

# Management Discussion and Analysis of the Financial Condition and Results of Operations

For the fiscal year ended April 30, 2016



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# Critical Outcome

## MD&A for the fiscal year ended April 30, 2016

#### 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 year ended April 30, 2016 and has been prepared with all information available up to July 29, 2016. The MD&A is intended to assist readers in understanding the dynamics of the Company's business and the key factors underlying its financial results. The Board of Directors of the Company approved the content of this MD&A on July 29, 2016.

This analysis should be read in conjunction with the Company's Annual Financial Statements and notes thereto for the year ended April 30, 2016. These financial statements were prepared in accordance with International Financial Reporting Standards ("IFRS").

All dollar amounts in this MD&A are expressed in Canadian dollars ("CAD") unless otherwise noted.

Quarterly interim reports for fiscal 2016, the Annual Financial Statements, and additional supplementary historic information concerning the Company can be found on SEDAR at www.sedar.com and on the Company's website at www.criticaloutcome.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.

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;
- The continued advancement and positive outcomes from the Company's Phase 1 clinical trial with COTI-2 in gynecological cancers that was in progress at the fiscal 2016 year-end;
- An ability to further enhance and add features to the CHEMSAS® technology or incorporate advances in artificial intelligence technologies for internal and collaborative purposes;
- The ability to obtain patent protection for the Company's compounds and other intellectual property;
- An ability to attract and retain skilled and experienced personnel to support research development; and,
- An ability to establish preferred supplier relationships with reputable and reliable third party clinical research organizations.

Table 1: Forward-looking Statements

MD&A Section Heading	Nature of Forward-looking Information Disclosed
Our Business	<ul> <li>Plans to further advance COTI-2 in the Phase 1 clinical trial in fiscal 2017</li> <li>Plans to establish collaborations to expand the applications of the CHEMSAS® technology</li> <li>Plans to seek strategic collaborations to advance its pipeline</li> <li>Plans to further develop ROSALIND™</li> </ul>
Operational Progress and Outlook	<ul> <li>Plans to obtain additional funding</li> <li>Intent to advance the Phase 1 clinical trial with MD Anderson and Northwestern University in fiscal 2017</li> <li>Pursuing new cancer indications for COTI-2</li> <li>Plans to advance at least one new compound into IND-enabling studies to position an IND filing in 2017</li> <li>Further development of the ROSALIND™ technology</li> </ul>
Liquidity and Cash Resources	<ul> <li>Plans to seek additional cash resources</li> <li>Plans to raise capital in the U.S.</li> <li>Expectation of additional investments in patents and computer hardware and software</li> </ul>
Foreign Exchange Exposure	<ul> <li>Expectation of exposure to currency fluctuations resulting from clinical trial costs being undertaken with U.Sbased investigator institutions</li> </ul>
Industry and Economic Risk Factors Affecting Performance	<ul> <li>The expectation of continued losses until a revenue transaction is secured</li> <li>Ability to negotiate and consummate future licensing and collaboration agreements for its lead program, pipeline assets and platform technology</li> <li>Ability to raise additional capital through different avenues and mechanisms available to the Company</li> </ul>



MD&A Section Heading	Nature of Forward-looking Information Disclosed			
	•	Risks associated with the outcome of ongoing clinical trials		
Changes in Accounting	•	The adoption in fiscal 2017 of new accounting standards issued		
Policies		by the International Accounting Standards Board		

The Management of COTI considers the assumptions on which the FLS are based to be reasonable. Management cautions the reader that there are many risk factors, including those specifically discussed later in the MD&A, which are of particular importance to the assumptions above, and actual results could differ materially from those expressed or implied in the FLS and as such, undue reliance should not be placed on any individual FLS.

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 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 molecules, initially targeted at small cell lung cancer, that were identified by COTI 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.

On June 16, 2014, the Company obtained a listing in the United States on the OTC Markets OTCQB trading platform for venture companies under the symbol COTQF.



#### **Our Business**

COTI is a clinical stage biopharmaceutical company built on a dynamic artificial intelligence ("AI") platform for drug development and the modeling of biological systems. Our corporate structure allows for strategic focus in the following areas:

#### i. COTI-2

The Company's lead drug compound is COTI-2, which received investigational new drug ("IND") status from the United States Food and Drug Administration ("FDA") in May 2015. A Phase 1 clinical trial with COTI-2 commenced in gynecological cancers at the University of Texas, MD Anderson Cancer Center, in December 2015.

Extensive preclinical studies demonstrated COTI-2's ability to restore mutant p53 function and thus induce cancer cell death in many common p53 mutations. COTI-2 is being developed as an oral treatment for solid tumors; it is easily synthesized and has good in vitro and in vivo efficacy against multiple human cancers including small cell lung, non-small cell lung, colon, brain, ovarian, endometrial, triple negative breast, head and neck, and pancreatic. We believe COTI-2's important protein target, low toxicity in preclinical development, and combination effectiveness with standard agents, and potential for longer term outpatient therapy as an oral agent, supports a dramatic change in the treatment of susceptible cancers.

#### ii. CHEMSAS® & Drug Candidate Pipeline

The Company's proprietary AI platform, CHEMSAS®, provides us with the opportunity to identify potential treatments for a broad range of serious diseases. Our predictive computer models identify compounds with a high probability of success with disease specific drug discovery through chemical optimization, and preclinical testing. The technology is designed for small molecules, and as a drug candidate discovery engine can be applied to any disease target with a modest amount of information for the target of interest.

The Company has created a pipeline of novel, proprietary, small molecules for specific therapy targets with high morbidity and mortality rates, which currently have either poor, and or, no effective therapies.

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. This service offering would provide prospective customers with an efficient reasonably-priced approach for generating targeted discovery stage compounds while enhancing value to COTI and its shareholders from monetizing the underlying CHEMSAS® technology.

#### iii. ROSALIND™

Currently in the validation phase of development, ROSALIND™ is a smart data platform for realizing the promise of personalized medicine for cancer patients everywhere. Using our proprietary programmable computer simulation of cancer cell signaling, ROSALIND™ is designed to realize the therapeutic potential



of the important information derived from increasingly accessible cancer gene mutation profiles. The goal of ROSALIND™ is to identify personalized treatment options based on the genetic profile of the patient's cancer and to provide these to the oncologist for consideration in treating their patient.

### **Operational Progress and Outlook**

#### Operations

The Company made substantial progress on a number of fronts during the year.

The major focus was moving the Company's lead oncology compound, COTI-2, into a clinical trial. COTI-2 had received an orphan drug designation for ovarian cancer from the FDA in June 2014 and the Company subsequently filed its IND application in April 2015. On May 22, 2015, the FDA granted approval to proceed with the proposed clinical investigation and treatment use of COTI-2 for advanced and recurrent gynecologic malignancies (the "Trial").

Following the grant of IND status, the Company moved ahead with the detailed planning of the Phase 1 clinical trial with the University of Texas, MD Anderson Cancer Center ("MD Anderson") in Houston, TX, and with obtaining the necessary internal board and committee approvals from the institution, and negotiating the terms of the clinical trial agreement ("CTA").

The CTA is the key legal agreement between the Company and MD Anderson and includes the financial budget and payment terms and the detailed clinical study protocol for the clinical investigators. The CTA was signed on December 8, 2015, and a site visit to MD Anderson for training of the MD Anderson clinical trial staff occurred in mid-December shortly after signing the CTA. Following a period of patient pre-screening, enrollment, and testing, the first cohort of the Trial commenced treatment in the fourth quarter with the initiation of patient dosing on February 15, 2016.

The Trial, identified as COTI2-101, is designed primarily to assess the safety and tolerability of COTI-2 in patients with advanced and recurrent gynecologic malignancies, and, by identifying a maximum tolerated dose ("MTD"), enable the determination of a recommended Phase 2 dose ("RP2D") for future studies in Phase 2 clinical trials.

The Trial commenced as a single arm, single-center, open-label, Phase 1, first time in human study of COTI-2 in female patients with recurrent ovarian, fallopian tube, endometrial, or cervical cancer. However, the Company announced subsequent to year-end on June 6, 2016, the addition of a second site at the Lurie Cancer Center at Northwestern University, in Chicago, II. Adding this second site broadens the base of patients who can potentially qualify for the study allowing the overall trial to move forward on a faster basis than is possible with a single site.

The Trial has a standard 3+3 study design typically used in the dose escalation portion of a Phase 1 study to establish the MTD. COTI-2 is being self-administered as a single agent, orally, with a dosing regimen of once daily for 5 days (Monday to Friday) followed by 2 treatment-free days each week (the weekend).



One cycle is defined as 4 weeks of treatment at the dosing regimen. Each new cohort commences dosing once all three patients in the preceding cohort have successfully completed a cycle.

Approximately 30 patients are planned to be enrolled in the dose escalation portion of the Trial to identify the RP2D. This is based upon an anticipation of six cohorts (3 women per cohort) being evaluated in the dose escalation portion of the Trial at the following escalation doses for each respective cohort (0.25, 0.5, 1.0, 1.7, 2.5, 3.5mg/kg). Approximately 10 additional patients with ovarian cancer will be enrolled and treated in an expansion cohort at the RP2D to further characterize the safety, tolerability, and potential clinical activity of this dose.

On April 18, 2016, the Company began dosing patients in the second cohort following the independent Dose Escalation Committee's review of the safety data from all patients in the first cohort and their unanimous approval to proceed with dosing of the second cohort. Subsequent to the year-end on July 11, 2016, the Company commenced dosing the third cohort.

Progress in the Trial with successive cohorts represents achievement of positive milestones, as the ability to start successive cohorts indicates that any signs of potential toxicity seen for the drug in the patients were not consequential enough to constitute what is commonly referred to as a dose limiting toxicity, meaning that the dosing of patients could not move to a higher dose level. While these are early days in this dose escalation Trial, the Company is encouraged by the outcomes to date.

During the quarter, the Company also continued its strategic efforts to broaden the number of oncology indications for which COTI-2 would be a valuable therapy. This included further discussions with other major research institutions in using COTI-2 for the treatment of patients with recurrent squamous cell head and neck cancer ("HNSCC"), acute myelogenous leukemia ("AML"), lung cancer, and Li-Fraumeni Syndrome ("LFS").

Scientific developments of importance for COTI-2 were announced throughout FYE 2016 and are summarized in Table 2 below.

