Zacks Small-Cap Research

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Galena Biopharma Inc. (GALE-NASDAQ)

Galena: Strong financial results reported for 2Q12s, balance sheet boosted---Outperform

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	11/14/2011
Current Price (08/20/12)	$1.66
Twelve-Month Target Price	**$4.00**

OUTLOOK

Galena recently raised $14.5 million in equity financing, which boosted its balance sheet. With the final spin-off of its subsidiary RXi Pharma, GALE will be more focused on cancer targeted immunotherapy and will have less cash burn. The Company also strengthened IP for its FBP asset with the US patent allowance.

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	**$2.77**
52-Week Low	**$0.37**
One-Year Return (%)	**56.60**
Beta	**0.66**
Average Daily Volume (sh)	**1,369,789**
Shares Outstanding (mil)	**66**
Market Capitalization ($mil)	**$109**
Short Interest Ratio (days)	**1.87**
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)
2010	0.00 A	0.00 A	0.00 A	0.10 A	0.10 A
2011	0.00 A	0.00 A	0.00 A	0.00 A	0.00 A
2012	0.00 A	0.00 A	0.00 E	0.00 E	0.00 E
2013					0.00 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	-$0.24 A	-$0.26 A	-$0.23 A	-$0.21 A	-$0.93 A
2011	-$0.26 A	-$0.12 A	-$0.13 A	-$0.13 A	-$0.58 A
2012	-$0.12 A	-$0.09 A	-$0.09 E	-$0.10 E	-$0.40 E
2013					-$0.40 E

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

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WHAT'S NEW

Strong Financial Results for Second Quarter of 2012 Reported

On August 14, Galena Biopharma (GALE) reported financial results for the second quarter of 2012.

There was no revenue for the quarter.

Operating loss from continuing operations for the three months ended June 30, 2012 was approximately $5.7 million compared with $2.3 million for the three months ended June 30, 2011. Loss from discontinued operations was $0.4 million for the three months ended June 30, 2012, as compared to $2.2 million for the three months ended June 30, 2011.

Net loss for the three months ended June 30, 2012 was $0.2 million or $0.003 per share on a basic and diluted basis, versus a net loss of $3.8 million, or $0.10 per share on a basic and diluted basis for the three months ended June 30, 2011.

The period to period changes in net income, loss from continued operations and net loss from discontinued operations are primarily driven by the spin-off of the Company's former RXi Pharmaceuticals subsidiary on April 27, 2012 and the related focus of its continuing operations on late-stage NeuVax product candidate.

Other income for the three months ended June 30, 2012 was $5.9 million versus other income of $0.7 million for the three months ended June 30, 2011. The period to period changes in other income (expense) were due to non-cash charges related to changes in the fair value estimates of the Company's warrant liabilities and contingent purchase price liability.

In connection with the RXi spin-off on April 27, 2012, approximately 67.0 million shares of RXi common stock were distributed as a dividend to the Galena shareholders, representing a net liability position of $2.2 million at historical cost. GALE retained a 4% interest in RXi, or approximately 32.7 million shares of RXi common stock, which is carried at historical cost, effectively zero, at June 30, 2012. The market value of the RXi shares held by Galena at June 30, 2012 was approximately $4.3 million.

Balance Sheet Boosted with $14.5 Million Equity Financing

On April 16, 2012, Galena Biopharma (GALE) closed a public offering of 9,751,500 shares of its common stock at a price of $1.50 per share for gross proceeds of approximately $14.5 million. The shares include 1,251,000 shares of common stock sold pursuant to the over-allotment option granted by the Company to the underwriters. The net proceeds from the sale of the shares, after deducting the underwriters' discounts and other estimated offering expenses will be approximately $13.3 million.

The proceeds will be used to advance its clinical programs including the on-going Phase III PRESENT trial of NeuVax for the prevention of recurrence in early stage, node positive breast cancer patients with low to intermediate HER2 expression.

Although the equity financing dilutes existing shareholder base, it greatly boosts the Company's balance sheet.

As of June 30, 2012, Galena had cash and cash equivalents of $19.2 million, compared with cash and cash equivalents of $11.4 million as of December 31, 2011. Current cash could last through the first quarter of 2013.

5-Year Follow-Up Data Presented for NeuVax Phase I/II Trials

Recently, Galena (GALE) presented data from the Phase I/II clinical trial of NeuVax (E75) at some meetings including the ASCO 2012 Annual Meeting. At the ASCO, the poster was entitled "Safety and Long-Term Maintenance of Anti-HER2 Immunity Following Booster Inoculations of the E75 Breast Cancer Vaccine" (Abstract #2529).

