Zacks Small-Cap Research

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Galena Biopharma Inc. (GALE-NASDAQ)

Galena: Reported in line 1Q12 results, balance sheet boosted---Outperform

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	11/14/2011
Current Price (05/16/12)	$1.25
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	**$0.37**
One-Year Return (%)	**48.11**
Beta	**0.99**
Average Daily Volume (sh)	**2,453,009**
Shares Outstanding (mil)	**48**
Market Capitalization ($mil)	**$65**
Short Interest Ratio (days)	**1.02**
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 E	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	-$0.13 E	-$0.14 E	-$0.14 E	-$0.54 E
2013					-$0.55 E

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

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WHAT'S NEW

Galena Biopharma Reports First Quarter 2012 Financial Results

On May 14, 2012, Galena Biopharma (GALE) reported its financial results for the first quarter ended March 31, 2012 and provided an update on recent business developments.

There was no revenue recorded for 1Q12.

Operating loss for the three months ended March 31, 2012 increased to $5.6 million, versus $5.2 million for the three months ended March 31, 2011. The increase of $0.4 million in operating loss was due primarily to an increase of $1.5 million for research and development expense partially offset by a $1.1 million decrease in general and administrative expense.

Net loss for the three months ended March 31, 2012 was $24.8 million or $0.52 per share, versus a net loss of $3.8 million, or $0.19 per share, for the three months ended March 31, 2011. Other expense for the three months ended March 31, 2012 was $19.2 million, versus other income of $1.4 million. The increase of $20.6 million in other expense was due primarily to an increase of $19.8 million in non-cash expense for the change in the fair value of warrants accounted for as a liability and an increase of $0.8 million in non-cash expense related to the change in fair value of a contingent purchase price consideration liability.

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 March 31, 2012, the Company had cash and cash equivalents of $8.7 million. With the addition of the proceeds from the April financing, the Company had cash and cash equivalents of $24.9 million as of April 30, 2012, which could last through the end of 2012.

IP Expanded for Folate Binding Protein Vaccine with US Patent Allowance

On May 1, 2012, Galena Biopharma, Inc. (GALE) announced that it has received a Notice of Allowance from the U.S. Patent and Trademark Office (USPTO) for a Composition of Matter patent covering Folate Binding Peptide (FBP) peptide variants for use either alone or in combination with the FBP vaccine, E39. Additionally, the patent lays the foundation for additional intellectual property for the use of these variants in a novel vaccination strategy that could be applied to any peptide-based vaccine.

The patent protection includes the following aspects:

- The composition of matter patent covers FBP peptide variants for individual or expanded use in combination with the FBP vaccine, E39;
- The patent provides exclusivity until 2029, not including any patent term extensions;
- The patent also protects new methodology of peptide vaccination with wide applicability;

Galena Biopharma recently licensed worldwide rights from The University of Texas M D Anderson Cancer Center and Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. (HJF) to develop and commercialize a Folate Binding Protein-E39 (**FBP**) targeted vaccine to prevent recurrence in **gynecological cancers** such as ovarian and endometrial adenocarcinomas.

The FBP vaccine consists of the **E39 peptide** combined with the immune adjuvant granulocyte macrophage colony stimulating factor (**GM-CSF**). FBP is over-expressed (20-80 fold) in more than 90% of ovarian and aggressive endometrial cancers, as well as 20--50% of breast, lung, colorectal, and renal cell carcinomas. FBP has very limited tissue distribution and expression in non-malignant tissue and has many years of validation as an ideal immunotherapy target.

The broad overexpression of FBP in a wide variety of cancers indicates that FBP vaccine has a potential targeting multiple cancer indications.

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.

