Zacks Small-Cap Research

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MethylGene Inc.

(MYG-TO, MYLGF-OTC)

T.MYG: Enrollment of MGCD290 Phase II completed and balance sheet boosted -- Outperform

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	05/22/2012
Current Price (01/21/2013)	$0.17
Twelve- Month Target Price	**$0.75**

OUTLOOK

MethylGene is a mid-stage development biotech company. The Company's two lead drug candidates MGCD290 and MGCD265 are differentiated agents targeting the fungal and cancer market respectively. MGCD290 is in Phase II, and MGCD265 is in Phase I/II clinical trials; and approval could happen in 2015 and 2017 respectively.

In addition to the two lead candidates, MethylGene also has established an impressive pipeline with diversified candidates, with some under development by its collaborators.

MethylGene is well capitalized with a strong balance sheet. We rate the Company shares Outperform.

SUMMARY DATA

52-Week High	**$0.50**
52-Week Low	**$0.19**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**8,860**
Shares Outstanding (mil)	**318**
Market Capitalization ($mil)	**$60**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**71**
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 2012 Estimate	**N/A**
P/E using 2013 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Blend**
Industry	**Med-Biomed/Gene**
Zacks Rank in Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	1.28 A	1.27 A	0.07 A	0.47 A	3.09 A
2012	0.00 A	0.00 A	0.00 A	0.00 E	0.00 E
2013					0.00 E
2014					0.50 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	-$0.04 A	-$0.01 A	-$0.01 A	-$0.01 A	-$0.04 A
2012	-$0.01 A	-$0.01 A	-$0.02 A	-$0.02 E	-$0.06 E
2013					-$0.03 E
2014					-$0.03 E

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

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WHAT'S NEW

Enrollment in Phase II Trial of MGCD290 Completed

On December 19, 2012, MethylGene Inc. (TSX:MYG) announced that it has completed enrollment in its multi-center, randomized, double-blind, placebo-controlled trial (**Trial 290-005**) evaluating MGCD290 plus fluconazole versus fluconazole alone in patients with **moderate-to-severe vulvovaginal candidiasis (VVC).**

Trial 290-005 was initiated in October 2011 and began enrolling patients with moderate to severe VVC in the first quarter of 2012, and **over 200 patients** were enrolled at 19 sites in North America.

This study is a multicenter, randomized, double-blinded, placebo-controlled trial. This trial focuses on the most severe infections and therefore patients with mild disease are excluded. The purpose of the trial is to evaluate the safety and efficacy of fluconazole versus fluconazole + MGCD290.

- Subjects will be randomized in a 1:1 ratio to one of two arms of this study as follows: 150mg fluconazole + 540mg MGCD290, or 150mg fluconazole + placebo;
- 75 evaluable patients will be enrolled in each treatment arm; about 200 patients will be enrolled to get 150 evaluable patients in two arms;
- Subjects will be dosed on Day 1, and followed for one month after dosing;
- The **primary endpoint** for the study will be the **Therapeutic Cure Rate,** a composite endpoint of Clinical Cure (a resolution of clinical signs and symptoms) plus Mycologocial Cure (negative results on microscopy and culture) at Day 28;
- The primary endpoint population for this study will be based on the Modified Intent To Treat (MITT) population, which removes those patients who have been determined by screening not to have a fungal infection from analysis;
- Secondary endpoints will be:
    - Clinical Cure and Mycological Cure at 28 days;
    - Therapeutic Cure, Clinical Cure and Mycological Cure at 14 days;
    - Time to Resolution of Symptoms;
    - Safety of the combination of MGCD290 and fluconazole compared to fluconazole alone;