Patient Demographics

The trials included SN-33 (Node Positive, n=97) and SN-34 (Node Negative, n=90), which evaluated a combined 187 patients with 108 in the vaccine group (VG) and 79 in the unvaccinated control group (CG).

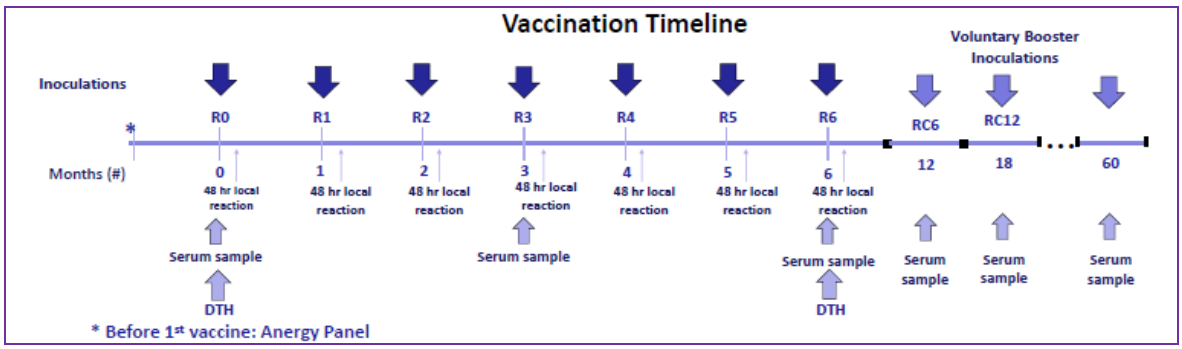
In terms of patient demographics, we think the vaccine and control groups were generally well-matched. Although there were some imbalances between VG and CG, they were not significant. The only statistically significant difference was ER-/PR- status (31.1% in VG vs 17.7% in CG, p=0.04).

E75 Demographics			
	Vaccine	Control	p value
n=	108	79	
Age (median)	57	53	0.26
Node Positive (%)	49.1	55.7	0.38
Tumor Size (T2-T4) (%)	34.3	46.2	0.13
Histologic Grade 3 (%)	40.0	39.5	1.00
ER/PR negative (%)	31.1	17.7	0.04
HER2/*neu* overexpression (%)	31.7	26.8	0.50
Hormonal Therapy (%)	66.7	76.9	0.14
Chemotherapy (%)	75.0	72.2	0.74
XRT (%)	72.2	81.0	0.17
Trastuzamab Therapy (%)	11.1	3.8	0.10

The Rational for Booster Inoculation

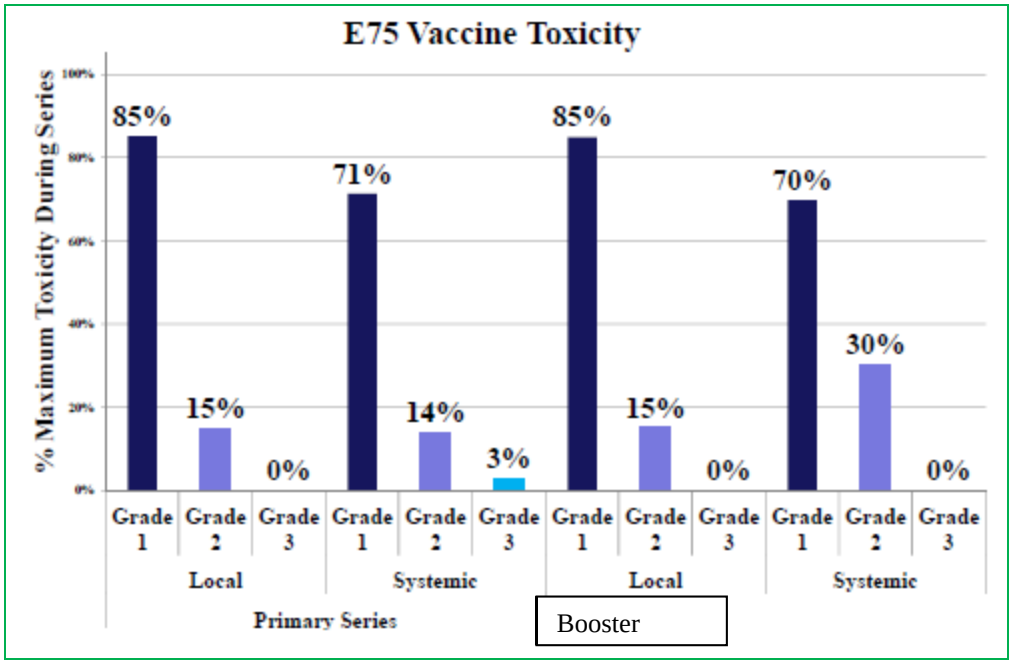
Patients were initially given a series of up to six inoculations of NeuVax once a month. As the trials progressed, the physicians noticed that E75-specific immunity waned after this initial monthly primary vaccine series (PVS) and translated to late recurrences of cancer in some patients. As a result of this finding, a voluntary booster program was added to the trials to maintain long-term immunity following the initial monthly PVS.