Table 2: Key Scientific Announcements for COTI-2

	Press	Key Scientific Advancement Regarding COTI-2
	Release Date	
1	May 11/15	Announced the granting of our first European patent covering the composition of matter for the COTI-2 family of compounds, pharmaceutical preparations containing COTI-2, methods of manufacturing and use of the compounds in the treatment of cancer in the European market.
2	May 2/15	Announced the grant from the FDA of IND status for COTI-2 in gynecological cancers.
3	Dec 2/15	Announced the submission to the FDA of an Orphan Drug Application for COTI-2 intended to treat patients afflicted by LFS.
4	Dec 10/15	Announced the signing of a Clinical Trial agreement ("CTA") with the University of Texas, MD Anderson Cancer Center to conduct a Phase 1 clinical trial of COTI-2 in gynecological cancers.



	Press	Key Scientific Advancement Regarding COTI-2
	Release Date	
5	Feb 16/16	Announced the treatment of the first patient of the first cohort in the COTI-2 Trial.
6	Apr 19/16	Announced the commencement of dosing of the first patient in the second cohort in the COTI-2 Trial.

#### Financing

The Company has a number of important objectives planned for fiscal 2017 to drive the business forward with the primary objective being the successful execution and completion of the COTI-2 Trial. Costs of approximately \$900,000 have been committed to the Trial in the next year as noted in "Liquidity and Cash Resources" under the "Working Capital" section and the Company is also incurring internal labour costs in support of the Trial. To fund these and other project costs in realizing its objectives will require the Company to seek additional working capital. Funding achievements for the quarter and year-to-date are highlighted in "Liquidity and Cash Resources". For the fourth quarter, this included the completion of a private placement for gross proceeds of approximately \$1,450,000 on March 29, 2016; and, the realization of additional gross proceeds from the exercise of warrants of approximately \$2,550,000. However, additional financing will be required to fund operations through fiscal 2017 and to the extent this funding cannot be obtained on a timely basis, the Company will manage its activities within its available cash resources. This funding is expected to come from a combination of sources but primarily:

- the exercise of options and warrants; and,
- private or public financings with an emphasis on accredited and institutional investors with a
  focus on U.S.-based investors due to the primary location of potential customers for one or
  more COTI products and services.

The Company will also be looking at government funding, co-development project funding from interested partners, and a development partnership agreement for COTI-2 or one of the other collaboration assets.

## **Key Operational Objectives for 2017**

The Company has established key operational objectives for fiscal 2017 as set out below.

#### 1. COTI-2

a) To complete the MTD determination component of the Phase 1 gynecologic study at the two clinical trial sites.

The timing of completion of this segment is uncertain as the progress of patients in a cohort cannot be predicted given the health status of the patients and the unknown response to each dose level as cohorts are activated. Toxicity and pharmacokinetic data from this segment of the



Trial is pivotal for planning additional COTI-2 studies as noted below including any interim efficacy evaluation.

- b) To commence the extension arm of the Phase 1 gynecologic study of 10 women following the MTD determination that allows the Company to establish a therapeutic dose level to use in this segment.
  - In this segment of the Trial, the Company will be specifically enrolling patients with ovarian cancer only. The p53 status of the patient's tumour will be known but will not be used as an inclusion or exclusion criteria but rather a basis for analyzing patient outcomes with the goal of providing important data around initial safety, pharmacokinetic results, and any early efficacy signal. This data will be useful in planning future Phase 2 studies.
- c) To evaluate, plan, and commence additional multi-centre clinical studies for COTI-2 beyond gynecologic cancers with the start of at least one new trial in a new indication.
  - The Company is currently evaluating cancer indications for this new trial that include HNSCC, LFS, and AML. There are many factors involved in this review. A primary consideration to guide the path forward with new indications is data from the completion of the MTD segment of the Phase 1 gynecologic study.

#### 2. Future Clinical Candidates

The Company is evaluating a number of therapeutic programs to identify the next clinical candidate to follow COTI-2 into the clinic. There are a number of programs in development and further research work is planned on these during 2017. At present, the Company believes COTI-219 is the most likely candidate given its current state of development and therapeutic target(s). Development on these programs is set out below.

- To continue the preclinical evaluation of COTI-219, a cancer drug candidate, for potentially starting a Phase 1 trial in early fiscal 2018. Activities planned include:
  - (i) completing the determination and validation of the mechanism of action ("MOA") of the compound;
  - (ii) conducting a 28-day two-species toxicity study on the specific cancer cell lines determined to be appropriate from the MOA work;
  - (iii) completing additional preclinical tests related to drug formulation and pharmacokinetics resulting from the MOA research; and,
  - (iv) commencing the preparation of the investigational new drug submission to FDA.
- b) To continue the preclinical evaluation of our library of methicillin-resistant staphylococcus aureus ("MRSA") compounds. These compounds are designed to overcome the issue of bacterial resistance responsible for several difficult-to-treat infections in humans. This MRSA



resistance relates to the beta-lactam antibiotics, which include the penicillins (methicillin, dicloxacillin, nafcillin, oxacillin, etc.) and the cephalosporins. Activities planned include:

- Completing synthesis of the compounds following substantial progress in fiscal 2016;
   and,
- (ii) Conducting confirmatory *in vitro* and *in vivo* studies based upon the timing of completing the synthesis.
- c) To continue our preclinical evaluation of our library of acute myelogenous leukemia compounds. Activities planned include:
  - (i) Conducting efficacy and maximum tolerated dose studies in animals to enable the selection of the final compound for moving forward in further preclinical testing; and,
  - (ii) Initiating qualification discussions with a list of prospective licensees with the objective of positioning for a license or co-development of the program as the preclinical scientific data package builds.

#### New Technologies – ROSALIND™

The Company continued development of its ROSALIND™ project during 2016. ROSALIND™ is designed to provide more precise oncology drug treatment recommendations to physicians based on the genetic profile of each individual patient's specific cancer.

The Company continued to work on the commercialization plan necessary to validate and develop this technology. Some of the key issues addressed in fiscal 2016 included:

- (i) Completion of initial proof of concept validation with oncology practitioners using an advanced working prototype in a limited number of patients;
- (ii) Identification and engagement of collaborative development partners;
- (iii) Launch of a website in March 2016 to invite collaborations with oncologists; and,
- (iv) Development of a large scale validation study plan.

For fiscal 2017, the Company is planning to further the development of ROSALIND™ with the following activities:

- (i) Conducting a larger scale validation study with a goal of building a 100 patient database reflecting evaluation outcomes from the ROSALIND™ analysis and its recommendations; and,
- (ii) Developing the business case to bring the technology to market.



#### **Selected Annual Information**

Table 3 below sets out selected annual financial information for the Company for FYE 2016 and the two preceding fiscal years.

Table 3: Selected Annual Financial Information

	FYE 2016	FYE 2015 FYE 2014
Revenue	\$ -	\$ - \$ -
Loss before finance income (loss)	3,920,815	3,853,824 2,979,706
Finance income (loss)	(1,003,612)	40,639 (16,473)
Loss and comprehensive loss	4,924,427	3,813,186 2,996,179
Basic and diluted loss per common share	\$ 0.04	\$ 0.04 \$ 0.03
Dividends declared and paid	-	
Total assets	\$ 6,863,260	\$ 3,493,189 \$ 2,527,703
Long term liabilities	-	-

The Company had no revenue licensing or collaboration contracts to generate revenue during the three year period and accordingly there was no revenue recognized.

The "Loss before finance income (loss)" and the "Loss and comprehensive loss" increased significantly during FYE 2015 and FYE 2016 due two factors; first, the change in fair value of the warrant liability recorded in FYE 2015 related to the issuance of warrants denominated in USD that are required under IFRS to be accounted for as a current liability and then re-measured at each reporting date at their fair value; and, second, year over year changes in two functional expense categories, research and development expenses ("R&D") and sales and marketing expenses ("S&M"). The trend in the functional expense categories is highlighted in Table 4.

Table 4: Summary of Functional Expense Categories

Description	FYE 2016	FYE 2015 FYE 20			
R&D	\$ 1,503,385	\$ 1,355,508	\$ 1,034,416		
G&A	2,000,043	2,342,054	1,958,185		
S&M	530,782	285,929	105,217		
	\$ 4,034,210	\$ 3,983,491	\$ 3,097,818		

The increase in total assets from FYE 2014 to FYE 2016 is attributable to higher levels of cash and cash equivalents, investments, and prepaid expenses and deposits. The trend for these balances is set out in Table 5. The major increase in prepaid expenses and deposits in FYE 2016 relates primarily to deposits made under the CTA and trial monitor agreements, which deposits of approximately \$356,000 at FYE 2016, will be applied to invoices for activities as the clinical trial progresses.



Table 5: Key Components of Total Assets

Asset type	FYE 2016	FYE 2015	FYE 2014		
Cash and cash equivalents	\$ 2,141,978	\$ 1,599,220	\$ 830,275		
Investments	2,587,946	266,464	-		
Prepaid expenses and deposits	\$ 546,802	\$ 90,626	\$ 79,673		

## **Financial Review of Full Year Operations**

A summary of the Company's financial results for the fiscal years ended April 30, 2016 and 2015, setting out the comparative changes between the years appears in Table 6 below. This financial information should be read in conjunction with the Company's 2016 Annual Financial Statements, which can be found on SEDAR at www.sedar.com.

Table 6: Comparative Financial Results for the years ended April 30

	2016	2015	Change
Expenses (income):			
Research and product development	\$1,503,385	\$1,355,508	\$ (147,877)
Sales and marketing	530,782	285,929	(244,853)
General and administration	2,000,043	2,342,054	342,011
Investment tax credits	(113,395)	(129,666)	(16,271)
	3,920,815	3,853,825	(66,990)
Loss before finance income (expense)	(3,920,815)	(3,853,825)	(66,990)
Finance income (expense):			
Interest and financing, net	11,593	(219,088)	230,681
Change in fair value of warrant liability	(965,869)	235,120	(1,200,989)
Foreign exchange gain (loss)	(49,336)	24,607	(73,943)
	(1,003,612)	40,639	(1,044,251)
Loss and comprehensive loss	\$ (4,924,427)	\$ (3,813,186)	\$ (1,111,241)
Weighted average shares outstanding	127,103,152	108,691,326	
Loss per common share	\$ (0.04)	\$ (0.04)	

#### Revenue

The Company does not currently have any revenue licenses or other revenue contracts accordingly, there was no revenue generated in FYE 2016 or FYE 2015. The Company's increased focus on Research and product development, and Sales and marketing during FYE 2016 that related primarily to COTI-2, as discussed below and in the "Operational Progress and Outlook", will position this compound, and the other assets being developed, for revenue events in future periods.



#### **Expenses**

Expenses increased \$66,990 year over year, however, spending in the major functional expense categories varied significantly. The increase reflected higher spending in Research and product development of \$147,877 as well as Sales and marketing of \$244,853 that was partially offset by a decrease in General and administration expense of \$342,011. A slight decrease in investment tax credits earned of \$16,271 also contributed to the higher expense.

