Zacks Small-Cap Research

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Galena Biopharma Inc. (GALE-NASDAQ)

Galena: Proprietary platform technologies with a late stage pipeline targeting cancer indications---Outperform

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	11/14/2011
Current Price (02/07/12)	$1.01
Twelve-Month Target Price	**$4.00**

OUTLOOK

Galena has been transformed into a late stage development biotech company through its acquisition of Apthera. The Company is focused on cancer vaccines. Lead drug candidate NeuVax™ has demonstrated excellent efficacy data and safety profile for breast cancer patients in Phase II trials. NeuVax has entered into a Phase III trial in Jan 2012. Newly acquired cancer vaccine FBP targets gynecological cancers and is going to enter into the clinic in 1H2012. Galena has a relatively strong balance sheet. Current valuation is low based on the Company's strong fundamentals. We have an Outperform rating on Galena.

SUMMARY DATA

52-Week High	**$2.08**
52-Week Low	**$0.37**
One-Year Return (%)	**-43.89**
Beta	**0.17**
Average Daily Volume (sh)	**955,181**
Shares Outstanding (mil)	**43**
Market Capitalization ($mil)	**$43**
Short Interest Ratio (days)	**6.21**
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 E	0.00 E
2012					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	-$0.12 E	-$0.57 E
2012					-$0.31 E
2013					-$0.33 E

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

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WHAT'S NEW

Galena Biopharma Initiates Phase III PRESENT Trial Of NeuVax 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.

We think the initiation of the PRESENT Phase III trial of NeuVax is a major milestone for GALE. This trial brings NeuVax a step closer to the market and to the breast cancer patients who need new treatment options. The initiation also is ahead of our expectation.

The market for NueVax is huge in our view. 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 (see below for detailed information), we believe the Phase III trial has a very good chance to achieve its primary end points.

Galena Reports Positive NeuVax™ Phase II Results After 36 Months of Follow-Up

On June 6, 2011, Galena Biopharma announced updated data from its Phase II clinical trial of NeuVax™ at the American Society of Clinical Oncology (ASCO) annual meeting.

Galena is developing NeuVax for the adjuvant treatment of low to intermediate HER2 expressing breast cancer. The NeuVax **Phase II** trials enrolled 182 patients, including node positive and node negative, HER2 1+, 2+ and 3+ patients. All patients received standard of care (SoC) therapy and were confirmed to be disease-free prior to enrollment. Following enrollment, eligible patients were administered the

NeuVax vaccine once a month for six months, followed by booster shots one every 6 months thereafter. The efficacy endpoint for the trial was disease free survival (DFS).

Key highlights from the Phase II trial include:

- Statistically significant increase in disease free survival (DFS) at 36 months in the NeuVax treated group vs the control group for the planned Phase III patient population (p=0.035). The vaccine treated group showed no recurrences of cancer (0% recurrence rate), while the control group demonstrated a 22% recurrence rate which is consistent with historical norms. The planned Phase III patient population as defined in the FDA approved Special Protocol Assessment (SPA) includes breast cancer patients who are node positive, have low to intermediate HER2 expression (HER2 1+ and 2+ by IHC), are HLA A2+ & A3+ and who are disease free following standard of care therapy.

- An excellent safety profile, with no serious adverse events related to drug reported to date. All adverse events reported were minor and resolved within 24 hours.

- In the ITT (intent to treat) population who received all ranges of doses and schedules, the low to intermediate HER2 expressers continued to show significant activity in improvement of DFS (p=0.045), with the vaccine group demonstrating a reduction of 66% in relative risk for recurrence. This data demonstrates strong support for targeting of low to intermediate HER2 expressers, a group for which there is currently no HER2 directed therapies.

- The optimally dosed (1 milligram of E75 plus 250 micrograms of GM-CSF) group continues to demonstrate superior efficacy compared to sub-optimal doses (varying doses from 100 – 500 micrograms E75 plus 125 – 500 micrograms GM-CSF), with a recurrence rate of 3% for the optimally dosed group vs 12% for the sub-optimally dosed group and 14% for the control group.

The above 36-monthy follow-up data are very encouraging, which underscore the potential for cancer immunotherapy to develop into potent and well tolerated targeted therapies. The Company plans to initiate **Phase III PRESENT** (Prevention of Recurrence in Early-Stage, Node-Positive Breast Cancer with Low to Intermediate HER2 Expression with NeuVax™ Treatment) trial in 1H 2012 under FDA approved Special Protocol Assessment (SPA).

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

GALE 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 report in June 2011.