The booster program offered patients an additional inoculation every six months with a maximum of six boosters. Because the booster program was voluntary, not all women chose to receive the full six additional doses.



The Results

NeuVax was well tolerated with primarily grade 1 and grade 2 toxicity in the PVS (Local Toxicity: 85% Grade 1, 15% Grade 2, 0% Grade 3; systemic toxicity: 71% Grade 1, 14% Grade 2, and 3% Grade 3). Booster inoculations were well-tolerated with only grade 1 and 2 local and systemic toxicities.



After a median follow-up of 60 months, there has been a non-significant increase in the Disease Free Survival (DFS) observed in the VG compared to the CG (89.7% vs 79.6%, p=0.098)—a recurrence reduction of 49.5% among all patients at any dose.

However, in the booster group (to date, 53 patients received at least one booster), the results show that, at a median of 60-months, the disease-free survival (DFS) for the booster group (n=53) was 96.2% vs 80.5% in the control group (n=79) (p=0.01); and, the recurrence rate for the booster group was 3.8% vs 18.9% in the control group.

The final patients are completing their booster treatments and final follow-up visits are expected by September 2012. The final data analysis is expected to be reported in the fourth quarter of this year.

Our assessment of the booster inoculations from the data presented: the booster inoculations are well-tolerated and don't increase any side effects compared to the primary vaccine series. Further, booster inoculations appear to assist in the maintenance of long-term peptide-specific immunity. In terms of efficacy, boosted patients have better recurrence rates and improved DFS compared to patients who did not receive vaccine. This may be attributed to increased immunity induced by the booster inoculations.

As a result of these findings, booster inoculations have been incorporated into the design of the ongoing Phase III PRESENT study.

SN-33 HER2 Negative Booster Patients Established the Phase III PRESENT

At this year's ASCO meeting, GALE also presented 5-year follow up data of NeuVax from the SN-33 trial separately at a physician panel.

SN-33 was conducted in node positive patients, and was well balanced between the two arms: Vaccine HLA-A2/A3 positive (n=53) vs Control HLA-A2/A3 negative (n=44). During the conduct of this trial, Herceptin® (trastuzumab; Genentech/Roche) became commercially available for HER2 IHC Positive (3+) patients, and the trial was modified accordingly to allow these patients to receive Herceptin, and exclude this patient group from future enrollment and analysis.

Below are the summary results from the SN-33 trial. SN-33 Intent-to-treat (ITT) population (n=97):

- 24-month Landmark Analysis: 90.6% of NeuVax patients (n=53) were disease-free versus 79.5% of patients on the control arm (n=44) (p=0.1155).
- 60-month Analysis: 84.5% of NeuVax patients (n=53) remain disease-free versus 77.1% of patients on the control arm (n=44).

Following is the summary of SN-33 HER2 Negative (IHC 1+,2+ and/or FISH < 2.0) patients who received boosters (n=45).

- 24-month Landmark Analysis: 0% recurrences for patients treated with NeuVax: statistically significant DFS for NeuVax at 100% (n=18) vs 77.8% Control (n=27) (p=0.0358).
- 36-month Landmark Analysis: 0% recurrences for patients treated with NeuVax for a statistically significant DFS for NeuVax at 100% (n=18) vs 77.8% Control (n=27) (p=0.035). Of note, no patients receiving booster inoculations had a recurrence through 36 months, which is the Phase III PRESENT study endpoint.
- 60-month Analysis: 5.6% recurrence rate with NeuVax versus 25.9% recurrence rate in the control arm.
- DFS for NeuVax at 94.4% (n=18) vs 74.1% Control (n=27)—a recurrence reduction of 78.4% in the target patient population.