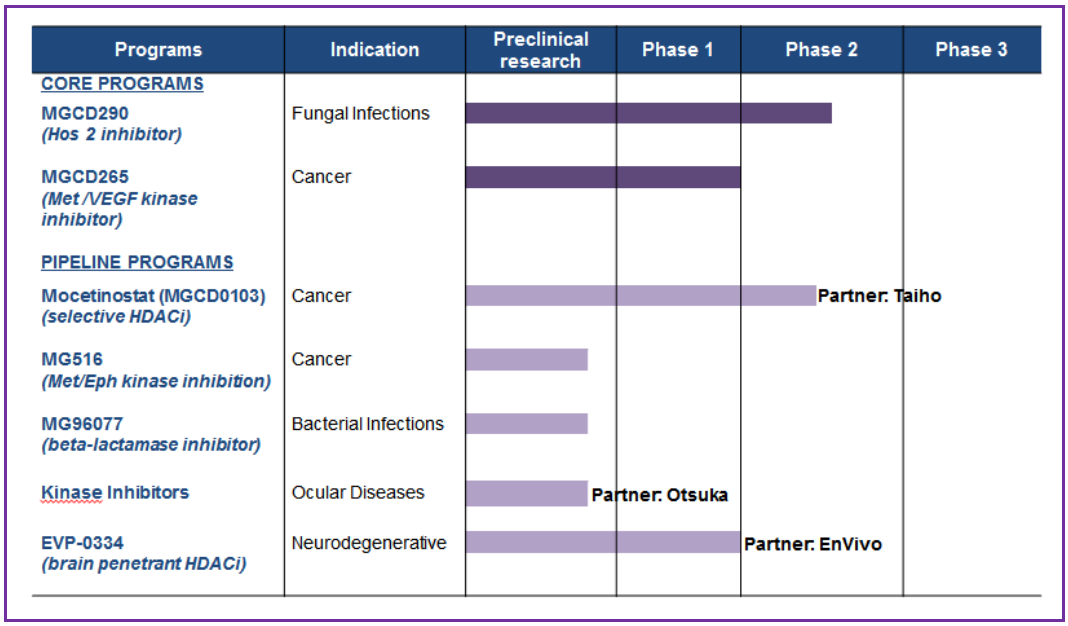
Dr. Jack Sobel, Chief of Infectious Diseases, Distinguished Professor of Medicine, Department of Internal Medicine, Wayne State University School of Medicine is the lead investigator for this study.

Topline data are expected **in March of 2013**.

While 90% cure rate is observed in the mild patients group for fluconazole, we are expecting the control group in this moderate to severe patient subset to have a 30-50% cure rate and the trail is powered to show (roughly, without going into the stats) a 20% absolute improvement i.e. improvement from 40% control to 60% treatment.

Other indications for MGCD290, such as **onychomycosis** (fungal infection of the toenail) and invasive fungal infections (such as **candidemia**), are under consideration. In its clinical trials different formulations

of MGCD290 were tested, including capsules, unmicronized tablets and micronized tablets, in order to improve drug manufacturability and exposure.



Balance Sheet Boosted by Recent Financing

On November 21, 2012, MethylGene Inc. (TSX:MYG) completed a private placement of 179,690,970 units at a subscription price per unit of Cdn.$0.145. Each unit consisting of one common share and thirty one-hundredths (0.30) of a common share purchase warrant, exercisable until November 19, 2017 at an exercise price of Cdn.$0.174 (being 120% of the Subscription Price), for gross proceeds to MethylGene of approximately Cdn.$26.1 million.

The lead investor in the Offering was Tavistock Life Sciences, an insider of the Company, and other insiders participating in the Offering included funds managed by Baker Bros. Advisors, LLC, a fund managed by OrbiMed Advisors LLC, and Tang Capital Partners, LP. Other investors participating in the Offering included RA Capital Management and BVF Partners L.P.
This financing not only provides much needed cash for the Company, but also validates the Company's technology and clinical programs. We think the net proceeds from the Offering will enable the Company to reach significant milestones in its two lead programs, MGCD265 and MGCD290, in 2013 and 2014.

As at September 30, 2012, MethylGene had $18.0 million of cash, cash equivalents and marketable securities. With the proceeds of $26.1 million from the Offering, and based on its current clinical development and operating plans, the Company's cash runway is expected to extend into the **second half of 2014.**

MGCD290 Phase I Clinical Data Presented at IDWEEK 2012

On October 22, 2012, MethylGene Inc. (TSX: MYG) presented Phase I data for its novel clinical-stage antifungal, MGCD290, at the 2012 IDWeek™ meeting, held in San Diego, California from October 17-21, 2012.

