Zacks Small-Cap Research

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Grant Zeng, CFA
312-265-9421
gzeng@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Cotinga Pharmaceuticals (V.COT-TSX, COTQF-OTC)

V.COT: A Phase I trial for lead candidate COTI-2 is on-going; New candidate COTI-219 announced, balance sheet boosted by recent financing.

We use relative valuation metrics to arrive at our fair value of Cotinga shares at $4.50/share.

Current Price (01/31/18)	$0.75
Valuation	**$4.50**

OUTLOOK

Cotinga is a clinical stage biopharmaceutical Company. The Company's CHEMSAS® platform technology utilizes a series of predictive computer models to identify potential drug candidates. This technology greatly shortens the timeframe of drug discovery with a high probability of success, therefore saving a great deal of money and increasing revenue potential.

Its lead candidate COTI-2 is in Phase I study with a potential to target multiple cancers.

We are optimistic about the prospects of the Company.

SUMMARY DATA

52-Week High	**$0.90**
52-Week Low	**$0.20**
One-Year Return (%)	**50%**
Beta	**-0.03**
Average Daily Volume (sh)	**78,615**
Shares Outstanding (mil)	**148**
Market Capitalization ($mil)	**$71**
Short Interest	**N/A**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**N/A**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2016 Estimate	**N/A**
P/E using 2017 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
Type of Stock	**Small-Growth**
Industry	**Med Products**
Zacks Rank in Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of C$)

	Q1 (Jul)	Q2 (Oct)	Q3 (Jan)	Q4 (Apr)	Year (Apr)
2016	0.00 A	0.00 A	0.00 A	0.00 A	0.00 A
2017	0.00 A	0.00 A	0.00 A	0.00 A	0.00 A
2018	0.00 A	0.00 A	0.00 E	0.05 E	0.05 E
2019					1.50 E

Earnings per Share
(EPS is operating earnings before non- recurring items)

	Q1 (Jul)	Q2 (Oct)	Q3 (Jan)	Q4 (Apr)	Year (Apr)
2016	-$0.08 A	-$0.07 A	-$0.05 A	-$0.12 A	-$0.35 A
2017	-$0.16 A	-$0.05 A	-$0.08 A	-$0.13 A	-$0.42 A
2018	-$0.10 A	-$0.11 A	-$0.13 E	-$0.10 E	-$0.45 E
2019					-$0.53 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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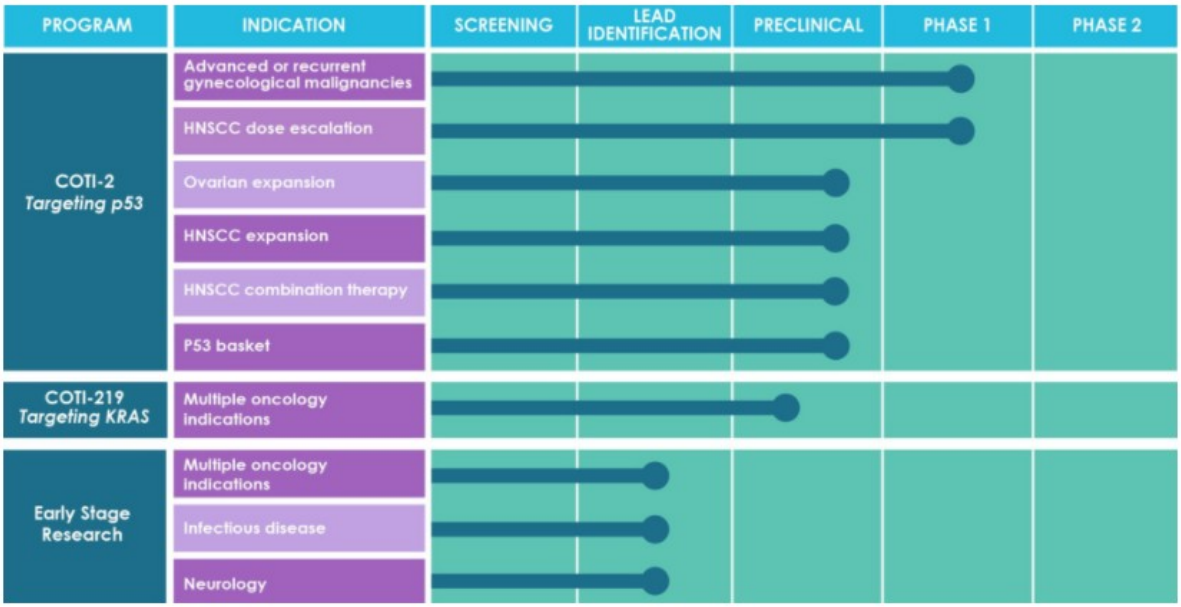
WHAT'S NEW

Name Change to Reflect Core Business in Drug Research and Development

In early Jan 2018, Critical Outcome Technologies Inc. changed its name to Cotinga Pharmaceuticals Inc. The trading ticker remains the same (TSX Venture: COT; OTCQB: COTQF).