This new, 60-month data analysis shows that breast cancer recurrence is greatly reduced for patients treated with NeuVax and that these results are both clinically relevant and durable over time.

The Phase III PRESENT Trial is Underway

Based on the SN-33 booster data, on Jan. 20, 2012, 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 will be 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, 35 sites are approved in four countries, over 20 sites are enrolling, and expanding to approximately 100 sites total in 2012.

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.

IP Further Expanded for NeuVax and Folate Binding Protein

On July 18, 2012, GALE announced the issuance of a key patent, originally allowed in March 2012, from the U.S. Patent and Trademark Office (USPTO) covering the use of its product candidate, NeuVax™, a HER2/neu peptide vaccine, for inducing immunity to breast cancer recurrence in patients having low-to-intermediate IHC levels of 1+ or 2+ and a FISH rating of less than 2.0. These patients represent a significant unmet medical need, with as much as 80% of breast cancer patients who do not qualify for Herceptin® therapy.

- The patent strengthens NeuVax Intellectual Property position for treating Phase III target population of low-to-intermediate (IHC 1+/2+) HER2 patients;

- The patent provides NeuVax exclusivity for this indication until 2028, not including any patent term extensions.

On August 13, 2012, GALE announced the issuance of a patent from the Japan Patent Office (JPO) for a Composition of Matter and Method of Treatment patent covering Folate Binding Protein (FBP) peptide variants for use either alone or in combination with the FBP cancer vaccine, E39. The Japanese patent provides exclusivity in the country until 2022, with additional worldwide patent filings pending.

- Composition of Matter and Treatment patent covers Folate Binding Protein (FBP) peptide variants for individual or expanded use in combination with the novel FBP vaccine, E39.

- The patent provides exclusivity in Japan until 2022, with additional worldwide patent filings pending.

- Folate Binding Protein Phase 1/2 trial on track for results in 2013.

GALE's current FBP vaccine, E39, is in an ongoing **Phase I/II** clinical trial in **two gynecological cancers**: ovarian and endometrial adenocarcinomas. The Company has already designed a new **Phase Ib** trial studying the benefit of these FBP peptide variants in combination with E39 that is awaiting Institutional Review Board (IRB) approval.

The market for FBP vaccine is big. Ovarian cancer occurs in over 22,000 patients per year in the U.S. alone and is the most lethal gynecologic cancer. Endometrial cancer is the most common gynecologic cancer and occurs in over 43,000 women in the US annually. If developed successfully, FBP vaccine could be an important option for physicians to target ovarian and endometrial cancers.

The Spin-off of RXi Pharmaceuticals Will Create Shareholder Value

GALE announced in Sep 2011 that it will separate its programs into two publicly traded companies: Galena Biopharma will focus on the development of targeted cancer therapies; and RXi Pharmaceuticals will focus on the development of RNAi-based therapeutics.

As part of these transactions, institutional investors have agreed to invest $9.5 million in RXi preferred stock and $2.5 million in Galena common stock, for a total of $12 million. The investment in Galena common stock will be priced "at market" based on a volume-weighted average trading price. No warrants will be issued in the transaction.

Galena will retain a 4% equity position in RXi after the spin-off. In addition to the $2.5 million immediate funding, Galena also is to receive up to $45 million in milestones.

On April 26, 2012, GALE announced that it has initiated the final steps to complete the spin-off of RXi Pharmaceuticals Corporation. To effectuate the spin-off, Galena is paying a dividend of one share of RXi Pharmaceuticals common stock for each outstanding share of Galena common stock. The dividend is being paid at the close of business on April 26, 2012 to Galena stockholders who owned shares of Galena common stock as of close of business on April 23, 2012, the record date for the dividend.

RXi Pharmaceuticals will operate as an independent, publicly-traded company. RXi Pharmaceuticals common stock is currently trading under the symbol "RXII" on the OTC Bulletin Board.

We think the spin-off will create shareholder value in the following aspects:

- This spin-off will transform GALE into a late clinical stage, targeted cancer therapeutics company;
- Galena will continue focusing on development-stage, targeted oncology pipeline, led by NeuVax™, which recently commenced a pivotal, Phase III clinical trial for low-to-intermediate HER2 breast cancer patients;
- With the spin-off of RXi, GALE will be more focused cancer programs and will have less cash burn for its operations.
- Both companies will have greater flexibility to focus on and pursue their respective growth strategies, while potentially providing shareholders with greater value over the longer term.

VALUATION AND RECOMMENDATION

We are still bullish on GALE based on the recent progresses the Company has made. Therefore, we maintain an Outperform rating on Galena shares and reiterate our 12-month price target of $4.0 per share.

