Zacks Small-Cap Research

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Galena Biopharma Inc. (GALE-NASDAQ)

Galena: Reported sales from Abstral ahead of official launch and advanced clinical programs---Outperform

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	11/14/2011
Current Price (11/06/13)	$2.27
Twelve-Month Target Price	**$4.50**

OUTLOOK

GALE officially launched Abstral, the **first and only** fentanyl sublingual tablet for the management of breakthrough cancer pain, in October 2013. The acquisition of Abstral has transformed GALE to a commercial stage biotech company.

The company reported initial sales from Abstral ahead of its official launch.

Currently, the Company has 5 programs in clinic including Phase III NeuVax for breast cancer, Phase I/II FBP for gynecological cancers. This is quite unusual for a small cap biotech company.

We continue rate GALE Outperform based on recent progress the Company has made.

SUMMARY DATA

52-Week High	**$2.87**
52-Week Low	**$1.40**
One-Year Return (%)	**8.10**
Beta	**1.09**
Average Daily Volume (sh)	**1,741,882**
Shares Outstanding (mil)	**103**
Market Capitalization ($mil)	**$232**
Short Interest Ratio (days)	**4.11**
Institutional Ownership (%)	**17**
Insider Ownership (%)	**6**
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 2011 Estimate	**N/A**
P/E using 2012 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Growth**
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)
2012	0.00 A	0.00 A	0.00 A	0.00 A	0.00 A
2013	0.00 A	0.00 A	1.17 A	2.00 E	3.17 E
2014					10.00 E
2015					25.00 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2012	-$0.12 A	-$0.09 A	-$0.09 A	-$0.05 A	-$0.34 A
2013	-$0.05 A	-$0.11 A	-$0.11 A	-$0.07 E	-$0.28 E
2014					-$0.26 E
2015					-$0.15 E

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

WHAT'S NEW

- **GALE reports third quarter financials with initial sales from Abstral ahead of its official launch;**
- **Balance sheet remains strong;**
- **GALE is making progresses in its three clinical programs;**
- **PRESENT Phase III is well under way;**
- **We continue to rate GALE shares Outperform, and reiterate our price target of $4.50 per share.**

GALE Reports 3Q13 Financials with Abstral Revenue Ahead of Official Launch

On Nov 6, Galena (GALE) reported its fiscal third quarter financials and corporate updates.

The company reported net revenue of $1.2 million from Abstral sales for the three months ended September 30, 2013, the first quarter of Abstral (fentanyl) sublingual tablet sales, ahead of its official launch and commencement of promotional efforts in the fourth quarter.

Cost of revenue and gross profit for the three months ended September 30, 2013 were $0.3 and $0.9 million, respectively.

R&D costs were $3.63 million, SG&A costs were $4.13 million, respectively for the three month ended September 30, 2013.

Total Operating loss for the three months ended September 30, 2013 was $6.9 million, including $0.5 million in stock-based compensation charges, compared with an operating loss of $5.5 million for the three months ended September 30, 2012, which includes $0.4 million in stock-based compensation charges.

The non-cash expenses related to the changes in values of warrant and contingent purchase price liabilities for the three months ended September 30, 2013 were $1.8 million versus $0.7 million for the three months ended September 30, 2012. Other income from the realized gain on the sale of marketable securities was $0.8 million and $1.4 million for the three and nine months ended September 30, 2013, respectively.

Net loss for the three months ended September 30, 2013 was $9.3 million, or $0.11 per basic and diluted share, versus a net loss of $6.3 million, or $0.09 per basic and diluted share, for the three months ended September 30, 2012.

It's a surprise to us that GALE reported Abstral sales ahead of its official launch and we are pleased with the initial commercial success to date with Abstral(R) which is very encouraging. With its sales force and commercial organization fully deployed, GALE continues to make significant strides with physicians, payors and patients—and expect continuing strength with the launch. As a result, we expect to see continued Abstral sales growth in the fourth quarter of 2013 and fiscal 2014.

Balance Sheet Boosted with Recent Financing

In Sept. 23, 2013, GALE completed a share offering which provided net proceeds of $37.6 million.

