Zacks Small-Cap Research

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Critical Outcome Technologies (V.COT-TSX, COTQF-OTC)

V.COT: Zacks Company Report

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

Current Price (11/04/16)	$0.50
Valuation	**$1.50**

OUTLOOK

COTI 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 has entered into the clinic recently 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)
2015	0.00 A	0.00 A	0.00 A	0.00 A	0.00 A
2016	0.00 A	0.00 A	0.00 A	0.00 A	0.00 A
2017	0.00 A	0.00 E	0.00 E	0.00 E	0.00 E
2018					0.50 E

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

	Q1 (Jul)	Q2 (Oct)	Q3 (Jan)	Q4 (Apr)	Year (Apr)
2015	-$0.01 A	-$0.01 A	-$0.01 A	-$0.01 A	-$0.03 E
2016	-$0.01 A	-$0.01 A	-$0.00 A	-$0.01 A	-$0.03 A
2017	-$0.02 A	-$0.01 E	-$0.01 E	-$0.01 E	-$0.05 E
2018					-$0.04 E

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

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WHAT'S NEW

New Candidate COTI-219 to be Advanced to Clinical Development

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

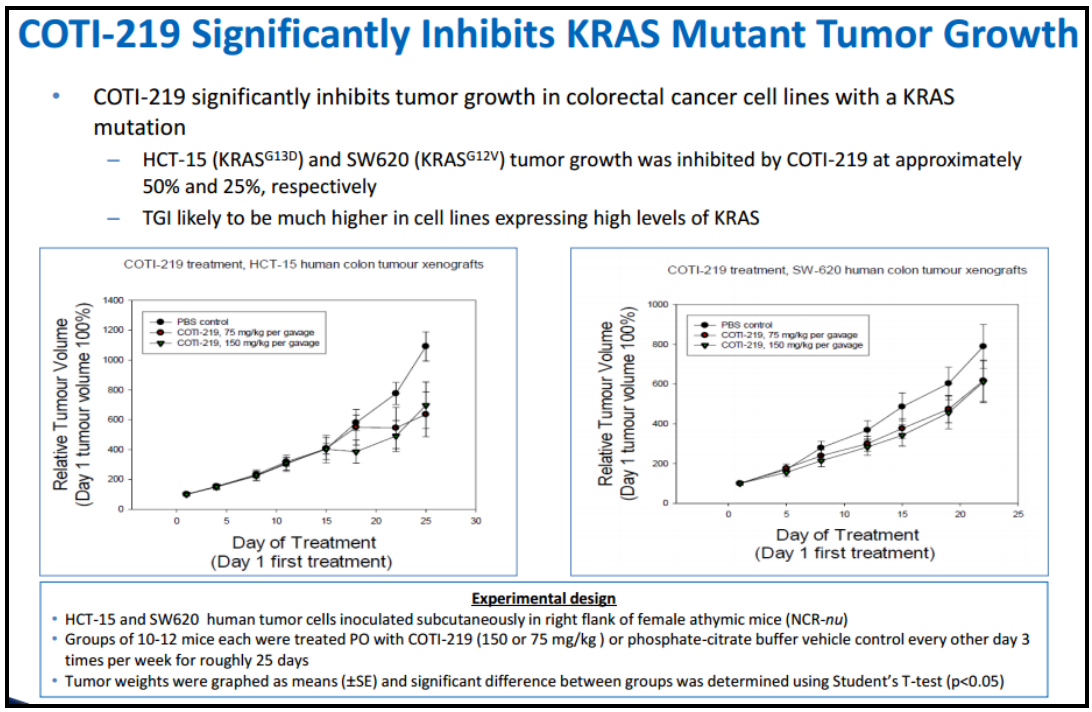
COTI-219 is a novel oral small molecule compound targeting the mutant forms of **KRAS**. COTI-219 was discovered using the Company's proprietary drug discovery technology platform, CHEMSAS®.