The name change was a result of a close review of the company's business by management. The change reflects the Company's evolution from a technology-driven company to a clinical-stage pharmaceutical company. The name is derived from the Cotingas, one of the world's largest and most diverse bird species, and symbolizes the Company's focus on developing innovative therapies to treat a wide spectrum of cancers.

Cotinga Pharmaceuticals is a clinical-stage pharmaceutical company with multiple drug candidates in different development stages. The Company's CHEMSAS® platform evaluates biological activity from molecular structures, allowing the Company to build a pipeline of potential drug candidates with predictive accuracy and expediency when compared to traditional development methods.



Balance Sheet Boosted by Recent Financing

There was no revenue generated in the fiscal second quarter ended October 31, 2017, nor in the comparative periods.

R&D expense in the fiscal second quarter ended October 31, 2017 were $1.00 million, an increase of $0.25 million from the $0.74 million for the same quarter of last year. This increase was primarily due to an increase in synthesis and miscellaneous R&D expenses, other costs, and salaries and benefits. These increases were partially offset by a decrease in clinical trial expenses.

G&A expense in the fiscal second quarter ended October 31, 2017 were $0.78 million, a decrease of $0.181 million from the $1.03 million for the same quarter of last year. The decrease was primarily due to reduction in professional fees, corporate governance, marketing and travel, and share□based compensation expense. These decreases were partially offset by an increase in salaries, benefits, rent and insurance.

For the three□months ended October 31, 2017, the Company incurred a net loss of $1.781 million ($0.11 per share), compared to a net loss of $0.748 million ($0.05 per share), for the three□months ended October 31, 2016.

The Company's operational activities during the quarter were primarily focused on advancing the **Phase I** clinical trial of **COTI□2** in gynecological malignancies and HNSCC.

As of October 31, 2017, the company held $1.25 million in cash and cash equivalents.

The Company closed two tranches of a non□brokered private placement with accredited investors in September and October 2017 for approximately $2.1 million in gross proceeds. Subsequent to the reporting quarter, the Company entered into an engagement with a U.S. investment bank in connection with proposed financing efforts in the U.S.

We are pleased to see that the company secured these financings, which not only boost the company's balance sheet, but more importantly validate the company's technology and preclinical and clinical programs.

Update on Phase I Study of COTI-2

Background of the Phase I Trial

At the end of 2015, Cotinga, together with its collaborator MD Anderson, initiated a **Phase I** clinical trial to evaluate COTI-2 for the treatment of patients with **gynecological cancers** including ovarian cancer, fallopian tube cancer, endometrial cancer, cervical cancer, and peritoneal cancer (NCT02433626).

This **Phase I** trial is a single arm, single center, open-label study of COTI-2 in female patients with platinum-resistant, recurrent ovarian (including fallopian tube or primary peritoneal cancer), endometrial, or cervical cancer. COTI-2 will be self-administered as a single agent, orally, once daily for 5 days followed by 2 treatment-free days each week. 1 cycle will be defined as 4 weeks of treatment as described (5 days on, 2 days off per week). Participants will remain on treatment until they experience a lack of benefit.

- The **primary endpoints** will be safety and tolerability.
- **Secondary and exploratory** outcome measures were designed to evaluate pharmacodynamics and various signals of efficacy.

The trial will enroll up to 46 patients.

Updates

Treatment of the **first cohort** commenced on **February 15**, 2016.

In August 2017, the company completed the dose escalation portion of the **Phase I study** of COTI-2 in women with advanced gynecologic cancers who have failed conventional therapy. In addition, Cotinga announced that it has initiated **an expansion arm** of the Phase I study in patients with head and neck squamous cell carcinoma **(HNSCC).** The initial clinical data were reviewed and the Dose Escalation Committee (DEC) unanimously voted to complete this phase of the trial and progress the study into the HNSCC indication at a starting dose of 1.0 mg/kg.