#### a) Research and Product Development Expense ("R&D")

The increase in R&D expense was primarily driven by development efforts in moving COTI-2 through the final IND application granting process and then into the COTI-2 Trial. There were, however, other development areas of note which included: preclinical work on potential follow-on compounds to COTI-2, such as COTI-219 and the MRSA compounds; and development of a new clinical personalized oncology decision tool, ROSALIND™. Table 7 provides a breakdown of R&D costs by major expense type for FYE 2016 and FYE 2015.

Table 7: R&D Expense - Comparative Years Ended April 30

	FYE 2016	FYE 2015	Change
Clinical trial expenses	\$ 397,313	\$ -	\$ (397,313)
In vivo/in vitro testing	175,320	204,283	28,963
Synthesis and miscellaneous R&D expenses	158,406	324,777	166,371
	731,039	529,060	(201,979)
Salaries and benefits	562,353	420,876	(141,477)
Other	79,970	60,897	(19,073)
Professional fees	36,192	47,452	11,260
Drug Development Consulting	33,368	274,288	240,920
	1,442,922	1,332,573	(110,349)
Share-based compensation	60,463	22,935	(37,528)
Total	\$ 1,503,385	\$ 1,355,508	\$ (147,877)

The major change in the nature of R&D expense was the commencement of the COTI-2 Trial following the grant of the Company's IND application in the latter part of May 2015. Planning for the Trial commenced immediately and the first patient was dosed in February 2016. Activities captured in the Clinical trial expense category include: trial supplies, trial drug manufacturing costs, fees from the clinical trial site investigator, and oversight costs from the contract research organization engaged to provide the trial monitoring, data capture, analysis, and related services.

In vivo/in vitro testing for FYE 2016 decreased \$28,963 year over year. All of the testing in FYE 2015 related to development expenses associated with COTI-2, however, in FYE 2016, 59% of the expense related to COTI-219 with testing focused on understanding the MOA of the compound.



Synthesis and miscellaneous R&D expenses decreased \$166,371 year over year with approximately 70% of the cost in FYE 2016 related to development work on the Company's MRSA compounds. In FYE 2015, approximately 75% of the expense related to development work on COTI-2 for; synthesis of the oral formulation, bio-availability testing, and support for the chemistry reporting section of the IND application.

In support of the R&D development efforts, there were increases in Salaries and benefits, and changes in personnel, resulting in an expense increase of \$141,477 year over year. The primary change was an increase in staff with the hiring of a Clinical Trials Manager early in the fourth quarter of FYE 2015 to manage the execution of the COTI-2 Trial planned to start in the first quarter of FYE 2016. Recognition of the R&D team's efforts was also reflected in a grant of options in October 2015 to all employees with Share-based compensation recorded during the year of \$60,463.

The decrease in Drug development consulting of \$240,920 relates to the costs incurred for the COTI-2 IND submission in FYE 2015 that was filed late in fiscal 2015 and accordingly did not reoccur in FYE 2016.

#### b) General and Administration Expense ("G&A")

There were two areas of major expense reduction in G&A during FYE 2016 compared to FYE 2015. Professional fees decreased \$209,986 and the Company re-evaluated the estimated life of its molecules and accordingly reduced the rate of amortization resulting in a decrease in the expense of \$320,217. The combined decrease in these two categories of \$530,203 year over year was offset by increases in other expense categories primarily Share-based compensation, Salaries and benefits, and Other expense. Table 8 provides a breakdown of G&A expense by major expense type for FYE 2016 and FYE 2015.

Table 8: G&A Expense – Comparative Years Ended April 30

	FYE 2016	FYE 2015	Change
Professional fees	\$ 547,212	\$ 757,198	\$ 209,986
Salaries and benefits	480,432	393,338	(87,094)
Amortization	216,243	536,460	320,217
Marketing and travel	132,163	113,124	(19,039)
Other	83,304	45,857	(37,447)
Corporate governance	81,387	115,815	34,428
Insurance	62,214	57,187	(5,027)
Rent	40,800	40,515	(285)
	1,643,755	2,059,494	415,739
Share-based compensation	356,288	282,560	(73,728)
Total	\$ 2,000,043	\$ 2,342,054	\$ 342,011

The decrease in Professional fees year over year primarily reflects a decrease of \$345,491 in U.S. financial markets advisory services partially offset by an increase in other investor relations efforts.



Table 9 provides a comparison of the major expense categories grouped in Professional fees for the past two years.

Table 9: G&A Professional Fees

	FYE 2016	FYE 2015	Change
Investor relations	\$ 300,643	\$ 138,032	\$ (162,611)
Audit and accounting	101,744	86,308	(15,436)
Legal	99,144	86,066	(13,078)
Other	38,943	45,999	7,056
Business development	6,738	55,302	48,564
U.S. financial markets advisory	-	345,491	345,491
Total	\$ 547,212	\$ 757,198	\$ 209,986

The major consultant for U.S. financial markets advisory services was a U.S. investment bank operating under an agreement that provided a combination of cash and common share purchase warrants as compensation for their efforts. A fair value for the warrants granted in FYE 2015 was determined using a Black-Scholes valuation model in the amount of \$265,200 and this expense did not recur in FYE 2016 as reflected in the reduction in these fees.

The decline in business development consulting reflects a change in the timing and use of consultants during the respective years as business development consulting costs were captured in Sales and marketing expense during FYE 2016.

The year over year decrease in Amortization occurred as management reassessed the period over which future economic benefits would be realized for its purchased molecules classified as intangible assets. This reassessment occurred in Q1-FYE'16 following the settlement in May 2015 of contingent purchase consideration for \$250,502 that was recognized with an increase in the value of the molecules. The amortization period of the molecules had historically been 96 months commencing December 1, 2007. This period was based upon the original purchase agreement wherein if the contingent purchase consideration for the molecules was not paid by November 27, 2015, the molecules were required to be returned to the seller. Following the settlement, the Company reviewed the useful life and the expected pattern of consumption of the future economic benefits of the molecules and determined that the future economic benefits of the molecules were more appropriately reflected in the period remaining to the date of expiry of the patents granted for the respective molecules. This change in amortization commenced June 1, 2015.

The Share-based compensation increase of \$73,728 year over year was primarily related to a change in the Board of Directors ("Board") compensation plan that allowed them to take more of their compensation as share options ("Options") rather than cash, and the timing of these grants in the fiscal year compared to the prior year. This timing affects compensation expense recognition since all such grants made by the Company vest on a quarterly basis in arrears over a one year period from the date of the grant. Details for Share-based compensation for the respective years are set out in Table 10.



Table 10: Share-based Compensation in G&A – Comparative Years Ended April 30

	FYE 2016	FYE 2015	Change
Directors	\$ 312,265	\$ 224,825	\$ (87,440)
Employees	6,499	57,735	51,236
Consultants	37,524	-	(37,524)
Total	\$ 356,288	\$ 282,560	\$ (73,728)

The increase in Salaries and benefits relates primarily to salary increases for the senior officers of the Company that came into effect in January 2015 and thus were included in FYE 2016 for the full year as compared to approximately four months in FYE 2015.

Other expense increased \$37,447 year over year related primarily to \$50,351 in business expenses for the ROSALIND<sup>TM</sup> technology. These expenses consisted primarily of the design and creation of a ROSALIND<sup>TM</sup> web site and legal fees for the creation of user access agreements for the site.

### c) Sales and Marketing Expense ("S&M")

The Company's S&M activities are related primarily to business development efforts and support of these in communicating the science and commercial opportunity related to the Company's pipeline of molecules, primarily COTI-2, and its technologies, CHEMSAS® and ROSALIND™. Table 11 provides a breakdown of S&M expense by major expense type for FYE 2016 and FYE 2015. The increase of \$244,853 year over year reflects an increase primarily in Professional fees. This increase relates to the engagement of two consultants on annual contracts dedicated to business development efforts across a number of commercial revenue initiatives including licensing efforts for COTI-2.

Table 11: S&M Expense – Comparative Years Ended April 30

	FYE 2016	FYE 2015	Change
Marketing and travel	\$ 146,815 \$	140,365 \$	(6,450)
Professional fees	354,054	135,250	(218,804)
Salaries and benefits	15,915	9,136	(6,779)
Other	1,865	1,178	(687)
	518,649	285,929	(232,720)
Share-based compensation	12,133	-	(12,133)
Total	\$ 530,782 \$	285,929 \$	(244,853)

#### d) Investment Tax Credits ("ITC")

The Company uses contract research organizations for many of its scientific studies that are located in various jurisdictions both in Canada and internationally. As a general rule, only expenditures incurred in Canada qualify for the federal scientific research and experimental development ("SRED") program. For a public company such as COTI, ITC earned under this program are not refundable but rather are eligible as a tax credit against taxes payable, and to



the extent not used in the year earned can be carried forward to a future period. In addition to qualifying for the SRED program, the Company also can qualify for provincial ITC programs. Certain of these programs provide for refundable tax credits and COTI records ITC income earned in such situations. Gross ITC eligible expenditures for SRED increased from \$741,696 for FYE 2015 to \$917,531 for FYE 2016. Despite this increase, ITC income decreased \$16,271 year over year due primarily to changes in provincial eligibility rules.

### e) Interest and Financing Income (Expense)

The decrease of \$230,681 in interest and financing income (expense) relates primarily to two items as set out in Table 12. Both of these items relate to activities occurring in FYE 2015 that did not recur in FYE 2016.

Table 12: Interest and Financing Expense

Year ended April 30	2016	2015	Change
Interest income	\$ 15,780	12,768 \$	3,012
Finance costs:			
Interest expense	(2,764)	(62,609)	59,845
Bank charges	(1,423)	(1,613)	190
Private placement issuance costs allocated to warrant liability	-	(167,634)	167,634
	(4,187)	(231,856)	227,669
	\$ 11,593	\$ (219,088) \$	230,681

First, during FYE 2015, the Company issued warrants as part of an offering of units in a non-brokered private placement consisting of one common share of the Company and one warrant to purchase a common share. The warrants' exercise price is in USD. Under IFRS, a warrant with an exercise price in a currency other than the functional currency of the Issuer (in COTI's case CAD) is considered a derivative financial instrument and treated for accounting purposes as a warrant liability. Accordingly, the private placement issuance costs allocated to the warrants constituting the warrant liability were required to be expensed. The amount of these costs was \$167,634.

Second, the decrease in interest expense related primarily to a \$400,000 debenture issued in February 2014 that was repaid in FYE 2015. The amount expensed was for the direct interest cost incurred at a rate of 10% and the related accretion of the financing expense deferred at the issuance and subsequently amortized.