MethylGene has completed **five Phase I** studies, including single-ascending dose studies (SAD) and multiple ascending dose studies (MAD), in healthy adult volunteers. In the SAD studies, MGCD290 was administered once orally either as a single agent (Study 290-001) or in combination with fluconazole (Study 290-002). In the MAD studies, volunteers received MGCD290 orally either as a single agent (Study 290-003) or in combination with fluconazole (Study 290-004) daily for 14 days. In addition,

MGCD290 was administered once orally as a single agent (Study 290-007) in healthy female volunteers to assess the bioavailability and tissue distribution under fed versus fasting conditions.

Phase I	Monotherapy/ Combination	SAD/MAD	Patients enrolled	Cohorts/ Patient #	Dose range (mg)
Study 001	Monotherapy	SAD	56	7/8	100/200/300/450/600/810/1000
Study 002	Combination	SAD	16	2/8	300/450+400mg Fluconazole
Study 003	Monotherapy	MAD	32	4/8	100/180/360/540
Study 004	Combination	MAD	16	2/8	270/540+400mg Fluconazole
Study 007	Monotherapy	single dose		1	540

Source: Zacks Investment Research

The Company presented data from Study 001, 002, 003 and 004 at the IDweek meeting. Data describing the safety and pharmacokinetics of MGCD290 in the above four Phase I clinical trials in healthy adult volunteers were presented in a poster entitled “Safety and Pharmacokinetics of MGCD290, an Oral fungal Hos2 Inhibitor, Alone and in Combination with Fluconazole: Single and Multiple Ascending Dose Studies in Healthy Subjects (290-001, 002, 003, 004)” (presentation #1619).

MGCD290 has been well tolerated at all doses, both alone and in combination with fluconazole. Data also suggest that food increased exposure by approximately three-fold, and MGCD290 was detected in vaginal secretions and in patients’ toenails.

Favorable PK values were observed for repeated dosing of MGCD290 alone and in combination with Flu For up to 14 days. Mean elimination half□life was approximately 7□14 hours. Peak plasma concentration was observed at 1.5□3 hrs post administration. Mean plasma exposure (AUC) was approximately proportional to dose. No drug□drug interactions (DDI) were observed for either MGCD290 or Flu

We think data from these Phase I studies indicate that MGCD290 has an attractive pharmacokinetic and safety profile. Based on our analysis of the Phase I and preclinical data, we are comfortable with the safety and tolerability of MGCD290 dosed both alone and in combination with fluconazole.

MGCD265 Clinical Program Update

As a reminder, MGCD265 is an oral, multi-targeted kinase inhibitor rationally designed to target the Met, VEGFR, RON and Tie-2 RTKs, key kinases involved in cancer and angiogenesis.

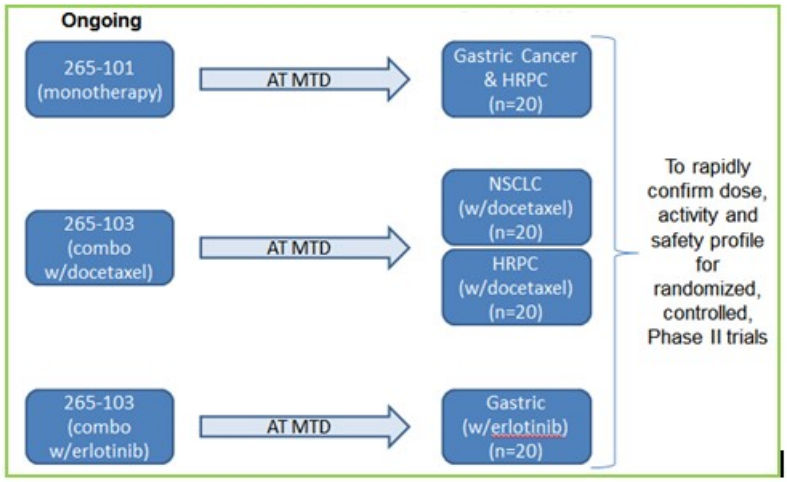
Enrollment is ongoing in the Phase I/II trials **MGCD265-101** (monotherapy) and **MGCD265-103** (combination therapy with docetaxel or erlotinib).