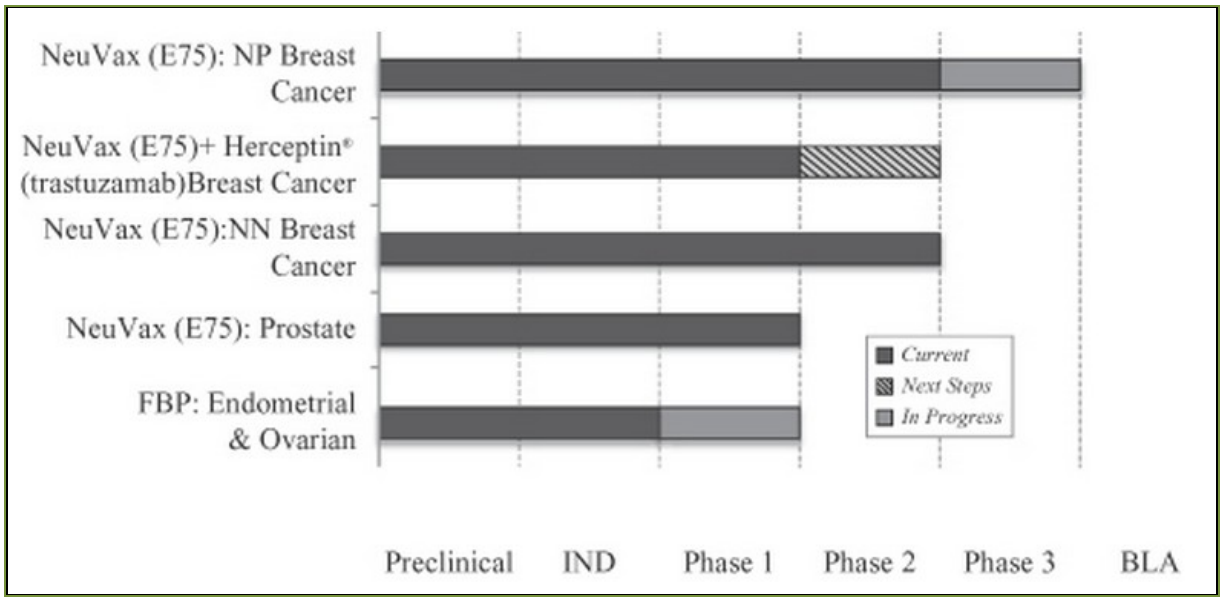
Phase I/II Trial Initiated for FBP (E39) Vaccine in Ovarian and Endometrial Cancer Patients

On Feb. 14, 2012, GALE started the enrollment of **Phase I/II** trial of Folate Binding Protein (E39) vaccine in two gynecological cancers: **ovarian** and **endometrial** adenocarcinomas. The Folate Binding Protein (FBP) vaccine consists of the E39 peptide plus GM-CSF. The Phase I/II study will test the safety and efficacy of the vaccine. Furthermore, the study will determine the optimal dose of the vaccine, and whether immunity to FBP will prevent clinical recurrence in patients with ovarian and aggressive endometrial cancer.

FBP is an ideal immunotherapy target for ovarian and endometrial cancers since this protein is over-expressed (20-80 fold) in more than 90% of ovarian and aggressive endometrial cancers. FBP is also over-expressed in 20-50% of breast, lung, colorectal, and renal cell carcinomas, but has very limited tissue distribution and expression in non-malignant tissue.

In this dose escalation Phase I/II study, patients will be identified that have ovarian or endometrial cancer, are post-menopausal or have been rendered surgically infertile, have completed their standard courses of therapy and have no evidence of disease. Once enrolled, they will be tested for FBP expression status. FBP positive patients will be tested for HLA status, and HLA-A2+ patients will be vaccinated with the FBP peptide (E39) and GM-CSF. The primary endpoints are the safety and optimal dosing of the vaccine to induce an in vivo peptide-specific immune response. The clinical endpoint is time to recurrence from date of enrollment. Those individuals who are HLA-A2- or HLA-A2+ who decline the vaccine will be followed clinically as matched controls for disease recurrence.

The initiation of the Phase I/II trial is important to GALE. The FBP vaccine platform expands GALE's pipeline with a second asset in human clinical trials. With the addition of FBP vaccine, GALE currently has 5 programs in clinical trials.



Phase III PRESENT Trial Of NeuVax Was Initiated Ahead of Schedule

On Jan. 20, 2012, Galena Biopharma, Inc. (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. Galena is currently on track for the initiation of approximately 100 investigator sites in the U.S. and abroad.

The initiation of the Phase III trial is ahead of our expectation. We think the initiation of the PRESENT Phase III trial of NeuVax represents a major milestone for GALE, which brings NeuVax a step closer to the market.

