Zacks Small-Cap Research

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EpiCept Corp (EPCT-NASDAQ)

EPCT: Partnership talks may take time--- Neutral

Current Recommendation	**Neutral**
Prior Recommendation	Outperform
Date of Last Change	05/09/2012
Current Price (08/10/12)	$0.14
12-Month Target Price	**$0.50**

OUTLOOK

EpiCept is a commercial stage specialty pharmaceutical company targeting cancer and pain markets. The Company's lead cancer candidate Ceplene has been already approved in EU and Israel for the remission maintenance of AML. Another important candidate is AmiKet for peripheral neuropathy, which is approved for Phase III trial. The Company has engaged SunTrust Robinson Humphrey to assist in exploring strategic alternatives to maximize its shareholder value, which include possible sale of the Company.

We are Neutral at this point of time on EpiCept shares.

SUMMARY DATA

52-Week High	**$0.49**
52-Week Low	**$0.13**
One-Year Return (%)	**-70.83**
Beta	**1.36**
Average Daily Volume (sh)	**36,412**
Shares Outstanding (mil)	**83**
Market Capitalization ($mil)	**$12**
Short Interest Ratio (days)	**6.28**
Institutional Ownership (%)	**5**
Insider Ownership (%)	**4**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-18.2**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2011 Estimate	**N/A**
P/E using 2012 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**N/A**
Industry	**Med-Drugs**
Zacks Rank in Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	0.24 A	0.22 A	0.28 A	0.21 A	0.94 A
2012	0.24 A	6.60 A	0.24 E	0.27 E	7.35 E
2013					2.00 E
2014					4.00 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	-$0.06 A	-$0.07 A	-$0.05 A	-$0.22 A
2012	-$0.05 A	-$0.00 A	-$0.02 E	-$0.02 E	-$0.10 E
2013					-$0.09 E
2014					-$0.08 E

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

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WHAT'S NEW

EpiCept Reports 2012 Second Quarter Results

On August 8, 2012, EpiCept (EPCT) reported operating and financial results for the three months ended June 30, 2012.

Total revenue was $6.6 million during the second quarter of 2012, compared with $0.2 million during the second quarter of 2011. For the second quarter of 2012, revenue consisted primarily of license fee payments and product revenue from the sale of the Company's rights to Ceplene to Meda AB. For the second quarter of 2011, revenue consisted primarily of the recognition of license fee payments previously received from strategic alliances.

Cost of goods sold was $0.4 million in the second quarter of 2012, which consisted solely of the costs from the sale of Ceplene to Meda AB. Cost of goods sold in the second quarter of 2011 consisted primarily of a $0.3 million expense for Ceplene inventory the Company believed would not be sold prior to reaching its product expiration date.

SG&A expense in the second quarter of 2012 decreased by approximately 30%, or $0.6 million, to $1.4 million, compared with $2.0 million in the second quarter of 2011. The decrease was primarily attributable to lower legal expenses, lower salary and salary related expenses as the result of a reduction in projected bonus payments for 2012 and lower investor relations expenses. Selling expense has been significantly reduced, and the Company expects general and administrative expenses to remain at approximately current levels over the next few quarters.

R&D expense in the second quarter of 2012 decreased by 50%, or $1.0 million, to $1.0 million from $2.0 million in the second quarter of 2011. The decrease was primarily attributable to lower clinical trial costs for Ceplene®, lower salary and salary related expenses and lower patent expenses. The Company expects research and development expenses to remain at approximately current levels over the next few quarters.

Net income was $3.0 million for the three months ended June 30, 2012 primarily as a result of the Company's sale of its Ceplene®-related assets and contract rights to Meda AB. The net loss for the three ended June 30, 2011 was $4.3 million.

Adjusted net loss was $0.4 million or -$0.00 per share for the second quarter of 2012.

EpiCept had $4.8 million in cash and cash equivalents as of June 30, 2012. Current cash is anticipated to be sufficient to run operations into the fourth quarter of 2012.

