

Management Discussion and Analysis of Financial Condition and Results of Operations

Fiscal 2012 – Second Quarter for the three and six month periods ended October 31, 2011

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#### Overview

The following management discussion and analysis (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 October 31, 2011, and has been prepared with all information available up to and including <u>December 14, 2011</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) 1, First-time Adoption of IFRS. By their nature, the interim financial statements do not conform in all respects with disclosures for annual financial statements and should be read in conjunction with the Company's audited financial statements for the year ended April 30, 2011, prepared in accordance with Canadian Generally Accepted Accounting Principles (CGAAP). The Company adopted IFRS effective May 1, 2011. While the Company's annual financial statements for the year ended April 30, 2011 have been audited in accordance with CGAAP, they were not audited in accordance with IFRS. Further discussion related to the impact of the transition to IFRS is noted as appropriate throughout this MD&A.

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 <a href="https://www.sedar.com">www.sedar.com</a>.

#### **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 for future research and development projects and additional financing raises</li> </ul>
Financial and Operational Progress and Outlook	<ul> <li>Scientific experiments planned to optimize the licensing value of COTI-2</li> <li>Synthesis and <i>in vitro</i> testing planned for the AML program</li> <li>Seeking partners to develop and market the HIV-1 integrase program for co-development</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 particularly those related to Financial Instruments

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 develop the CHEMSAS® technology 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 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 compound, COTI-2
- The ability to meet future regulatory requirements to commercialize compounds, in particular COTI-2, the Company's lead oncology compound
- 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.

# Critical Outcome

# MD&A for the fiscal 2012 second quarter ended October 31, 2011

#### **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 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.

Although the Company intends to license its targeted molecules following synthesis and completion of confirmatory preclinical tests, the Company may also choose to take particularly promising individual molecules forward through various preclinical tests to Phase 1 clinical trials. In this regard, COTI is currently focused on preparing for an investigational new drug (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 2012. Once an IND filing is accepted, COTI-2 would be available for licensing or co-development 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 preferred 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.

#### **Financial Review of Operations**

#### Revenues

#### Operating:

There were no operating revenues in the quarter ended October 31, 2011 (Q2-F'12) or in the quarter ended October 31, 2010 (Q2-F'11) or for the six months ended October 31, 2011 (YTD-F'12) or for the six months ended October 31, 2010 (YTD-F'11). The Company continued to pursue a licensing agreement for its preclinical lead oncology compound, COTI-2, during Q2-F'12 with several interested parties but without reaching mutual agreement on contractual terms.



#### Non-operating:

Investment tax credit (ITC) income of \$19,887 was recognized in the quarter, relating to scientific research and development tax credits earned in the second quarter of 2012 for eligible expenditures. In Q2-F'11, ITC income totaling \$122,244 was recognized. This apparent decrease year over year reflects that the Company changed the timing recognition of ITC income in Q2-F'11. Prior to this time, recognition occurred when ITCs were collected but having established a seven-year history of successful filings, collection was deemed reasonably certain on a prospective basis. This resulted in Q2-F'11 recognition of ITCs earned for expenditures related to all of fiscal 2010 and the first two quarters of fiscal 2011.

The Company earned \$3,142 in interest income on its cash, cash equivalents and short-term investments in Q2-F'12 compared to \$1,851 in Q2-F'11. This increase of \$1,291 primarily reflects the higher average balances held by the Company during Q2-F'12 compared to Q2-F'11 (Q2-F'12 - \$1,259,894; Q2-F'11 - \$1,131,830).

#### **Operating Expenses**

Operating expenses increased from \$335,758 in Q2-F'11 to \$657,773 for Q2-F'12, an increase of \$322,015. Operating expenses increased from \$898,210 for YTD-F'11 to \$1,306,868 for YTD-F'12, an increase of \$408,750. Two major expense items accounted for the comparable quarterly change as stock-based compensation expense increased \$157,595 to \$66,717 from a net recovery amount of \$(90,878) in Q2-F'11 and the recognition of investment tax credits decreased from \$122,244 in Q2-F'11 to \$19,887 in Q2-F'12.

The higher stock-based compensation expense for YTD-F'12 resulted primarily from YTD-F'11 benefitting from a recovery of \$110,509 in previously recognized stock-based compensation expense. Table 2 provides a breakdown of the components of stock-based compensation expense for Q2-F'12 and Q2-F'11 and YTD-F'12 and YTD-F'11 respectively.