Combination of NeuVax And Herceptin May Expand NeuVax Indication

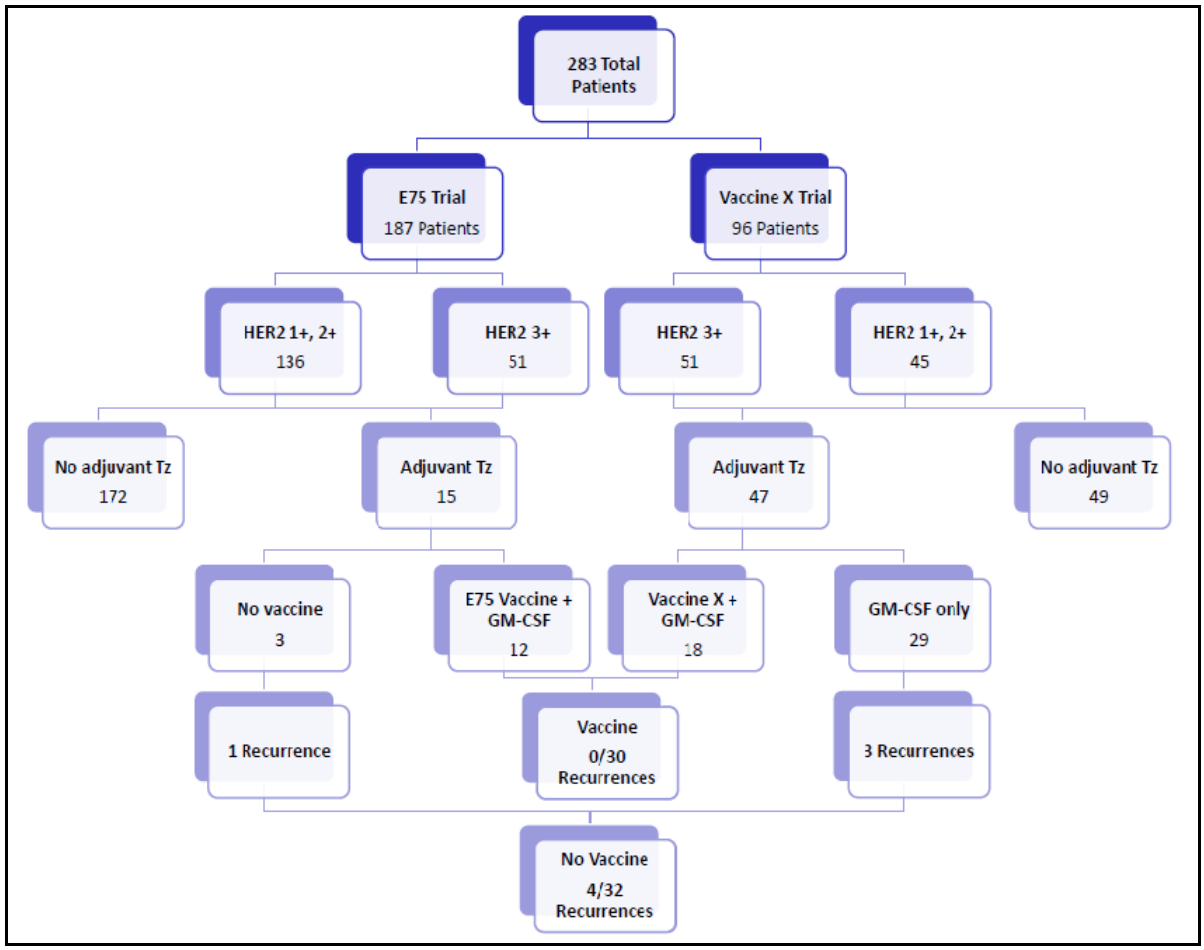
On June 8, 2011, Galena presented **Phase II** efficacy results for NeuVax™ **in combination with trastuzumab** (Herceptin®; Genentech/Roche) at the ASCO annual meeting.

Data from two combination Phase II breast cancer trials were analyzed. One combination trial is NeuVax (E75) + Tz (trastuzumab); another combination trial is Vaccine X + Tz. Vaccine X is also a HER2-derived vaccine. A total of 283 patients have enrolled in the two trials (E75=187, Vaccine X=96). Overall median length of follow-up is 48 months (E75=57 months, Vaccine X=19 months).

Of 187 patients enrolled in the E75 trial, 108 patients were vaccinated with E75 + GM-CSF; 79 patients were in the control arm. Of the 187 total patients, 15 (8%) received adjuvant Tz therapy (the E75 trial was primarily conducted prior to the widespread acceptance of Tz as standard of care adjuvant therapy for HER2-overexpressing breast cancer).

In the Vaccine X trial, 41 patients were vaccinated with Vaccine X + GM-CSF while 55 patients were given GM-CSF alone (control arm). Of these 96 patients, 47 (49%) received adjuvant Tz therapy.

Of the patients who received adjuvant Tz treatment, 32 received no vaccine, and their recurrence rate is 12.5% (4/32)—comparable with reported rates of similarly staged and treated patients. In contrast, 30 patients received either E75 + GM-CSF (12) or Vaccine X + GM-CSF (18) after completing adjuvant Tz, with a recurrence rate of 0% (0/30) (*p=0.064)*.



These preliminary results indicate the potential for NeuVax combined with Tz therapy for the improved treatment for HER2 3+ breast cancer patients. The results of this trial clearly warrant a randomized Phase II study with NeuVax in combination with trastuzumab to confirm efficacy and safety in a larger population.

The data may provide **another indication** for NeuVax in the treatment of HER2 3+ breast cancer patients. Combination of NeuVax and trastuzumab represents a potential expansion of the market for NeuVax to HER2 3+ breast cancer patients in the adjuvant setting.

What Do All These Mean For GALE?

Apparently, Galena has made great progress in the past few months for its clinical programs while balance sheet has been boosted. 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.

