Zacks Small-Cap Research

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MethylGene Inc.

(MYG-TO, MYLGF-OTC)

T.MYG: On track to advance its clinical programs and balance sheet continues to be strong--Outperform

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	05/22/2012
Current Price (10/22/2012)	$0.19
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 E	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	-$0.01 E	-$0.01 E	-$0.05 E
2013					-$0.04 E
2014					-$0.04 E

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

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WHAT'S NEW

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.

MGCD290 Has Entered Into Proof Of Concept Phase II Clinical Trials

Based on preclinical and Phase I results, in October 2011, MethylGene initiated a **Phase II (Study 290-005)** clinical study evaluating MGCD290 in combination with fluconazole vs. fluconazole alone in patients with **moderate to severe** vulvovaginal candidiasis **(VVC).**

This study is a multicenter, randomized, double-blinded, placebo-controlled trial and is currently enrolling subjects at sites in the US and Canada with moderate to severe AVVC. 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. The Company expects to report topline data from this trial in **Q1 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.

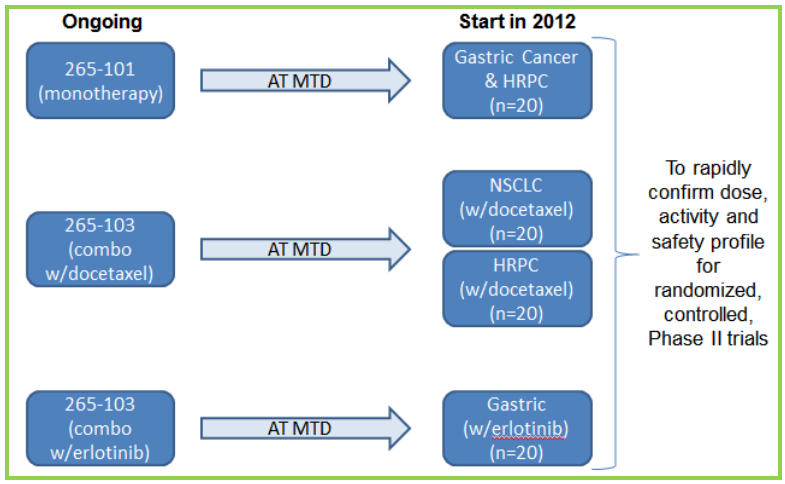
Encouraging Clinical Data on MGCD265 Presented at the ESMO 2012 Congress

On October 1, 2012, MethylGene Inc. (MYG) presented clinical data from its MGCD265 Met/VEGFR-targeted oncology program at the European Society for Medical Oncology (ESMO) 2012 Congress, held in Vienna, Austria. Three poster presentations provided updates on the ongoing monotherapy, combination therapy and healthy volunteer trials.

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.

MethylGene has completed a Phase I monotherapy study (**Trial 265-102**, intermittent dosing) for MGCD265. Another monotherapy Phase I study (**Trial 265-101**, continuous dosing) and a Phase I/II

(**Trial 265-103** combination study with two arms: MGCD265+full dose docetaxel, or MGCD265+full dose erlotinib) are ongoing.



Phase	Study	Schedule of Administration	N	Early Signs of Clinical Activity	DLTs
I	265-101	Single-agent Continuous daily	57	Colorectal, thymic, bladder, renal, neuroendocrine	Fatigue, hypertension (n=1), lipase elevation
I	265-102 Complete	Single-agent Daily, one week on/one week off	47		Fatigue, mood change, hemoptysis (n=1)
I/II	265-103	Combination Docetaxel arm: Continuous daily	36	NSCLC, prostate, endometrial	Fatigue, diarrhea, lipase elevation
		Combination Erlotinib arm: Continuous daily	46	NSCLC, gastroesophageal	Fatigue, diarrhea, rash, rhabdomyolosis (n=1)

Source: Company presentation as of March 2012

At the ESMO Congress, MethylGene presented updated data on the two ongoing Phase I clinical trials (101 and 103) and on the recently completed Phase I Trial 265-105.

Update on trial 101:

The trial 101 poster is entitled "A Phase I, dose-escalation study of MGCD265, a multi-targeted oral tyrosine kinase receptor inhibitor, for treatment of advanced solid tumors" (abstract 471P), which documented the safety profile, pharmacokinetics, pharmacodynamics and clinical response observed as of October 1, 2012, in the ongoing monotherapy trial 265-101. MGCD265 continues to exhibit a favorable safety profile with drug-related adverse events being mostly mild to moderate. The maximum tolerated dose (MTD) has not yet been reached. Drug-related grade 3 adverse events seen in more than one patient were diarrhea, fatigue and elevated lipase (n=2 for each). Stable disease was achieved in 36% of patients (24/67 patients). No objective responses have been seen to date. Dose-dependent Met inhibition was demonstrated using samples of patient plasma, and drug exposures have reached the range shown to have antitumor effects in animal models.