Table 2: Stock-Based Compensation Expense – Comparative Periods Ended October 31

	•	Q2-F'12	Q2-F'11	Change
Recognized on new option grants	\$	44,075	\$ 2,481	\$ 41,594
Recognized on existing options		22,642	1,722	20,921
Re-measurement of consultant options		-	(55,405)	55,405
Reversal of unvested cancelled options		-	(39,675)	39,675
	\$	66,717	\$ (90,878)	\$ 157,595
		YTD-F'12	YTD-F'11	Change
Recognized on new option grants	\$	85,257	\$ 2,481	\$ 82,776
Recognized on existing options		22,642	51,722	(29,080)
Re-measurement of consultant options		-	(91,728)	91,728
Reversal of unvested cancelled options		-	(110,509)	110,509
	\$	107,899	\$ (148,034)	\$ 255,933



The quarterly Research and product development (R&D) expenditures were relatively consistent year over year. Table 3 provides a breakdown of R&D costs by major expense types for the comparable three and six month fiscal periods ended October 31 respectively.

Table 3: R&D Expenses – Comparative Periods Ended October 31

	Q2-F'12	Q2-F'11	Change
R&D testing, consulting and materials	\$ 29,524 \$	42,586 \$	(13,062)
Synthesis	3,004	1,265	1,739
	32,529	43,851	(11,322)
Labour including benefits	80,725	88,113	(7,388)
Other	6,754	5,256	1,498
	120,008	137,220	(17,212)
Stock-based compensation	6,126	-	6,126
Total	\$ 126,134 \$	137,220 \$	(11,086)

	YTD-F'12	YTD-F'11	Change
R&D testing, consulting and materials	\$ 63,719 \$	73,201 \$	(9,482)
Synthesis	89,752	59,145	30,607
	153,471	132,346	21,125
Labour including benefits	159,667	192,166	(32,499)
Other	12,811	9,082	3,729
	325,949	333,594	(7,645)
Stock-based compensation	6,126	-	6,126
Total	\$ 332,075 \$	333,594 \$	(1,519)

R&D testing, consulting and materials decreased \$13,062 for Q2-F'12 compared to Q2-F'11 due to reductions in the extent of *in vitro* and *in vivo* testing for COTI-2. For Q2-F'12, synthesis costs increased a modest \$1,739 compared to Q2-F'11, however, this was due to an over accrual in the prior quarter related to the estimated percentage of completion related to the oral formulation of COTI-2. On a year to date basis, synthesis costs increased \$47,768 offset by \$17,161 in government assistance for a net increase of \$30,607. These costs were on COTI-2's oral formulation and synthesis of the Company's AML compounds.

R&D labour costs decreased year over year primarily related to the allocation of a portion of the Chief Scientific Officer's (CSO) salary costs to General and administrative (G&A) salary expense. The allocation was based on time commitments in his various roles as President, Chief Executive Officer (CEO) and CSO. The Company also recovered \$2,851 in salary costs in Q2-F'12 from government assistance received for its acute myelogenous leukemia (AML) project with the National Research Council of Canada Industrial Research Assistance Program (NRC-IRAP). There were no changes in R&D staff levels during the comparable periods.

Table 4 provides a breakdown of (G&A) costs by major expense types for the comparable three and six month fiscal periods ended October 31 respectively. The increase in G&A for the quarter of \$222,042 related primarily to stock-based compensation of \$150,620 (as discussed above)



and increased professional fees of \$70,883. This variance was consistent for the YTD-F'12 and YTD-F'11 comparables.

The professional fee increase year to date consisted primarily of \$43,900 for IFRS transitional support services with the balance of the increase resulting from a number of consulting engagements to assist with a variety of services including licensing, investor relations, financing and strategic planning.