GALE offered 17,500,000 shares of common stock, and warrants to purchase an aggregate of 6,125,000 shares of common stock at an exercise price of $2.50 per share. The underwriters also exercised their over-allotment option to purchase warrants to purchase an aggregate of 918,750 shares of common stock. The warrants are immediately exercisable and expire on the fifth anniversary of the date of

issuance. The shares of common stock and the warrants were issued separately and are separately transferable immediately upon issuance.

The underwriters also exercised their option to purchase an additional 2,625,000 shares of common stock.

As of September 30, 2013, Galena had cash, cash equivalents, and marketable securities of $54 million. The company's marketable securities consisted of approximately 0.8 million shares of common stock in RXi Pharmaceuticals (RXII) with a market value of approximately $2.8 million as of September 30, 2013.

Current cash balance plus the outstanding $5 million debt as well as cash from product sales could run through 2015.

GALE Officially Launched Abstral for the Treatment of Breakthrough Cancer Pain

On October 3, 2013, Galena Biopharma (GALE) announced the official product launch of Abstral® (fentanyl) Sublingual Tablets in the United States.

Abstral is a novel, rapidly-disintegrating, sublingual (under the tongue) rapid acting formulation of fentanyl, a well-established opioid, and is indicated for the management of **breakthrough cancer pain (BTcP)** in patients who are already receiving, and who are tolerant to, background opioid therapy for their persistent baseline cancer pain.

Despite already receiving long acting opioid pain management, 40-80% of cancer patients experience episodes of severe tumor- and treatment-related breakthrough pain that is associated with high distress and impaired quality of life according to breakthroughcancerpain.org. Physicians and patients with breakthrough cancer pain want a pain killer with fast relief, ease of use and short duration of action.

Galena acquired Abstral in March 2013 and since that time has scaled its field commercial team, manufactured the drug for commercial sale, secured broad access and reimbursement support from commercial and federal health insurance entities, implemented a robust patient assistance program, and developed a broad product distribution network. Abstral can be prescribed by healthcare professionals and is available to patients at all retail pharmacies nationwide now.

Abstral is the leading rapid acting fentanyl product in Europe, where it achieved full year sales of US$54 million by ProStrakan/Kyowa Hakko Kirin in 2012, and continues to exhibit a steady growth of 42% for Q4-2012 over Q4-2011. By the second half of 2012, the average volume market share of Abstral in the major European markets reached 29%. Abstral is marketed in Canada by Paladin Labs, and has been filed for regulatory approval in Japan by Kyowa Hakko Kirin Co Ltd.

Abstral was approved by the FDA in January 2011. Orexo announced in June 2012 the acquisition of all US rights to Abstral from ProStrakan Group plc as a part of a reconfiguration of the worldwide rights to Abstral. The US market for rapid acting fentanyl products reached US$400 million in 2012. Market research has documented a substantial unmet patient need for improved treatment of breakthrough cancer pain across oncology centers in the United States.

With the official launch of Abstral, GALE initiated RELIEF Patient Registry for Abstral and Debuted Marketing Campaign at PAINWeek. RELIEF (Rapid Evaluation of Lifestyle, Independence, and Elimination of breakthrough cancer pain with Freedom from oral discomfort through the use of Abstral(R) (fentanyl) Sublingual Tablets) is a post-marketing, multicenter trial to assess Abstral for breakthrough cancer pain (BTcP) in opioid-tolerant cancer patients. RELIEF is an observational registry study to be completed by enrolled patients over a thirty-day period while using Abstral for treatment of their BTcP. Approximately 2,500 patients are expected to enroll in the program.

The launch of Abstral will **accelerate revenue initiation** to 2013 reaching cash flow positive in 18-24 months; and reduce overall company cash burn through the launch of NeuVax. The acquisition of Abstral diversifies and deepens the breadth, depth and pace of pipeline towards becoming a mid-cap oncology company (not just a cancer immunotherapy company).

We estimate that sales of Abstral will be $10 million for GALE in 2014, and reach $65 million in 2017. Due to the growth of Abstral, GALE will become profitable with earnings per share of $0.17 in fiscal 2017.