Ceplene Rights are Sold to Meda AB

Ceplene has been approved in the EU and Israel for administration with low-dose interleukin-2 (IL-2) for the remission maintenance and prevention of relapse of patients with Acute Myeloid Leukemia (AML) in first remission; AML is the deadliest form of leukemia in adults. **In June 2012**, the Company sold all of its rights to Ceplene® in the territories previously licensed to Meda AB, and a portion of its remaining Ceplene® inventory, to Meda for approximately $2.6 million in cash and the assumption of EpiCept's ongoing responsibilities related to the manufacture of, and maintenance of the marketing authorization for, Ceplene® in the European Union. EpiCept also agreed to relinquish all future milestone payments and royalties on future sales of Ceplene® by Meda. In conjunction with the closing of this transaction EpiCept will close its EpiCept GmbH facility in Munich, Germany over the next several months. Ceplene® is licensed to Megapharm Ltd. to market and sell in Israel. Following Ministry of Health approval of labeling and other reimbursement matters expected this year, Megapharm Ltd. is expected to

commence the commercial launch of Ceplene® in Israel, until which time it is available there on a named-patient basis. EpiCept retains rights to Ceplene® in all other countries, including countries in North and South America.

Success will be Dependent on AmiKet

EpiCept's focus has shifted to AmiKet from Ceplene recently and the Company's success will be dependent on finding a partner for AmiKet or a buyer for the Company.

On January 24, 2012, EpiCept Corporation (EPCT) received further encouraging guidance for the **Phase III** clinical and nonclinical development and subsequent New Drug Application (NDA) filing of **AmiKet**™ in the treatment of chemotherapy- induced peripheral neuropathy (CIPN) based on the issuance of the final minutes of the Company's meeting with the FDA in December 2011.

AmiKet™ is a prescription, topical analgesic cream containing amitriptyline 4% and ketamine 2% designed to provide relief from neuropathic pain, which affects more than 15 million people in the U.S. alone. In the first half of 2011, EpiCept announced positive results from a National Cancer Institute-sponsored study evaluating the efficacy and safety of AmiKet™ in chemotherapy-induced peripheral neuropathy (**CIPN**), a painful condition that frequently occurs following systemic chemotherapy and that may interrupt, delay or even prevent completion of potentially curative chemotherapy regimens. A safe and effective therapeutic option for neuropathic pain associated with CIPN would address a significant unmet medical need.

In addition to the positive outcome previously reported for AmiKet™ in CIPN, EpiCept has reported statistically significant positive results in the treatment of pain from post-herpetic neuralgia in several Phase II studies, the non-inferiority of AmiKet™ compared with gabapentin in another placebo controlled study, and a positive trend in the treatment of pain in a diabetic neuropathy Phase II study.

In the final meeting minutes recently received by EpiCept, the FDA acknowledged that painful symptoms due to CIPN represent a significant unmet medical need and encouraged EpiCept to apply for Fast Track designation. Further, the FDA waived several expensive and time consuming non-clinical toxicology studies, and indicated that a single four-arm factorial trial might suffice for regulatory approval if combined with other pivotal data in another neuropathy such as diabetic peripheral neuropathy.

The key element of the proposed Phase III clinical program is a 12-week, four-arm, factorial designed trial in CIPN that would seek to demonstrate AmiKet's superiority compared with placebo and with each of the component drugs of AmiKet™, amitriptyline and ketamine. EpiCept intends to submit the protocol for this trial to the FDA via a Special Protocol Assessment (SPA). An additional two-arm efficacy study in another painful peripheral neuropathy may be performed as an alternative strategy to a second factorial-designed trial for the NDA filing, which could potentially lead to a broader label in the treatment of peripheral neuropathic pain.

The meeting minutes included a summary of the nonclinical program requirements to file an NDA, which notably included only a single dermal carcinogenicity study. The dermal photo-irritation/toxicity assessment may be waived, provided dermal photo-irritation is assessed in the clinical program. A COMET assay (Single Cell Gel Electrophoresis to detect DNA damage) study is required prior to initiation of the long-term open label clinical safety study.