#### f) Change in Fair Value of Warrant Liability

The warrant liability is required to be measured at fair value in the Company's Statements of Financial Position. Accordingly, at each reporting date the liability is adjusted for any change in fair value using a currency translated option valuation model, which uses appropriate assumptions for the model at the respective valuation date. The key assumptions having the greatest effect on the valuation are: the estimated volatility, the USD-CAD foreign exchange rate, the estimated life of the warrants, and the market price of the Company's underlying common shares at the date of measurement. The table of



assumptions below highlights that the doubling of the market price of the Company's shares for the one year period from FYE 2015 to FYE 2016 had the greatest impact on the valuation increase in the liability of \$965,869.

Table 13: Key Assumptions of Warrant Liability Remeasurement

	Model Key Assumption	FYE 2016	FYE 2015
1	Estimated volatility	55.92 – 56.28%	78.42 – 78.62%
2	USD-CAD foreign exchange rate	1.2556	1.2077
3	Estimated life in years	2.96 -3.02	4.2 – 4.29
4	Market price in CAD at April 30	\$0.49	\$0.24
5	Exercise price in USD	\$0.34	\$0.34

## g) Foreign Exchange Gain

The swing of \$73,943 from a foreign exchange gain to a foreign exchange loss year over year is primarily explained by the closing of a private placement financing in March 2016 that was priced in CAD but where the gross proceeds were received in USD and subsequently invested in USD investments. As a result of holding the \$1.1m USD proceeds, the Company recorded an unrealized foreign exchange loss during this period due to the decline in the USD-CAD exchange rate since the private placement closed (April 30, 2016, 1 USD = 1.2584 CAD, March 29, 2016, 1 USD = 1.3203 CAD).



#### **Analysis of Financial Results Fourth Quarter Fiscal 2016**

Summary financial information for the comparative fourth quarter periods ended April 30, 2016, and 2015 (Q4-FYE'16 and Q4-FYE'15) is set out in Table 14.

Table 14: Summary Financial Information – Fourth Quarter Comparison

	Q4-FYE'16		Q4-FYE'15	Change
Expenses (income):				
Research and product development	\$ 459,507	\$	420,046	\$ (39,461)
Sales and marketing	115,012		94,668	(20,344)
General and administration	565,444		497,851	(67,593)
Investment tax credits	(55,868)		(17,836)	38,032
	1,084,095		994,729	(89,366)
Loss before finance income (expense)	(1,084,095)		(994,729)	(89,366)
Finance income (expense):				
Interest and financing, net	3,991		(165,911)	169,902
Change in fair value of warrant liability	(1,191,918)		235,120	(1,427,038)
Foreign exchange gain (loss)	(91,249)		(21,163)	(70,086)
	(1,279,176)		48,046	(1,327,222)
Loss and comprehensive loss	\$ (2,363,271)	\$	(946,683)	\$ (1,416,588)
Weighted average shares outstanding	133,890,985	1	17,272,583	
Loss per common share	\$ (0.018)	\$	(0.008)	

#### Revenue

There was no revenue generated for Q4-FYE'16 or the comparative period.

#### **Expenses**

As highlighted in Table 14, the expense increase of \$89,366 for the comparable quarters was related to increases in all three functional expense categories. These increases were partially offset by an increase in ITC income during the quarter.

#### a) R&D Expense

Table 15 provides a breakdown of R&D expenses by major expense type for the comparable quarterly periods Q4-FYE'16 and Q4-FYE'15, respectively.

The quarterly R&D expense increase year over year was primarily due to an increase of \$176,574 in Clinical trial expenses. Approval to move ahead with the COTI-2 Trial from the FDA was received in the latter part of May 2015 and accordingly there was no comparable expense in Q4-FYE'15.



The increase in Clinical trial expenses was partially offset by a reduction of \$157,469 in Synthesis and miscellaneous R&D expenses with much of this reduction related to consulting fees incurred in writing and conducting additional tests in support of the IND submission to the FDA which occurred late in Q4-FYE'15.

The change in Professional fees in the quarterly comparison resulted from a re-allocation in Q4-FYE'15 of certain consulting costs incurred for COTI-2 activities in prior reporting periods directly to Synthesis and miscellaneous R&D expenses for consistency with prior period reporting.

Table 15: R&D Expense – Fourth Quarter Comparison

	Q4-FYE'16	Q4-FYE'15	Change
Clinical trial expenses	\$ 176,574 \$	- \$	(176,574)
In vivo/in vitro testing	64,760	56,262	(8,498)
Synthesis and miscellaneous R&D expenses	43,621	201,090	157,469
	284,955	257,352	(27,603)
Salaries and benefits	134,448	129,171	(5,277)
Other	22,280	19,586	(2,694)
Share-based compensation	13,760	22,935	9,175
Professional fees	4,065	(8,998)	(13,063)
Total	\$ 459,507 \$	420,046 \$	(39,461)

#### b) G&A Expense

G&A expense increased \$67,593 year over year with the major change occurring in Amortization, which decreased \$84,365 compared to Q4-FYE'15. This decrease was offset by increases in all other categories but with the more significant increases in Salaries and benefits, Corporate governance, Share-based compensation and Other expense.

Table 16 provides a breakdown of G&A expenses by major expense type for the comparable quarterly periods Q4-FYE'16 and Q4-FYE'15, respectively.

Table 16: G&A Expense – Fourth Quarter Comparison

	Q4-FYE'16	Q4-FYE'15	Change
Professional fees	\$ 124,826	\$ 122,588	\$ (2,238)
Salaries and benefits	110,838	77,219	(33,619)
Share-based compensation	86,119	63,146	(22,973)
Other	63,497	6,500	(56,997)
Corporate governance	62,136	28,864	(33,272)
Amortization	50,673	135,038	84,365
Promotion and travel	42,748	40,372	(2,376)
Insurance	14,407	13,924	(483)
Rent	10,200	10,200	-
	\$ 565,444	\$ 497,851	\$ (67,593)



The decrease in Amortization as discussed in the "Financial Review of Full Year Operations" occurred as the Company changed the amortization rate on its molecules following a review of their estimated life. Molecule amortization was \$7,751 in Q4-FYE'16 compared to \$107,302 in Q4-FYE'15.

Other G&A expense changes included:

- an increase in Salaries and benefits reflecting a higher allocation of the President & CEO's activities to G&A rather than R&D compared to the functional allocation rates in Q4-FYE'15;
- an increase in Share-based compensation reflecting the awarding of share options to consultants in September and November 2015 that did not occur in the prior comparable period. In addition, there were two additional directors added to the Board during FYE 2016 than existed in Q4-FYE'15 resulting in an increase in director compensation;
- an increase in Other expense relating primarily to \$50,351 in business development expenses
  for the ROSALIND™ technology that were recognized in the quarter that did not occur in Q4FYE'15. As noted in the "Financial Review of Full Year Operations" these were predominantly
  for the ROSALIND™ website launched in March 2016; and,
- an increase in Corporate governance fees reflecting U.S. legal expenses incurred in complying
  with U.S. securities filings for various securities issued in the current and prior years, investor
  relations support software, and higher director fees paid in cash following the increase in the
  number of directors noted above.

#### c) S&M Expense

S&M expenses increased \$20,344 in Q4-FYE'16 compared Q4-FYE'15. Table 17 provides a breakdown of S&M expense by major expense types for the comparable quarterly periods Q4-FYE'16 and Q4-FYE'15, respectively.

The increase related primarily to Professional fees of \$39,230 reflecting the engagement of two consultants on annual contracts dedicated to business development efforts across a number of commercial revenue initiatives for which contracts were not in place during Q4-FYE'15.

Table 17: S&M Expense – Fourth Quarter Comparison

	Q4-FYE'16	Q4-FYE'15	Change
Professional fees	\$ 82,730	\$ 43,500	\$ (39,230)
Marketing and travel	32,084	41,743	9,659
Other	198	289	91
Salaries and benefits	-	9,136	9,136
Total	\$ 115,012	\$ 94,668	\$ (20,344)

The decrease in Marketing and travel expenses of \$9,659 in Q4-FYE'16 compared to Q4-FYE'15 reflects the timing of such expenses based upon the number of conferences attended as well as the number of



Company representatives participating at such forums in support of licensing and business development efforts.

The decrease of \$9,136 in Salaries and benefits reflects per diem fees paid to directors of the Company in consulting roles in support of business development efforts beyond their normal director duties which were incurred in Q4-FYE'15 that were not incurred in Q4-FYE'16.

#### d) Investment Tax Credits

ITC income increased \$38,032 in Q4-FYE'16 compared to Q4-FYE'15 related to an increase in the eligible R&D expenditures that qualified for refundable ITCs in the quarter compared to Q4-FYE'15.

#### e) Interest and Financing (Expense)

The decrease in Q4-FYE'16 compared to Q4-FYE'15, as noted in the "Financial Review of Full Year Operations", related primarily to the issuance costs allocated to the warrant liability being expensed for \$167,634 in that prior quarter.

## f) Change in fair value of warrant liability

As noted in the "Financial Review of Full Year Operations" the warrant liability must be revalued at each reporting period. The change in the assumptions for the Q4-FYE'16 period compared to Q3-FYE'16 were substantial as shown in Table 18 below. These significant changes in the quarterly assumptions had a major impact on the change in fair value of the warrant liability compared to Q4-FYE'15.

Table 18: Key Assumptions of Warrant Liability Remeasurement

	Model Key Assumption	Q4-FYE'16	Q3-FYE'16
1	Estimated volatility	55.92 – 56.28%	66.69 - 68.22%
2	USD-CAD foreign exchange rate	1.2556	1.4006
3	Estimated life in years	2.96 -3.02	3.63 – 3.75
4	Market price in CAD	\$0.49	\$0.27
5	Exercise price in USD	\$0.34	\$0.34

#### g) Foreign Exchange Gain (Loss)

The increased foreign exchange loss of \$70,086 during the quarter compared to Q4-FYE'15 related primarily to the holding of USD cash that on translation at the year-end, resulted in an unrealized holding loss from the change in the USD exchange rate, since the closing of a USD \$1.1m private placement on March 29, 2016, as discussed earlier.



#### **Financial Results Two Year Quarterly Summary**

Table 19 summarizes the financial results of the Company by quarter for the past two fiscal years.

Table 19: Summary of Quarterly Financial Results

FYE 2016	Q1	Q2			Q3	Q4			Full Year
	31-Jul 31-Oct			31-Jan	30-Apr				
Revenue	\$ -	\$	-	\$	-	\$	-	\$	-
Loss	(985,120)		(938,860)		(637,176)		(2,363,271)		(4,924,427)
Loss per common share (1) (2)	\$ (0.01)	\$	(0.01)	\$	(0.01)	\$	(0.01)	\$	(0.04)
FYE 2015	Q1		Q2		Q3		Q4	F	ull Year
	31-Jul		31-Oct		31-Jan		30-Apr		
Revenue	\$ -	\$	-	\$	-	\$	-	\$	-
Loss	(970,796)		(946,204)		(949,503)		(946,683)	(	3,813,186)
Loss per common share (1) (2)	\$ (0.01)	\$	(0.01)	\$	(0.01)	\$	(0.01)	\$	(0.04)

The Loss per common share calculated is for both basic and diluted.