The market for NueVax is very large. According to US centers for disease control and prevention (CDC), in the US alone, approximately 202,964 individuals are diagnosed with breast cancer each year. Among these patients, approximately 20,000 (around 10%) will be eligible for NeuVax treatment. This is a huge market for NeuVax, which can reach a blockbuster status easily.

With positive Phase II results, we believe the Phase III trial has a very good chance to achieve its primary end points.

A Phase II Combination Trial of NeuVax+ Herceptin is Planned in 1H12

GALE also plans to initiate a **Phase II combination trial** of NeuVax (E75 plus GM-CSF) and Herceptin (trastuzumab; Genentech/Roche) for the treatment of Her2 1+ or 2+ breast cancer patients in the 1H2012.

The planned Phase II trial is being funded by Galena Biopharma and Genentech/Roche through the Henry M. Jackson Foundation. Each company will provide their respective drugs for the 300 patient trial and approximately half of the funding necessary to complete the trial. The trial will be conducted at twenty sites worldwide and is expected to commence **in the first half of 2012.**

This trial will enroll **300 breast cancer patients** with HER2 low-expressing tumors in order to establish the benefit of the combination versus trastuzumab alone in the adjuvant setting.

The study will be a multi-center, prospective, randomized, single-blinded Phase II trial evaluating NeuVax + trastuzumab (vaccine) vs. trastuzumab + GM-CSF (control) alone in the adjuvant setting in breast cancer patients. HLA-A2/A3+ node positive (or node negative if also negative for both ER and PR) breast cancer patients with HER2 1+ or 2+ expressing tumors who are disease-free after completing standard adjuvant therapies will be enrolled and randomized. Patients must have adequate cardiac function for enrollment (LVEF >50%), and randomization will be further stratified based on HER2 status (1+ or 2+) and nodal status (N0, N1, N2, or N3).

This new Phase II trial is based on the positive results from a pilot Phase II trial results reported in June 2011.

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 $1.35 per share which values the Company at about $65 million in market cap based on 48 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 $190 million in market cap based on 48 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 end of 2012. 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	Q2E	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	$4.00	$4.20	$4.50	$16.37	$20.00	$17.50	$15.00
% R&D	-	-	-	-	-					-	-	-	-
SG&A	$3.12	$1.95	$2.07	$2.11	$9.25	$1.94	$2.20	$2.30	$2.35	$8.79	$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)**	**($6.2)**	**($6.5)**	**($6.9)**	**($25.2)**	**($29.5)**	**($27.5)**	**($25.5)**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Net	$1.4	$3.2	($0.4)	$7.4	$11.7	($19.2)	($0.2)	($0.2)	($0.2)	($19.8)	($0.8)	($1.0)	($1.0)
Pre-Tax Income	**($3.8)**	**($1.4)**	**($5.5)**	**$1.6**	**($9.1)**	**($24.8)**	**($6.4)**	**($6.7)**	**($7.1)**	**($44.9)**	**($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)**	**($6.4)**	**($6.7)**	**($7.1)**	**($44.9)**	**($30.3)**	**($28.5)**	**($26.5)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-
Shares Out	*20.3*	*38.6*	*42.0*	*44.2*	*36.3*	*48.0*	*56.0*	*57.5*	*58.0*	*54.9*	*60.0*	*65.0*	*70.0*
Reported EPS	**($0.19)**	**($0.04)**	**($0.13)**	**$0.04**	**($0.25)**	**($0.52)**	**($0.11)**	**($0.12)**	**($0.12)**	**($0.82)**	**($0.51)**	**($0.44)**	**($0.38)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
One time charge	*($1.40)*	*($3.24)*	*$0.00*	*($7.40)*	*($12.04)*	*$19.15*	*$0.00*	*$0.00*	*$0.00*	*$19.15*	*$0.00*	*$0.00*	*$0.00*
Non GAAP Net Income	**($5.2)**	**($4.6)**	**($5.5)**	**($5.8)**	**($21.2)**	**($5.6)**	**($6.4)**	**($6.7)**	**($7.1)**	**($25.8)**	**($30.3)**	**($28.5)**	**($26.5)**
Non GAAP EPS	**($0.26)**	**($0.12)**	**($0.13)**	**($0.13)**	**($0.58)**	**($0.12)**	**($0.11)**	**($0.12)**	**($0.12)**	**($0.47)**	**($0.51)**	**($0.44)**	**($0.38)**