During the second quarter of 2012, EpiCept received written advice from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) concerning the clinical and nonclinical development and subsequent Marketing Authorization Approval (MAA) filing of AmiKet. In its written advice the CHMP recommended that the proposed clinical program consist of a single 12-week, four-arm, factorial-designed trial in CIPN that would seek to demonstrate AmiKet's superiority compared with placebo and with each of the component drugs of AmiKet, amitriptyline and ketamine. An additional two-arm efficacy study in CIPN or another neuropathy is required to complete the clinical requirements of

the application. The advice provided a summary of the additional nonclinical program requirements to file an MAA, which included a 90-day dermal toxicity study in a non-rodent species, a dermal phototoxicity study in a rodent and an ocular toxicity study. The advice received from the CHMP is consistent with the guidance given to the Company by the FDA in January 2012, in which the FDA waived several expensive and time-consuming non-clinical toxicology studies, and indicated that a single four-arm factorial trial might suffice for regulatory approval if combined with other pivotal data in another neuropathy such as diabetic peripheral neuropathy.

We think responses from both the FDA and CHMP are positive. This is a very favorable outcome that will likely benefit AmiKet's market opportunity and time to NDA or MAA filing. Further, this will facilitate SunTrust Robinson Humphrey's efforts to identify potential acquirers or strategic partners to advance AmiKet™ towards approval and commercialization in the United States.

The FDA granted **Fast Track Status** to AmiKet in April 2012 and has agreed that a Special Protocol Assessment (**SPA**) would be available upon formal submission and agreement on the Phase III trial protocol.

A Strategic Partner is Needed to Advance AmiKet™

On January 9, EpiCept announced that it has engaged SunTrust Robinson Humphrey to assist in exploring strategic alternatives to maximize the commercial opportunity of AmiKet™. The engagement is focused on the identification and implementation of a strategy that will optimize AmiKet's value for the Company's stockholders, which includes the evaluation of potential transactions involving the sale of the Company.

During the fourth quarter of 2011, a U.S. market evaluation of the CIPN opportunity was completed by an independent market assessment firm engaged by EpiCept. Among the study's conclusions was that peak annual revenue for AmiKet™ treating CIPN in the U.S. alone could exceed $400 million through a specialty pharmaceutical sales force of less than 150 targeting the top six deciles of prescribing oncologists, pain specialists and neurologists. The study determined that the number of cases of malignant cancer diagnoses of breast, prostate, lung and ovarian cancers currently exceeds 3.5 million, and estimated that 90% of all prostate and ovarian cancer patients, 75% of all breast cancer patients and more than 60% of all lung cancer patients are treated with taxanes, either alone or in combination with other chemotherapeutic drugs. Based on physician interviews, expert opinions and a review of the medical literature, the study concluded that a significant percentage of this group develops some form of CIPN.

A successful outcome of this engagement will enable the product to move forward quickly through its final stage of clinical and regulatory development. This will optimize AmiKet's value for the Company's shareholders in our view.

Update on Other Clinical Programs

F573 (previously known as EP1013) is a di-peptide small-molecule compound licensed by EpiCept to GNI Group Ltd. in China, Japan and other key Asian territories that has demonstrated a potent inhibitory effect on caspases, a class of enzymes involved in cell death and inflammation. Drug efficacy has been shown in animal models relating to liver failure, brain ischemia and myocardial infarction. Data published in the Chinese Pharmacological Bulletin (2102 Volume 28 (1):136-139) during the first quarter of 2012 concluded that F573 is a new therapeutic drug candidate for the treatment of late-stage **viral infection-induced hepatitis**. F573 delivered intravenously demonstrated a therapeutic effect in a study involving 60 mice with acute liver injury, including a reduction in TNF-a and cell apoptosis. As part of its license agreement with GNI Group Ltd., EpiCept received a small upfront fee upon signing the agreement and is eligible to receive milestone payments of more than $12 million based on the clinical advancement of F573 in in the licensed territories, as well as royalties on commercial sales. EpiCept retains the commercial rights to F573/EP1013 in all other markets. The next potential milestone payment will be in

conjunction with initiation of a Phase I trial in any of the territories outlined in the agreement. In July 2011 Shanghai Genomics, a wholly owned subsidiary of GNI Group Ltd., filed an Investigational New Drug (IND) application for F573 in China.

Crolibulin is a vascular disruption agent that has demonstrated potent anti-tumor activity in both preclinical and early clinical studies. In December 2010 the NCI initiated a **Phase Ib/II** trial with Crolibulin to assess safety and efficacy in combination with **cisplatin** in patients with anaplastic thyroid cancer. Trial enrollment has progressed to the third and final dosing cohort for the Phase Ib portion of this trial. The Phase II randomized proof-of-concept efficacy portion of the trial is anticipated to begin later in 2012.