In **monotherapy** studies, MGCD265 has been well tolerated with no grade 4 adverse events. Treatment-related grade 3-4 adverse events were infrequent. Long term stable disease (over 12 months in duration) has been observed in patients with bladder, renal cell and neuroendocrine cancer. One patient with squamous cell cancer achieved a partial response (PR), as determined by RECIST criteria, after ten cycles of monotherapy with MGCD265. The PR was based on one target axillary lesion, but the non-target bone lesions remained stable.

MGCD265 **in combination with docetaxel** continues to be well tolerated. Non-hematologic grade 3-4 adverse events occurring in more than one patient were infrequent and hematologic toxicities of grade 3-4 were as expected with docetaxel therapy. Objective responses have been observed in NSCLC, prostate cancer and endometrial cancer patients. Of twelve evaluable NSCLC patients, two achieved partial remission and eleven achieved disease control (partial remission or stable disease) at the first tumor assessment.

In the **MGCD265 plus erlotinib combination** studies there were no grade 4 toxicities and grade 3-4 adverse events were infrequent. Five of nine gastro-esophageal (GE) patients achieved stable disease at the first scan (disease control rate of 56%). Of these four patients remained stable for greater than 4 months and two remained stable for greater than 1 year.

Enrollment will continue in the 265-101 monotherapy and 265-103 combination trials with docetaxel or erlotinib until a maximum tolerated dose (MTD) is reached. Once the MTD is reached, the Company will define the optimal dose for **Phase II studies** and the product will advance into multiple Phase I/II expansion cohorts. Indications of interest include renal cell, gastric and hepatocellular cancer patients who are c-Met positive. Plans are also underway to initiate a study in NSCLC patients who express Axl.



We are very pleased to see MethylGene has made great progress in clinical development in recent months. Current share price should be boosted based on the Company's strong fundamentals.

VALUATION AND RECOMMENDATION

We maintain our Outperform rating on MethylGene (MYLGF) and reiterate our 12-month price target of $0.75 per share.

MethylGene is a middle stage development biotech company focused on development and commercialization of pharmaceuticals for the treatment of fungal infection and cancer. Based on its extensive knowledge and expertise in molecular biology and chemistry, the Company has built up an impressive pipeline with candidates in different development stages.

We think MethylGene's two lead candidates MGCD290 and MGCD265 are both highly promising and differentiated drug candidates. MGCD290 is a first in class anti-fungal agent, which has high synergy with marketed azole anti-fungal agents. MGCD290 also reduce drug resistance related to azole agents. Considering fluconazole is the most commonly used antifungal, the combination of MGCD290 with fluconazole will capture a significant market share of current anti-fungal market. MGCD290 is in Phase II clinical studies and we expect MGCD290 will enter into pivotal Phase III in 2013. Approval could happen in early 2015.

The Company's kinase inhibitor MGCD265 is also differentiated from other kinase inhibitors either in development or on the market. MGCD265 is a multi-targeted kinase inhibitor, which has shown favorable

safety profile and clinical activities. MGCD265 is in Phase I studies now, and will enter into Phase II soon. We estimate the FDA approval in 2017.

In addition to the above two lead candidates, MethylGene has additional products in its pipeline which also have the potential to address current medical needs.

In terms of valuation, we think MethylGene shares are undervalued. Currently, the shares are trading at $0.17 per share, which values the Company at $84.7 million in market cap based on 498 million shares outstanding. This is certainly a deep discount. As we discussed above, the Company's two lead drug candidates MGCD290 and MGCD265 have already entered into Phase II clinical studies and may be on the market in 2015 and 2017 respectively. According to our model, MethylGene will be close to breakeven in 2015, and turn profitable in 2016 with an EPS of $0.05 on total revenue of $46 million. We think MethylGene should be trading at 25x to 30x P/E multiples. Discount rate should be at 25% to 30%. Based on this, we think the Company should be valued at $0.50 to $0.75 per share, which values the Company at $250 to 374 million in market cap. Our $0.75 price target is based on our estimated EPS of $0.05 in 2016, multiplied by 30 x P/E ratio, discounted at 25% for 3 years.