Source: Company filings and Zacks estimates

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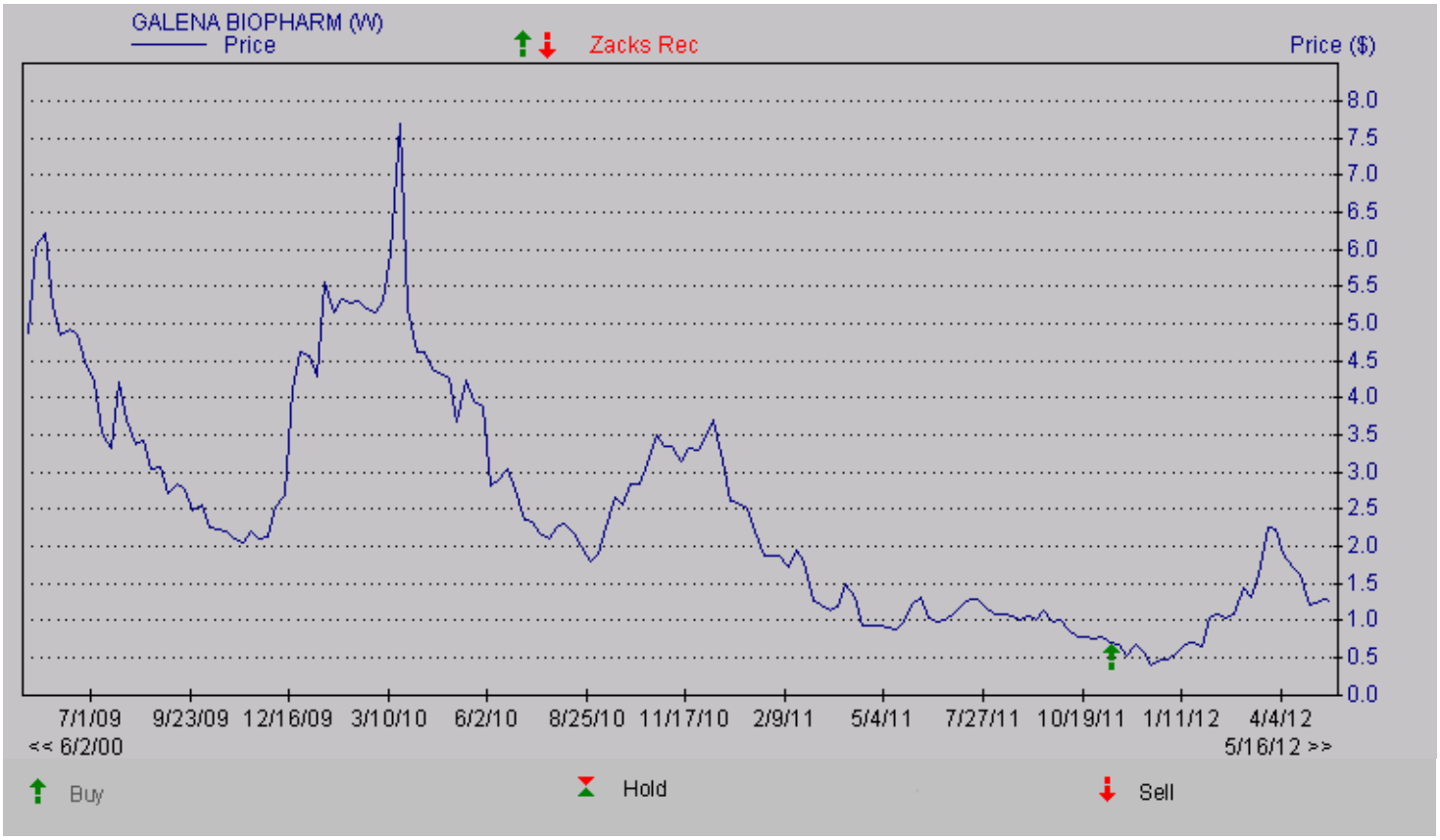
HISTORICAL ZACKS RECOMMENDATIONS



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The current distribution of Zacks Ratings is as follows on the 1025 companies covered: Buy/Outperform- 14.2%, Hold/Neutral- 79.9%, Sell/Underperform – 4.8%. Data is as of midnight on the business day immediately prior to this publication.

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