



# **Critical Outcome**

Technologies Inc.

**Management Discussion and Analysis of Financial Condition  
and Results of Operations**

**Fiscal 2010 - First Quarter  
for the three months ended July 31, 2009**

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## Overview

*The following discussion and analysis 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, 2009, and has been prepared with all information available up to and including September 9, 2009. This management discussion and analysis (MD&A) is intended to assist in understanding the dynamics of the Company’s business and the key factors underlying its financial results. This analysis should be read in conjunction with the audited financial statements and notes thereto for the year ended April 30, 2009. The financial information contained herein has been prepared in accordance with Canadian generally accepted accounting principles (“GAAP”); however, the information as presented herein represents unaudited disclosure. All dollar amounts are expressed in Canadian dollars. Quarterly interim reports and additional supplementary information concerning the Company can be found on SEDAR at [www.sedar.com](http://www.sedar.com).*

## Forward-looking Statements

This MD&A contains certain statements, which constitute “forward-looking statements” within the meaning of the *Securities Act* (Ontario) and applicable securities laws. These forward-looking statements, by their nature, are not guarantees of future performance and are based upon management’s current expectations, estimates, projections and assumptions. COTI operates in a highly competitive and regulated environment that involves significant risks and uncertainties. Management of COTI considers the assumptions on which these forward-looking statements are based to be reasonable, but because of the many risk factors, cautions the reader that actual results could differ materially from those expressed or implied in these forward-looking statements.

## The Company

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

On November 27, 2007, the Company completed an acquisition of all outstanding common shares in the capital of 3015402 Ontario Inc. (formerly 6441513 Canada 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 2006 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 its wholly owned subsidiary, DDP Therapeutics, under the laws of the Province of Ontario.

## **Our Business**

COTI is a biotechnology company focused on applying its proprietary computer-based technology, CHEMSAS<sup>®</sup>, to identify, profile and optimize commercially viable drug candidates at the earliest stage of preclinical drug development and thereby reduce the timeline and cost of getting new drug therapies to market.

Using CHEMSAS<sup>®</sup>, the Company is developing highly optimized libraries of 6 to 10 novel, proprietary, small molecules as potential drug candidates for specific therapeutic targets in diseases that have high morbidity and mortality and currently have either poor or no effective therapies. Following synthesis and completion of a core group of confirmatory in vitro and in vivo tests, the Company plans to license or co-develop these molecules with interested pharmaceutical partners for further drug development and human trials. Currently, libraries in various stages of development include small cell lung cancer, adult acute leukemia, colorectal cancer and other cancers, HIV integrase inhibitors, multiple sclerosis and secretase inhibitors for the treatment of Alzheimer's disease.

In addition to licensing its targeted libraries, the Company may also take particularly promising individual molecules forward through various preclinical tests and Phase 1 clinical trials. This activity involves additional preclinical testing and the associated costs with making an investigational new drug application (IND filing) in the United States or a new drug submission (NDS) in Canada and a plan for human Phase 1 clinical studies. These compounds would then be available for licensing or co-development with a pharmaceutical partner. In this regard, COTI continues to prepare for a Phase 1 clinical trial submission based on the positive preclinical results achieved from COTI-2, its lead cancer molecule with a number of cancer indications. Testing initiatives and planning for this event currently target an IND filing for April 2010.

The Company is also in discussion with several multinational pharmaceutical and biotechnology organizations related to leveraging CHEMSAS<sup>®</sup> in identifying lead candidates for targets of commercial interest to these prospective partners. This collaboration approach could provide another revenue stream as the Company concurrently develops its own novel drug candidates. The Company's preferred commercialization strategy for collaborations incorporates an upfront fee and a shared risk/reward revenue model delivered through a series of milestone payments based on preclinical and clinical test results. Management believes that this service offering to prospective customers represents an efficient and effective approach for them in providing discovery stage compounds while enhancing value to the Company and its shareholders from the underlying CHEMSAS<sup>®</sup> technology.

## **Results of Operations Review**

For the three months ended July 31, 2009 (Q1-F'10), the Company reported a net loss of \$979,089 or \$0.02 per common share compared to a net loss of \$858,771 or \$0.02 per common share on July 31, 2008 (Q1-F'09). This increased loss of \$120,318 resulted from five main sources; increased research and development (R&D) of \$183,092, increased salaries and benefits of \$137,328, lower interest revenue of \$31,208 offset by decreased stock based compensation of \$199,019 and lower professional fees of \$46,986.