Our valuation does not consider the value of the Company's preclinical and partnered programs. Any progress in these programs could be a bonus for the Company and drive share price higher.

Risks related to our price target include:

- Regulatory risk: Our valuation of MethylGene is based on the assumption that the Company's two lead drug candidates will be approved by the FDA in 2015 and 2016 respectively. Any clinical failure could deny or delay the approval, and share price will suffer.

- Trading risk: MethylGene is a Canadian company, which is traded in OTC market in the US. Trading on OTC market usually is more sporadic, liquidity may be an issue.

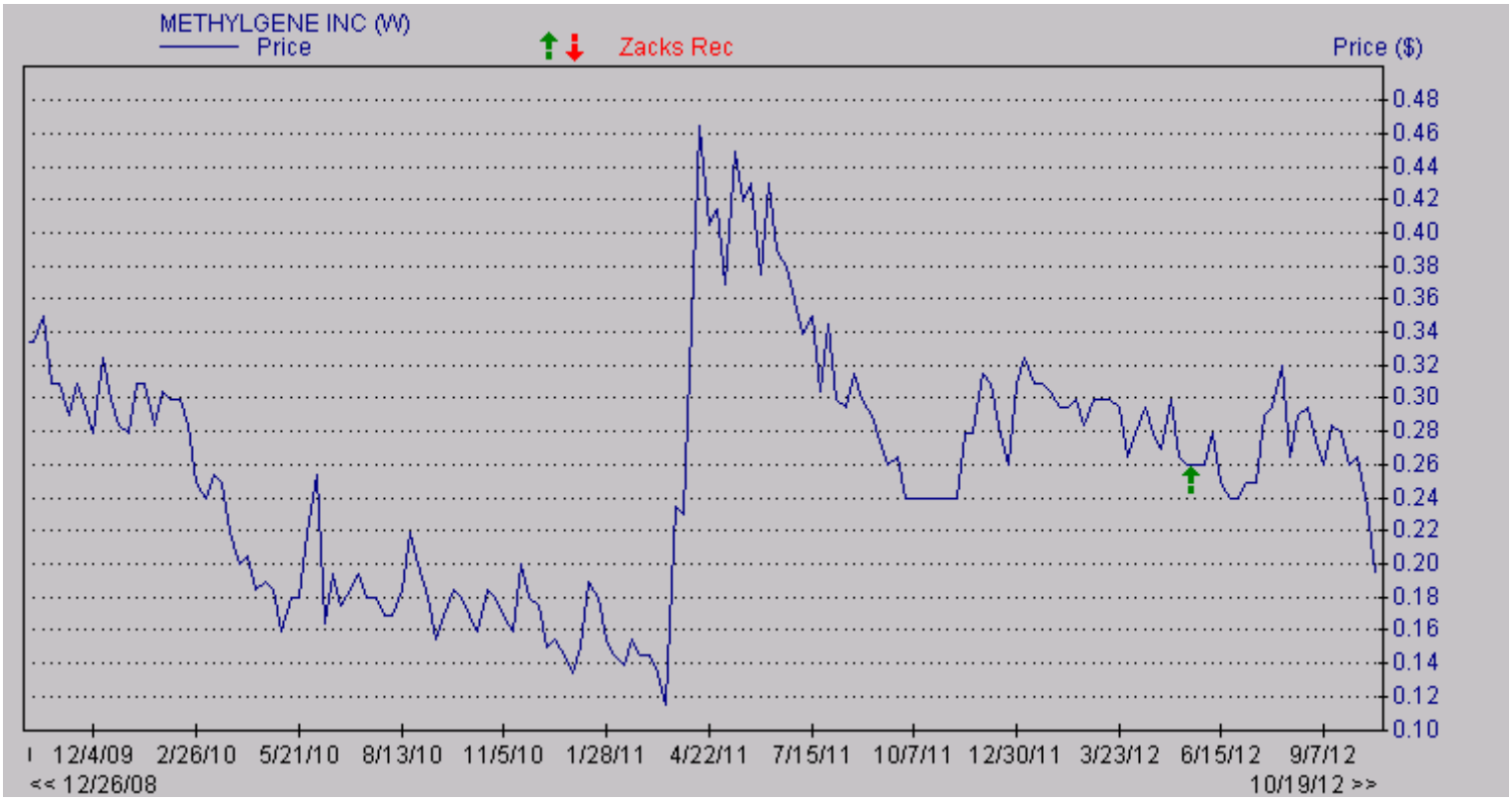
PROJECTED INCOME STATEMENT

	2011A (Dec)					2012E (Dec)					2013E (Dec)	2014E (Dec)	2015E (Dec)	2016E (Dec)
$ in million except per share data	Q1	Q2	Q3	Q4	FYA	Q1A	Q2A	Q3A	Q4E	FYE	FYE	FYE	FYE	FYE
R&D and Contract revenue	$0.40	$0.39	$0.00	$0.00	$0.79	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.50	$0.50	$1.00
License and Up-front revenue	$0.88	$0.88	$0.07	$0.47	$2.30	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$5.00	$15.00
Product Sales	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$10.00	$30.00
Total Revenues	**$1.28**	**$1.27**	**$0.07**	**$0.47**	**$3.09**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.50**	**$15.50**	**$46.00**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	*3000.0%*	*196.8%*
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	0.00	0.00
Gross Income	**$1.28**	**$1.27**	**$0.07**	**$0.47**	**$3.09**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.50**	**$15.50**	**$46.00**
Gross Margin	-	*100.0%*	-	-	-	-	-	-	-	-	-	*100.0%*	*100.0%*	*100.0%*
R&D	$1.83	$1.79	$2.09	$3.13	$8.83	$2.21	$3.69	$4.23	$4.30	$14.43	$9.50	$10.00	$10.50	$12.00
% SG&A	-	-	-	-	-	-	-	-	-	-	-	-	-	
SG&A	$1.03	$1.06	$1.18	$1.02	$4.29	$1.22	$1.09	$1.71	$1.75	$5.77	$5.00	$6.50	$7.00	$7.50