The majority of the variation by quarter across the two years and quarterly year over year is explained by two functional expense categories, General and administration and Research and product development, as set out in Tables 20 and 21.

Table 20: Selected Quarterly Expense Categories FYE 2016 (1)

FYE 2016		Q1		Q2		Q3		Q4		Year
	31-Jul		31-Oct		31-Jan		30-Apr			to Date
General and administration	\$	400,302	\$	446,267	\$	317,861	\$	479,325	\$	1,643,755
Research and product development		287,773		337,889		371,513		445,747		1,442,922
Share-based compensation		77,834		69,021		182,150		99,879		428,884
Total of expense categories		765,909		853,177		871,524		1,024,951		3,515,561
Total expense for the quarter	\$	902,865	\$	969,786	\$	964,069	\$	1,084,095	\$	3,920,815
Expense categories as a % of total expense		84.8%		88.0%		90.4%		94.5%		89.7%

<sup>(1)</sup> The presentation noted in this table does not conform to the functional presentation in the Company's interim and annual financial statements. Share-based compensation included in the functional expense categories in the financial statements has been removed from the functional disclosure and shown separately in this table.

G&A expense peaked in the first quarter of FYE 2015 and declined through the balance of the year. The high level of G&A in the first quarter of FYE 2015 continued the trend from the fourth quarter of FYE 2014 and reflected the impact of consulting costs with a U.S. investment bank that were not incurred in the last three quarters of the year or in FYE 2016. R&D expense decreased sharply in the first quarter of FYE 2015 with the completion of the 28-day two-species toxicity testing for COTI-2 and then increased over the succeeding quarters as work continued toward the completion of an IND filing for COTI-2. This similar trend occurred in FYE 2016 with R&D expenses decreasing in the first quarter of FYE 2016

<sup>(2)</sup> The Loss per common share by quarter may not cross-add for the full-year as a result of changes in the number of common shares outstanding in the applicable period and used in the specific period calculation.



awaiting the approval of the IND filing with the FDA and then a gradual ramp up of costs as the planning of the clinical trial with the trial site and site investigator proceeded. On a total expense basis, these two categories declined as a share of overall costs in the first three quarters of FYE 2016 as S&M expense increased to support business development initiatives for COTI-2 and other potential revenue streams.

Table 21: Selected Quarterly Expense Categories FYE 2015 (1)

FYE 2015	Q1		Q2		Q3		Q4		Full Year
	31-Jul		31-Oct		31-Jan		30-Apr		
General and administration	\$	693,846	\$	512,570	\$	418,373	\$	434,705	\$ 2,059,494
Research and product development		234,841		355,101		345,520		397,111	1,332,573
Share-based compensation		24,928		28,860		165,626		86,081	305,495
Total of expense categories		953,615		896,531		929,519		917,897	3,697,562
Total expense for the quarter	\$	1,018,907	\$	987,533	\$	980,702	\$	968,477	\$ 3,955,619
Expense categories as a % of total expense		93.6%		90.8%		94.8%		94.8%	93.5%

The presentation noted in this table does not conform to the functional presentation in the Company's interim and annual financial statements. Share-based compensation included in the functional expense categories in the financial statements has been removed from the functional disclosure and shown separately in this table.

The variability in the comparable year over year quarters is primarily due to a higher level of spending in R&D activities throughout FYE 2016 and for G&A expenses in the first two quarters of FYE 2015 compared to FYE 2016. The increase in Share-based compensation in the third quarter of each fiscal year reflects the timing of share option awards typically granted at the October Board of Directors meeting following the Annual General Meeting and does not correlate to the changes in the other expense categories during these years.

#### **Liquidity and Cash Resources**

The Company's cash resources include cash, cash equivalents, and investments. Table 22 summarizes the changes in cash resources for FYE 2016 and FYE 2015. At FYE 2016, the Company had cash resources of \$4,729,924 compared to \$1,865,684 in cash resources at FYE 2015 reflecting an increase of \$2,864,240. The difference in the cash resources balances year over year primarily reflects the cash proceeds from a private placement closed on March 29, 2016, for gross proceeds of USD \$1.1m (CAD \$1,452,331) and the exercise of warrants expiring on April 29, 2016, for gross proceeds of \$992,900.



Table 22: Summary of Changes in Cash Resources (1)

	FYE 2016	FYE 2015
Used in:		
Operating activities	\$ (3,585,701) \$	(3,032,778)
Investing activities	(282,956)	(194,312)
Decrease in cash resources before financing activities	(3,868,657)	(3,227,090)
Proceeds from issuance of common shares and warrants	6,725,263	4,909,314
Costs of issuing common shares and warrants	(119,289)	(379,226)
Proceeds (repayment) of debenture	-	(400,000)
Costs of warrant amendments	-	(10,160)
Investment tax credit recoveries	116,408	119,031
Interest paid	(4,187)	(35,954)
Increase (decrease) in cash resources	2,849,538	975,915
Less: unrealized foreign exchange loss on capital resources	19,145	59,494
unrealized loss on market value of investments	(4,443)	-
Cash resources - beginning of period	1,865,684	830,275
Cash resources - end of period	\$ 4,729,924 \$	1,865,684

<sup>(1)</sup> See Use of Non-GAAP Financial Measures and Table 36

#### **Financing Activities**

#### 1. During FYE 2016

#### a) Private Placements

The Company entered fiscal 2016 with \$1,865,684 in cash resources. Additional funding was necessary to complete operational plans to progress COTI-2 into the clinical trial and to support additional follow-on R&D development programs. In this regard, the Company completed two non-brokered private placement financings with accredited investors during the year that generated gross proceeds of \$2,738,891 as summarized in Table 23 below. Cash issuance costs of \$115,542 associated with these private placements resulted in net proceeds from the financings of \$2,623,349.

Table 23: Summary of Fiscal 2016 Private Placement Equity Financings

<b>Closing Date</b>	Approximate	Number of	Warrant	Warrant Expiry
	<b>Gross Proceeds</b>	Gross Proceeds Warrants Issued		Term in Months
Jul 31, 2015	\$ 1,286,560	2,144,267	\$ 0.42	24
Mar 29, 2016	1,452,331	2,420,551	\$ 0.38	24
Total	\$ 2,738,891	4,564,818		

## b) Warrant Exercises

In addition to financing received from private placements during the year, the Company realized additional cash for operations of \$3,846,903 from the exercise of common share purchase warrants and compensation warrants as summarized in Table 24 below.



Table 24: Summary of Fiscal 2016 Warrant Exercises

	Number of		Share	
	warrants	Gross	issuance	Net
Warrant description	exercised	proceeds	costs	Proceeds
\$0.22 compensation	267,000	\$ 58,740	\$ (205)	\$ 58,535
\$0.26 common share	3,684,198	957,892	(597)	957,295
\$0.26 USD compensation	29,563	9,648	(169)	9,479
\$0.28 common share	3,620,119	1,013,633	(1,197)	1,012,436
\$0.29 compensation	19,539	5,666	(38)	5,628
\$0.30 common share	5,963,750	1,789,125	(1,123)	1,788,002
\$0.315 compensation	49,500	15,593	(65)	15,528
	13,633,669	\$ 3,850,297	\$ (3,394)	\$ 3,846,903

The Company also realized net proceeds of \$27,286 from the exercise of 60,739 warrants whose exercise price is denominated in USD and that are accounted for as a warrant liability prior to exercise.

## c) Share Option Exercises

A final source of cash during the year came from the exercise of 662,016 share options for net cash proceeds of \$108,599 as summarized in Table 25 below.

Table 25: Summary of Fiscal 2016 Share Option Exercises

	Number of		Т	ransfer from	Share	
Exercise	Options	Gross		contributed	issuance	Increase in
 Price	exercised	proceeds		surplus	costs	share capital
\$ 0.160	100,000 \$	16,000	\$	10,536	\$ 48	\$ 26,584
\$ 0.165	562,016	92,733		72,500	(183)	165,050
	662,016 \$	108,733	\$	83,036	\$ (135)	\$ 191,634

## 2. Subsequent to FYE 2016

The Company realized gross proceeds of \$1,607,542 from the exercise, on various dates subsequent to the year-end, of 5,438,266 common share purchase warrants and 270,660 compensation warrants to support operations including the Phase 1 clinical trial for COTI-2 and other Company initiatives. Summary details of these exercises are set out in Table 26.



Table 26: Warrant Exercises Subsequent to FYE 2016

		Number of	
		warrants	Gross
Warrant description	Expiry date	exercised	proceeds
\$0.22 compensation	Jun 2, 2016	194,110	\$ 42,704
\$0.26 compensation	Nov 25, 2019	64,450	21,725
\$0.28 common share	Jun 2, 2016	5,331,266	1,492,754
0.315 compensation	Jul 30, 2017	12,000	3,780
\$0.34 USD common share	Oct 17 - Nov 6, 2019	107,000	46,579
		5,708,826	\$ 1,607,542

## **Future Financing**

The Company has 22,163,113 warrants outstanding as set out in Table 35, Outstanding Share Information, below at the date of this MD&A. All of these warrants are currently in-the-money as they were at year-end. Certain of these warrants contain a trigger provision that provides the Company with the discretionary ability to accelerate the expiry date to a period of 21 days, if for any ten consecutive trading days during the unexpired term of the warrants (the "Premium Trading Days"), the closing price of the common shares on the TSXV equals or exceeds three times the exercise price set out in the warrant certificate. If this occurs, the reduced exercise period of 21 days will begin seven calendar days after the tenth Premium Trading Day. Any warrants not exercised during this reduced exercise period will expire.

To the extent these warrants are exercised will be a function of the market price of the Company's underlying common shares and investor perspectives on the opportunity for shareholder value creation over the investment time horizon for each individual investor. Management believes that continued achievement of milestones, particularly in the development of COTI-2, will be supportive of an increase in shareholder value and will provide the Company with an opportunity to realize funding from a portion of these outstanding warrants in fiscal 2017. Table 27 sets out the warrants outstanding that have, and do not have, a trigger provision, and the potential financing available from their exercise.