The Company recently enhanced the NeuVax patent portfolio by acquiring patent rights covering the use of NeuVax in combination with trastuzumab (Herceptin); and use in low-to-intermediate HER2+ breast cancer patients not eligible for Herceptin therapy. NeuVax Phase I/II clinical trial results was cited in the journal *Cancer*, published by the American Cancer Society. Positive data from the Phase II NeuVax clinical trials was presented at the 26th Annual Meeting of the Society for the Immunotherapy of Cancer (SITC) which demonstrated that patients with less aggressive disease traits may derive greater clinical benefit from vaccination and have lower rates of breast cancer recurrence. The addition of FBP further expanded the Company's focused cancer pipeline.

We are certainly impressed by the progress Galena has made recently which has demonstrated the Company's commitment to maximizing shareholder value. As such, we continue to rate the Company an Outperform and reiterate our price target of $4.0 per share.

KEY POINTS

- We maintain our Outperform rating on Galena Biopharma (GALE) and reiterate our 12-month price target of $4.0 reflecting the recent developments and progress the Company has made in terms of pipeline advancement and boosted balance sheet.

- Galena holds two unique proprietary drug discovery platform technologies: the peptide based immunotherapy and FBP targeted cancer vaccine. Both technologies have broad applications in various cancer indications, and have advantages over existing technologies in each respective field.

- The recent acquisition of Apthera has transformed Galena from an early stage development company into a late stage development company with a Phase III candidate NeuVax™, a peptide cancer vaccine for the treatment of breast cancer. The Phase II clinical trials have demonstrated excellent efficacy data and safety profile of NeuVax for breast cancer patients. The Company is moving the candidate into a Phase III clinical trial in the first half of 2012.

- The acquisition of FBP targeted cancer vaccine further expanded Galena's focused cancer pipeline.

- The split of Galena Biopharma from RXi Pharmaceuticals makes Galena stronger than ever with more focused cancer programs and less cash burn for its operations

- Valuation for Galena is attractive at the current price based on the Company's fundamentals. Therefore we rate the Company's shares a market Outperform with a twelve-month price target of $4.0 per share. Risks include clinical and regulatory uncertainties and cash burn concern.

OVERVIEW

Galena Biopharma is a late stage biotechnology company focused on the discovery, development and commercialization of cancer immunotherapeutics. The Company holds **two proprietary drug discovery platform technologies**: peptide-based immunotherapy and FBP targeted cancer vaccine.

Cancer Immunotherapy: Galena's lead product candidate for cancer immunotherapy is **NeuVax**, which is a peptide-based immunotherapy to reduce the recurrence of breast cancer in node-positive, low-to-intermediate HER2-positive breast cancer patients not eligible for Herceptin. The Company acquired NeuVax from privately held **Apthera** in April 2011. Apthera completed Phase II trials of NeuVax with positive efficacy data and favorable safety profile. Galena initiated Phase III clinical trial (**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) under FDA approved Special Protocol Assessment (SPA) of NeuVax in January 2012. In addition to breast cancer, NeuVax has the potential to treat other cancers, including prostate, bladder and ovarian cancers.

Galena Biopharma recently licensed worldwide rights 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 was licensed from The University of Texas M D Anderson Cancer Center and Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. (HJF).

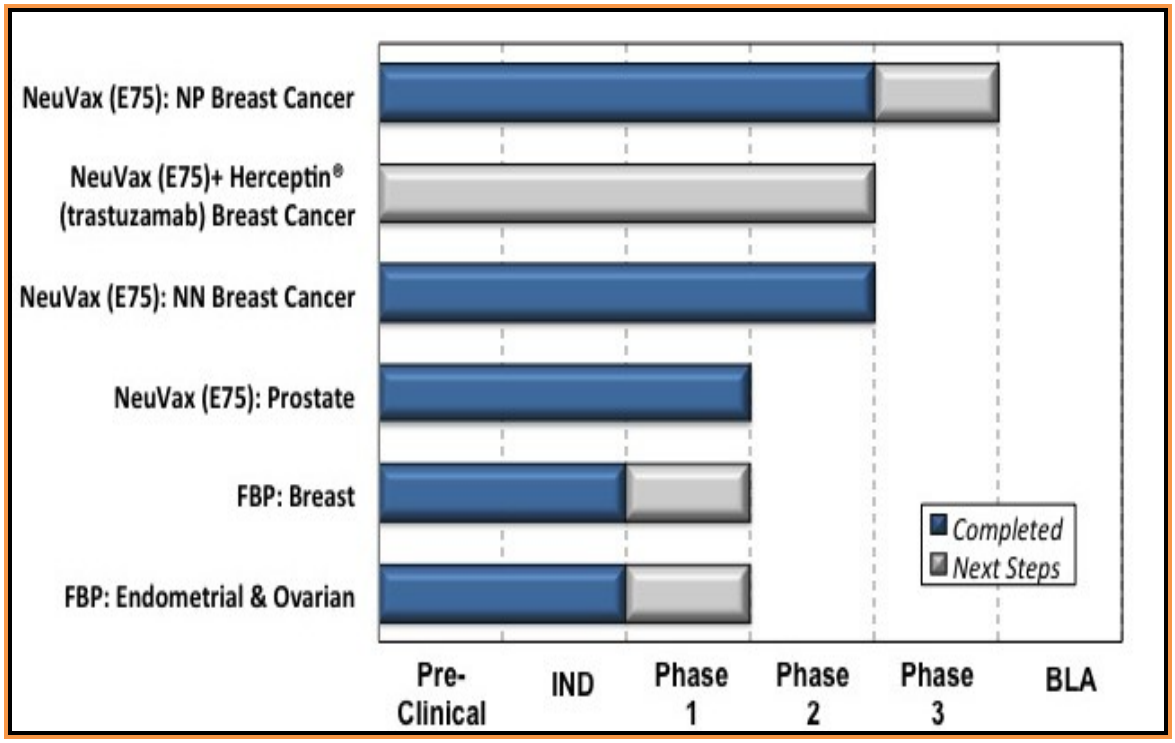
FBP has been granted Investigational New Drug (IND) by the FDA to enter clinical trials. Institutional Review Board (IRB) approval has also been received. Galena plans to initiate **Phase I** trials in 2012.