Azixa is a vascular disruption agent discovered by EpiCept and licensed to Myrexis, Inc. as part of an exclusive, worldwide development and commercialization agreement. Azixa has received orphan drug status in the U.S. for the treatment of glioblastoma multiforme. In February 2012 Myrexis suspended development activities of all its preclinical and clinical programs in oncology and autoimmune diseases, and in May 2012 the company stated that it is focused on the identification, evaluation and acquisition of appropriate commercial-stage assets. EpiCept believes that in light of its new strategic direction, Myrexis does not intend to comply with its development obligations; therefore, the Company intends to enforce its rights under the license agreement with Myrexis.

VALUATION AND RECOMMENDATION

We maintain our Neutral rating on EpiCept shares. Our new 12-month price target is $0.50 per share.

Our call is based on the change of the Company's fundamentals.

EpiCept is a specialty pharmaceutical company targeting two large and underserved markets: cancer treatment and pain management. The Company's key product candidate Ceplene has been approved in Europe and Israel for the maintenance therapy of AML. Ceplene has been commercially launched in UK, Germany and Austria and will continue to be launched in other European countries and Israel this year. However, sales continue to be immaterial in these approved markets. As a result, the Company has sold the rights to Ceplene to in the territories previously licensed to Meda AB.

We think Ceplene is almost dead in the US due to the new regulatory requirements issued by the FDA. The Company filed its protocol for a **Phase III** confirmatory clinical trial for Ceplene with the FDA in the second quarter of 2011, and a meeting with the FDA was held in September 2011 to reconcile the major protocol elements. At the meeting, the FDA indicated that as part of a registration study, the effect of Ceplene must be isolated from the effect of IL-2; therefore the FDA's preferred study design is a comparison of Ceplene/IL-2 vs. IL-2 monotherapy at the same IL-2 dosing regimen as those patients receiving Ceplene/IL-2 in combination. The FDA also indicated the need to demonstrate as the primary endpoint a significant benefit of Ceplene/IL-2 vs. IL-2 monotherapy on overall survival. At this time, **the Company is not pursuing the Phase III trial** given that IL-2 monotherapy has failed to demonstrate any significant statistical or clinical benefit in maintaining AML remission in six separate clinical trials conducted by several prominent international study groups in the past several years. Further, the significant cost to run such a trial and the time required to achieve a meaningful overall survival endpoint render its undertaking by the Company impractical at this time.

Therefore, the Company has shifted its focus to Amiket. We believe AmiKet has great potential, but a partner is needed to advance this candidate into Phase III trial and commercialization considering a huge amount of money is needed for the Phase III trial alone.

Currently, the Company shares are trading at about $0.15 per share which values the Company at about $12 million based on 83 million shares outstanding. We believe the share price will stay around $0.15 for a while until a final deal is closed for AmiKet.

But Cash Position is still Our Chief Concern

EpiCept has a relatively weak balance sheet. Since its inception, the Company has been losing money due to lack of meaningful revenue and high costs related to R&D programs and SG&A.

EpiCept had $4.8 million in cash and cash equivalents as of June 30, 2012. Current cash is anticipated to be sufficient to run operations into the fourth quarter of 2012. If the Company can't find a partner for AmiKet, it may need to tap the capital market very soon.

We remind investors, equity financing will dilute existing shareholder base, and share price will suffer.