Table 4: G&A Expenses – Comparative Periods Ended October 31

	Q2-F'12	Q2-F'11	Change
Salaries and benefits	\$ 98,185 \$	89,506 \$	8,679
Amortization	118,849	123,209	(4,360)
Corporate governance	31,158	44,099	(12,941)
Promotion and travel	7,428	3,581	3,847
Professional fees	132,938	62,055	70,883
Rent	9,346	9,568	(222)
Insurance	14,866	14,909	(43)
Other	11,563	5,984	5,579
	424,333	352,911	71,422
Stock-based compensation	58,020	(92,600)	150,620
Total	\$ 482,353 \$	260,311 \$	222,042

	YTD-F'12	YTD-F'11	Change
Salaries and benefits	\$ 209,940 \$	197,416 \$	12,524
Amortization	238,123	246,690	(8,567)
Corporate governance	48,242	61,383	(13,141)
Promotion and travel	16,917	9,604	7,313
Professional fees	219,736	134,672	85,064
Rent	18,692	19,247	(555)
Insurance	29,833	29,817	16
Other	16,993	13,068	3,925
	798,476	711,897	86,579
Stock-based compensation	99,202	(148,035)	247,237
Total	\$ 897,678 \$	563,862 \$	333,816

There were no significant changes in Sales and marketing expense (S&M) on a quarterly or year over year basis. Table 5 provides a breakdown of S&M costs by major expense types for the comparable three and six month fiscal periods ended October 31 respectively.



Table 5: S&M Expenses – Comparative Periods Ended October 31

	Q2-F'12	Q2-F'11	Change
Salaries and benefits	\$ 46,391 \$	46,056 \$	335
Marketing and travel	19,639	9,672	9,967
Other	573	3,021	(2,448)
	66,602	58,749	7,853
Stock-based compensation	2,571	1,722	849
Total	\$ 69,173 \$	60,471 \$	8,702

	YTD-F'12	YTD-F'11	Change
Salaries and benefits	\$ 91,059 \$	82,364 \$	8,695
Marketing and travel	30,814	29,348	1,466
Other	2,447	6,056	(3,609)
	124,320	117,768	6,552
Stock-based compensation	2,571	5,230	(2,659)
Total	\$ 126,891 \$	122,998 \$	3,893

# **Financial Results Summary by Quarter**

Table 6 summarizes the financial results of COTI by quarter for the past two fiscal years and the most recent two quarters. The two quarters of FYE 2012 and the four quarters of FYE 2011 are restated in compliance with IFRS. The four quarters presented for FYE 2010 were prepared under the Canadian Generally Accepted Accounting Principles framework required at that time and have not been adjusted to conform to IFRS.

Table 6: Summary of Quarterly Financial Results

FYE 2012		Q1	С	(2		Q3		Q4	F	ull Year
	3	31-Jul	31-	31-Oct		31-Jan	30-Apr			
Revenue	\$	- \$	;	-					\$	-
Loss	(	642,256)	(	648,530)					(	1,290,786)
Loss per common share	\$	(0.01) \$	5	(0.01)					\$	(0.02)
FYE 2011		Q1		12		Q3		Q4	F	ull Year
	3	31-Jul		Oct		31-Jan		30-Apr		un rear
Revenue	\$	- \$	5	_	\$	-	\$	-	\$	-
Loss	(	558,950)	(	334,498)		(634,345)		(473,585)	(	2,001,378)
Loss per common share	\$	(0.01) \$	5	(0.01)	\$	(0.01)	\$	(0.01)	\$	(0.04)
FYE 2010		Q1	С	(2		Q3		Q4	F	ull Year
	3	31-Jul	31-	Oct		31-Jan		30-Apr		
Revenue	\$	- \$	5	-	\$	-	\$	-	\$	-
Loss	(	979,089)	(	976,678)		(773,217)		(831,326)	(	3,560,310)
Loss per common share	\$	(0.02) \$	;	(0.02)	\$	(0.02)	\$	(0.02)	\$	(0.08)



The majority of the variation by quarter across the years, and year over year, is explained by four expense categories as set out in Table 7.

Table 7: Selected Quarterly Expense Categories (1)

FYE 2012	Q1		Q2	Q3	Q4	
		31-Jul	31-Oct	31-Jan	30-Apr	Full Year
General and administration	\$	374,143	\$ 424,333			\$ 798,476
Research and product development		205,941	120,008			325,949
Investment tax credit recovery		(29,889)	(19,887)			(49,776)
Stock-based compensation		41,182	66,717			107,899
Total of expense categories		591,377	591,171			1,182,548
Total expense for the quarter	\$	649,095	\$ 657,773			\$ 1,306,868
Expense categories as a % of total expense		91.1%	89.9%	0.0%	0.0%	90.5%

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 presentation in the Company's financial statements. Stock-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 variability in the second quarter trend is largely due to the impact of the recovery of \$110,509 in previously recognized stock-based compensation costs on the cancellation of options upon the resignation of the former CEO in June 2010 and the investment tax credits recognized in Q2-F'11.