*Revenues*

There were no operating revenues recorded during the quarter.

The Company earned \$8,325 in interest income in Q1-F'10 compared to \$39,533 in Q1-F'09. The decrease reflects the lower cash, cash equivalent and short-term investment balances held by the Company as illustrated in Table 1, as well as the lower interest rates available during the current quarter compared to Q1-F'09.

*Table 1: Comparative Summary of Cash, Cash Equivalents and Short-term Investments*

	July 31, 2009	July 31, 2008
Cash	\$ 184,171	\$ 253,171
Cash equivalents	559,666	1,563,712
Short-term investments	2,116,880	3,049,846
Total	\$2,860,717	\$4,866,729

*Operating Expenses*

Operating expenses increased from \$898,304 for Q1-F'09 to \$986,899 for Q1-F'10, an increase of \$88,595. Four expense categories as set out in Table 2 accounted for the majority of this change.

*Table 2: Major Expense Items*

Expense	Q1-F'10	Q1-F'09	Change	Change as % of Total
Research and product development <sup>(1)</sup>	\$ 316,306	\$ 133,214	\$ 183,092	206.7%
Salaries and benefits	287,708	150,380	137,328	155.0%
Professional fees	66,317	113,303	(46,986)	-53.0%
Stock-based compensation	33,602	232,621	(199,019)	-224.6%
	703,933	629,518	74,415	84.0%
Other expenses	282,966	268,786	14,180	16.0%
Total	\$ 986,899	\$ 898,304	\$ 88,595	100.0%

<sup>(1)</sup> Consists of third party contracted testing and synthesis costs, consulting and materials.

The salaries and benefits increase of \$137,328 relates to increased staffing since Q1-F'09.

The decline in professional fees of \$46,986 relates to lower costs across all consulting categories: audit, accounting, legal, intellectual property consulting, human resource consulting and miscellaneous consulting. A portion of this decline reflects the impact of the staffing increase in salaries and benefits as previous external consulting services are now done in-house.

The stock-based compensation decline of \$199,019 in Q1-F'10 reflects only the compensation cost of options vesting in the quarter from prior period option grants. There were no new options granted in Q1-F'10.

Table 3 summarizes the third party R&D costs for Q1-F'10 and Q1-F'09 in conjunction with the Company's internal R&D labour costs. Overall R&D increased \$222,523 in Q1-F'10 compared to Q1-F'09. Contract R&D testing and materials increased \$85,431 with the majority of this cost focused on COTI-2. Contract synthesis costs increased \$97,661 with \$42,258 or 26.5% of Q1-F'10 expenditures for COTI-2. Internal R&D labour costs increased \$39,431 reflecting the addition of staff in this area since Q1-F'09.

*Table 3: R&D Costs*

	Q1-F'10	Q1-F'09	Change
R&D testing, consulting and materials	\$ 156,760	\$ 71,329	\$ 85,431
Synthesis	159,546	61,885	97,661
	316,306	133,214	183,092
R&D labour	106,517	67,086	39,431
Total	\$ 422,823	\$ 200,300	\$ 222,523

### Two Year Operational Results Summary by Quarter

Table 4 below summarizes the operating results by quarter for the past two fiscal years.

*Table 4: Two Year Summary of Quarterly Results*

FYE 2010	Q1 31-Jul	Q2 31-Oct	Q3 31-Jan	Q4 30-Apr	3 Mths YTD
Revenue	\$ -				\$ -
Loss before other income	(986,899)				(986,899)
Other income	7,810				7,810
Loss	(979,089)				(979,089)
Loss per common share	\$ (0.02)				\$ (0.02)

FYE 2009	Q1 31-Jul	Q2 31-Oct	Q3 31-Jan	Q4 30-Apr	Full Year
Revenue	\$ -	\$ 5,982	\$ 13,204	\$ 29,972	\$ 49,158
Loss before other income	(898,304)	(759,908)	(1,036,831)	(1,400,319)	(4,095,362)
Other income	39,533	34,906	38,530	63,374	176,343
Loss	(858,771)	(725,002)	(998,301)	(1,336,945)	(3,919,019)
Loss per common share	\$ (0.02)	\$ (0.01)	\$ (0.02)	\$ (0.03)	\$ (0.08)

