. With few exceptions, traditional therapies that target a single abnormal kinase have produced disappointing long-term results. COTI's program targets multiple kinases commonly mutated in AML and accordingly its compounds are believed to have a higher probability of success in improving outcomes for patients through the potential to treat acute leukemias with different gene mutation profiles.

On January 24, 2012, the Company announced it had completed synthesis of compounds from COTI's AML program and had initiated confirmatory preclinical tests. These efficacy and activity experiments were completed during Q1-F'13 and analysis of the test data will enable the Company to identify the most promising compounds to take forward for further testing. This evaluation will be completed in Q2-F'13.

# Critical Outcome

# MD&A for the fiscal 2013 first quarter ended July 31, 2012

### <u>Collaborations and Co-Development Projects</u>

### Western University

The Company continued to pursue R&D collaborations as part of its strategy to achieve commercial validation of the Company's CHEMSAS® platform. These efforts led to the signing of a collaboration agreement on July 16, 2012 with Western University (Western) (formerly the University of Western Ontario) to discover and advance potential therapies designed to minimize Central Nervous System (CNS) scarring following trauma or stroke.

Under this engagement, COTI will utilize its proprietary technology CHEMSAS® to discover and optimize novel drug candidates against a specific cellular target of importance to Western researcher Dr. Arthur Brown that can effectively target a number of CNS scarring indications where current treatments are lacking or ineffective. This is an area of clear unmet medical need with at least 1.7 million incidents annually of traumatic brain injury in the United States alone with no effective therapies available to minimize the scarring that results from the injury.

Under the agreement, COTI receives an upfront payment of \$25,000 to identify the lead candidates and Dr. Brown and Western will then evaluate the identified compounds to test the suitability of the molecules as leads for the cellular target. With any of the candidates that meet pre-determined development criteria, COTI and Western will work jointly to move the candidates towards clinical confirmation of activity and a commercial licensing transaction.

This agreement was announced subsequent to the quarter end on September 6, 2012.

### **Industry and Economic Risk Factors Affecting Performance**

The biotechnology industry is regarded as high risk given the uncertain nature of developing drug candidates and limited access to capital. On the other hand, success in this industry can be highly rewarding. COTI operates in the discovery and preclinical stage of the drug development cycle. The realization of COTI's long-term potential is dependent upon the successful development and commercialization of molecules discovered using the Company's drug discovery technology either for its own account or in collaboration agreements for others, and in utilizing the technology to provide profiling and screening services on a fee for service basis. The major industry and economic risk factors affecting realization of this potential in Q1-F'13 remain substantially unchanged from the analysis discussed at length in the Company's 2012 AIF filed in July 2012 and the risks discussed in the FYE 2012 MD&A.

The four risk categories having the greatest affect on the Company during the quarter were:

- 1. the uncertainties related to research;
- 2. the lack of product revenues;



- 3. securing licensing agreements; and,
- 4. access to capital.

### Uncertainties Related to Research

Like other biotech and pharmaceutical companies, COTI's research programs are based on scientific hypotheses and experimental approaches that may not lead to desired results. In addition, the timeframe for obtaining test results may be considerably longer than originally anticipated, or may not be possible given time, resources, and financial, strategic, and scientific constraints. Success in one stage of testing is not necessarily an indication that a particular compound or program will succeed in later stages of testing and development. It is not possible to guarantee, based upon studies in *in vitro* models and in animals, whether any of the compounds made for a therapeutic program will prove to be safe, effective, and suitable for human use. Each compound will require additional research and development, scale-up, formulation and extensive clinical testing in humans. COTI believes its CHEMSAS® process serves to mitigate or reduce this risk by virtue of its profiling across many variables in identifying compounds with high probability of successfully becoming drugs, however, it remains a probability only and failure can occur. COTI's lead compound, COTI-2, continued to progress through preclinical testing and to perform as predicted during Q1-F'13.

### **Lack of Product Revenues**

The revenue cycle for drug development is a long one; typically 5 to 10 years depending upon the point along development that monetization of the asset occurs. Since inception as a public company in October 2006, COTI has worked to develop relationships with prospective customers, and strived to obtain licensing and collaboration agreements for its own products and therapeutic targets of interest to partners. The continued development of COTI-2 and the nurturing of relationships with licensees concerning the strong scientific test results are critical to achieving a revenue realization stage. Accordingly, operating losses are expected to be incurred until upfront licensing, milestone and royalty payments are sufficient to generate revenues to fund continuing operations. COTI is unable to predict with any certainty when it will become profitable, or the extent of any future losses or profits.