In October 2017, the company dosed the first patient in the expansion arm of its Phase I trial of COTI□2 in head and neck squamous cell carcinoma (HNSCC).

The trial enrolled **24 patients** with ovarian, fallopian tube, primary peritoneal, endometrial or cervical cancer that was recurrent, metastatic or unresectable and for which no effective or curative measures existed.

Data from the Phase I trial suggest that COTI-2 was generally safe and well-tolerated by patients at doses up to 1.7 mg/kg. Patients were enrolled in the study at four dose levels ranging from 0.25 mg/kg to 1.7 mg/kg once daily. Preliminary results indicate that the most common adverse events (AEs) included nausea and vomiting, fatigue and abdominal pain.

In November 2017, the Company announced pharmacokinetic **(PK)** data demonstrating rapid oral absorption across all dose levels, with the highest concentrations of COTI-2 measured at approximately one hour after dosing. The mean half-life was approximately 8 to 10 hours, and this exposure was in the expected therapeutic range based on preclinical data in gynecological malignancies. In addition, there was no evidence of long-term drug accumulation following multiple cycles of treatment. Following the last cycle of treatment, clearance of the drug takes approximately one week.

In this first **Phase I** trial, 15 patients were evaluated for **secondary and exploratory outcome measures**, including various signals of efficacy measured using RECIST criteria1. Eleven (11) of the 15 patients evaluated for secondary and exploratory outcome measures had ovarian cancer. Twelve (12) of the 15 patients evaluated for secondary and exploratory outcome measures were genetically-profiled; 9 of the 12 genetically-profiled patients exhibited a variety of p53 mutations. One (1) of the 15 patients evaluated for secondary and exploratory outcome measures was determined to have overall stable disease. Four (4) of the 15 patients evaluated for secondary and exploratory outcome measures were determined to have progressing disease, but stable target lesions; target lesions are lesions specifically chosen and measured to assess whether a patient's tumor burden is increasing or decreasing. Five (5) of the 15 patients evaluated for secondary and exploratory outcome measures were determined to have progressing disease but stable non-target tumors; stable non-target tumors indicate that no new lesions were identified. Patients were also assessed for Cancer Antigen-125 (CA-125) levels, a protein found in the blood which can be used to monitor certain cancers. One patient in the study was observed to have a decrease in CA-125.

The Company has established a recommended **Phase II** dose for COTI-2 in ovarian cancer of **1.0 mg/kg orally 5 days per week.**

Cotinga is continuing to analyze results from the gynecological arm of the Phase I trial of COTI-2, and expects to provide an update when further data are available in the **first quarter of 2018**.

The company is also currently enrolling patients in the HNSCC dose-escalation arm of the Phase I trial of COTI-2, and expects to report top-line data **in 2018**.

Based on these results and subject to sufficient financing, Cotinga will advance the HNSCC expansion arm of the Phase I program for COTI-2. The Company expects top-line data from the HNSCC expansion arm in 2018. Also in 2018, Cotinga expects to initiate expansion arms evaluating COTI-2 in combination with standard of care chemotherapy and radiation therapy in patients with gynecological malignancies and HNSCC.

The next step with COTI-2 will be the initiation of a **Phase II** trial for **ovarian cancer** in 2018 following the conclusion of the Phase I trial. The logic of choosing ovarian cancer is because as many as 95% of ovarian cancer patients have a p53 gene mutation, and the market for ovarian cancer treatment in the US will well surpass $1 billion.

COTI-2 received an **orphan-drug designation** for ovarian cancer by the FDA in June 2014.

New Candidate COTI-219 to be Advanced to Clinical Development

On October 11, 2016, Critical Outcome Technologies Inc. (COT.V, COTQF) declared its next clinical candidate, **COTI-219** for the treatment of **cancers**.