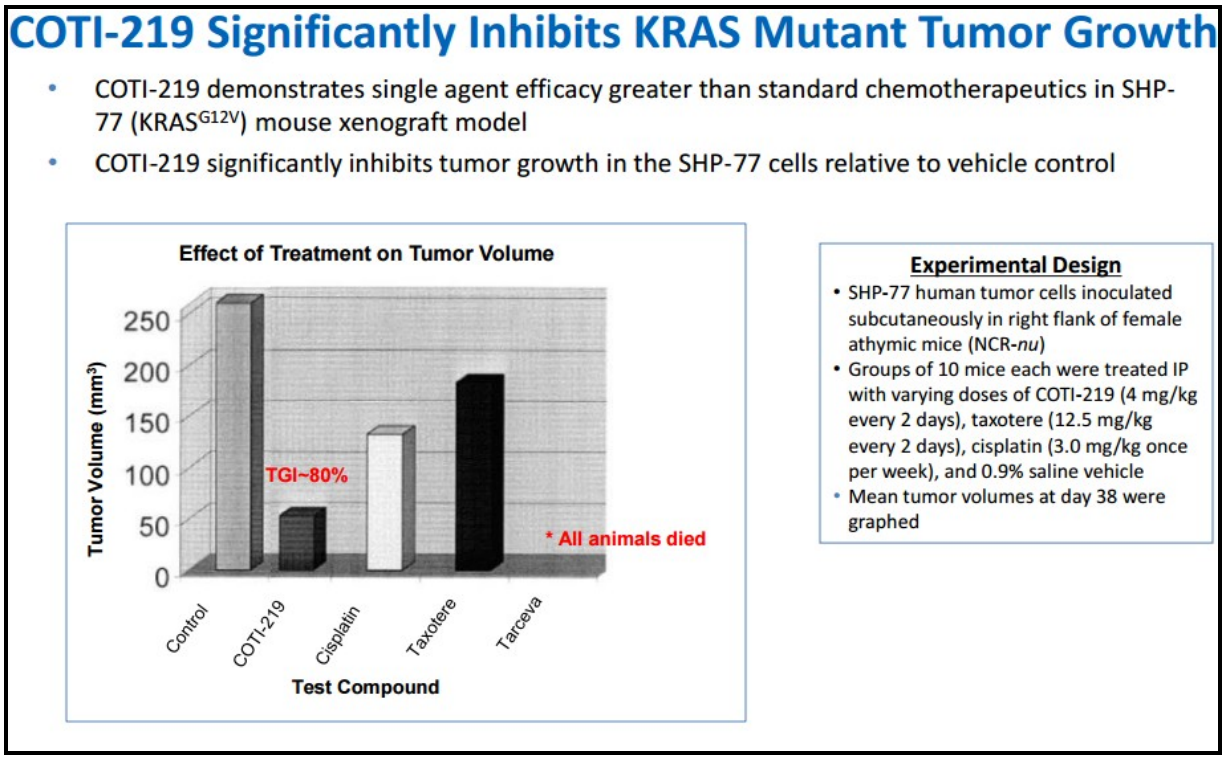
KRAS is an essential protein that plays a central role in cell growth and proliferation. The KRAS signaling pathway is tightly controlled within cells to ensure coordinated cell growth. Mutations in KRAS gene interrupt this coordination and represent an essential step in the development of many cancers. 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.





COTI is planning to file an Investigational New Drug (IND) application in **late 2017**.

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.

COTI Exited Fiscal First Quarter of 2017 with a Relatively Strong Balance Sheet

R&D expenses for fiscal 1Q17 ended July 2016 were $0.61 million, an increase of $315,483, primarily reflecting costs related to COTI-2 development.

SG&A expenses for fiscal 1Q17 were $0.76 million, as compared to $0.61 million for fiscal 1Q16.

Net loss for fiscal 1Q17 was $2.3 million ($0.02 per share), as compared to net loss of $1.0 million ($0.01 per share) for fiscal 1Q16.

As of July 31, 2016, COTI had $5.37 million in cash and investments.

During the quarter, the Company realized approximately $1.6 million in net proceeds through the exercise of warrants to provide further funding for operations. This included a 100% exercise of the 5,814,245 warrants that would otherwise have expired on June 2, 2016.

During the fiscal year ended April 30, 2016, the Company completed **two non-brokered private placement** financings with accredited investors, realizing gross proceeds of approximately $2.7 million. In addition, the Company realized additional cash of $3,846,903 from the exercise of common share purchase warrants and compensation warrants.

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

Current cash balance could carry the company's operations into the end of fiscal 2017 according to our financial model.

Enrollment in Phase I Study of COTI-2 is Accelerating

At the end of 2015, COTI, 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 endpoints include clinical response and progression free survival (PFS). The trial will enroll up to **46 patients**.

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

The company commenced treating patients in the **second cohort** on **April 18**, 2016. Treatment of the second cohort will continue to evaluate COTI□2's safety profile at a dosage level twice that of the first cohort. Prior to initiating cohort two, the independent Dose Escalation Committee reviewed the safety data from all patients in the first cohort and unanimously approved moving to dosing the next cohort.

On **June 3, 2016**, the company activated a second treatment site at the Lurie Cancer Center at Northwestern University in Chicago, Illinois. This will broaden the base of patients who can potentially qualify for the study with the goal of expediting the enrollment of patients into the trial and thus allowing the overall trial to move forward on a timelier basis.