FYE 2008	Q1 31-Jul	Q2 31-Oct	Q3 31-Jan	Q4 30-Apr	Full Year
Revenue	\$ -	\$ -	\$ 30,822	\$ -	\$ 30,822
Loss before other income	(524,674)	(604,035)	(331,269)	(669,672)	(2,129,650)
Other income	24,216	84,067	61,865	57,130	227,278
Loss	(500,458)	(519,968)	(269,404)	(612,542)	(1,902,372)
Loss per common share	\$ (0.01)	\$ (0.01)	\$ (0.01)	\$ (0.02)	\$ (0.05)

The increasing quarterly loss trend reflects the Company's acceleration of research and product development as well as the administrative costs associated with the higher level of activity. The majority of the variation by quarter across the years, and year over year, is explained by the following few expense categories: R&D, salaries and benefits and stock-based compensation. Research and product development spending will continue to increase in FYE 2010 as the Company continues to develop not only COTI-2 but also its other drug candidates. The increasing trend for salaries will be highly dependent upon additional staffing needs. The Company sees the need to add science expertise in its sales, market research and business development areas to interface with prospective customers, subject to available funding.

### **Liquidity and Capital Resources**

At Q1-F'10, the Company had cash, cash equivalents and short-term investments of \$2,860,717 compared to \$3,652,459 at the April 30, 2009 year-end (FYE 2009) for a decrease of \$791,742 in Q1-F'10. This represents a monthly cash burn rate of \$263,914 during the quarter.

The Company's current accounting policy is to only record investment tax credit (ITC) revenue when received, due to the contingent nature of these credits that require review and approval by the tax authorities well after the Company's year end. The estimated cash refund related to the filing of the April 30, 2009 year end corporate tax returns that has not been recorded by the Company in accordance with this accounting policy is \$137,301.

The only investing activity of significance during the quarter was \$48,921 on the Company's patents with a further \$5,038 expenditure on equipment.

During Q1-F'10, the Company exercised its early purchase option on the assets that were under lease to the end of September 2009 for some minor cash savings.

There were no warrant or stock option exercises during Q1-F'10.

The Company's working capital at Q1-F'10 was \$2,505,352 compared to \$3,367,742 at FYE 2009. Current assets decreased to \$2,990,991 at Q1-F'10 from \$3,804,279 at FYE 2009 for a decrease of \$813,288, primarily due to a decrease in cash, cash equivalents and short-term investments. Current liabilities increased \$49,102 to \$485,639 at Q1-F'10 from \$436,537 at FYE 2009. This increase relates to accounts payable that increased \$50,771 due to R&D spending.

The Company's long-term contractual obligations as at July 31, 2009 for the remainder of fiscal 2010 and fiscal 2011 are summarized in Table 5.

*Table 5: Contractual Obligations  
for the years ended April 30*

Obligation	Total	2010	2011
Premises rent <sup>(1)</sup>	9,345	9,345	-
Research and development contracts	124,535	114,535	10,000
<b>Total contractual obligations</b>	<b>\$ 133,880</b>	<b>\$ 123,880</b>	<b>\$ 10,000</b>

(1) During fiscal 2009 the Company was assessed additional property taxes of \$6,400, which the Company is contesting. 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.

On June 10, 2009, the Company announced that it was undertaking a non-brokered private placement of common share units with accredited investors to raise up to \$5,500,000. Each unit consisted of one common share and one-half warrant with an issue price of \$0.85. Each whole common share purchase warrant would be exercisable for one common share at a price of \$1.11 for up to thirty-six months following closing. If fully subscribed the Company would issue 6,470,588 common shares and 3,235,294 whole warrants. Costs of the private placement were estimated to be \$390,000 if fully subscribed.

On July 23, 2009, the Company announced that it was continuing to work on the private placement with a closing to occur on all subscriptions received on Friday August 14, 2009.

Subsequent to the quarter end, the Company announced on August 24, 2009 that it had withdrawn its non-brokered private placement offering due to market conditions. The offering received strong interest from investors; however, market conditions and investor circumstances prevented a conclusion that met the needs of the Company.