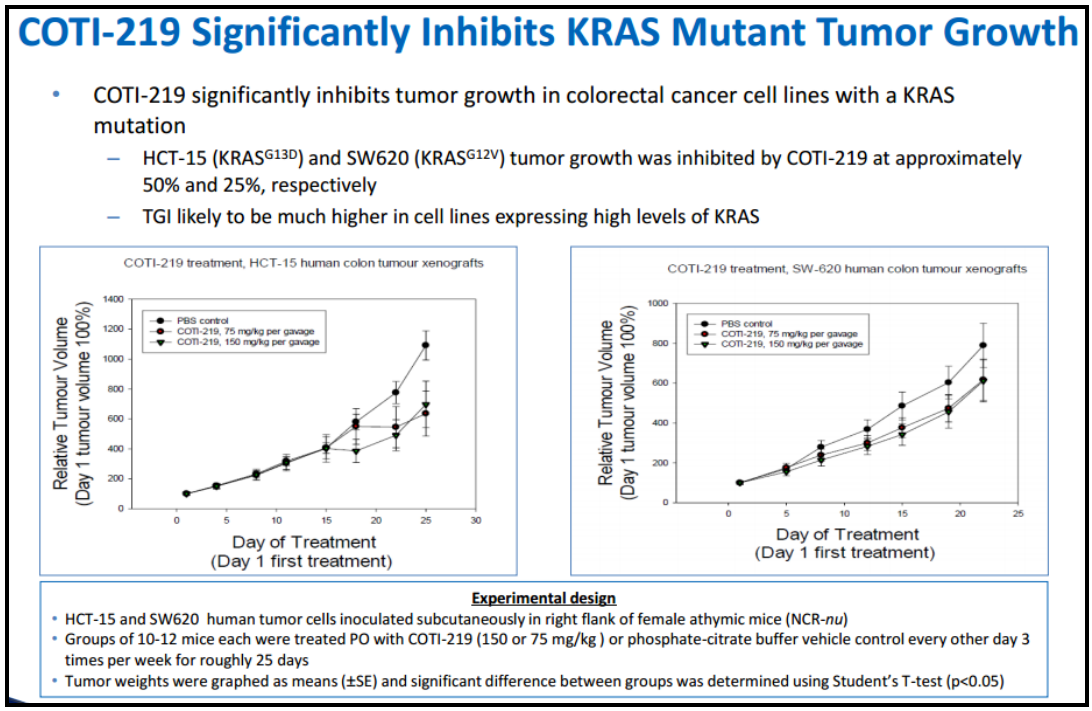
COTI-219 is a novel oral small molecule compound targeting the mutant forms of **KRAS**. COTI-219 was discovered using the Company's proprietary drug discovery technology platform, CHEMSAS®.

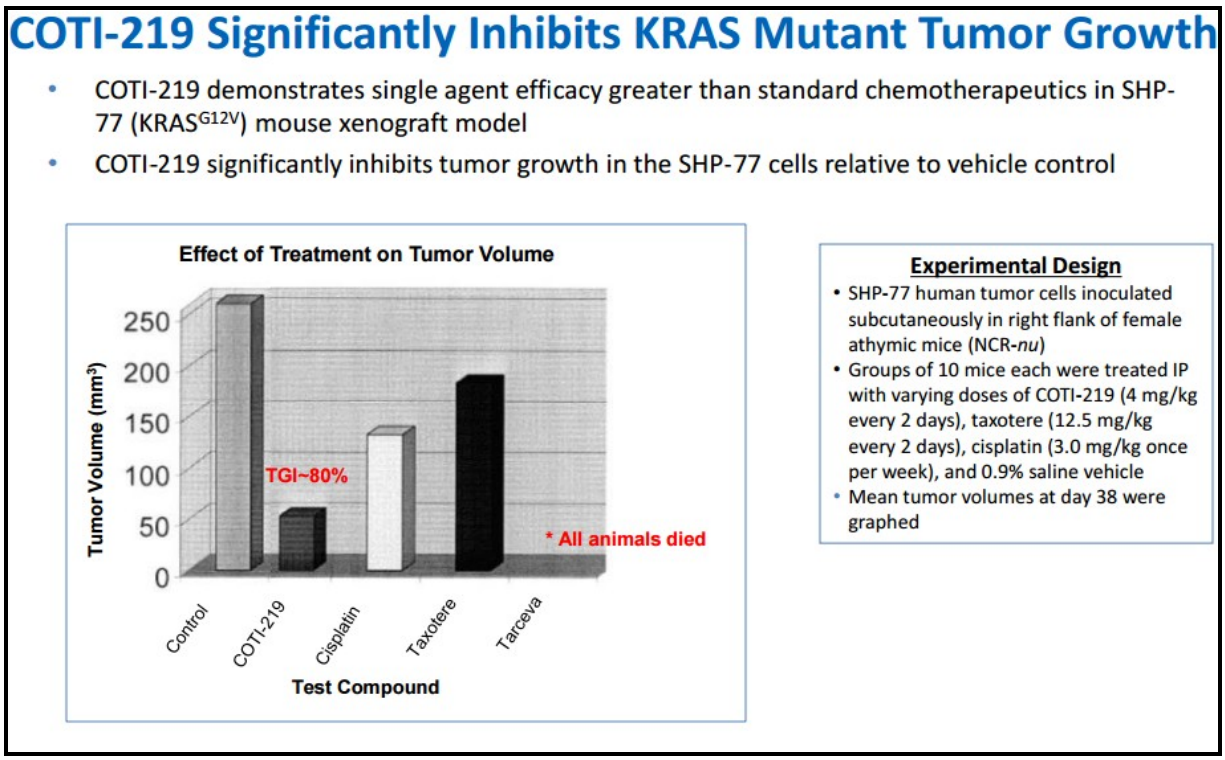
KRAS is an essential protein that plays a central role in cell growth and proliferation. The KRAS signaling pathway is tightly controlled within cells to ensure coordinated cell growth. Mutations in KRAS gene interrupt this coordination and represent an essential step in the development of many cancers. KRAS mutations are found in many human cancers, with the highest prevalence in pancreatic adenocarcinomas (90%), colorectal cancers (45%) and lung cancers (35%). KRAS mutations are also predictive of a very poor response to colorectal cancer therapies, such as panitumumab and cetuximab.