Update on trial 103:

Data from the ongoing combination trial 265-103 was presented in the poster entitled “Clinical effects of MGCD265, an oral tyrosine kinase inhibitor, in combination with erlotinib or docetaxel for treatment of advanced gastroesophageal and NSCLC tumors” (abstract 492P). This poster highlighted the clinical responses seen in patients with non-small cell lung cancer (NSCLC, n=12) or gastro-esophageal cancer (GE, n=9) treated with MGCD265 in combination with docetaxel or erlotinib in an ongoing dose-escalating Phase I study. Among twelve patients with NSCLC treated with MGCD265 (up to 600 mg / m2), nine achieved disease control (seven stable disease and two partial responses). Four NSCLC patients were progression-free for 7-11 months. In the GE cohort, five of nine patients treated with MGCD265 (up to 324 mg / m2) achieved disease control (all stable disease). Three of these patients remained stable for 11-22 months, an increase of 6-11 fold compared to the length of time on prior therapy. The safety profile of MGCD265 in combination with docetaxel or erlotinib was acceptable at doses up to 600 mg / day with no apparent increase in frequency of the adverse events that are commonly associated with docetaxel and erlotinib, respectively. Dose escalation is ongoing and the MTD has not been defined for either combination.

Update on trial 105:

The third poster entitled “Pharmacokinetic profile of MGCD265, an oral tyrosine kinase inhibitor, with or without food in healthy volunteers” (abstract 493P) described the recently completed **Phase I Trial 265-105** which assessed the effect of food on MGCD265 pharmacokinetics. This study showed that administration of MGCD265 in the presence of food increased drug exposure significantly, with no added toxicity. Based on these findings, food has been incorporated into all ongoing MGCD265 clinical trials.

Our Takeaways from the ESMO Presentation

We think the data presented at the ESMO Congress are encouraging. These data have demonstrated further favorable safety and efficacious clinical activity of MGCD265 as a single agent as well as in combination with other anticancer agents.

We are especially encouraged by the safety profile and clinical benefits of MGCD265 in combination with erlotinib or docetaxel for treatment of advanced gastroesophageal and NSCLC tumors. We believe MGCD265 plus erlotinib or docetaxel has the potential to provide additional treatment options for patients of NSCLC and gastroesophageal cancers as well as other cancer types.

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.

Balance Sheet Continues to be Strong

On August 2, MethylGene reported its financial results for the second quarter ended June 30, 2012.

There was no revenue in the second quarter of 2012 compared to $1.3 million for the second quarter of 2011. The decline in revenue was due to the completion of the research component of the agreement with Otsuka Pharmaceutical Co. Ltd. in June of 2011.

Research and development expenditures for the second quarter of 2012 were $3.7 million versus $1.8 million in the second quarter of 2011. This increase was primarily due to increased clinical development activity for both the MGCD290 and MGCD265 programs.

General and administrative expenses in the second quarter of 2012 were $1.1 million, no change versus the second quarter of 2011.

Net loss for the second quarter of 2012 was $4.7 million, or $0.01 per share, compared to a net of $1.5 million, or $0.005 per share, for the same period last year.

We are very pleased to see the Company's balance sheet continued to be strong at the end of second quarter of 2012. Cash, cash equivalents, marketable securities and restricted cash totaled $22.2 million as at June 30, 2012. According to our model, the cash balance can last into the fourth quarter of 2013.

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/II studies now. 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 $0.20 per share, which values the Company at $60 million in market cap based on 318 million shares outstanding. This is certainly a deep discount. As we discussed about, 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 $0.06 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 $160 to 240 million in market cap. Our $0.75 price target is based on our estimated EPS of $0.06 in 2016, multiplied by 30 x P/E ratio, discounted at 25% for 4 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.