Apparently, Galena has made great progress in the past few months in its clinical programs, IP protection and strengthening its balance sheet. The Company has become stronger than ever with the split of RXi Pharmaceuticals with more focused cancer programs and less cash burn for its operations.

Galena’s cancer program NeuVax and FBP provide significant leverage in cancer immunotherapy generally, as well as in "off the shelf" vaccines specifically.

We believe NeuVax has a blockbuster potential if it reaches the market. FBP also targets the relatively large gynecological cancer market, which is underserved and has unmet medical needs.

Based on the Company’s strong fundamentals, we believe Galena’s shares are undervalued compared to its peers. Currently, the Company’s shares are trading at about $1.66 per share which values the Company at about $102 million in market cap based on 65 million shares outstanding. This is a deep discount compared to its peers. Most small biotech companies of development stage in the business of

cancer are valued from $50 million to $500 million in market cap depending on how advanced the pipeline is and which indications the company is targeting. Galena is a late stage development biotech company, and its lead candidate NeuVax is already in Phase III clinical trials.

We believe Galena should be valued at $150 to $250 million in market cap. Our price of $4.0 per share corresponds to a $260 million in market cap based on 65 million outstanding shares.

Cash burn is still a concern even with the April $14.5 million financing. Current cash balance will only last through the first quarter of end of 2013. More financing is needed to fund its ongoing clinical trials. We believe GALE needs to tap the capital market soon, probably by the end of 2012. Equity financing is still the primary choice in our view, which will dilute existing shareholder base.

PROJECTED INCOME STATEMENT

	2011A (Dec)					2012E (Dec)					2013E (Dec)	2014E (Dec)	2015E (Dec)
$ in million except per share data	Q1A	Q2A	Q3A	Q4A	FYA	Q1A	Q2A	Q3E	Q4E	FYE	FYE	FYE	FYE
Total Revenues	**$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**
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	0.00
Gross Income	**$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 Margin	-	-	-	-	-	-	-	-	-	-	-	-	-
R&D	$2.16	$2.67	$3.00	$3.70	$11.53	$3.67	$3.72	$4.00	$4.20	$15.59	$20.00	$17.50	$15.00
% R&D	-	-	-	-	-					-	-	-	-
SG&A	$3.12	$1.95	$2.07	$2.11	$9.25	$1.94	$1.96	$2.10	$2.30	$8.30	$9.50	$10.00	$10.50
% SG&A	-	-	-	-	-	-	-	-	-	-	-	-	-
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	**($5.3)**	**($4.6)**	**($5.1)**	**($5.8)**	**($20.8)**	**($5.6)**	**($5.7)**	**($6.1)**	**($6.5)**	**($23.9)**	**($29.5)**	**($27.5)**	**($25.5)**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Net	$1.4	$3.2	($0.4)	$7.4	$11.7	($19.2)	$5.5	($0.2)	($0.2)	($14.1)	($0.8)	($1.0)	($1.0)
Pre-Tax Income	**($3.8)**	**($1.4)**	**($5.5)**	**$1.6**	**($9.1)**	**($24.8)**	**($0.2)**	**($6.3)**	**($6.7)**	**($38.0)**	**($30.3)**	**($28.5)**	**($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
Tax Rate	-	-	-	-	-	-	-	-	-	-	-	-	-
Reported Net Income	**($3.8)**	**($1.4)**	**($5.5)**	**$1.6**	**($9.1)**	**($24.8)**	**($0.2)**	**($6.3)**	**($6.7)**	**($38.0)**	**($30.3)**	**($28.5)**	**($26.5)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-
Shares Out	*20.3*	*38.6*	*42.0*	*44.2*	*36.3*	*48.0*	*67.2*	*67.3*	*67.5*	*62.5*	*75.0*	*80.0*	*85.0*
Reported EPS	**($0.19)**	**($0.04)**	**($0.13)**	**$0.04**	**($0.25)**	**($0.52)**	**($0.00)**	**($0.09)**	**($0.10)**	**($0.61)**	**($0.40)**	**($0.36)**	**($0.31)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
One time charge	*($1.40)*	*($3.24)*	*$0.00*	*($7.40)*	*($12.04)*	*$19.15*	*($5.90)*	*$0.00*	*$0.00*	*$13.25*	*$0.00*	*$0.00*	*$0.00*
Non GAAP Net Income	**($5.2)**	**($4.6)**	**($5.5)**	**($5.8)**	**($21.2)**	**($5.6)**	**($6.1)**	**($6.3)**	**($6.7)**	**($24.7)**	**($30.3)**	**($28.5)**	**($26.5)**
Non GAAP EPS	**($0.26)**	**($0.12)**	**($0.13)**	**($0.13)**	**($0.58)**	**($0.12)**	**($0.09)**	**($0.09)**	**($0.10)**	**($0.40)**	**($0.40)**	**($0.36)**	**($0.31)**