Targeted therapies that can block the function of mutant KRAS protein, but not the wild type KRAS, would be transformative in the successful treatment of a large number of cancer indications.

COTI-219 is an oral small molecule inhibitor of mutant KRAS protein. COTI-219 is designed to selectively bind to the mutant forms of KRAS protein, but not to the wild type KRAS, and block its function -- thereby inhibiting the downstream cell growth and proliferation signaling cascade. Since KRAS mutations occur in a large number of cancers, therefore, we believe COTI-219 represents a tremendous unmet clinical need.

In validated cell culture and in vivo **preclinical** rodent models of colorectal and lung cancers, COTI-219 as a single agent has demonstrated significant and robust efficacy. Moreover, in a **lung cancer** rodent model, COTI-219 performed significantly better in reducing tumor volume compared to certain approved standard-of-care lung cancer therapies.





Advancement of IND-enabling studies is ongoing and the company plans to file an IND with the FDA for **Phase I** study evaluating COTI-219 in multiple oncology indications **in 2018**.

We welcome the announcement that brings COTI-219 into clinic. COTI-219 is the company's second clinical candidate. Together with COTI-2 (currently in **Phase I**), the company is building a robust pipeline of novel oral small molecules targeting different cancer targets. COTI-2 and COTI-219 each have the potential to, either independently or in combination with other therapies, dramatically improve the outcome for many people with cancer.

Update on ROSALIND Technology

Overview

Critical Outcome Technologies Inc. (COT.V) is a clinical stage biopharmaceutical Company which is focused on the discovery and development of cancer treatments through targeted therapeutics.

The Company has developed a proprietary artificial intelligence platform, **CHEMSAS®**, which utilizes a series of predictive computer models to identify compounds with a high probability of being successfully developed from disease specific drug discovery through chemical optimization and preclinical testing.

In addition to CHEMSAS®, COTI has also developed ROSALIND. **ROSALIND** is a computer platform for realizing the promise of personalized medicine for cancer patients. The goal of ROSALIND is to provide better personalized treatment options based on the genetic profile of the patient's cancer.

ROSALIND is a dynamic, programmable computer simulation of how cell signaling pathways are altered by specific gene mutations that are associated with specific types of cancers. The technology produces a comprehensive mathematical model of cell signaling and identifies optimal personalized cancer treatment options.

While access to high-quality cancer gene mutation profiling continues to evolve, **personalized cancer therapy** is really a big data problem. For example, the number of unique single, double, and triple drug combinations from just 150 cancer drugs would be in excess of 540,000. This is simply too many potential therapies for any physician or group of physicians to evaluate. ROSALIND addresses this big data problem.

The technology uses a gene expression and mutation profile of a patient's tumor to evaluate a full range of available therapies. ROSALIND V2.0 can analyze more than 1000 gene mutations simultaneously.

ROSALIND targets the multi-billion dollar personalized cancer **gene profiling market**. The Company is seeking commercial and validation development partners.