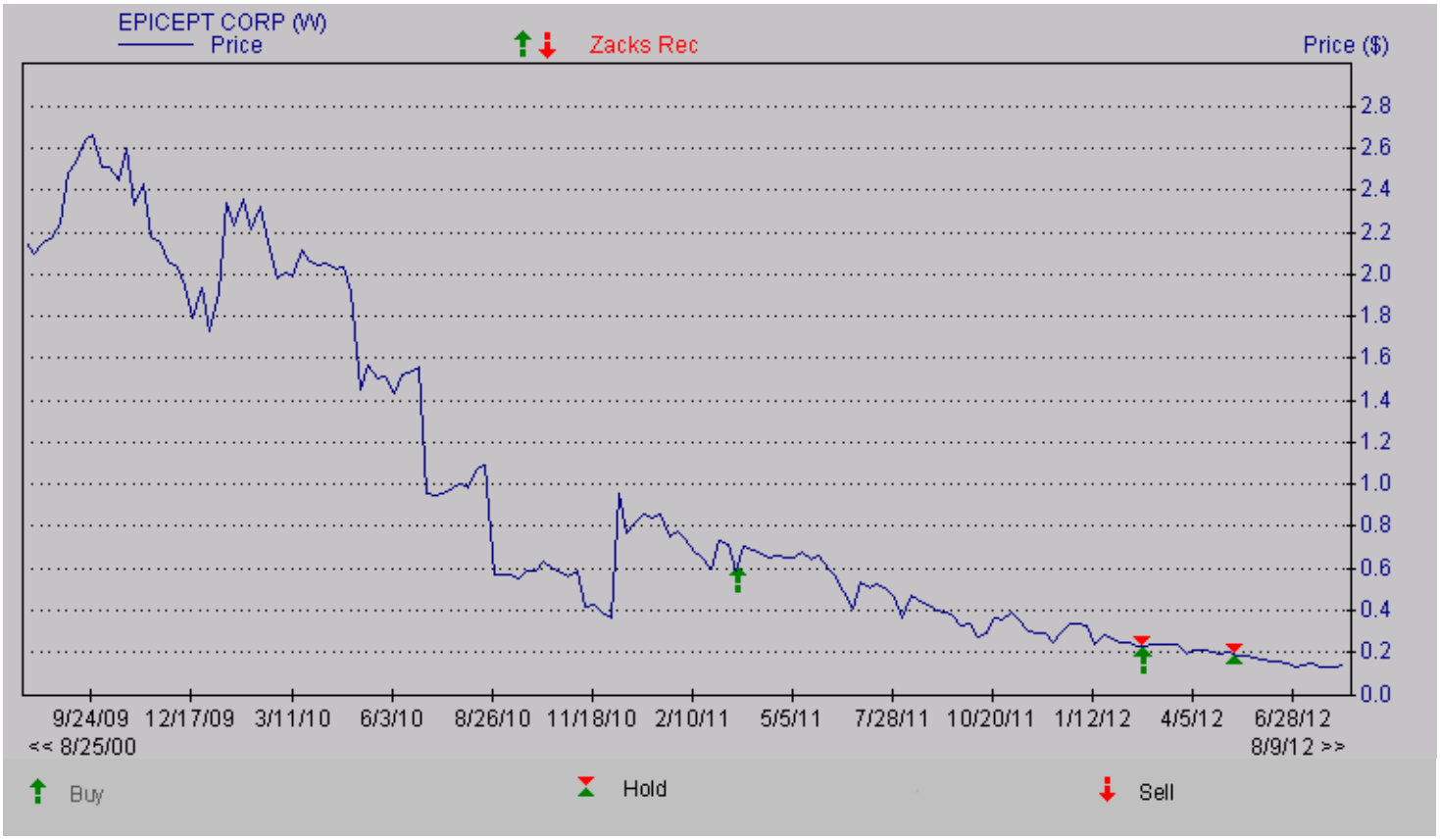
PROJECTED INCOME STATEMENT

	2011A (Dec)					2012E (Dec)					2013E (Dec)	2014E (Dec)	2015E (Dec)
$ in million except per share data	Q1A	Q2A	Q3A	Q4A	FYA	Q1	Q2	Q3	Q4	FYE	FYE	FYE	FYE
Product Revenue	$0.05	$0.00	$0.03	$0.00	$0.09	$0.05	$0.58	$0.09	$0.12	$0.84	$1.50	$3.50	$7.50
R&D revenue	$0.19	$0.22	$0.24	$0.20	$0.86	$0.19	$6.03	$0.15	$0.15	$6.52	$0.50	$0.50	$0.50
Total Revenues	**$0.24**	**$0.22**	**$0.28**	**$0.21**	**$0.94**	**$0.24**	**$6.60**	**$0.24**	**$0.27**	**$7.35**	**$2.00**	**$4.00**	**$8.00**
YOY Growth	*42.5%*	*-10.8%*	*7.0%*	*-28.9%*	*-2.3%*	*1.3%*	*2847.3%*	*-12.7%*	*30.4%*	*2989.5%*	*792.9%*	*1354.5%*	*3764.7%*
CoGS	0.09	0.27	0.05	0.28	0.69	0.00	0.40	0.05	0.05	0.50	1.00	2.00	3.60
Gross Income	**$0.15**	**($0.05)**	**$0.22**	**($0.07)**	**$0.25**	**$0.24**	**$6.21**	**$0.19**	**$0.22**	**$6.86**	**$1.00**	**$2.00**	**$4.40**
Gross Margin	*62.2%*	*-20.5%*	*81.5%*	*-35.7%*	*26.7%*	*99.6%*	*94.0%*	*79.2%*	*81.5%*	*93.2%*	*50.0%*	*50.0%*	*55.0%*
SG&A	$1.39	$2.04	$1.98	$1.04	$6.45	$1.43	$1.38	$1.35	$1.30	$5.46	$5.00	$4.50	$4.00
% SG&A	-	-	-	-	-	-	-	-	-	-	-	-	-
R&D	$1.68	$1.99	$2.62	$1.56	$7.85	$1.30	$0.96	$0.86	$0.75	$3.87	$4.00	$4.50	$5.00
% R&D	-	-	-	-	-					-	-	-	-
Other	$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
% Other	-	-	-	-	-					-	-	-	-
Operating Income	**($2.9)**	**($4.1)**	**($4.4)**	**($2.7)**	**($14.1)**	**($2.5)**	**$3.9**	**($2.0)**	**($1.8)**	**($2.5)**	**($8.0)**	**($7.0)**	**($4.6)**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Net	$0.5	($0.3)	($1.0)	($0.8)	($1.6)	($2.2)	($1.7)	($0.2)	($0.2)	($4.3)	($0.8)	($1.0)	($1.0)
