Zacks Small-Cap Research

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Galena Biopharma Inc. (GALE-NASDAQ)

Galena: Pipeline boosted with two new clinical trials, and IP further strengthened--- Outperform

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	11/14/2011
Current Price (03/28/12)	$2.00
Twelve-Month Target Price	**$4.00**

OUTLOOK

Galena recently initiated two new clinical trials. Lead drug candidate NeuVax for breast cancer has entered into a pivotal Phase III trial in Jan 2012. Newly acquired cancer vaccine FBP entered in to clinic in Feb 2012 targeting gynecological cancers.

The Company has 5 programs in clinic currently, which is quite unusual for a small cap biotech company.

Galena recently also strengthened its intellectual property for the protection of NeuVax vaccine rights until 2028.

SUMMARY DATA

52-Week High	**$2.77**
52-Week Low	**$0.37**
One-Year Return (%)	**33.33**
Beta	**0.21**
Average Daily Volume (sh)	**5,942,547**
Shares Outstanding (mil)	**48**
Market Capitalization ($mil)	**$95**
Short Interest Ratio (days)	**3.78**
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 E	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	-$0.13 E	-$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

GALE Reports Fourth Quarter and Year End Financials

On March 28, 2012, Galena Biopharma (GALE) reported its financial results for the fourth quarter and the year ended December 31, 2011.

Research and Development expense was $3.7 million for the fourth quarter of 2011 compared to $1.75 million for the fourth quarter of 2010. The increase of R&D costs was due to increased clinical trial costs in the fourth quarter of 2011.

Adjusted net loss was $5.8 million or $0.13 per share for the fourth quarter of 2011, compared with a net loss of $3.8 million, or $0.21per share, for the fourth quarter of 2010.

Adjust net loss for the year ended December 31, 2011 was $21.2 million or $0.58 per share, compared with a net loss of $16.8 million, or $0.93 per share, for the year ended December 31, 2010.

As of December 31, 2011, cash and cash equivalents totaled $11.4 million, compared with cash and cash equivalents of $6.9 million at December 31, 2010. Current cash could last through the second quarter of 2012.

Balance Sheet Could be Boosted by the Separation of RXi Pharmaceuticals

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 February 2012, GALE completed the registration of the spin-off with the Securities and Exchange Commission and announced a conditional dividend distribution to its stockholders with a record date as of the close of March 8, 2012. If the conditions to the distribution are satisfied and the distribution is completed, Galena stockholders will receive one share of the RXi common stock for each Galena common share owned.

In addition to the $2.5 million immediate funding, Galena also is to receive up to $45 million in milestones.

We think the earnings report is a non-event for Galena. Investors are focused on the clinical advancement of its drug candidates. In this regard, we think Galena is making great progress.