The Launch of ROSALIND Could Generate Revenue Soon

On March 14, 2016, COTI announced the launch of ROSALIND™.

The launch here means that the technology is available for use / testing by physicians – for them to try it out; see how it works and can work for them.

The use of the technology is being offered without a fee at this time to provide feedback on its use and for COTI to refine the service based upon this feedback. Part of this launch strategy is to get oncologists excited by the use and value the technology can bring them that will allow the Company to turn it in to a pay for use service.

Following validation, it is likely that patients will pay for the service/information initially like they now pay for the gene expression profile. The longer term plan would be to have the ROSALIND report paid for by insurance companies/third party payer.

ROSALIND has successfully undergone initial validation but now requires further real world testing. Assessments suggesting optimal personalized drug treatment options are immediately available for physicians to order free of charge during this validation phase. In a recent system stress test, ROSALIND evaluated 1.4 million drug combinations and provided multiple potential treatment options for patients in less than 90 minutes.

We believe ROSALIND will empower physicians to make efficient individual patient treatment decisions based on an individual's cancer gene mutation and expression profile. The services could begin generating meaningful revenue for COTI **in 2017**.

We continue to be Bullish on Cotinga Shares

We are optimistic about the prospect of Cotinga Pharmaceuticals. We adjust our fair value of the company at CAD$4.50 per share after the share consolidation. Our call is based on recent achievements the company has made, especially the advancement of its lead candidate **COTI-2** and the launch of new candidate **COTI-219**.

Cotinga is a clinical-stage biopharmaceutical company with a current focus on cancer. Over the years, the Company has developed a unique, proprietary drug discovery platform technology **CHEMSAS®**. This is the core value for the Company and differentiates the Company from other biotech companies in our view.

The CHEMSAS® platform has the advantages of dramatically shortening the timeframe of drug discovery with an increase in the probability of success, therefore saving millions of dollars in R&D costs and increasing the revenue potential of successful candidates.

Base on this CHEMSAS® platform, COTI has built a pipeline with a focus on cancer and other unmet medical needs. The Company's lead drug candidate **COTI-2** is a small molecule discovered using the CHEMSAS® technology. COTI-2 has a unique mechanism of action which not only restores p53 functions to a wide range of common p53 mutations but also negatively modulates the PI3K/AKT/mTOR pathway and as well inhibits cancer stem cells (CSC).

In preclinical studies, COTI-2 has demonstrated strong anti-cancer efficacy in different cancer types and a favorable safety profile. Currently COTI-2 is in a **Phase I** clinical study in patients with advanced or recurrent gynecologic malignancies including **ovarian cancer**.

The addition of **COTI-219** further expands the company's clinical pipeline. In addition to COTI-2 and COTI-219, the Company also has numerous other drug candidates in different discovery and development stages targeting different cancers including colon and AML as well as other programs including MRSA, multiple sclerosis, Alzheimer's, and HIV.

With respect to valuation, we think the current market price does not reflect the Company's true value. Currently, the Company's shares are trading at about CAD$0.68 per share, which values the Company at CAD$11 million in market capitalization. We think this undervalues the Company based on what we have discussed above.

We agree that it's always difficult to exactly value a development stage biotech Company. We don't think a DCF model is appropriate for the valuation of Cotinga since even the Company's lead candidate COTI-2 is still a few years away from reaching the market. Instead, one better way is to use relative value metrics to reach fair value for Cotinga. According to our experience and current market conditions, most small cap biotech companies are valued at from $50 million to $2 billion in market cap based on how advanced the Company's pipeline is and the market potential of the Company's drug candidates. Other factors affecting a small cap biotech valuation include cash balance, burn rate and management expertise and experience.

Our price target of CAD$4.50 per share values Cotinga at CAD$76 million in market cap, which we think is very conservative.

Data is the ultimate driving force of a biotech Company. We believe when more data are generated from the Company's lead candidate, COTI-2, and from other early stage candidates, value will also be generated for the Company and its shareholders. In this regard, we will keep a close eye on the Company's development plan and update investors on any new data (either clinical or preclinical) generated from its drug candidates.

We are also pleased to see that the Company is seeking collaboration opportunities for its **ROSALIND** technology. If successful, the collaboration could boost the Company's balance sheet in a non-dilutive way.

But keep in mind **the risks**. As we discussed, Cotinga is still a clinical stage biopharmaceutical company. Our valuation assumes the final approval of lead candidate COTI-2 and other candidates. In order for the candidates to reach the market, the Company still needs to overcome both clinical and regulatory hurdles which have proven to be high.