On **July 12, 2016**, COTI commenced dosing women in the **third cohort** of the ongoing Phase I clinical trial of COTI□2 intended for the treatment of gynecological cancers. The objective of the third cohort is to continue the evaluation of COTI□2's safety profile at a dosage level twice that of the second cohort.

We expect top line data to be available **in mid-2017**.

COTI is also planning clinical trials in Canada and the US for the treatment of patients with recurrent **head and neck** squamous cell cancer. The Company will file an Investigational New Drug application with the US FDA and is also completing a Clinical Trial Application for submission to Health Canada.

The next step with COTI-2 will be the initiation of a **Phase II** trial for **ovarian cancer** in 2017 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.

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 COTI Shares

We are optimistic about the prospect of Critical Outcome Technologies (COTI). We maintain our fair value of the company at CAD$1.50 per share. 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**.

COTI 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$0.48 per share, which values the Company at CAD$71 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 COTI 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 COTI. 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$1.50 per share values COTI at CAD$222 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, COTI 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 into the clinic, we expect R&D expenses will also increase. As of July 31, 2016, COTI held $5.37 million in cash and investments, which can only support the Company's operations into the end of fiscal 2017 according to our financial model. 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, we think 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

	2016 (Apr)					2017 (Apr)					2018 (Apr)	2019 (Apr)	2020 (Apr)	2021 (Apr)
C$ in million except per share data	Q1	Q2	Q3	Q4	FYE	Q1	Q2	Q3	Q4	FYE	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	$0.00
License/Royalties	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$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	$0.00	$5.00	$50.00
Total Revenues	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$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	0.00	1.60	11.00
Gross Income	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.50**	**$1.50**	**$6.40**	**$44.00**
Gross Margin	-	-	-	-	-	-	-	-	-	-	100.0%	100.0%	80.0%	80.0%
R&D	$0.30	$0.35	$0.40	$0.46	$1.50	$0.61	$0.65	$0.70	$0.80	$2.76	$4.00	$5.50	$7.50	$12.00
% R&D	-	-	-	-	-	-	-	-	-	-	-	-	-	-
SG&A	$0.61	$0.64	$0.60	$0.68	$2.53	$0.76	$0.78	$0.80	$0.85	$3.19	$4.00	$5.50	$10.00	$15.00
%SG&A	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Expenses	($0.01)	($0.02)	($0.03)	($0.05)	($0.11)	($0.04)	$0.00	$0.00	$0.00	($0.04)	$0.00	$0.00	$0.00	$0.00
Operating Income	**($0.9)**	**($1.0)**	**($1.0)**	**($1.1)**	**($3.9)**	**($1.3)**	**($1.4)**	**($1.5)**	**($1.7)**	**($5.9)**	**($7.5)**	**($9.5)**	**($11.1)**	**$17.0**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	30.91%
Other Net	($0.1)	$0.0	$0.3	($1.3)	($1.0)	($1.0)	$0.0	$0.0	$0.0	($1.0)	$0.0	($0.1)	($0.1)	($0.1)
Pre-Tax Income	**($1.0)**	**($0.9)**	**($0.6)**	**($2.4)**	**($4.9)**	**($2.3)**	**($1.4)**	**($1.5)**	**($1.7)**	**($6.9)**	**($7.5)**	**($9.6)**	**($11.2)**	**$16.9**
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	$0.0	$0.8
Tax Rate	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Reported Net Income	**($1.0)**	**($0.9)**	**($0.6)**	**($2.4)**	**($4.9)**	**($2.3)**	**($1.4)**	**($1.5)**	**($1.7)**	**($6.9)**	**($7.5)**	**($9.6)**	**($11.2)**	**$16.1**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Diluted Shares Out	125.9	126.4	127.9	190.4	142.6	146.9	146.0	148.0	155.0	149.0	200.0	250.0	300.0	350.0
Reported EPS	**($0.01)**	**($0.01)**	**($0.00)**	**($0.01)**	**($0.03)**	**($0.02)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.05)**	**($0.04)**	**($0.04)**	**($0.04)**	**$0.05**
One time charge	*$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*	*$0.00*
Non GAAP Net Income	**($1.0)**	**($0.9)**	**($0.6)**	**($2.4)**	**($4.9)**	**($2.3)**	**($1.4)**	**($1.5)**	**($1.7)**	**($6.9)**	**($7.5)**	**($9.6)**	**($11.2)**	**$16.1**
Non GAAP EPS	**($0.01)**	**($0.01)**	**($0.00)**	**($0.01)**	**($0.03)**	**($0.02)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.05)**	**($0.04)**	**($0.04)**	**($0.04)**	**$0.05**

Source: Company filings and Zacks estimates

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