Galena was formed in 2006 by CytRx Corporation and four prominent RNAi researchers, including Dr. Craig Mello, who was awarded the 2006 Nobel Prize in Medicine for his co-discovery of RNAi. Galena commenced operations in January 2007 after CytRx transferred to Galena substantially all of its RNAi-related technologies and assets in exchange for approximately 7.04 million shares of Galena common stock. Before early 2008, CytRx owned approximately 85% of the outstanding shares of common stock of Galena. Since then, CytRx has been reducing its ownership in Galena and sold its remaining number of shares of Galena common stock in December 2010.

In September 2011, **Galena** separated its RNAi-based programs to its subsidiary **RXi Pharmaceuticals** and Galena will be focused on the development of targeted cancer therapies;

Galena was incorporated in Delaware, and is headquartered in Worcester, MA.

Development Pipeline of Galena



Source: Company Presentation

INVESTMENT THESIS

Galena Biopharma Reports Third Quarter Financial Results

Galena Biopharma (GALE) reported fiscal third quarter financial results on November 14, 2011.

There was no revenue for the quarter ended September 30, 2011.

Research and development expenses increased to $3.0 million in the third quarter of 2011 from $1.9 million in the third quarter of 2010. The increase in research and development expenses for the third quarter of 2011 compared with the third quarter of 2010 of $1.1 million, or 58%, was primarily due to an increase in research and development expenses related to a ramp up in NeuVax-related fees and activities.

General and administrative expenses increased to $2.1 million in the third quarter of 2011 from $1.8 million in the third quarter of 2010. The increase in general and administrative expenses for the third quarter of 2011 compared with the third quarter of 2010 of $0.3 million, or 17%, was primarily due to an increase in expenses for professional services.

Net loss for the three months ended September 30, 2011 was $5.5 million or $0.13 per basic and diluted share, compared with a net loss of $4.1 million, or $0.23 per basic and diluted share, for the comparable period in 2010. The increase of $1.4 million, or 34%, in net loss for the quarter ended September 30, 2011 compared to the quarter ended September 30, 2010 was primarily due to a $1.4 million increase in net loss from operations.

Net loss from operations increased to $5.1 million in the third quarter of 2011 from $3.7 million in the third quarter of 2010. The increase of $1.4 million, or 38%, in net loss from operations for the quarter ended September 30, 2011 compared to the quarter ended September 30, 2010 was primarily due to a $1.0 million increase in research and development expenses and a $0.3 million increase in general and administrative expenses due to the focus on expenses related to the Apthera acquisition.

Balance sheet is strong

As of September 30, 2011, cash, cash equivalents and short-term investments totaled $15.7 million, compared with cash and cash equivalents of $6.9 million at December 31, 2010. The Company closed two underwritten public offerings that provided net cash proceeds of approximately $18.2 million after underwriting fees and other estimated offering expenses (the March 2011 offering resulting in net proceeds of $7.3 million and the April 2011 offering resulting in net proceeds of $10.9 million).

Cash burn was $10.5 million for the nine months ended September 30, 2011.

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, especially in the advancement of its lead candidate NeuVax™ for breast cancer. Galena is on track to initiate the Phase III PRESENT trial for NeuVax in 1H12.

Apthera Acquisition Has Transformed Galena Into A Late Stage Biotech Company

Prior to the acquisition of Apthera, Galena's principal activities consisted of conducting discovery research and pre-clinical development activities utilizing its **RNAi therapeutic platform**, acquiring RNAi technologies and patent rights through exclusive, co-exclusive and non-exclusive licenses, recruiting an RNAi-focused management and scientific/clinical advisory team, capital raising activities and conducting business development activities aimed at establishing research and development partnerships with pharmaceutical and biotechnology companies.

In April 2011, Galena completed the acquisition of Apthera Inc., a private biotech company focused on developing a pipeline of peptide-based immunotherapies for the adjuvant treatment of HER2-positive breast and other cancers. The acquisition provides Galena with the **cancer immunotherapy platform technology** and a late stage product candidate, **NeuVax**, a peptide-based immunotherapy for node-positive, low-to-intermediate HER2+ breast cancer, not eligible for Herceptin treatment. Apthera has completed **Phase II** trials for NeuVax with positive efficacy data and a favorable safety profile. Galena plans to initiate a **Phase III** clinical trial for NeuVax in the first half of 2012.