Cash burn is another concern. When new candidate COTI-219 enters the clinic, we expect R&D expenses will also increase. We expect the Company to tap the capital market for new funding on a regular basis. We reminder investors that equity financing will dilute the existing shareholder base, and could cause the share price to fall.

But generally speaking, the stock has a typical high risk/high return profile, which could be appropriate for investors with a high-risk tolerance and relatively long investment horizon.

INCOME STATEMENT

	2017 (Apr)					2018 (Apr)					2019 (Apr)	2020 (Apr)	2021 (Apr)
C$ in million except per share data	Q1	Q2	Q3	Q4	FY	Q1	Q2	Q3	Q4	FYE	FYE	FYE	FYE
Grant revenue	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
License/Royalties	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.50	$0.50	$1.50	$3.00	$5.00
Product revenue	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$5.00	$50.00
Total Revenues	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.50**	**$0.50**	**$1.50**	**$8.00**	**$55.00**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
CoGS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.60	11.00
Gross Income	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.50**	**$0.50**	**$1.50**	**$6.40**	**$44.00**
Gross Margin	-	-	-	-	-	-	-	-	100.0%	100.0%	100.0%	80.0%	80.0%
R&D	$0.61	$0.74	$0.68	$0.68	$2.73	$0.67	$1.00	$0.85	$1.00	$3.51	$5.50	$7.50	$12.00
% R&D	-	-	-	-	-	-	-	-	-	-	-	-	-
SG&A	$0.76	$1.03	$1.39	$1.18	$4.36	$0.87	$0.78	$1.28	$1.30	$4.23	$7.50	$10.00	$20.00
%SG&A	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Expenses	($0.04)	($0.04)	$0.00	($0.07)	($0.14)	($0.02)	$0.00	$0.00	$0.00	($0.02)	$0.00	$0.00	$0.00
Operating Income	**($1.3)**	**($1.7)**	**($2.1)**	**($1.8)**	**($6.9)**	**($1.5)**	**($1.8)**	**($2.1)**	**($1.8)**	**($7.2)**	**($11.5)**	**($11.1)**	**$12.0**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	21.82%
Other Net	($1.0)	$1.0	$0.8	($0.1)	$0.7	$1.3	($0.0)	$0.0	$0.0	$1.3	($0.1)	($0.1)	($0.1)
Pre-Tax Income	**($2.3)**	**($0.7)**	**($1.3)**	**($1.9)**	**($6.2)**	**($0.2)**	**($1.8)**	**($2.1)**	**($1.8)**	**($6.0)**	**($11.6)**	**($11.2)**	**$11.9**
Income taxes(benefit)	$0.0	$0.0	($0.0)	$0.0	($0.0)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$1.8
Tax Rate	-	-	-	-	-	-	-	-	-	-	-	-	-
Reported Net Income	**($2.3)**	**($0.7)**	**($1.2)**	**($1.9)**	**($6.2)**	**($0.2)**	**($1.8)**	**($2.1)**	**($1.8)**	**($6.0)**	**($11.6)**	**($11.2)**	**$10.1**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-
Diluted Shares Out	14.7	14.9	14.9	14.9	14.8	14.9	15.6	16.0	18.0	16.1	22.0	27.5	35.0
Reported EPS	**($0.16)**	**($0.05)**	**($0.08)**	**($0.13)**	**($0.42)**	**($0.02)**	**($0.11)**	**($0.13)**	**($0.10)**	**($0.37)**	**($0.53)**	**($0.41)**	**$0.29**
One time charge	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	($1.27)	*$0.00*	*$0.00*	*$0.00*	($1.27)	*$0.00*	*$0.00*	*$0.00*
Non GAAP Net Income	**($2.3)**	**($0.7)**	**($1.2)**	**($1.9)**	**($6.2)**	**($1.5)**	**($1.8)**	**($2.1)**	**($1.8)**	**($7.2)**	**($11.6)**	**($11.2)**	**$10.1**
Non GAAP EPS	**($0.16)**	**($0.05)**	**($0.08)**	**($0.13)**	**($0.42)**	**($0.10)**	**($0.11)**	**($0.13)**	**($0.10)**	**($0.45)**	**($0.53)**	**($0.41)**	**$0.29**

Source: Company filings and Zacks estimates

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HISTORICAL STOCK PRICE



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