Pre-Tax Income	**($2.5)**	**($4.3)**	**($5.4)**	**($3.5)**	**($15.7)**	**($4.7)**	**$2.2**	**($2.2)**	**($2.0)**	**($6.7)**	**($8.8)**	**($8.0)**	**($5.6)**
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
Tax Rate	-	-	-	-	-	-	-	-	-	-	-	-	-
Reported Net Income	**($2.5)**	**($4.3)**	**($5.4)**	**($3.5)**	**($15.7)**	**($4.7)**	**$2.2**	**($2.2)**	**($2.0)**	**($6.7)**	**($8.8)**	**($8.0)**	**($5.6)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-
Shares Out	*60.1*	*71.0*	*71.0*	*71.0*	*68.3*	*77.1*	*91.6*	*92.0*	*92.0*	*88.2*	*95.0*	*100.0*	*105.0*
Reported EPS	**($0.04)**	**($0.06)**	**($0.08)**	**($0.05)**	**($0.23)**	**($0.06)**	**$0.02**	**($0.02)**	**($0.02)**	**($0.08)**	**($0.09)**	**($0.08)**	**($0.05)**
YOY Growth					-	-	-	-	-	-	-	-	-
One time charge	*$0.00*	*$0.00*	*$0.62*	*$0.00*	*$0.62*	*$0.94*	*($2.60)*	*$0.00*	*$0.00*	*($1.67)*	*$0.00*	*$0.00*	*$0.00*
Non GAAP Net Income	**($2.5)**	**($4.3)**	**($4.8)**	**($3.5)**	**($15.0)**	**($3.8)**	**($0.4)**	**($2.2)**	**($2.0)**	**($8.4)**	**($8.8)**	**($8.0)**	**($5.6)**
Non GAAP EPS	**($0.04)**	**($0.06)**	**($0.07)**	**($0.05)**	**($0.22)**	**($0.05)**	**($0.00)**	**($0.02)**	**($0.02)**	**($0.10)**	**($0.09)**	**($0.08)**	**($0.05)**

Source: Company filings and Zacks Investment Research estimates

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HISTORICAL ZACKS RECOMMENDATIONS



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The current distribution of Zacks Ratings is as follows on the 1035 companies covered: Buy/Outperform- 15.3%, Hold/Neutral- 77.3%, Sell/Underperform – 6.9%. Data is as of midnight on the business day immediately prior to this publication.

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