Under the terms of the agreement, Apthera shareholders initially received approximately 5.0 million shares of Galena's common stock. Apthera's stockholders will also be entitled to contingent payments based on the achievement of certain development and commercial milestones relating to Apthera's NeuVax product candidate. In connection with the acquisition, Mark J. Ahn, PhD, a member of Galena's Board of Directors, succeeded Noah D. Beerman as President and Chief Executive Officer of Galena.

We think the acquisition of Apthera is an important milestone and represents a turning point for Galena. With the acquisition, Galena has been transformed from a pure pre-clinical technology platform company to a late stage product development company targeting significant unmet medical needs aimed at blockbuster therapeutic markets.

After the acquisition of Apthera, Galena's current focus will be developing its lead cancer immunotherapy candidate NeuVax and its FBP targeted cancer vaccine. Based on clinical trials, in addition to breast cancer, NeuVax has the potential to treat other cancers, including prostate, bladder and ovarian cancers. The acquisition of FBP vaccine further boosts Galena's cancer vaccine pipeline.

The Late Stage Cancer Immunotherapy Program

Galena is developing a pipeline of immunotherapy product candidates for the treatment of various cancers based on the E75 peptide. The most advanced candidate is **NeuVax**, which is targeted at preventing the recurrence of **breast cancer**.

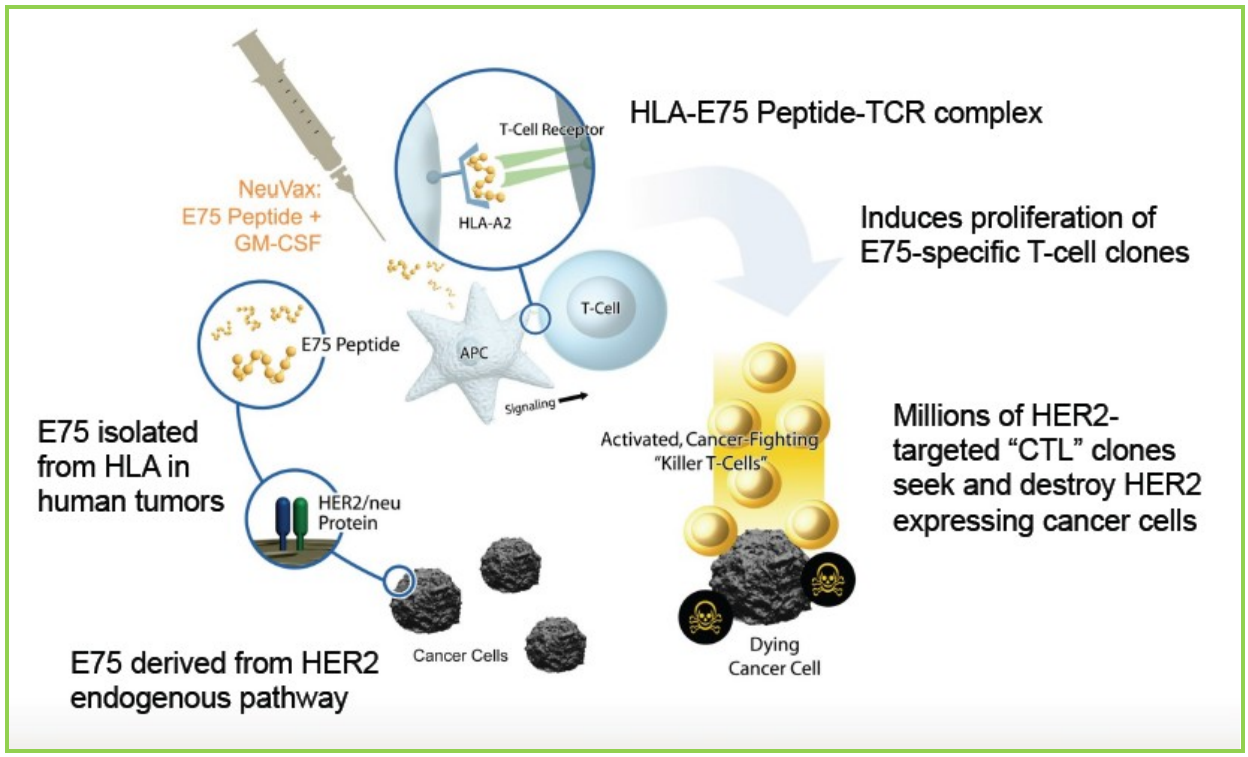
NeuVax has advantages over existing cancer vaccines

NeuVax is an immunotherapy that stimulates the immune system to actively seek out and selectively kill cancer cells. NeuVax directs "killer" T-cells to target and destroy cancer cells that express HER2/ neu, a protein associated with epithelial tumors in breast, ovarian, pancreatic, colon, bladder and prostate cancers.

HER2/ neu is expressed at very low levels in a number of normal epithelial tissues but is amplified and overexpressed in many epithelial tumors. HER2 is the key to the growth of cancer and has proven to be an ideal target for many drugs including Herceptin (Roche) and Tykerb (GSK).

NeuVax is comprised of two components: a HER2/ neu -derived peptide called **E75** and the immune adjuvant **GM-CSF**. E75 is a small 9-amino acid sequence that is immunogenic (produces an immune response) and GM-CSF is a commercially available protein that acts to stimulate and activate components of the immune system such as macrophages and dendritic cells.