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

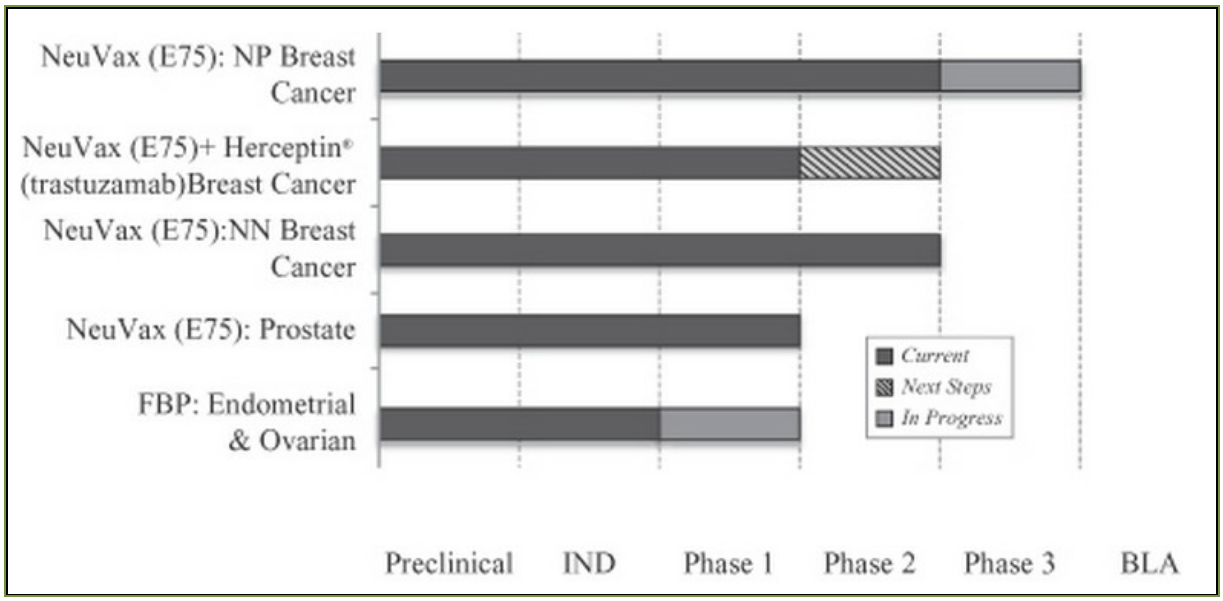
On Feb. 14, 2012, GALE started the enrollment of **Phase I/II** trial of Folate Binding Protein (E39) vaccine in two gynecological cancers: **ovarian** and **endometrial** adenocarcinomas. The Folate Binding Protein (FBP) vaccine consists of the E39 peptide plus GM-CSF. The Phase I/II study will test 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 for its clinical programs. The Company has become stronger than ever after the split with 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.

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 $2.00 per share which values the Company at about $96 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 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 our chief concern. Current cash balance will only last through the second quarter of 2012. An immediate financing is necessary to fund its ongoing clinical trials. 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	Q1E	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	$3.70	$4.00	$4.20	$4.50	$16.40	$20.00	$17.50	$15.00
% R&D	-	-	-	-	-					-	-	-	-
SG&A	$3.12	$1.95	$2.07	$2.11	$9.25	$2.15	$2.20	$2.30	$2.35	$9.00	$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)**	**($5.9)**	**($6.2)**	**($6.5)**	**($6.9)**	**($25.4)**	**($29.5)**	**($27.5)**	**($25.5)**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Net	$1.4	$3.2	($0.4)	$7.4	$11.7	($0.2)	($0.2)	($0.2)	($0.2)	($0.8)	($0.8)	($1.0)	($1.0)
Pre-Tax Income	**($3.8)**	**($1.4)**	**($5.5)**	**$1.6**	**($9.1)**	**($6.1)**	**($6.4)**	**($6.7)**	**($7.1)**	**($26.2)**	**($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)**	**($6.1)**	**($6.4)**	**($6.7)**	**($7.1)**	**($26.2)**	**($30.3)**	**($28.5)**	**($26.5)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-
Shares Out	*20.3*	*38.6*	*42.0*	*44.2*	*36.3*	*47.8*	*48.2*	*48.5*	*50.0*	*48.6*	*55.0*	*60.0*	*65.0*
Reported EPS	**($0.19)**	**($0.04)**	**($0.13)**	**$0.04**	**($0.25)**	**($0.13)**	**($0.13)**	**($0.14)**	**($0.14)**	**($0.54)**	**($0.55)**	**($0.48)**	**($0.41)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
One time charge	*($1.40)*	*($3.24)*	*$0.00*	*($7.40)*	*($12.04)*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*
Non GAAP Net Income	**($5.2)**	**($4.6)**	**($5.5)**	**($5.8)**	**($21.2)**	**($6.1)**	**($6.4)**	**($6.7)**	**($7.1)**	**($26.2)**	**($30.3)**	**($28.5)**	**($26.5)**
Non GAAP EPS	**($0.26)**	**($0.12)**	**($0.13)**	**($0.13)**	**($0.58)**	**($0.13)**	**($0.13)**	**($0.14)**	**($0.14)**	**($0.54)**	**($0.55)**	**($0.48)**	**($0.41)**

Source: Company filings and Zacks estimates

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HISTORICAL ZACKS RECOMMENDATIONS



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