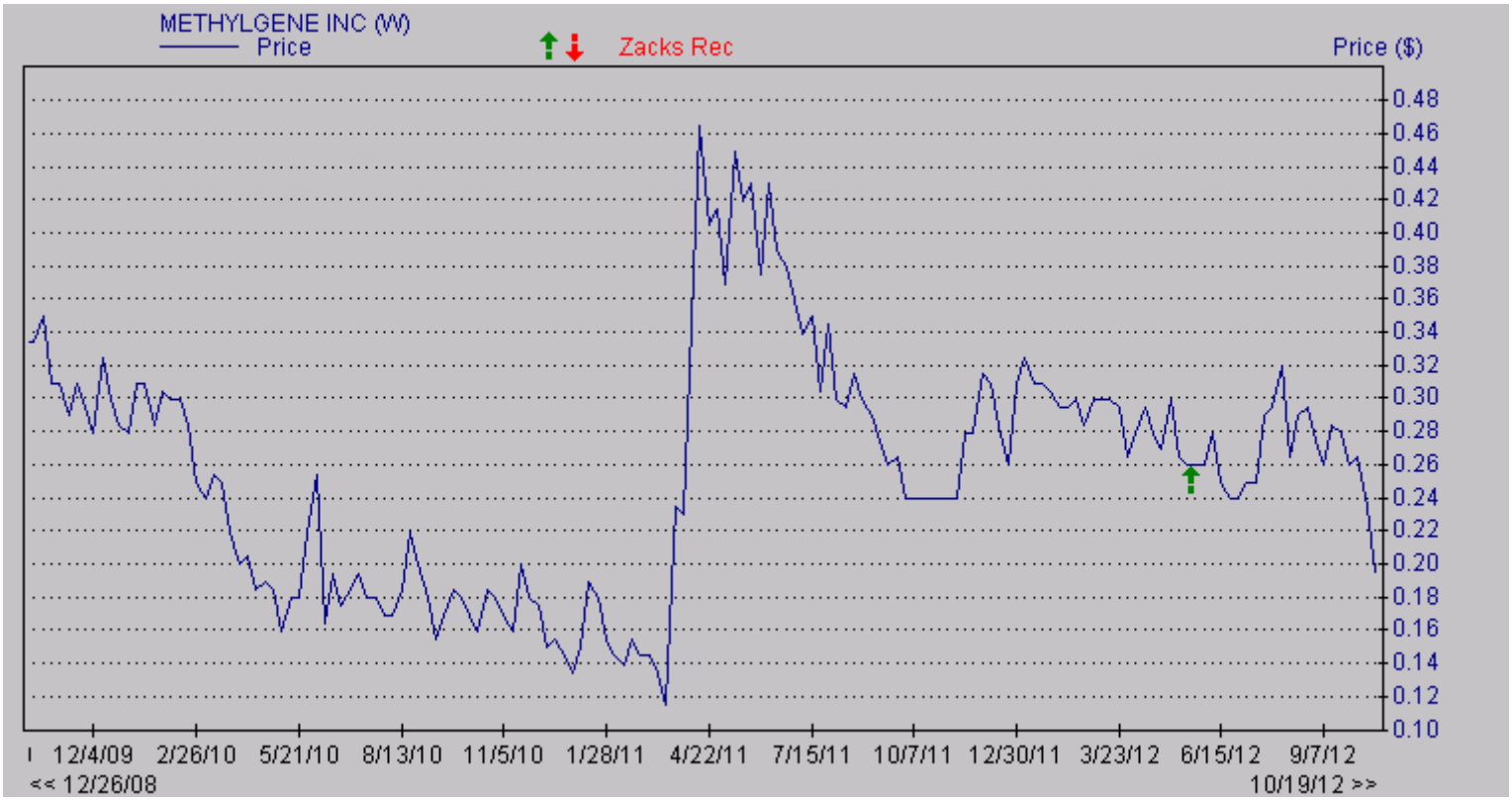
PROJECTED INCOME STATEMENT

	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	Q3E	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	$2.27	$2.30	$10.47	$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	$1.24	$1.25	$4.81	$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)**	**($3.5)**	**($3.6)**	**($15.3)**	**($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	$0.1	$0.1	$0.3	$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)**	**($3.5)**	**($3.5)**	**($15.0)**	**($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)**	**($3.5)**	**($3.5)**	**($15.0)**	**($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*	*317.9*	*317.9*	*317.9*	*345.0*	*365.0*	*400.0*	*450.0*
Reported EPS	**($0.04)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.04)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.05)**	**($0.04)**	**($0.04)**	**($0.01)**	**$0.06**
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)**	**($3.5)**	**($3.5)**	**($15.0)**	**($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)**	**($0.01)**	**($0.01)**	**($0.05)**	**($0.04)**	**($0.04)**	**($0.01)**	**$0.06**

Source: Company filing and Zacks Investment Research

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HISTORICAL ZACKS RECOMMENDATIONS



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