Table 27: Summary of Outstanding Warrants and Potential CAD Proceeds

Price	Warrants	CAD Proceeds
Trigger	18,497,333	\$ 7,631,558
No trigger	3,769,230	917,288
	22,266,563	\$ 8,548,846

Table 28 sets out the market prices where the trigger price would be reached for those warrants that have an acceleration clause that would force exercise.



Table 28: Warrants with Accelerated Expiry Dates and Estimated Trigger Prices

	Ex	cercise	Exercise		<sup>(1)</sup>	Estimated		
		Price	Currency	# of Warrants	Trigger Price		CAI	O Proceeds
Compensation Warrants	\$	0.29	CAD	162,811	\$	0.8700	\$	47,215
Compensation Warrants	\$	0.315	CAD	108,120	\$	0.9450		34,058
Compensation Warrants (1)	\$	0.26	USD	525,189	\$	0.9816		171,833
Warrants	\$	0.38	CAD	5,519,925	\$	1.1400		2,097,572
Warrants	\$	0.42	CAD	2,144,267	\$	1.2600		900,592
Warrants <sup>(1)</sup>	\$	0.34	USD	10,037,021	\$	1.2836		4,380,288
Totals				18,497,333			\$	7,631,558

Note: <sup>(1)</sup> These estimated trigger prices were calculated based upon the closing price of the USD-CAD exchange rate at April 30, 2016. These trigger prices will vary based upon fluctuations in this conversion rate.

As the extent and timing of warrant exercise as a source of financing is uncertain, the Company continues to look at alternative financing sources to support operations going forward and particularly the completion of the COTI-2 Trial that drives significant future revenue potential from COTI-2. The current focus in this regard is on private placements with U.S.-based accredited and institutional investors.

#### **Investing Activities**

Investing activities in FYE 2016 consisted of the purchase of \$32,578 in computer equipment (FYE 2015 – \$16,543), \$177,552 in computer software (FYE 2015 – \$79,376), and \$72,826 in patent costs (FYE 2015 – \$98,393). The investment in computer software included \$88,811 for an electronic data capture system used in the COTI-2 Trial to record, track, and analyze the patient test data. Investment in such items will continue into the future as the Company relies heavily on computing technology to run its CHEMSAS® process and ROSALIND™ technology, and investing in patents for the molecules identified from the process ensures that the value of this intellectual property is protected for generating future licensing revenue. At FYE 2016, the Company had 21 patents granted and 12 patents pending in various jurisdictions with a carrying value of \$785,958 (FYE 2015 – \$746,998). A summary related to these patents appears in Table 29.



Table 29: Summary of Patent Investments

Patents	Therapeutic Target	April 30, 2016	Ар	ril 30, 2015
Granted:				
COTI-2	Oncology	239,201	\$	200,464
COTI-219	Oncology	7,554		8,104
COTI-4	Oncology	33,008		35,313
HIV	HIV	14,237		14,980
Three compounds	Acute myelogenous leukemia	114,331		127,379
		408,331		386,240
Pending:				
COTI-2	Oncology	123,662		139,037
COTI-4	Oncology	90,748		80,848
Other	Various indications/technologies	163,217		140,873
	<u> </u>	377,627		360,758
Total patents	Ş	785,958	\$	746,998

The Company conducts periodic reviews of its tangible and intangible assets for impairment indicators, including its most recent analysis at FYE 2016 to ensure the carrying value of these assets (equipment, molecules, patents, and computer software) are not impaired. Management determined there were no impairment indicators affecting the carrying values of these assets at FYE 2016.

#### **Working Capital**

The Company had Adjusted Working Capital at FYE 2016 of \$4,602,044 compared to \$1,591,160 at FYE 2015 (see Table 37). The Company defines Adjusted Working Capital as the standard working capital calculation adjusted for non-cash liabilities. This definition is a non-GAAP financial measure and does not have a prescribed meaning under IFRS and therefore may not be comparable to similarly described measures when presented by other issuers. Details concerning the calculation of this working capital measure can be found under the discussion concerning Use of Non-GAAP Financial Measures.

Cash equivalents are invested in money market instruments with maturities of three months or less. The investments consist of guaranteed investment certificates and provincial government USD stripped bonds, which can be readily converted to cash. Details of these investments appear in Table 30 below.



Table 30: Summary of Investments

	Fiscal Year	Effective		ed	
Investment description	of Maturity	interest rate	Cost	Gain / (Lo	ss) Fair value
Guaranteed investment certificates	2017	0.95 - 1.4%	\$ 1,415,000	\$ 3,0	59 \$ 1,418,059
	2018	1.40%	500,000		500,000
Canadian provincial government USD stripped bonds:					
Province of British Columbia	2018	1.04%	125,581	(1	.91) 125,390
Province of British Columbia	2019	1.44%	125,623	(5	01) 125,122
Province of Manitoba	2020	1.82%	423,126	(3,7	(51) 419,375
Total			\$ 2,589,330	\$ (1,3	84) \$ 2,587,946

Current assets increased to \$5,431,410 at FYE 2016 from \$2,126,755 at FYE 2015 for an increase of \$3,304,655 primarily due to an increase in Cash Resources. Current liabilities increased \$996,217 to \$2,952,384 at FYE 2016 from \$1,956,167 at FYE 2015 primarily due to the accounting for the warrant liability that increased \$952,948. 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. 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 limited risk that future settlement amounts will differ from carrying values.

The Company had commitments at the year-end to pay for the completion of work primarily under research and development contracts related to the Company's Phase 1 clinical trial for COTI-2 in gynecologic cancers. Payment timing of clinical trial costs is subject to the actual timing of trial activities such as the enrollment of patients, completion of patient testing, and administration of drug, as well as the negotiated payment terms with the trial site. The Company currently expects the clinical trial to conclude at the end of December 2017. Summary details of the estimated timing of the Company's commitments are set out below.

Table 31: R&D Commitments

		Years ending April 30						
			2017		2018		2019	Total
COTI-2:								
	Clinical trial costs	\$	824,502	\$	552,182	\$	-	\$ 1,376,684
	Other preclinical		72,136		39,526		4,407	116,069
			896,638		591,708		4,407	1,492,753
Other mol	ecules		88,660		-		-	88,660
Other non	-R&D consulting contracts		102,711		-		-	102,711
Total		\$ :	1,088,009	\$	591,708	\$	4,407	\$ 1,684,124



## **Off-Balance Sheet Arrangements**

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

#### **Foreign Exchange Exposure**

The Company has historically had occasion to enter into R&D contracts denominated in foreign currencies. These contracts have primarily been in United States dollars ("USD") but have also included Euros ("EUR"), British pound sterling ("GBP") and Swiss Francs ("CHF") and, as a result, the Company has exposure to risk from fluctuations in exchange rates between the CAD and such currencies. Up to the end of fiscal 2015, these foreign currency contracts had individually been valued at less than \$150,000 CAD. As exposure was not significant, the Company has not used derivative instruments to reduce its exposure to this foreign currency risk.

The Company completed a financing in the fall of 2014 that was priced in USD and was partially settled in USD. These USD funds provided some natural hedging against changes in the USD and on the Company's USD expenditures in fiscal 2016 up to the end of November 2015. In December 2015, the Company purchased \$200,000 USD at a rate of 1.3825 CAD to cover its forecast USD expenditures in the succeeding quarter and provide certainty of cost in the face of increasing CAD weakness.

During Q4-FYE'16, as in prior fiscal 2016 quarters, the Company's foreign exchange exposure was related primarily to the USD with some modest exposure to CHF (CAD  $\sim$  \$129k). The Company raised USD \$1.1m in financing on March 29, 2016, which provides some natural hedging against its future USD expenditures related to the Phase 1 clinical trial. These clinical trial costs will occur over an estimated 18 month period and are expected to be in the range of USD \$736,000 – \$1,211,000.

The USD/CAD exchange rate was quite volatile from January 31, 2016 (1.4006) to April 30, 2016 (1.2548). At the time of closing the March financing the rate was 1.3203. As a result of investing the proceeds of the March financing, the Company incurred an unrealized foreign exchange holding loss from these investments which is a major part of the loss reflected at the year-end.

As for future exposure, the Company has warrants outstanding and exercisable at USD prices that could generate USD proceeds to the Company. The amount and timing of such exercise is not presently determinable. In addition, the Company has been focusing on U.S.-based investors for future financings that could provide USD funds and a further hedge for the Company's USD expenditures. Because of these exposures, variations in foreign exchange rates could cause some fluctuation in the Company's operating results and cashflow, however, management does not expect the changes in foreign exchange will have a material impact on operations.

The Company's exposure to foreign currency risk based upon foreign currency amounts expressed in CAD at FYE 2016 is set out in Table 32 below. Excluding the currency impact of the warrant liability, which is a liability not settled in cash, a 5% strengthening of the CAD against the USD at April 30, 2016 would have increased the Company's loss by approximately \$57,000 (2015 – \$20,000). A 5% weakening of the CAD against the USD at those dates would have had the equal but opposite effect assuming all other variables remain constant.



Table 32: Foreign Exchange Balances Held

As at April 30, 2016				
	CAD	USD	Other	Total
Cash and cash equivalents	\$ 1,498,467	\$ 643,372	\$ 139	2,141,978
Investments	1,918,174	669,772	-	2,587,946
Other receivables	2,122	-	-	2,122
Accounts payable and accrued liabilities	(592,868)	(180,731)	(20,655)	(794,254)
Warrant liability	-	(2,123,018)	-	(2,123,018)
	\$ 2,825,894	\$ (990,605)	\$ (20,516)	5 1,814,773

## **Related Party Transactions**

Related party transactions of a material amount that occurred in the current and prior year are set out under selected headings below.

#### a) Share-based compensation

Table 33 sets out the amount of share-based compensation for option grant transactions with related parties that occurred during FYE 2015 and FYE 2016 based upon the total fair value of each option grant at the date of the transaction using a Black-Scholes valuation model and the model input assumptions applicable at the time of the grant.

Table 33: Share-based Compensation Affecting Related Parties

Relationship	nship Description of Transaction		ount
		FYE 2015	FYE 2016
Directors	September 9, 2014, 481,483 Options expired	\$ -	
Directors	October 22, 2014, 1,191,099 Options granted (1)	235,242	
Officers	October 22, 2014, 200,000 Options granted (2)	\$ 51,837	
Director	May 13, 2015, 104,350 Options granted (3)		\$ 17,426
Directors	October 15, 2015, 1,451,611 Options granted (4)		267,000
Director	October 27, 2015, 135,659 Options expired		-
Directors	October 26-27, 2015, 562,016 Options exercised <sup>(5)</sup>		72,500
Director	November 30, 2016, 100,000 Options exercised <sup>(6)</sup>		10,536
Director	January 8, 2016, 147,850 Options granted (7)		\$ 24,839

On October 22, 2014, 1,191,099 Options were granted to the Board as retainer compensation for directorship responsibilities. The Options have a five-year life and an exercise price of \$0.29 with 25% vesting at the end of each quarter from the date of grant.