Mechanism of Action for NeuVax



Source: Company Presentation

Galena's approach to cancer immunotherapy is unique and has potential advantages over existing cancer vaccines. The Company's NeuVax uses a specific epitope instead of an antigen or whole cell lysate as the activator of the body's immune system. An epitope is a short sequence of an antigen which is responsible for the activation of T-Cells in the body's immune system. NeuVax uses E75, a small 9-amino acid sequence epitope that is derived from amino acids 369-377 in the extracellular domain of the HER2 protein, a 185-Kd transmembrane glycoprotein that is part of the epidermal growth factor (EGF)

family of tyrosine kinases, plus GM-CSF, a recombinant human granulocyte-macrophage colony stimulating factor, a stimulator and activator of macrophages and dendritic cells.

Therefore, NeuVax is an **epitope-specific immunotherapy**. This class of therapies has the highest specificity for tumor cells compared to antigen-specific and polyvalent/whole-cell cancer vaccines and do not contain "self" epitopes or tolerogenic antigens, which are often found in antigen-specific and polyvalent/whole-cell vaccines. NeuVax differs from other cancer vaccines, which utilize partial or entire tumor antigens or polyvalent/whole-cell vaccines (e.g., autologous or patient-specific vaccines) that require presentation on cytokine-activated, dendritic cells, derived from the patient, cultured for a period of time and then re-administered to the patient (e.g., Dendreon's **Provenge**, an autologous cellular immunotherapy indicated for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant prostate cancer). Vaccination with self-epitopes can theoretically result in the immune system breaking tolerance to "self" and lead to autoimmune reactions against normal tissues while tolerogenic antigens can dampen the immune response to the tumor. In the case of NeuVax, the presence of a single, immunodominant T-cell epitope will confer both high tumor-specificity, lack of self-epitopes and high immunogenicity.

Another potential significant advantage of NeuVax is that the process to manufacture it is relatively simple and can be accomplished using standard peptide synthesis techniques and automated methods. This results in cost of goods that are potentially significantly lower than both antigen-specific and polyvalent/whole-cell vaccines, which have increasingly complex manufacturing and administrative procedures.

Galena has developed this therapy using a paradigm that focuses on treating early-stage cancer patients with no/low tumor burden and relatively healthy immune systems compared to patients with advanced/metastatic disease. Also, the Company intends to use a clinical trial endpoint focused on disease recurrence and disease-free survival in its Phase III trial for breast cancer as the basis for conditional approval of NeuVax rather than an overall survival endpoint. This development strategy could improve the chance of approval.

Table 1: Potential advantages of NeuVax versus other cancer vaccines

Parameter	NeuVax	Antigen-Specific Vaccines	Polyvalent/Whole-Cell Vaccines
Tumor Specificity	***Highest***	Less specific than peptide vaccines	Lowest
Presence of Self and/or Tolerogenic Antigens	***None*** --E75 peptide contains a single, immunodominant epitope	Potential for multiple self-epitopes that may be immunodominant over E75	Mostly self-antigens that may be immunodominant over E75
Cost/Ease of Manufacturing	***Relatively easy and inexpensive*** automated peptide synthesis	More complex; requires recombinant or DNA plasmid; often requires autologous dendritic cells for presentation	Very complex, multi-step and expensive process for culturing cells; fraught with batch-to-batch inconsistency
Clinical Development Path	***Early-stage patients*** with low tumor burden and robust immune systems	Advanced/metastatic patients with high tumor burden and poorly functioning immune systems	Advanced/metastatic patients with high tumor burden and poorly functioning immune systems
Trial Endpoints	***Disease recurrence***	Survival and disease recurrence	Survival and disease recurrence