The remaining variability by quarter over the years is largely explained by the following: variable spending on third party R&D testing and synthesis; changes in salary and benefits based upon annual increases; changes in stock-based compensation related to both changes in the assumptions used and the number of stock options granted; and, the use of consultants. The balance of the remaining expense categories remained relatively consistent.

# **Liquidity and Capital Resources**

At the end of Q2-F'12, the Company had cash, cash equivalents and short-term investments of \$1,094,143 compared to \$2,094,917 cash, cash equivalents and short-term investments at the end of FYE 2011 reflecting a decrease of \$1,000,774 as summarized in Table 8.



Table 8: Summary of Changes in Capital Resources (1)

	Q2-F'12	Q2-F'11
Increase (decrease) from:		
Operating activities	\$ (988,830)	\$ (918,881)
Investing activities excluding changes in short-term investments	(23,945)	(28,896)
(Decrease) in capital resources before issuance of common shares		
and warrants	(1,012,776)	(947,777)
Proceeds from issuance of common shares and warrants	11,763	32,848
Interest paid	(1,593)	(1,096)
(Decrease) increase in capital resources	(1,002,606)	(916,025)
Less: unrealized foreign exchange loss on capital resources	(55)	370
Capital resources - beginning of period	1,794,621	1,945,376
Capital resources - end of period	\$ 791,960	\$ 1,029,721

<sup>(1)</sup> Capital resources = cash, cash equivalents and short-term investments

Investing activities in Q2-F'12 related primarily 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.

In Q2-F'12, there were no options or warrants exercised.

The Company's working capital at Q2-F'12 was \$996,542 compared to \$1,953,489 at FYE 2011. 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 30, 2011. Current assets decreased to \$1,351,442 at Q2-F'12 from \$2,297,132 at FYE 2011 for a decrease of \$945,690, primarily due to the decrease in cash and cash equivalents. Current liabilities increased \$11,257 to \$354,900 at Q2-F'12 from \$343,643 at FYE 2011 because of increased project accruals and reduced trade payables related to professional fees.

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 9.



Table 9: Contractual Obligations

Obligation	Total	2012	2013
Premises rent <sup>(1)</sup>	\$ 9,345	\$ 9,345	\$ -
Research and development contracts	102,764	102,764	-
Consulting services	9,300	9,300	_
Total contractual obligations	\$ 121,409	\$ 121,409	\$ -

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

#### **Amended Warrants**

During the quarter, the Company recognized that 1,575,500 warrants issued pursuant to a private placement of 3,151,101 shares in fiscal 2010 were due to expire unexercised on October 27, 2011 and November 27, 2011. The exercise price of the warrants was \$0.55 and the Company's shares were trading in a range well below this price. The Company noted that maintaining these warrants as a source of financing was a cheaper alternative than seeking a further raise for such funds given that the initial costs of putting the warrants in place had already occurred with the private placement in 2010. Accordingly, the Company amended the warrants following consent from the TSXV. The amendments were as follows:

- a) the exercise price was reduced to \$0.37 per share for all warrants except 129,020 warrants held by insiders (Insider Warrants) of the Company, which were not eligible for price amendment. The exercise price of these Insider Warrants remains at \$0.55; and,
- b) the expiry date was extended to January 31, 2013 (the New Expiry Date), provided that the New Expiry Date of the warrants will be reduced to a period of 14 days if, for any ten consecutive trading days during the unexpired term of the warrant (the Premium Trading Days), the closing price of the common shares on the TSX equals or exceeds \$0.55. The reduced exercise period of 14 days will begin seven calendar days after the tenth Premium Trading Day.

All other provisions of the warrants remain unchanged.

The compensation warrants, with an exercise price of \$0.40 and expiring on October 27, 2011 and November 27, 2011, were not amended, as they were not eligible for amendment under the rules of the TSXV. These 106,250 compensation warrants expired unexercised on their respective expiry dates.

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

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



#### Foreign Exchange Exposure

During Q2-F'12, the Company recorded a foreign exchange gain of \$7,543 compared to a loss of \$591 in Q2-F'11. The gain recorded in Q2-F'12 reflects \$55 in unrealized losses resulting from holding foreign currency balances at the quarter end compared to \$370 in unrealized gains at Q2-F'11. The foreign currency exposure in Q2-F'12 was immaterial and unchanged from FYE 2011.