Source: Company filings and Zacks estimates

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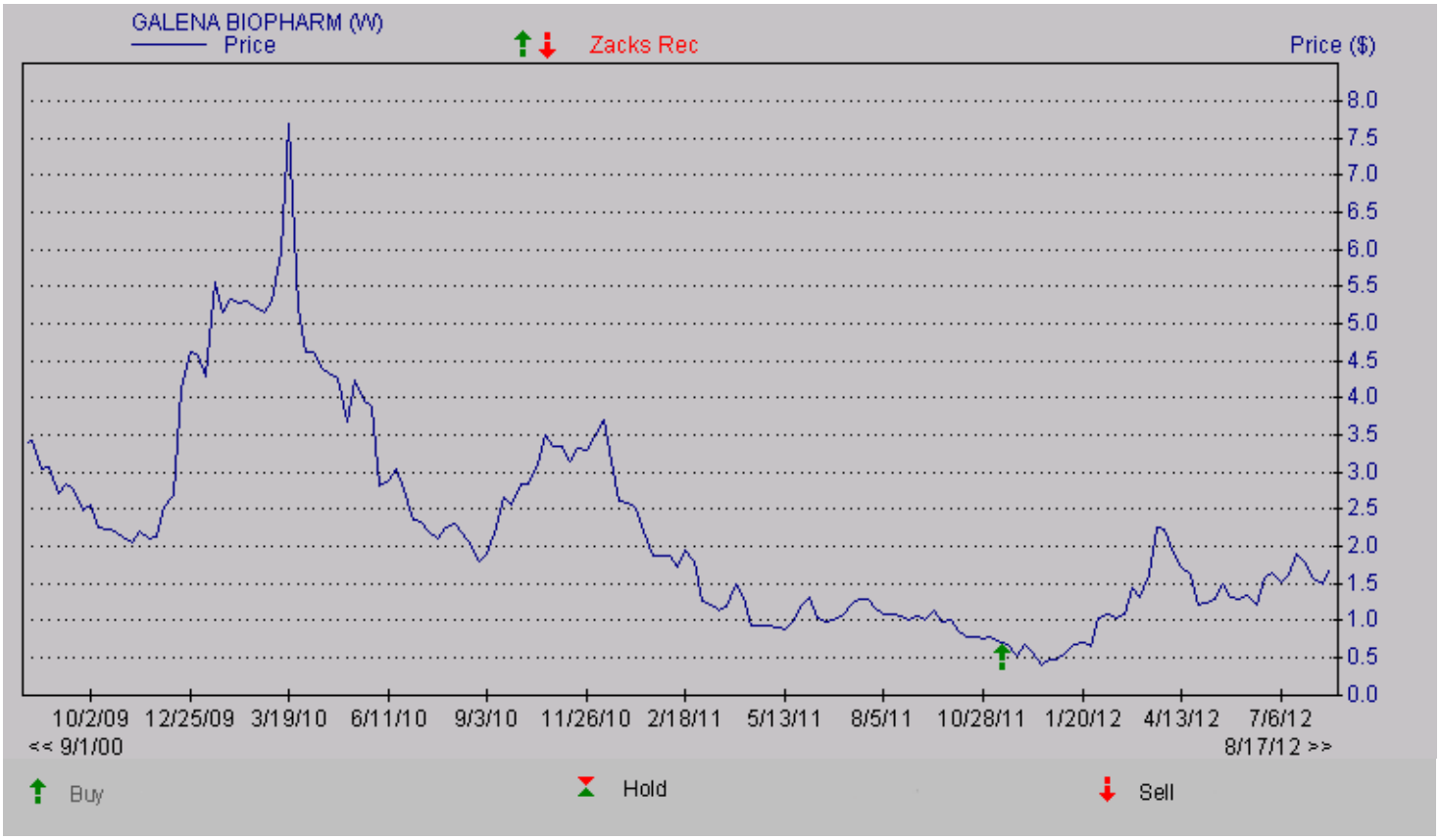
HISTORICAL ZACKS RECOMMENDATIONS



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