On October 22, 2014, 200,000 Options were granted to the Officers of the Company. The Options have a five-year life and an exercise price of \$0.29 with 25% vesting at the end of each quarter from the date of grant.



- On May 13, 2015, 104,350 Options were granted to a director as retainer compensation for directorship responsibilities. The Options have a five-year life and an exercise price of \$0.29 with 25% vesting at the end of each quarter from the date of grant.
- On October 15, 2015, 1,451,611 Options were granted to the Board as retainer compensation for directorship responsibilities. The Options have a five-year life and an exercise price of \$0.305 with 25% vesting at the end of each quarter from the date of grant.
- On October 26 and 27, 2015, 562,016 Options were exercised by various directors at an exercise price of \$0.165.
- On November 30, 2015, 100,000 Options were exercised by a director at an exercise price of \$0.16.
- On January 8, 2016, 147,850 Options were granted to a director as retainer compensation for directorship responsibilities. The Options have a five-year life and an exercise price of \$0.305 with 25% vesting at the end of each quarter from the date of grant.

### b) Share equity and other transactions

Details related to the FYE 2016 private placements are described under Liquidity and Cash Resources. The share purchases by related parties who participated in a private placement were measured at the exchange amount consistent with all other participants in the private placements. Related party participation in private placements and other transactions during FYE 2015 and FYE 2016 are summarized in Table 34.

Table 34: Share Equity and Other Transactions

Relationship	Description of Transaction	Amount	
		FYE 2015	FYE 2016
Director	October 17, 2014, participated in a private placement acquiring 119,500 units representing 6% of the total private placement (1)	\$ 30,995	
Director	November 6, 2014, participated in a private placement acquiring 159,110 units representing 3% of the total private placement <sup>(1)</sup>	41,814	
Director	November 25, 2014, participated in a private placement acquiring 95,000 units representing 3% of the total private placement <sup>(1)</sup>	24,586	
Directors and officers	March 31, 2015, 103,673 \$0.37 warrants expired	-	
Directors and officers	March 31, 2015, 84,897 \$0.55 warrants expired	-	
Directors and officers	April 23, 2015, 243,750 \$0.30 warrants expired	ı	
Director	July 31, 2015, participated in private placement acquiring 60,000 units representing 2.8% of total private placement (2)		\$ 8,000
Officer	January 13, 2016, 35,800 \$0.26 warrants exercised (3)		9,308
Director and officer	March 15-16, 2016, 50,000 \$0.30 warrants were exercised (3)		15,000
Director	Consulting agreement service payments (4)	\$ 8,097	\$ 36,650



- The Company completed a private placement in three tranches closing October 17, November 6, and November 25, 2015, respectively. A director participated in the private placement with a gross investment in the three tranches of \$97,395 on the same terms and conditions as all other investors.
- (2) The Company completed a private placement in two tranches closing on June 29 and July 31, 2015. A director participated in the private placement with a gross investment of \$18,000 on the same terms and conditions as all other investors.
- Warrants held by certain key personnel to acquire 85,800 common shares arising from various private placements were exercised for \$24,308.
- The Company engaged a human resource-consulting firm under a contract at standard market terms. The President of the consulting firm is related to a director of the Company. Fees and expenses paid or accrued for services rendered in the year were \$36,650 (2015 \$8,097).

#### c) Contingent transactions

Upon the purchase of a library of molecules 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 was payable upon the first occasion any molecule achieved one of the following milestones:

- (i) when the Company was given notification of acceptance of an IND and an IND acceptance number was received; or,
- (ii) when either the United States or the European patent authorities issued the Company a final patent.

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

In 2012, the Company received a patent from the United States Patent and Trademark Office for a U.S. patent filing related to COTI-2. COTI-2 is a molecule from the SCLC library acquired under the purchase. Upon receipt of the patent, the Company issued 715,720 common shares to the former owners of the SCLC library (which includes the Company's current Chairman and the current President and CEO) representing one-half of the contingent consideration for meeting the milestone of the issuance of a final patent in either the U.S. or Europe. The fair market value of the share consideration issued was \$164,616 as determined upon issuance.

On May 22, 2015, the FDA advised the Company that it had completed its review of the Company's IND application for COTI-2. The IND was granted and enabled the Company to proceed with its proposed clinical investigation. This grant satisfied the second milestone for COTI-2, being notification of acceptance of an IND and issuance of an IND acceptance number. Accordingly, on May 26, 2015, the Company issued 715,720 common shares as final payment of the contingent share consideration that



arose from the acquisition. This consideration had a fair value of \$250,502 based upon the closing market price of the Company's shares on May 22, 2015, the date of the grant.

#### d) Amounts due to related parties

At April 30, 2016, there were directors' fees payable of \$5,104 (2015 – \$1,422) and accrued salaries, benefits, and outstanding vacation pay owing to Executives of \$113,829 (2015 – \$85,777).

## **Outstanding Share Information**

Outstanding share information at the close of business on July 28, 2016 is set out in Table 35.

Table 35: Outstanding Share Information

	Outstanding	Expiry Date
Common shares		
Authorized - unlimited		
Issued	148,346,123	
Diluted (1)	180,827,556	
Weighted average outstanding (2)	130,960,465	
Common share warrants		
\$0.42 half warrants	2,144,267	Jun 28/17 - Jul 30/17
\$0.315 compensation warrants	96,120	Jun 28/17 - Jul 30/17
\$0.38 half warrants	2,420,551	Mar 29/18
\$0.26 warrants	769,230	Feb 4/19
\$0.19 USD compensation warrants	3,000,000	Apr 11 - Jun 6/19
\$0.34 USD warrants (3)	10,010,021	Oct 16 - Nov 24/19
\$0.26 USD compensation warrants	460,739	Oct 16 - Nov 24/19
\$0.38 warrants	3,099,374	Dec 18/19 - Feb 16/20
\$0.29 compensation warrants	162,811	Dec 18/19 - Feb 16/20
	22,163,113	
Common share stock options		
\$0.14 - \$0.25	2,609,995	Oct 27/15 - Mar 19/20
\$0.26 - \$0.44	4,658,325	Sep 26/16 - Apr 25/21
\$0.45 - \$0.72	3,050,000	Jul 4/21 - Jul 16/21
	10,318,320	

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

## **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 has historically operated in the discovery and preclinical development stages of the

<sup>(2)</sup> Weighted average shares outstanding calculated from May 1, 2015 to the close of business on July 28, 2016.

<sup>(3)</sup> See Use of Non-GAAP Financial Measures



drug development cycle but moved into the Phase 1 clinical stage during Q3-FYE'16 with the signing of the CTA with MD Anderson in December 2015. 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 R&D collaboration agreements for others. The major industry and economic risk factors affecting realization of this potential were reviewed in detail in the Company's 2014 Annual Information Form. Those risk factors most significant to the Company during fiscal 2016 and for the year ahead are discussed below as follows:

- 1. going concern risk;
- 2. uncertainties related to research;
- 3. clinical trial risks;
- 4. the lack of revenues;
- 5. securing licensing agreements;
- 6. access to capital; and,
- 7. foreign currency exposure.

#### Going Concern Risk

The Company has formulated goals for the upcoming year to advance the Phase 1 testing of COTI-2 to enhance its attractiveness to potential licensees and to move other revenue initiatives and development projects forward as resources permit. For COTI, the material uncertainties discussed under "Liquidity and Cash Resources" and as specifically highlighted in note 3 of the Financial Statements raise significant doubts about the ability of the Company to accomplish its goals. These conditions highlight that the Company has not yet established commercial operating revenues to fund its operations and accordingly operating cash flows continue to be negative.

In order to accomplish its goals, the Company is taking steps to obtain additional cash resources as described under Financing above. The Company has discretion with many of its expenditure activities and plans to responsibly manage these activities in FYE 2017 within the limits of available cash resources. While the Company has a history of obtaining financing, there is no certainty that sufficient funding can be obtained that will enable the Company to alleviate the going concern risk in future periods.

## **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. Development of compounds may require further investigation into the MOA where this is not fully understood as many compounds have multiple MOAs. The discovery of unexpected toxicities, lack of sufficient efficacy, poor physiochemical properties, unacceptable ADME properties (absorption, distribution, metabolism, and excretion) and pharmacokinetics, inability to increase the scale of manufacture, lack of market attractiveness, regulatory hurdles, as well as other factors, may make COTI's therapeutic targets, or product candidates, unattractive or unsuitable for human use and COTI may abandon its commitment to that program, target, or product candidate. COTI believes its CHEMSAS® process serves to mitigate or reduce these risks compared to traditional historic approaches or other new computational approaches by virtue of profiling across many variables in identifying compounds with high probability of successfully becoming drugs, however, its predictions remain a probability only, and even at a very high probability there is an error rate such that failure can occur. Despite these uncertainties, COTI's lead compound, COTI-2, progressed through preclinical testing, received a grant to proceed to a Phase 1 clinical trial in Q1-FYE'16, and commenced patient treatment early in Q4-FYE'16. This success to date was predicted by CHEMSAS®.

These uncertainties and the attendant delays were experienced by COTI with its lead compound, COTI-2, during Q2 and Q3-FYE'16. Although the IND grant to proceed with the clinical trial was received on May 22, 2015, the internal review and approval process for a clinical trial agreement with MD Anderson proved to be a logistical challenge to navigate resulting in delays and revised target dates for actually commencing to treat patients. Despite these delays, COTI-2 entered into the Phase 1 clinical trial in Q4-FYE'16. Success in this clinical trial will provide further support for the scientific validation of the CHEMSAS® technology platform's predictions but it is such delays that can affect the timing of achieving profitable operations and cause a continual need to seek financing.

#### Clinical Trial Risks

Clinical trials are very expensive, time-consuming and difficult to design, implement and successfully execute. There are many risks associated with clinical trials that are responsible for this, some of which include:

- a) the extensive regulatory requirements from government authorities;
- the rigorous requirements of clinical investigator institutions whose protocols are intended to protect the patient but also the investigating institution from liability associated with trial failures and compliance with government regulations;
- c) the failure of trial compounds to achieve the targeted safety and efficacy endpoints of the trial during, and at completion of the trial;
- d) the potential suspension of our clinical trial by regulatory officials at any time if it appears that we are exposing participants to unacceptable health risks;



- e) the substantial periods of time necessary to complete the trial that cannot be easily predicted or controlled due to unknown or unexpected events involving patients and other external factors such as; weather affecting a patient's ability to attend for dosing, or, statutory holidays affecting the start date of a cohort;
- f) the potential for failure at any stage of the trial due to the occurrence of unacceptable toxicities or other unforeseen safety issues;
- g) the potential for problems being encountered during the trial that cause the Company to repeat parts, or all of the trial, or even abandon the trial;
- h) the occurrence of slower than expected rates of patient enrollment; and,
- i) the inability to monitor trial participants receiving an oral treatment taken on an out-patient basis adequately, during or after dosing.