# **Related Party Transactions**

The related party transactions of a material nature that occurred during Q2-F'12 are described below.

# **Grant of Stock Options**

Consistent with the Company's practice of conserving cash, the Company granted on September 27, 2011, 756,098 stock options with an exercise price of \$0.30 to the members of its Board of Directors as a retainer for their services in the next year. The options have a five-year maturity from the date of grant with 189,027 vesting December 27, 2011, 189,026 vesting March 27, 2012, 189,023 vesting June 27, 2012 and 189,022 vesting September 27, 2012.

The Company also granted 71,449 stock options with an exercise price of \$0.25 to its nine employees as part of their compensation package on October 18, 2011. The options have a five-year maturity from the date of grant and vested immediately.

#### **Warrant Amendment**

As noted under Liquidity, the Company amended warrants expiring on October 27, 2011 and November 27, 2011. Insiders of the Company consisting of directors and officers held 286,570 warrants representing 18.2% of the outstanding expiring warrants. Under the rules of the TSXV, insiders were limited to amendment of pricing to a maximum of 10% of the outstanding warrants. Accordingly, 157,550 warrants were eligible for amendment at the new price of \$0.37 with the balance of 129,019 warrants remaining at the pre-amendment exercise price of \$0.55.

#### **Contingent Transaction**

Upon the purchase of DDP Therapeutics in November 2007, the Company became contingently liable for the issuance of 1,431,441 common shares as part of the purchase consideration should certain development milestones be subsequently achieved by any molecule from the small cell lung cancer (SCLC) library acquired under the purchase. One-half of this contingent share consideration is payable upon the first occasion any molecule achieves one of the following milestones:

a) when the Company is given notification of acceptance of an investigational new drug filing (IND) and an IND acceptance number is received; or,



b) when either the United States (US) or the European patent authorities issue the Company a final patent.

The second half of this contingent share consideration is payable upon any molecule achieving both milestones.

If by November 27, 2015, the eighth anniversary date of the transaction, these milestones are not achieved and the contingent consideration is not paid, and if the Company has not abandoned its efforts to develop and commercialize the molecules by this anniversary date, the Company is required to:

- a) issue the contingent consideration of 1,431,441 common shares at fair value, or
- b) pay cash consideration equal to the amount by which the fair value of the molecules purchased in the transaction exceed the amount invested in the molecules by the Company. If the fair value of the molecules purchased in the transaction is less than the amount invested in the molecules by the Company, no consideration is payable.

The Company's lead oncology compound COTI-2 is a molecule from the SCLC library acquired under the purchase. On October 11, 2011, the Company received a patent from the United States Patent and Trademark Office (USPTO) for its US patent filing related to COTI-2. Upon receipt of the patent, the Company issued 715,720 common shares to the former shareholders of DDP (which includes the Company's current Chairman and the current President and CEO) representing one-half of the contingent consideration for meeting the milestone requiring the issuance of a final patent in either the United States or Europe. The fair market value of this consideration was determined as \$164,616 based upon the fair value of the common shares at the close of business on October 11, 2011, the date when the patent was granted.

The Company has determined that the achievement of the second milestone for COTI-2 does not meet IFRS guidance providing that where the event is "more likely than not" to occur such event should be recognized. Major factors considered in the likelihood determination included: the uncertainty inherent in the remaining testing for COTI-2 prior to filing an IND application; the cost, time and expertise required in the IND application and approval process itself; and the Company's current financial capacity to develop COTI-2 successfully through to achieving this milestone.

The inability to meet the more likely than not criteria would apply to any of the other molecules based upon the significant cost and timeline in advancing them through both milestones.

# **Director's Management Consulting Contract**

Effective June 1, 2011, the Company entered into an executive management consulting services agreement with one of its directors (Consultant). The agreement has a six-month term with two, three-month renewal periods that automatically renew unless either party gives 30 days notice of intent not to renew. The Company shall pay a contract termination fee of \$9,300 if the first renewal term is unexercised. The Company did not give notice on December 1, 2011, the



first renewal date and accordingly the contract automatically renewed and the termination fee expired.

The Consultant is paid a daily rate for invoiced time as services are provided. During the quarter, the Company paid or accrued \$48,750 (YTD - \$84,375).

Under the agreement, the Consultant also received 200,000 stock options exercisable at a price of \$0.35 with a five-year life and future vesting. On September 1, 2011, the first 50,000 of these options vested.