Source: Company filings and Zacks Investment Research

NeuVax holds promise for the treatment of breast cancer

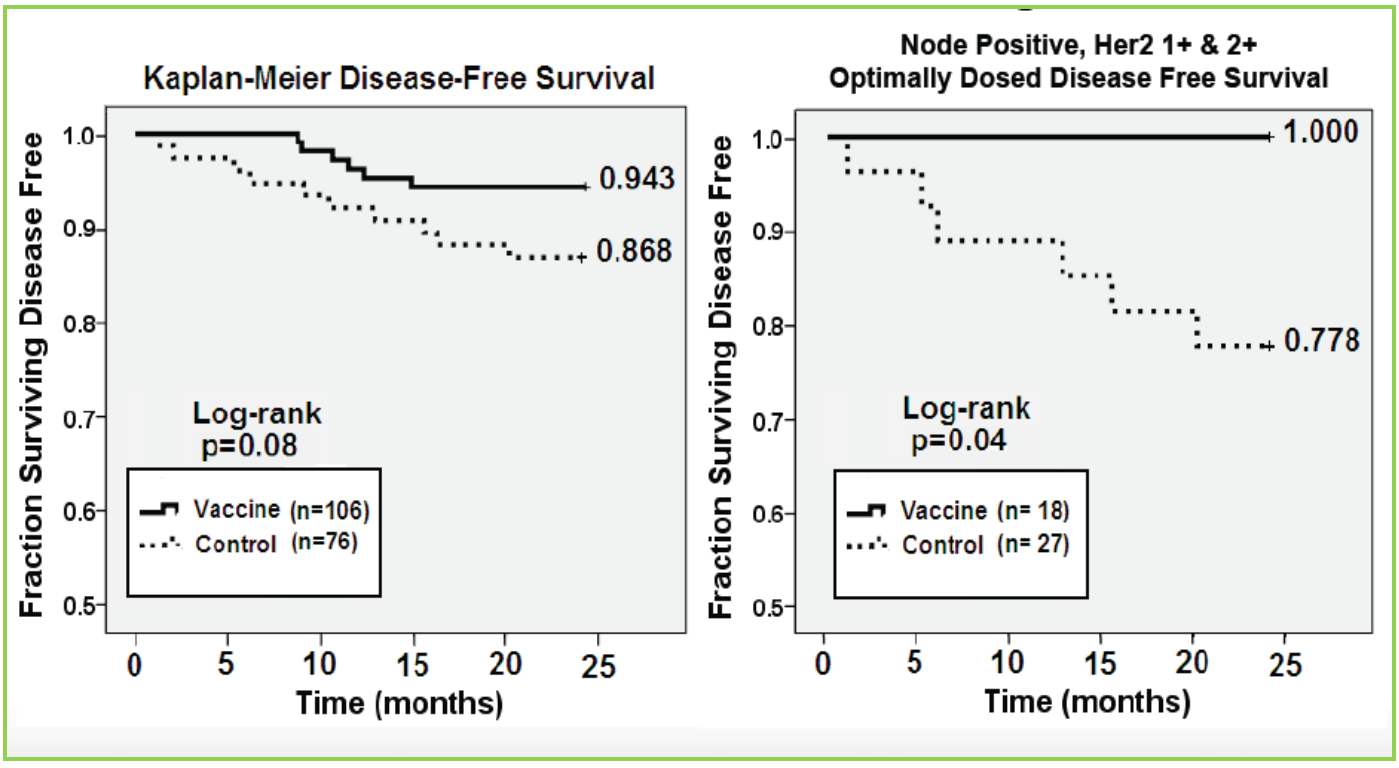
Apthera's studies have shown that NeuVax boosts a pre-existing immune response to the E75 peptide found in most cancer patients. Its active component, the 9-amino acid peptide, E75, is the synthetic version of an epitope recognized by cytotoxic T-lymphocytes (CTLs) and was originally found in tumor-infiltrating lymphocytes of breast and ovarian cancer patients.

In contrast to previous clinical studies with peptides, E75 induces up to a 1,000-fold increased T-cell response; typically 1-2% of circulating T-cells become reactive to the E75 peptide. Such E75-reactive T-cells are therapeutically active as measured by a reduction in disease recurrence in early-stage breast cancer patients.

Figure 3 below shows the landmark 24-month follow-up data for the completed **Phase II** trial for **breast cancer**. The **left part** of the chart shows data for all patients treated during the Phase II clinical trial, including both node positive and node negative patients, HER2 1+, 2+, and 3+ patients, as well as optimally dosed and sub-optimally dosed. The **right part** of the chart shows data for patients who were node positive, HER2 1+ &2+, optimally dosed. This is the target population for the Phase III trial as defined in the SPA.

For all patients (left part), the Kaplan-Meier Disease Free Survival rate improved for the patients receiving NeuVax (N=106) compared to the control group (N=76). An even greater improvement (right part) can be seen for a subgroup patients who were node-positive, low and intermediate HER2+ expressor, and were optimally-dosed (N=18) compared to the control (N=27). The results are statistically significant.

Disease-free survival for all patients and node-positive low-expressor patients



Source: Company presentation

Phase III Trial is Initiated for NeuVax for Breast Cancer

Based on the positive Phase II clinical trial results and feedback from Apthera's End-of-Phase-II meeting with the FDA, Galena initiated in January 2011 the planned **RESENT Phase III** trial of NeuVax for node positive with low to mediate HER2 expression breast cancer patients who will be optimally dosed. These patients bear similar characteristics as those in the Phase II sub-group who achieved statistically significant improvement in disease free survival rate. This Phase III trial will be a multi-center trial in breast cancer under a Special Protocol Assessment (SPA) from the FDA. The trial will **enroll 700 patients** with randomization of 1:1. The primary end point will be disease free survival.

From a clinical trial perspective, we believe the design of the Phase III clinical trial has a very good chance to meet its primary end points (disease free survival).

If the pre-planned interim analysis (analysis planned at trial halfway point) is positive, Galena expects to commence a **second Phase III** trial immediately following completion of patient enrollment into the first Phase III trial and would then expect to conclude both trials in 2018.

In addition to breast cancer, the Company intends to further develop NeuVax for the treatment of **prostate cancer** patients at high risk for disease recurrence, as well as for other **solid tumor** types that express HER2.

Market Opportunities For NeuVax

Current treatment options for breast cancer

Breast cancer is *usually* treated with surgery and then possibly with radiation or chemotherapy, or both. Hormone positive cancers are treated with long term hormone blocking therapy. Treatments are given with increasing aggressiveness according to the prognosis and risk of recurrence.

Surgery is the first step for breast cancer especially for early stage cancer patients.