GALE's launch of Abstral will also **build relationships with future prescribers** of NeuVax™, which is currently in global **Phase III** clinical trials in node positive HER2 IHC 1+/2+ breast cancer patients. Medical oncologists, who manage tumor and treatment related pain, predominantly prescribe TIRFs for advanced breast cancer and other solid tumor patients which represent the majority of overall prescriptions.

Two Important Near Term Catalysts

Enrollment in NeuVax Phase III trial is expected to be completed the end of 2013

GALE initiated the **Phase III PRESENT** trial for NeuVax (E75 peptide plus GM-CSF) vaccine in HER2 1+ and 2+ breast cancer patients in the adjuvant setting to **prevent recurrence**.

The PRESENT (**P**revention of **R**ecurrence in **E**arly-**S**tage, Node-Positive Breast Cancer with Low to Intermediate HER2 **E**xpression with **N**euVax **T**reatment) study is a randomized, multicenter, multinational clinical trial that will enroll approximately 700 breast cancer patients. The trial design has been updated to include current National Comprehensive Cancer Network guidelines and recently received **Special Protocol Assessment (SPA)** concurrence from the FDA. Based on a successful Phase II trial, which achieved its primary endpoint of disease-free survival (DFS), the FDA has agreed that the design and planned analysis of the Phase III study adequately address the objectives necessary to support an acceptable regulatory submission for marketing approval.

The NeuVax Phase III trial is conducted in adjuvant breast cancer patients who are node positive, have an HLA status of A2/A3+, and have low or intermediate HER2 expression (IHC 1+, 2+, sometimes referred to as HER2 negative). These patients are not eligible to receive Herceptin (trastuzumab, marketed by Roche-Genentech) therapy that is currently approved only for patients with high HER2, or 3+ expression.

According to the protocol, once qualified patients have achieved a complete response from current standard-of-care treatment (surgery, radiation and/or chemotherapy), they will be randomized and dosed with either NeuVax (E75 + GM-CSF) or control (placebo plus GM-CSF). Patients will receive one intradermal injection every month for six months, followed by a booster inoculation every six months thereafter. **The primary endpoint is disease-free survival at three years** or 139 events (recurrence of cancer). A data safety monitoring board will conduct an interim analysis for safety and futility after 70 events.

To date, the trial is currently enrolling in 11 countries and over 130 clinical sites worldwide. The completion of enrollment in NeuVax Phase III PRESENT trial is expected to be the end of 2013, and an interim analysis (70 events) for NeuVax Phase III PRESENT trial is expected to be in 1H14.

We think the Phase III trial design is prudent based on the existing data from the Phase I/II trials. This Phase III trial is well designed and better controlled one compared to the Phase I/II trials.

We believe NeuVax has a blockbuster potential if it finally reaches the market.

Initial results from FBP Phase I/IIa trial is expected in 4Q13

GALE is conducting a **Phase I/IIa** FBP (E39) clinical trial which **has enrolled more than 20 patients** to date.

GALE initiated its Phase I/IIa study of its Folate Binding Protein (E39) vaccine in two gynecological cancers: **ovarian** and **endometrial adenocarcinomas** in Feb, 2012.

The FBP vaccine consists of the E39 peptide combined with the immune adjuvant, granulocyte macrophage-colony stimulating factor (GM-CSF). The Phase I/IIa study will test whether the FBP vaccine is safe and effective at inducing an anti-tumor immune response. Furthermore, the study will determine the optimal dose of the vaccine to produce this immunity most efficiently, and whether immunity to FBP will prevent clinical recurrence in patients with ovarian and aggressive endometrial cancer.

The study arms are well-balanced with no differences in age, grade, stage III, or node positivity status between groups. Overall, E39 was well-tolerated and the study to date has demonstrated an 11.1% recurrence rate with E39 vs. a 27.3% recurrence rate in the control group—a recurrence reduction of 59.3%.

Initial results from the Phase I portion of the trial will be presented at the Society for Immunotherapy of Cancer (SITC) conference taking place this weekend, November 7-10, 2013.