#### **Outstanding Share Information**

Outstanding share information as at the close of business December 14, 2011 is set out in Table 10.

Table 10: Outstanding Share Information

	Outstanding	
Common shares		
Authorized - unlimited		
Issued	63,203,214	
Fully diluted (1)	82,608,185	
Weighted average outstanding (2)	62,824,303	
Common share warrants		
\$0.40 compensation warrants	643	Nov 27/11
\$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
\$0.55 warrants	72,590	Oct 27/11
\$0.55 warrants	56,430	Nov 27/11
\$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	1,446,480	Jan 31/13
	14,583,643	
Common share stock options		
\$0.01 - \$0.50	2,905,144	Sep 9/14 - Oct 17/16
\$0.51 - \$1.00	1,566,184	Jan 11/12 - Mar 14/15
\$1.01 - \$1.50	250,000	Mar 25/12 - Jul 15/13
\$1.51 - \$2.00	100,000	Oct 8/12
	4,821,328	·

<sup>(1)</sup> Assumes conversion of all outstanding common share stock options and warrants.

# Financial and Operational Progress & Outlook

# Financial Outlook to FYE 2012

The Company continues to meet with prospective partners and anticipates that it will be in a good position to negotiate a licensing deal for COTI-2 in calendar 2012. As announced on April

<sup>(2)</sup> Weighted average shares outstanding calculated from May 1, 2011 to December 14, 2011.



12, 2011, the Company responded to scientific and business feedback from prospective licensing partners by initiating a series of three experiments to address risk reduction points common to these prospects. These experiments will strengthen the scientific data package of COTI-2 making it more valuable to a potential partner through the reduction in the risk profile of the compound. Information from these scientific experiments is being shared with prospective licensees as it becomes available. At October 31, 2011, the first of the three experiments was completed as discussed in more detail below. The second set of experiments related to finding an optimal oral formulation continued to progress with a completion target early in calendar 2012. The last of the three experiments related to two species toxicity studies will commence early in calendar 2012 based upon finalizing the oral formulation. The Company is focused on getting COTI-2 to a licensing agreement 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.

R&D expenditures have 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 planned as the Company works to finalize its plans for the two species toxicity studies.

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 2012 within the context of the Company's ability to finance such development. In this regard, the AML project is progressing through synthesis, with *in vitro* testing planned for the fourth quarter of FYE 2012. Spending on the project is being partially offset through the recovery of approximately \$100,000 from an NRC-IRAP funding commitment available for FYE 2012. To the end of Q1-F'12, the Company had recovered \$23,705, which recovery will increase substantially in the third quarter, as synthesis is completed and *in vitro* testing is initiated on the compounds.

Expenditures on G&A and S&M activities for FYE 2012 are expected to remain consistent with those budgeted for the year with results for the first six months being higher than budget by \$45,500.

Expenditures on intangible assets and capital assets are trending to budget and are anticipated to remain consistent with the budget amount of approximately \$150,000 and consistent with the prior year. This spending is primarily on the Company's patent portfolio.

As noted above, the Company has goals for fiscal 2012 and subsequent years to advance the testing for COTI-2 in enhancing its attractiveness 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 will continue its efforts in obtaining financing over the next year to accomplish its goals.



#### Product Development Progress – Q2-F'12 and Future Outlook

The Company continued to make progress in developing its drug candidate pipeline during Q2-F'12 with primary focus on COTI-2, the Company's lead oncology compound, and the AML project. Because of limited financial resources, the Company has a number of drug compounds and programs whose further development remains on hold, the primary one of these being the HIV project. 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 including the following:

- On August 16, 2011, the Company followed up its June 26 announcement on pharmacodynamic (PD) testing with results demonstrating clear evidence of COTI-2's ability to significantly inhibit the growth of cancer cells that over express AKT/AKT2 confirming it as a promising targeted therapy candidate. A clear relationship was established between the dose of COTI-2 and reduced levels of AKT/AKT2 protein, activated AKT/AKT2 in tumour tissues and observed tumour growth inhibition.
- On October 13, 2011, the Company announced the receipt of a composition of matter patent for COTI-2 from the US Patent and Trademark Office. This patent strengthens the commercial value of COTI-2 and provides patent protection until 2030.
- On October 20, 2011, the Company announced the final PD and pharmacokinetics test
  results that demonstrate COTI-2 is an orally effective and selective allosteric
  modulator/inhibitor of AKT/AKT2 with low toxicity. Moreover, COTI-2 demonstrates a
  good pharmacokinetic profile, indicating that a once-daily oral administration of COTI-2
  may be optimal; an ideal attribute for a chronic cancer therapy.