### Securing Adequate Licensing Agreements

The Company's ability to commercialize its products successfully will depend first, on meeting the scientific due diligence requirements of prospective customers and second, on its ability to negotiate satisfactory licensing terms with pharmaceutical or biotechnology organizations for preclinical compounds. While positive test results during fiscal 2013 continued to generate positive feedback from potential licensees, these test outcomes have not translated into a contractual agreement to date. Licensing discussions during Q1-F'13 continued to find interest for early stage deals of novel compounds or classes of compounds. This reflects the macro



events occurring within the pharmaceutical industry such as; the large number of blockbuster drugs that continue to come off patent protection; the need to find drugs to replace the revenues lost to generic competition and lower margins on the unprotected brand; and the continued productivity challenges of the pharmaceutical industry in generating new compounds from their R&D spending.

### Access to Capital

The Company continually monitors its cash resources to support its R&D programs in an effort to move its compounds, particularly COTI-2, as rapidly as possible through development. If additional funding cannot be obtained, COTI may be required to delay, reduce, or eliminate one or more of its R&D programs or obtain funds through corporate partners or others who may require it to relinquish significant rights to its product candidates or obtain funds on less favourable terms than COTI would otherwise accept. COTI's success in obtaining future capital requirements will depend on many factors, such as establishing and maintaining investment industry relationships, collaborative partnering relationships, achieving a licensing agreement for COTI-2, and the general economic conditions and access to capital in the equity markets for biotechnology companies. Despite the Company's financing efforts, there can be no assurance additional funding can be obtained.

### **Use of Non-GAAP Financial Measures**

Management has included a non-GAAP financial measure, Capital Resources, to supplement information contained in the MD&A. This non-GAAP measure does not have any standardized meaning prescribed under IFRS and therefore it may not be comparable to similar measures when presented by other issuers. Capital Resources is defined and calculated by the Company as cash, cash equivalents and short-term investments. This differs from IFRS disclosure where cash and cash equivalents are included in the Statement of Financial Position as cash and the Statement of Cash Flows is reconciled to this cash balance. Short-term investments are disclosed separately in the Statement of Financial Position and changes in short-term investments are disclosed separately in the Statement of Cash Flows in determining cash. The short-term investment is a guaranteed investment certificate encashable at any time up to its maturity date and with such high liquidity characteristics is a readily available source of capital. Consequently, the Company uses Capital Resources, which includes short-term investments in this measure as its view on readily available cash with respect to the liquidity of the Company.

Table 10: Reconciliation to Capital Resources

	Q1-F'13	Q1-F'12
Cash and cash equivalents	\$ 508,404	\$ 1,256,961
Short-term investments	520,225	301,236
Capital resources	\$ 1,028,629	\$ 1,558,197



### **Changes in Accounting Policies including Initial Adoption**

There was only one change in the International Financial Reporting Standards that had potential impact on the Company's financial reporting for the quarter.

### (a) IFRS 7 - Financial Instruments: Disclosures

In October 2010, the IASB amended IFRS 7 - Financial Instruments: Disclosures. This amendment enhanced disclosure requirements to aid financial statement users in evaluating the nature of, and risks associated with, an entity's continuing involvement in derecognized financial assets. The amendment was effective for the Company's interim and annual financial statements commencing May 1, 2012. The Company assessed the impact of this amended standard and determined there to be no impact on its financial statements.

### **Future Accounting Policy Changes**

Certain pronouncements have been issued by the International Accounting Standards Board (IASB) or the International Financial Reporting Interpretation Committee that are mandatory for annual periods beginning subsequent to the current reporting period. Many of these updates are not applicable to COTI or are inconsequential to the Company. The following accounting pronouncements are applicable beginning on or after January 1, 2013 and accordingly would affect COTI for its fiscal year beginning May 1, 2013:

- IAS 1 Presentation of Financial Statements
- IFRS 9 Financial Instruments Classification and Measurement
- IFRS 12 Disclosure of Interests in Other Entities
- IFRS 13 Fair Value Measurement

A brief description of each accounting pronouncement may be found at pages 26 and 27 of the Company's fiscal 2012 MD&A and note 5(p) of the Company's audited financial statements for the year ended April 30, 2012. The Company is assessing the impact of these accounting pronouncements on its financial statements and does not expect adoption to have a material impact on its financial statements.

In addition to these pronouncements, the IASB published Annual Improvements to IFRSs – 2009-2011 Cycle in May 2012 as part of its annual improvements process to make non-urgent but necessary amendments to IFRS. These amendments are effective for annual periods beginning on or after January 1, 2013, with retrospective application permitted. The new cycle of improvements contains amendments to the following standards and interpretations:

- IAS 1 Presentation of Financial Statements
  - o Comparative information beyond minimum requirements



- o Presentation of the opening statement of financial position
- IAS 16 Property, Plant and Equipment
  - o Classification of servicing equipment
- IAS 32 Financial Instruments: Presentation
  - o Income tax consequences of distributions
- IAS 34 Interim Financial Reporting
  - o Segment assets and liabilities

The Company intends to adopt the amendments to the standards in its financial statements for the annual period beginning on May 1, 2013. The extent of the impact of adoption of the amendments has not yet been determined.