In summary, our clinical trials may fail to produce successful results or could be suspended due to unacceptable safety risks, which could cause our trial to fail and which event could have severe consequences for the business.

#### **Lack of 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 its inception to April 30, 2016, 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. While collaborative agreements on CHEMSAS® projects to discover compounds for some partners have been undertaken in the past, the Company has not yet entered into a licensing agreement for one of its compounds. The continued development of COTI-2 and the nurturing of relationships with licensees concerning the strong scientific test results for the compound are critical to achieving a revenue realization stage that is expected to be based upon having positive human test data as to toxicity and efficacy. Accordingly, operating losses are expected to be incurred until revenues from upfront licensing, milestone, and royalty payments are sufficient 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. Without generating revenues and positive cash flows the Company will continually need to seek additional financing until such time as profitable operations occur.

## Securing Adequate Licensing Agreements

The Company's ability to commercialize its products successfully will depend on its ability to negotiate licensing agreements with biotech or Pharma companies for its compounds. This will first require meeting the scientific due diligence requirements of prospective customers. While continued positive test results for COTI-2 during the quarter and throughout fiscal 2016 generated positive feedback from potential licensees, these test outcomes have not translated into a contractual agreement to date.



Licensing discussions during fiscal 2016 continued to find interest in the compound but the novel nature of the compound and class has caused licensees to seek further proof of the MOA through test results in humans. Positive results in the Phase 1 human testing are expected to provide the risk reduction data that will make licensing attractive to potential licensees.

Industry reviews of pharmaceutical industry productivity in generating new compounds have not been favourable. This is based upon the high level of R&D spending by major pharmaceutical companies compared to their discovery of new compounds that go on to become approved drugs. This is based upon the number of new drugs produced relative to the amount of R&D dollars invested. Despite this industry performance, there is no certainty that licensing deals can be negotiated for COTI-2 or COTI's other compounds. Major pharmaceutical companies are seeking assets with as low a risk profile as possible, hence a preference for later stage clinical compounds with lower risk profiles having successfully reached as far as, or through, Phase 3 clinical trials. While it may seem a reasonable strategy for a major pharmaceutical company to have a drug development pipeline across the entire development cycle there is no certainty that COTI can be a licensed provider of compounds to the preclinical or early clinical stage segment of such a pipeline. There is also no certainty that COTI can obtain licensing terms that are acceptable in indicating a commercially viable market for its products.

#### 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. These efforts were highlighted under "Liquidity and Cash Resources" where the Company noted the continuing need to raise financing to support project development until a revenue event can provide sufficient operating cash flows to sustain the business. 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. Despite the Company's financing efforts, there can be no assurance that additional funding can be obtained.

#### Foreign Currency Risk

Foreign currency risk is the risk that the fair values of future cash flows of a financial instrument will fluctuate because they are denominated in currencies that differ from the respective functional currency of the Company. The Company is also exposed to foreign currency risk as a result of financial assets, liabilities and investments being denominated in a foreign currency. For COTI this is primarily related to the USD but to a lesser extent includes the Euro and Swiss franc. The effect of this risk on operations for fiscal 2016 was discussed at "Foreign Exchange Exposure". The Company's clinical trial is being conducted at U.S sites under clinical trial agreements that require payment for these services in USD. Accordingly, the Company is exposed to foreign exchange risk on its payments for these services. The Company also holds USD investments whose values in CAD fluctuate with the underlying exchange rates and could affect the amount of CAD cash realized compared to the value of such investments as



determined at the Company's year-end. The Company does not currently formally hedge its exposure to fluctuations in foreign exchange rates.

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

Management has included two non-GAAP financial measures, first Cash Resources and second, Adjusted Working Capital, to supplement information contained in this MD&A. These non-GAAP measures do not have any standardized meaning prescribed under IFRS and therefore may not be comparable to similar measures when presented by other issuers.

#### 1. Cash Resources

The Company looks at its available cash for operations on the basis of all Cash Resources, which is defined by the Company as the sum of its cash, cash equivalents, and investments. This differs from IFRS disclosure in the Company's financial statements where Cash is defined as cash and cash equivalents. The essential difference therefore is the inclusion of investments in the Company's view of cash available for operations. Under IFRS, an investment made with a maturity greater than 90 days at the date of purchase is considered an investment characterized under a hierarchy by its intended use and thus not included in cash and cash equivalents. The investments at FYE 2016 consisted of guaranteed investment certificates and provincial government stripped bonds. These investments can be readily cashed and the Company has treated these for accounting purposes as "held for trading" under the hierarchy reflecting the expectation that they would be used in operations during the upcoming year when the need arises. With high liquidity characteristics, management considers such investments as a readily available source of cash for operations. The decision by management to earn higher returns on cash balances by investing in securities readily converted to cash where the Company's cash flow projections determine such funds would not be needed in shorter time frames is not viewed by management as a basis for exclusion in its view of cash. Accordingly, management believes the inclusion of the investments as part of Cash Resources provides more meaningful information with respect to the liquidity of the Company and the cash available for operations.

Table 36: Reconciliation to Cash

	April 30, 2016		April 30, 2015	
	Cash per MD&A	Cash per Financial Statements	Cash per MD&A	Cash per Financial Statements
Cash and cash equivalents	\$2,141,978	\$2,141,978	\$1,599,220	\$1,599,220
Investments	2,587,946	-	266,464	-
Cash	\$4,729,924	\$2,141,978	\$1,865,684	\$1,599,220



#### 2. Adjusted Working Capital

The Company uses Adjusted Working Capital in its monitoring and review of cash required for operations. Adjusted Working Capital is defined as the standard working capital calculation adjusted for non-cash liabilities as set out in Table 37.

The standard working capital calculation results in a lower amount of working capital than what the Company measures as working capital. This happens as the accounting under IFRS for warrants issued with an exercise price denominated in USD requires these warrants to be accounted for as a warrant liability.

During FYE 2015, the Company completed a private placement financing of units in three tranches consisting of one common share and one warrant. The 10,177,760 warrants issued had an exercise price of USD \$0.34. As this exercise price was not the functional currency of the Company, the warrants were required to be presented as a "warrant liability" on initial recognition rather than equity if they had been issued in the functional currency of the Company. At each subsequent reporting date, the warrants are measured at their fair value and the change in fair value is recognized through profit or loss.

When such warrants are exercised by the warrant holders the warrant liability will be reduced and the related amount transferred to equity reflecting the accounting treatment were these warrants to have been issued originally with a CAD exercise price. For emphasis, this warrant liability represents warrants denominated with a USD exercise price which if exercised will bring in cash to the Company and accordingly represent a "liability not settled in cash".

In addition to the non-cash impact of the warrant liability in FYE 2015, the Company accrued the fair value of \$250,502 for common shares of the Company to be issued in settlement of contingent consideration as discussed under Related Parties – Contingent transactions.

Thus, the Company uses Adjusted Working Capital to reflect the reality of the Company's working capital position as it relates to liabilities where the Company has an actual legal expectation to issue cash in settlement.

Table 37: Adjusted Working Capital

	April 30, 2016	April 30, 2015
Amounts per financial statements:		
Current assets	\$5,431,410	\$2,126,755
Current liabilities	2,952,384	1,956,167
Working capital	2,479,026	170,588
Adjustment for non-cash items:		
Warrant liability	2,123,018	1,170,070
Contingent share consideration on IND grant	-	250,502
	\$4,602,044	\$1,591,160



### **Changes in Accounting Policies**

Details regarding the adoption of new accounting pronouncements in FYE 2016 and future accounting policy changes affecting FYE 2017 based upon new accounting pronouncements are set out below.

## a) Adoption of new accounting pronouncements:

The IASB issued new standards and amendments or interpretations to existing standards that were effective for the Company's fiscal year beginning May 1, 2015. Of the new or amended pronouncements, there were only two standards applicable to the Company's operations and these were adopted during the year with no material impact on the financial statements as described below.

- (i) Definition of "vesting condition" in IFRS 2 Share-based payments; and,
- (ii) Measurement of short-term receivables and payables; and scope of portfolio exception in IFRS 13 Fair Value Measurement.

#### b) Recent accounting pronouncements not yet adopted:

Certain pronouncements have been issued by the IASB or the International Financial Reporting Interpretations Committee that are mandatory for annual periods beginning subsequent to the April 30, 2016 year-end. Many of these updates are not applicable to COTI or are inconsequential to the Company and have been excluded from the discussion below. Those new or amended standards that may affect the Company for the financial reporting year ended April 30, 2017, are set out below. The Company does not expect the amendments to have a material impact on the financial statements.

#### (i) IAS 1 - Presentation of Financial Statements

On December 18, 2014, the IASB issued amendments to IAS 1 as part of its major initiative to improve presentation and disclosure in financial reports. The amendments are effective for annual periods beginning on or after January 1, 2016. These amendments will not require any significant change to current practice, but should facilitate improved financial statement disclosures. The Company intends to adopt these amendments in its financial statements for the annual period beginning on May 1, 2016. The Company does not expect the amendments to have a material impact on the financial statements.

#### (ii) IFRS 9 - Financial Instruments

In July 2014, the IASB issued the final publication of the IFRS 9 standard, superseding the current IAS39 - Financial Instruments: recognition and measurement standard. IFRS 9 includes revised guidance on the classification and measurement of financial instruments and carries forward the guidance on recognition and de-recognition of financial instruments from IAS 39. The standard is effective for annual periods beginning on or after January 1, 2018. Management is assessing the impact of this standard on its financial statements.



#### (iii) IFRS 15 - Revenue from Contracts with Customers

In May 2014, the IASB issued IFRS 15 - Revenue from Contracts with Customers, which introduces a single model for recognizing revenue from contracts with customers except leases, financial instruments, and insurance contracts. The standard requires revenue to be recognized in a manner that depicts the transfer of promised goods or services to a customer and at an amount that reflects the expected consideration receivable in exchange for transferring those goods or services.

IFRS 15 also provides guidance related to the treatment of contract acquisition and contract fulfillment costs. The standard is effective for annual periods beginning on or after January 1, 2017 with retroactive application. The Company intends to adopt IFRS 15 in its financial statements for the annual period beginning on May 1, 2017. The extent of the impact of adopting the standard has not yet been determined, as the Company has not generated revenues to date; however, the Company is evaluating the standard in light of the types of anticipated revenue.