Based upon the balance of cash, cash equivalents and short-term investments at the quarter-end, and given the Company's current monthly burn rate it has sufficient cash resources to carry out its operations for the balance of FYE 2010 that ends April 30, 2010 and into June 2010 of fiscal 2011 at budgeted operating levels. The Company is focusing its operations on very specific revenue initiatives to generate cash and on reducing discretionary spending and operating costs to conserve cash. The Company will continue to look at different sources of financing to extend and expand its operations in the coming months to ensure the success of the Company.

### **Off Balance Sheet Arrangements**

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

### **Related Party Transactions**

No related party transactions of a material amount occurred during Q1-F'10.



**Outstanding Share Data**

Outstanding share information as at the close of business on September 9, 2009 is set out in Table 6.

*Table 6: Outstanding Share Data*

	Outstanding	Expiry Date
<b>Common shares</b>		
Authorized - unlimited		
Issued	46,720,214	
Fully diluted <sup>(1)</sup>	49,531,583	
Weighted average outstanding <sup>(2)</sup>	46,720,214	
<b>Common share warrants</b>		
\$0.70 warrants	14,902	Dec 31/09 to Apr 10/10
<b>Common share stock options</b>		
\$0.50	500,000	Oct 30/13
\$0.64	1,035,000	Jan 11/12
\$0.70	50,000	Jan 14/12
\$0.75	309,078	Jun 9/13
\$0.90	422,389	Feb 16/14
\$1.00	130,000	Apr 30/12
\$1.20	100,000	Jul 15/13
\$1.35	150,000	Mar 25/12
\$2.00	100,000	Oct 8/12
	<b>2,796,467</b>	

(1) Assumes conversion of all outstanding common share stock options and warrants.

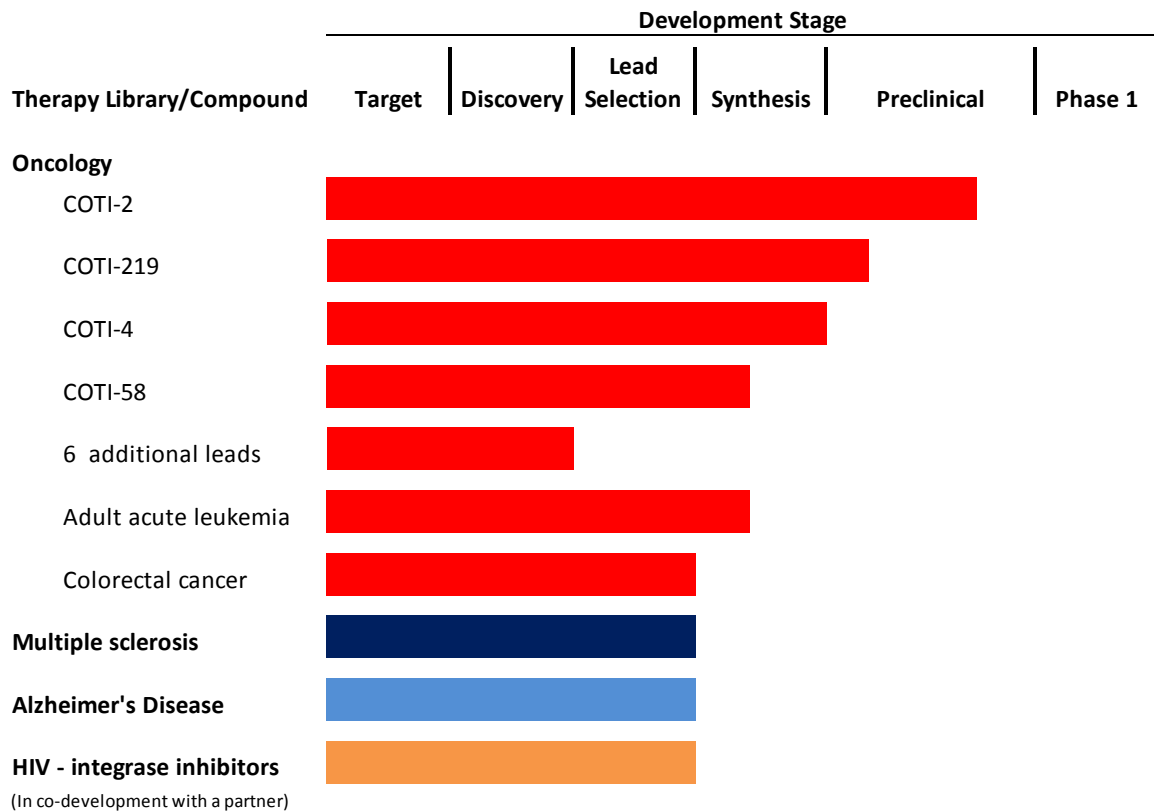
(2) Weighted average shares outstanding calculated from May 1, 2009 to Sept 9, 2009.