There is Plenty of Room for further Price Appreciation

We initiated coverage of Galena Biopharma (GALE) in mid-November 2011. At that time, share price of GALE was at about $0.70 per share. As of Nov 7, 2013, share price of GALE is $2.28, an appreciation of 226%.

We think the impressive appreciation of share price has been based on many positive developments within the company in the past two years, such as the advancement of the company's clinical programs, expansion of pipeline and boosting of their balance sheet.

But we think there is still enough room for significant price appreciation for GALE in the next few quarters.

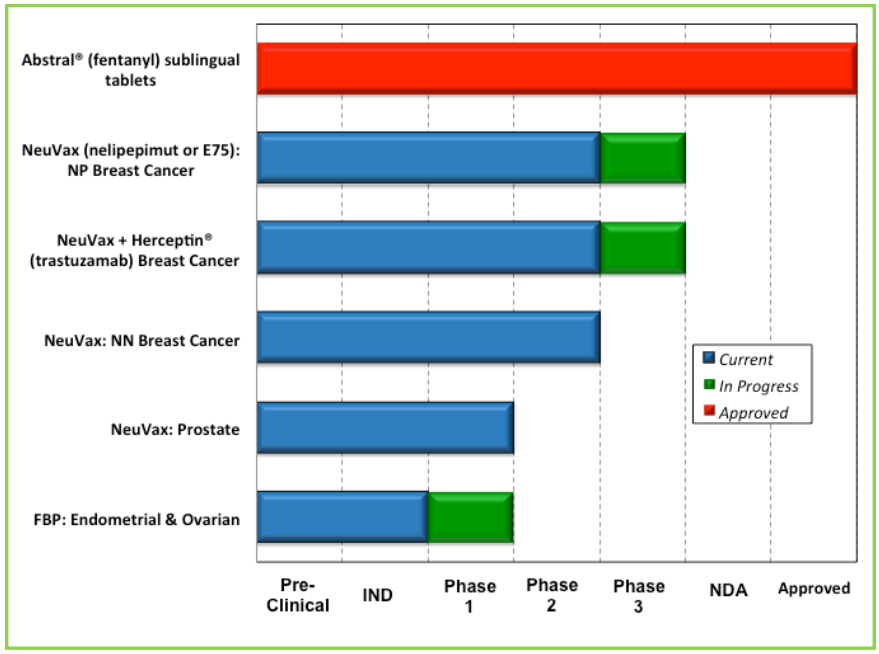
With the acquisition of the FDA approved Abstral, We maintain our Outperform rating on Galena shares and reiterate our 12-month price target of $4.50 per share.

The acquisition of Abstral has transformed GALE to a commercial organization from a pure development stage biotech company. The acquisition diversifies and strengthens GALE's pipeline. The launch of Abstral will build relationships with future prescribers of NeuVax, which is currently in global Phase III clinical trials. The launch of Abstral will also accelerate revenue initiation to 2013 reaching cash flow positive in 18-24 months; and reduce overall company cash burn through the launch of NeuVax. The acquisition of Abstral diversifies and deepens the breadth, depth and pace of pipeline towards becoming a mid-cap oncology company (not just a cancer immunotherapy company).

Apparently, Galena has made great progress in the past few months. The Company has become stronger than ever.

Galena's cancer program NeuVax and FBP provide significant leverage in cancer immunotherapy generally, as well as in "off the shelf" vaccines specifically. Currently, the Company has 5 programs in clinic including Phase III NeuVax for breast cancer, Phase I/II FBP for gynecological cancers. This is quite unusual for a small cap biotech company.

We believe Galena should be valued at $300 to $500 million in market cap. Our price of $4.50 per share corresponds to a $460 million in market cap based on 103 million outstanding shares.