% R&D	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other	$0.00	($0.11)	($0.12)	$0.00	($0.23)	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
% Other	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Operating Income	**($1.6)**	**($1.5)**	**($3.1)**	**($3.7)**	**($9.8)**	**($3.4)**	**($4.8)**	**($5.9)**	**($6.1)**	**($20.2)**	**($14.5)**	**($16.0)**	**($2.0)**	**$26.5**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Net	$0.0	($0.3)	$0.0	$0.6	($0.4)	$0.1	$0.1	($0.0)	$0.1	$0.2	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	**($1.6)**	**($1.8)**	**($3.1)**	**($3.0)**	**($10.2)**	**($3.4)**	**($4.7)**	**($6.0)**	**($6.0)**	**($20.0)**	**($14.5)**	**($16.0)**	**($2.0)**	**$26.5**
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	$0.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*-0.1%*	*0.0%*	*0.0%*	*0.0%*	-
Reported Net Income	**($1.6)**	**($1.8)**	**($3.1)**	**($3.0)**	**($10.2)**	**($3.4)**	**($4.7)**	**($6.0)**	**($6.0)**	**($20.1)**	**($14.5)**	**($16.0)**	**($2.0)**	**$26.5**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Deluted Shares Out	*40.4*	*308.8*	*317.9*	*321.7*	*247.2*	*317.9*	*317.9*	*318.1*	*396.0*	*337.5*	*497.8*	*520.0*	*550.0*	*575.0*
Reported EPS	**($0.04)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.04)**	**($0.01)**	**($0.01)**	**($0.02)**	**($0.02)**	**($0.06)**	**($0.03)**	**($0.03)**	**($0.00)**	**$0.05**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
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	**($1.6)**	**($1.8)**	**($3.1)**	**($3.0)**	**($10.2)**	**($3.4)**	**($4.7)**	**($6.0)**	**($6.0)**	**($20.1)**	**($14.5)**	**($16.0)**	**($2.0)**	**$26.5**
Non GAAP EPS	**($0.04)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.04)**	**($0.01)**	**($0.01)**	**($0.02)**	**($0.02)**	**($0.06)**	**($0.03)**	**($0.03)**	**($0.00)**	**$0.05**

Source: Company filing and Zacks Investment Research

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HISTORICAL ZACKS RECOMMENDATIONS



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