**Operational Progress and Outlook – Q1-F’10**

**Product Development**

The Company continued to make progress in developing its drug candidate pipeline during Q1-F’10. Figure 1 highlights the development status of specific compounds and libraries, in particular the positive development of the Company’s lead oncology compound COTI-2.

Figure 1: COTI Product Development Pipeline at September 9, 2009



**COTI-2**

During Q1-F'10, Company representatives continued to foster discussions with pharmaceutical organizations regarding a prospective licensing agreement for COTI-2. Concurrently, the Company continued its investment in this promising molecule by carrying out additional animal experiments and laboratory work to determine an optimal formulation for PK-Tox animal testing. These results were highlighted in a number of press releases as follows:

	Press release	Announcement
1	May 14/09	COTI-2 in combination with Taxol® (Paclitaxel) is superior to treatment with Paclitaxel alone in an animal model of aggressive human endometrial cancer
2	July 2/09	Intravenous COTI-2 in combination with Doxil® (Doxorubicin HCl) is more effective than treatment with Doxil alone in an animal model of human ovarian cancer
3	Aug 6/09	COTI-2 demonstrates low in vitro toxicity in normal human white blood cells compared with multiple human cancer cell lines
4	Aug 18/09	Oral COTI-2 plus Doxil® is superior to doxil alone in an animal model of human ovarian cancer

These are important results adding to the impressive data set of COTI-2 showing efficacy against multiple cancers and low toxicity. Moreover, these results are significant in light of recent industry media activity related to the merit of combination treatment in oncology, as many leading oncology experts believe that it is unrealistic for a single agent to be dramatically active in a broad population of cancer patients.

#### COTI-219

Experiments designed to determine the mechanism of action of COTI-219 continued during Q1-F'10. These experiments will assist management with determining the nature and design of the next tests in preclinical development. The Company also moved forward with planning for additional animal experiments to contribute to a growing data package in preparation for licensing this compound in calendar 2010.

#### COTI-4

During Q1-F'10, the Company completed its intellectual property strategy related to a derivative of the original COTI-4 scaffold. This molecule or an analog will move through preclinical testing during fiscal 2010 provided funds are available.

#### Adult Acute Leukemia (AAL)

The AAL project is based upon patents received by COTI for three tyrosine kinase inhibitor scaffolds. Tyrosine kinase mutations have been identified as common factors in many cancers and may specifically promote uncontrolled white blood cell proliferation common in leukemia. Management continued actively seeking a licensing or co-development partner for these compounds during the quarter.

#### Colorectal Cancer

There was no further development of this library during Q1-F'10 as resources, both time and money, were focused on other initiatives.

#### Multiple Sclerosis

Management continues to delay its decision regarding the further advancement of this program until a patent review opinion from the US Patent and Trademark Office (USPTO) related to a potentially competing patent claim is rendered. Multiple Sclerosis continues to be an important project for the Company and the program is likely to proceed when the intellectual property approach can be clearly defined in relation to this potentially competing claim.

#### Alzheimer's Disease

During Q1-F'10, the Company announced it had undertaken the discovery and optimization of novel lead compounds for the treatment of AD. The Company completed an extensive computational and human medicinal chemistry optimization, a chemical synthetic feasibility review and an intellectual property assessment on the novel compounds during the quarter.

The first six dual secretase inhibitors on three different scaffolds are ready for synthesis and preclinical evaluation.

#### Collaborations and Co-Development Projects

##### (i) Oncology Pilot Project

Subsequent to the end of Q1-F'10, on August 17, 2009, the Company announced that it had received notification from Merck KGaA of Darmstadt, Germany that it decided to discontinue the pursuit of compounds under the pilot project announced on October 17, 2007. The project called for COTI to identify drug discovery candidates for a specific oncology cellular target of importance to Merck KGaA.