This new data in addition to previously generated results has COTI-2 well positioned for further development, including into a Phase 1 clinical trial.

Subsequent to the quarter end, the Company announced the delivery of a podium presentation on November 2, 2011 at Discovery on Target: Emerging Targets for the Kinase Inhibitor Pipeline held in Boston, MA. The presentation was entitled "COTI-2: A highly effective and selective modulator of AKT/AKT2 protein levels and phospho-activation for the treatment of susceptible human cancers".

The presentation highlighted the scientific results from recent pharmacodynamic and pharmacokinetic experiments demonstrating COTI-2's ability to significantly inhibit the growth of cancer cells that over express AKT/AKT2, confirming it as a targeted therapy candidate. The presentation provided the Company an opportunity to share its insights into the potential for



COTI-2 with a targeted scientific audience of key influencers from many potential partnering organizations.

Acute Myelogenous Leukemia (AML)

The synthesis initiated at the end of the first quarter as announced on July 28, 2011 progressed during the second quarter and the Company anticipates completion during the third quarter and initiation of *in vitro* testing on the compounds.

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

HIV-1 Integrase Co-development

On May 5, 2011, the Company announced that it was seeking a new pharmaceutical partner to continue the development of its novel scaffolds for inhibiting HIV-1 integrase as part of a program with the potential to lead to a new drug therapy to help fight HIV. The agreement with its former partner concluded in early May as the partner advised they were suspending all new HIV-related work that was not already in an advanced stage in the clinic. A number of interested parties have been identified and possible co-development discussions are ongoing.

As previously announced, the Company made a submission to a new initiative of the NRC-IRAP called the Canadian HIV Technology Development Program, as part of a wider Canadian HIV Vaccine Initiative under collaboration between the Government of Canada and the Bill and Melinda Gates Foundation. The funding grants remain on hold and whether project approval and funding will be obtained is unknown.

#### **Industry and Economic 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 Q2-F'12 remain substantially unchanged from the analysis discussed at length in the Company's AIF and the risks discussed in the FYE 2011 MD&A and Q1-F'12 MD&A.

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

- the lack of product revenues;
- 2. securing adequate licensing agreements; and
- 3. access to capital.



#### **Lack of Product Revenues**

COTI has not recorded any revenues from the sale or license of any drug compounds or compound libraries during its first five years as a public company consistent with the most recent quarter, Q2-F'12. COTI has an accumulated deficit since its inception through to October 31, 2011 of \$15,027,797. This deficit is expected to increase in the near term as COTI continues its product development efforts, develops relationships with prospective customers, and strives to obtain licensing and collaboration agreements. Operating losses are expected to be incurred until upfront licensing, milestone and royalty payments are sufficient to generate revenues to fund its 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 and biotechnology organizations for preclinical compounds. While continued positive test results during this fiscal year generate positive feedback from potential licensees, efforts have not translated into a contractual agreement. Licensing discussions during Q2-F'12 continued to find interest for novel early stage deals, as the focus on late stage compounds during the past three years has diminished the availability of good compounds in the mid to late stages of clinical development held by companies looking to license. This is reflected in an increasing number of early stage deals in many therapeutic areas during calendar 2011. Industry reporting continues to highlight the productivity challenges of pharmaceutical industry R&D spending in generating new compounds (see US Food and Drug Administration Center for Drug Evaluation – FDA Approvals Since 1996) but there is no certainty that licensing deals can be successfully negotiated for COTI's preclinical compounds.

#### **Access to Capital**

The Company is seeking additional funds to continue to develop its R&D programs and to move its compounds more rapidly through development in calendar 2012. The Company intends to raise these funds through public or private equity offerings and collaborations with other pharmaceutical and biotechnology organizations or from other sources. If adequate funding is not available, 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 and the general economic conditions and access to capital in the equity markets for biotechnology companies.

COTI is a Tier 2 issuer on the TSXV and accordingly is not required to file an AIF; however, the Company voluntarily filed an AIF on July 13, 2011 to strengthen its ability to raise public financing. This filing enables the Company to proceed with a short form prospectus offering at a later date should the Company determine this to be an appropriate course of action at that time.