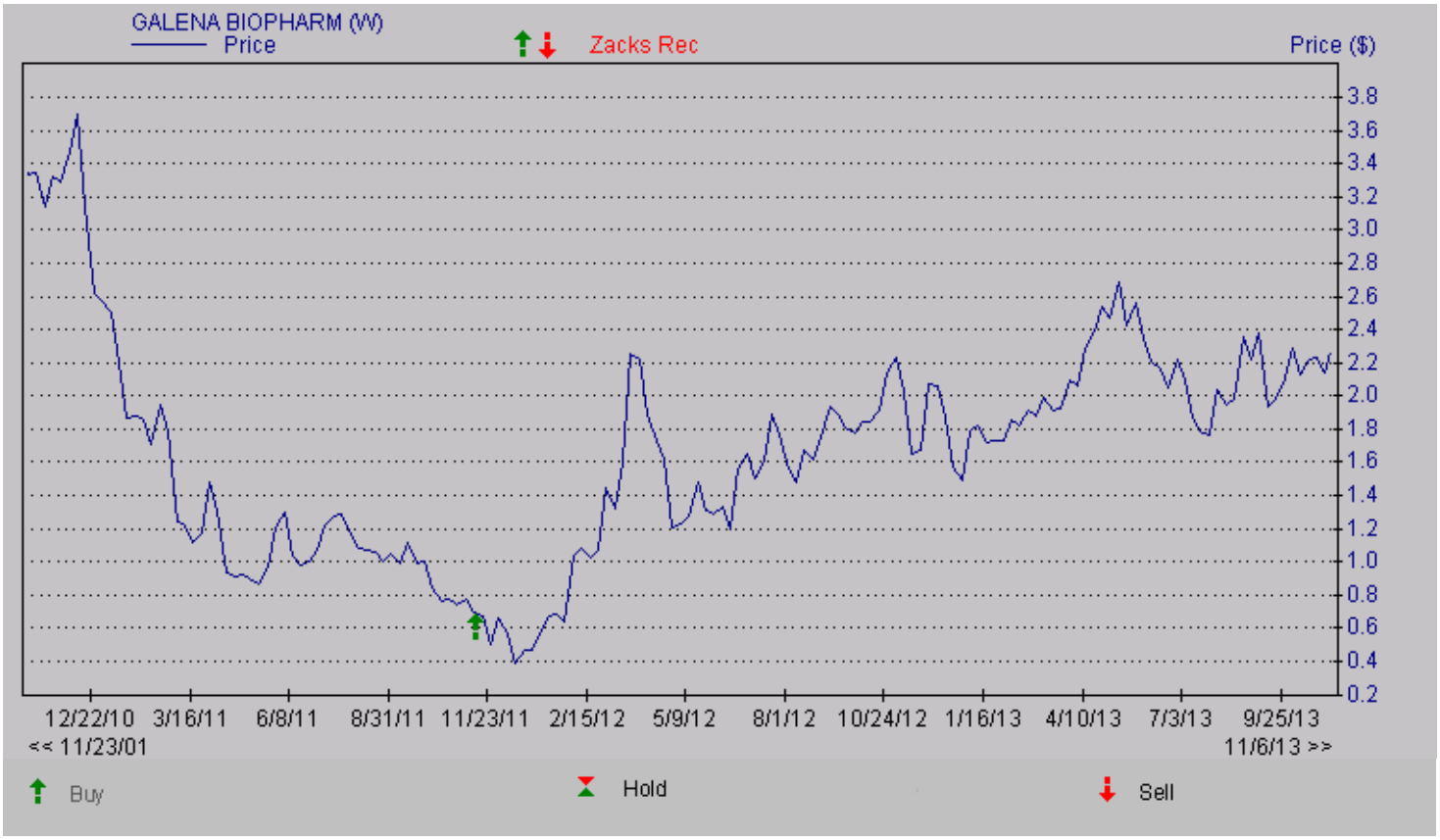

Abstral® (fentanyl) sublingual tablets
NeuVax (nelipepimut or E75): NP Breast Cancer
NeuVax + Herceptin® (trastuzamab) Breast Cancer
NeuVax: NN Breast Cancer
NeuVax: Prostate
FBP: Endometrial & Ovarian
Current
In Progress
Approved
Pre-Clinical
IND
Phase 1
Phase 2
Phase 3
NDA
Approved