##### (ii) HIV Integrase Co-development

Work on synthesizing six HIV-1 integrase inhibitor compounds under a co-development agreement with a major pharmaceutical company continued during Q1-F'10. Upon completion of synthesis, the major pharmaceutical company will manage, conduct and fund agreed upon preliminary preclinical experiments as part of its evaluation of these compounds. Once the final experiments have been completed and the results have been received by COTI, the major pharmaceutical company will have an exclusive period to negotiate a licensing agreement with COTI for the select compounds. If an agreement is not reached within this period, COTI will be able to engage other potential partners for its HIV-1 integrase inhibitor program.

#### Future Collaboration Projects

Building on the lead discovery collaboration strategy implemented to date in pilot project agreements, the Company is carrying out a targeted business development campaign to global pharmaceutical and biotechnology organizations in order to market the benefits of working with COTI on lead discovery collaborations. Discussions with multiple prospective customers are currently on-going.

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

The biotechnology industry is generally regarded as high risk given the uncertain nature of developing drug candidates. COTI operates in the discovery stage of the drug development cycle, which is the initial preclinical segment of the cycle. On the other hand, success in this area can be highly rewarding. The realization of COTI's long-term potential is dependent upon the successful development and commercialization of molecule profiling services and drug candidates. The major industry and economic risk factors affecting realization of this potential are highlighted in the annual MD&A and remain substantially unchanged from this analysis during Q1-F'10.

**Changes in Accounting Policies including Initial Adoption****(i) Adopted in 2010**

The Canadian Institute of Chartered Accountants issued three new accounting standards that apply to the Company for its fiscal 2010 financial reporting and these were adopted for Q1-F'10. The impact of these accounting policies on the Company's current business was not material. These policies are described below.

**(a) Goodwill and intangible assets:**

Section 3064, "Goodwill and Intangible Assets", replaced Section 3062, "Goodwill and Other Intangible Assets" and Section 3450, "Research and Development Costs". This Section establishes standards for the recognition, measurement, and disclosure of goodwill and intangible assets. The Company does not have goodwill recorded on its books and there was no impact to the recognition, measurement and disclosure standards for intangible assets for the Company except that computer software not integral to the operating system of the Company's computers was reclassified on the balance sheet from equipment to intangible assets.

**(b) International financial reporting standards (IFRS):**

Based upon the decision of the Accounting Standards Board that Canadian generally accepted accounting principles for publicly accountable enterprises would converge with IFRS effective in calendar year 2011, the Company has commenced the process to transition from Canadian GAAP to IFRS. The transition process plan includes 3 phases. The first phase, the diagnostic phase, was completed in FYE 2009. During this phase, the Company prepared high-level diagnostic analyses of key financial statement components expected to be impacted upon transition to IFRS. As part of this process, the Company identified key data requirements and process modifications that would be required before transition could occur.

During Q1-F'10, the Company entered the development phase that involves more detailed analyses of the impact of IFRS on key financial statement components and focuses on implementation differences and issue resolution. During this stage of the transition process, management will finalize financial statement component evaluations (CEs) and make decisions on accounting policy options. The development phase will conclude with the preparation of a proforma set of financial statements prepared in accordance with IFRS. The Company anticipates completing the CEs in the third quarter of fiscal 2010.

The implementation phase will commence in Q4-F'10 involving the execution of changes to financial reporting and business processes that will enable the Company to compile financial statements, which are compliant with IFRS. Accounting policies compliant with IFRS will be approved and entrenched in the financial reporting system.

**(c) General standards of financial statement presentation:**

Section 1400, "General Standards of Financial Statement Presentation" was amended to require disclosure of material uncertainties that cast significant doubt as to an entity's ability to

continue as a going concern. It requires that financial statements be prepared on a going concern basis unless management either intends to liquidate the entity or to cease trading, or has no realistic alternative but to do so. While management is aware that additional current financing is necessary to continue development of its compounds it believes the going concern assumption remains applicable based upon a number of considerations including:

- management's plans to obtain additional financing;
- a history of being successful in obtaining financing when needed;
- the continued promising scientific development of its compounds with primary emphasis on COTI-2 supporting the financing; and,
- the ability to extend the Company's operating life beyond 12 months through the management of discretionary and operational spending.

(ii) To be adopted in 2011

In June 2009, Section 3862, "Financial Instruments - Disclosures" was amended to include additional disclosure requirements about fair value measurements and to enhance liquidity risk disclosure requirements. For the Company, this Section is effective for annual financial statements ending after September 30, 2009. This new standard is expected to have minimal impact on the financial statements.