Despite the Company's financing efforts, there can be no assurance additional funding will be available on terms acceptable to COTI.

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

Certain pronouncements were issued by the International Accounting Standards Board ("IASB") or International Financial Reporting Interpretation Committee that are mandatory for annual periods beginning after January 1, 2011 or later periods. Many of these updates are not applicable or are inconsequential to the Company and have been excluded from the discussion below. The remaining pronouncements are being assessed to determine their impact on the Company's results and financial position as follows:

(a) IFRS 7 Financial Instruments – Disclosures – Enhanced Derecognition Disclosure Requirements:

This amendment requires additional disclosure about financial assets that have been transferred but not derecognized to enable the user of the Company's financial statements to understand the relationship with those assets that have not been derecognized and their associated liabilities. In addition, the amendment requires disclosures about continuing involvement in derecognized assets to enable the user to evaluate the nature of, and risks associated with, the Company's continuing involvement in those derecognized assets. The amendment becomes effective for annual periods beginning on or after July 1, 2011. This amendment affects disclosure only and has no impact on the Company's financial position or performance.

(b) IFRS 9 Financial Instruments – Classification and Measurement:

IFRS 9 reflects the first phase of the IASB's work on the replacement of International Accounting Standard 39, Financial Instruments: Recognition and Measurement, and deals with the classification and measurement of financial assets and financial liabilities. The Standard eliminates the existing IAS 39 categories of held to maturity, available-for-sale, and loans and receivable. This standard establishes two primary measurement categories for financial assets and liabilities, amortized cost and fair value.

Gains and losses on re-measurement of financial assets measured at fair value are recognized in profit or loss, except that for an investment in an equity instrument, which is not held-fortrading, IFRS 9 provides, on initial recognition, an irrevocable election to present all fair value changes from the investment in other comprehensive income (OCI). The election is available on an individual share-by-share basis. Amounts presented in OCI will not be reclassified to profit or loss at a later date.

For financial liabilities measured at fair value under the fair value option, changes in fair value attributable to changes in credit risk will be recognized in profit or loss. However, if this requirement creates or enlarges an accounting mismatch in profit or loss, the entire change in fair value will be recognized in profit or loss. Amounts presented in OCI will not be reclassified to profit or loss at a later date.



The standard is effective for annual periods beginning on or after January 1, 2013 and the Company intends to adopt IFRS 9 in its financial statements for the annual period beginning May 1, 2013. The Company does not expect IFRS 9 to have a material impact on its financial statements.

#### (c) IFRS 13 Fair Value Measurement:

In May 2011, the IASB published IFRS 13 Fair Value Measurement, which is effective prospectively for annual periods beginning on or after January 1, 2013. The disclosure requirements of IFRS 13 need not be applied in comparative information for periods before initial application. IFRS 13 replaces the fair value measurement guidance contained in individual IFRSs with a single source of fair value measurement guidance. It defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, i.e. an exit price. The standard also establishes a framework for measuring fair value and sets out disclosure requirements for fair value measurements to provide information that enables financial statement users to assess the methods and inputs used to develop fair value measurements and, for recurring fair value measurements that use significant unobservable inputs (Level 3), the effect of the measurements on profit or loss or other comprehensive income. IFRS 13 explains 'how' to measure fair value when it is required or permitted by other IFRS. IFRS 13 does not introduce new requirements to measure assets or liabilities at fair value, nor does it eliminate the practical exceptions to fair value measurements that currently exist in certain standards. The Company intends to adopt IFRS 13 prospectively in its financial statements for the annual period beginning on May 1, 2013. The Company does not expect IFRS 13 to have a material impact on its financial statements.

#### (d) IAS 1 Presentation of Financial Statements

In June 2011, the IASB published amendments to IAS 1 Presentation of Financial Statements: Presentation of Items of Other Comprehensive Income, which are effective for annual periods beginning on or after July 1, 2012 and are to be applied retrospectively. Early adoption is permitted.

The amendments require that an entity present separately the items of OCI that may be reclassified to profit or loss in the future from those that would never be reclassified to profit or loss. Consequently, an entity that presents items of OCI before related tax effects will also have to allocate the aggregated tax amount between these categories. The existing option to present the profit or loss and other comprehensive income in two statements has remained unchanged. The Company intends to adopt the amendments in its financial statements for the annual period beginning on May 1, 2013. The Company does not expect adoption to have a material impact on its financial statements.