PROJECTED INCOME STATEMENT

	2011A	2012A	2013E (Dec)					2014E (Dec)	2015E (Dec)	2016E (Dec)	2017E (Dec)
$ in million except per share data	FYA	FYA	Q1A	Q2A	Q3A	Q4E	FYE	FYE	FYE	FYE	FYE
Total Revenues	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$1.17**	**$2.00**	**$3.17**	**$10.00**	**$25.00**	**$45.00**	**$65.00**
YOY Growth	-	-	-	-	-	-	-	*215.5%*	*150.0%*	*80.0%*	*44.4%*
CoGS	0.00	0.00	0.00	0.00	0.30	0.40	0.70	2.00	5.00	9.00	13.00
Gross Income	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.87**	**$1.60**	**$2.47**	**$8.00**	**$20.00**	**$36.00**	**$52.00**
Gross Margin	-	-	-	-	*74.3%*	*80.0%*	*77.9%*	*80.0%*	*80.0%*	*80.0%*	*80.0%*
R&D	$9.90	$14.61	$5.08	$5.28	$3.63	$5.50	$19.49	$25.00	$22.00	$20.00	$15.00
% R&D	-	-	-	-	-	*275.0%*	*614.8%*	*250.0%*	*88.0%*	*44.4%*	*23.1%*
SG&A	$9.25	$6.59	$1.53	$2.71	$4.13	$3.50	$11.87	$12.00	$15.00	$18.00	$20.00
% SG&A	-	-	-	-	-	*175.0%*	*374.4%*	*120.0%*	*60.0%*	*40.0%*	*30.8%*
Other	$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	**($19.1)**	**($21.2)**	**($6.6)**	**($8.0)**	**($6.9)**	**($7.4)**	**($28.9)**	**($29.0)**	**($17.0)**	**($2.0)**	**$17.0**
Operating Margin	-	-	-	-	-	-	-	-	-	*-4.4%*	*26.2%*
Other Net	$11.7	($14.8)	($5.4)	($0.1)	($1.2)	($0.2)	($6.9)	($1.0)	($1.0)	$0.0	$0.0
Pre-Tax Income	**($7.5)**	**($36.0)**	**($12.1)**	**($8.1)**	**($8.1)**	**($7.6)**	**($35.8)**	**($30.0)**	**($18.0)**	**($2.0)**	**$17.0**
Income taxes(benefit)	$0.0	($1.1)	($2.8)	$1.5	$1.2	$0.0	($0.1)	$0.0	$0.0	$0.0	$0.0
Tax Rate	-	-	-	-	-	-	-	-	-	-	-
Reported Net Income	**($7.5)**	**($35.0)**	**($9.3)**	**($9.6)**	**($9.3)**	**($7.6)**	**($35.8)**	**($30.0)**	**($18.0)**	**($2.0)**	**$17.0**
YOY Growth	-	-	-	-	-	-	-	-	-	-	*-950.0%*
Net Margin	-	-	-	-	-	-	-	-	-	*-4.4%*	*26.2%*
Shares Out	*36.3*	*62.5*	*83.0*	*83.7*	*87.3*	*105.0*	*110.0*	*115.0*	*120.0*	*125.0*	*128.0*
Reported EPS	**($0.21)**	**($0.56)**	**($0.11)**	**($0.11)**	**($0.11)**	**($0.07)**	**($0.33)**	**($0.26)**	**($0.15)**	**($0.02)**	**$0.13**
YOY Growth	-	-	-	-	-	-	-	-	-	-	*-930.1%*
One time charge	*($12.04)*	*$13.65*	*$5.44*	*$0.00*	*$0.00*	*$0.00*	*$5.44*	*$0.00*	*$0.00*	*$0.00*	*$0.00*
Non GAAP Net Income	**($19.5)**	**($21.3)**	**($3.8)**	**($9.6)**	**($9.3)**	**($7.6)**	**($30.3)**	**($30.0)**	**($18.0)**	**($2.0)**	**$17.0**
Non GAAP EPS	**($0.54)**	**($0.34)**	**($0.05)**	**($0.11)**	**($0.11)**	**($0.07)**	**($0.28)**	**($0.26)**	**($0.15)**	**($0.02)**	**$0.13**

Source: Company filings and Zacks estimates

HISTORICAL ZACKS RECOMMENDATIONS



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