Radiotherapy is given after surgery to the region of the tumor bed and regional lymph nodes, to destroy microscopic tumor cells that may have escaped surgery. It may also have a beneficial effect on tumor microenvironment. Radiation therapy can be delivered as external beam radiotherapy or as brachytherapy (internal radiotherapy). Radiation can reduce the risk of recurrence by 50-66% (1/2 - 2/3 reduction of risk) when delivered in the correct dose and is considered essential when breast cancer is treated by removing only the lump (lumpectomy or wide local excision).

There are currently three main groups of **medications** used for adjuvant breast cancer treatment. These drugs can be used individually or in different combinations.

Hormone Blocking Therapy: Some breast cancers require estrogen to continue growing. They can be identified by the presence of estrogen receptors (ER+) and progesterone receptors (PR+) on their surface. These ER+ cancers can be treated with drugs that either block the receptors, e.g.tamoxifen, or alternatively block the production of estrogen with an aromatase inhibitor, e.g. anastrozole (Arimidex) or letrozole (Femara). Aromatase inhibitors, however, are only suitable for post-menopausal patients.

Chemotherapy is predominately used for stage 2-4 disease, being particularly beneficial in estrogen receptor-negative (ER-) disease. They are given in combinations, usually for 3–6 months. One of the most common treatments is cyclophosphamide plus doxorubicin (Adriamycin), known as AC. Damage to the heart muscle is the most dangerous complication of doxorubicin. Sometimes a taxane drug, such as docetaxel, is added, and the regime is then known as CAT. Another common treatment, which produces equivalent results, is cyclophosphamide, methotrexate, and fluorouracil (CMF).

Targeted therapy is a relatively recent development in HER2+ breast cancer treatment. Approximately 15-20 percent of breast cancers have an amplification of the *HER2/neu* gene or overexpression of its protein product. This receptor is normally stimulated by a growth factor which causes the cell to divide. In the absence of the growth factor, the cell will normally stop growing. Overexpression of this receptor in breast cancer is associated with increased disease recurrence and worse prognosis. Herceptin (Trastuzumab) is a monoclonal antibody to HER2, has improved the 5 year disease free survival of stage 1–3 HER2+ breast cancers to about 87% (overall survival 95%). Trastuzumab, however, is expensive, and approximately 2% of patients suffer significant heart damage; it is otherwise well tolerated, with far milder side effects than conventional chemotherapy.

NeuVax is Positioned to Differ from Herceptin

NeuVax represents a new class of breast cancer therapy: **immunotherapy**. Galena intends to develop NeuVax for the treatment of node-positive (NP) breast cancer. NeuVax has different mechanism of action compared to Herceptin. NeuVax targets early stage cancer patients with low to intermediate HER2 expression.

How NeuVax differentiates from Herceptin

	Herceptin	NeuVax
Molecule/MOA	mAB against HER2	Vaccine targeting HER2
Patient Population	Early & advanced stage HER2 IHC 3+	Early stage HER2 IHC 1+ & 2+
Revenues 2010	$5 B worldwide ($2.4 B US, >80% of eligible patients receive adjuvant treatment)	-----

Low to intermediate HER2 expression is a significant unmet medical need not addressed by current therapies

Source: Company presentation and Zacks Investment Research

We believe there is a significant unmet medical need not addressed by current therapies for breast cancer patients. NeuVax could be a meaningful alternative for breast cancer.

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.

Galena Licenses Novel, Targeted Cancer Vaccine for Gynecological Cancers

Galena Biopharma recently licensed worldwide rights 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 was licensed from The University of Texas M D

Anderson Cancer Center and Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. (HJF).

FBP has been granted Investigational New Drug (IND) by the FDA to enter clinical trials. Institutional Review Board (IRB) approval has also been received. Galena plans to initiate Phase I trials by the end of 2011.

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.

The market for FBP vaccine is huge. 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.

We think the acquisition is positive to Galena. The license of FBP vaccine doubles Galena's oncology pipeline which includes NeuVax (E75), scheduled to commence its Phase III PRESENT study in breast cancer in 1H 2012.

Strong Management and Scientific Team

***Mark J. Ahn, Ph.D.**, President and Chief Executive Officer*

Dr. Ahn served as a director on Galena's board from 2007 until his appointment as President and Chief Executive Officer in 2011. He brings more than 20 years of experience in the biopharmaceutical industry, including as founder, President and Chief Executive Officer for Hana Biosciences, Inc. Prior to joining Hana, he served as Vice President, Hematology and corporate officer at Genentech, Inc., and held positions of increasing responsibility in strategy, general management, sales and marketing, business development, and finance with Amgen Inc. and Bristol-Myers Squibb Company.

***Mark W. Schwartz, Ph.D**., Executive Vice President and Chief Operating Officer*

Dr. Schwartz joins Galena as part of its acquisition of Apthera, where he had been the President and Chief Executive Officer. Prior to joining Apthera, Dr. Schwartz served for five years as President and Chief Executive Officer of Bayhill Therapeutics Inc., a company developing an innovative DNA vaccine platform for the treatment of autoimmune diseases, where he completed a successful partnership with Genentech for the development of the company's type 1 diabetes vaccine. He had also served as President and Chief Executive Officer of Calyx Therapeutics, Inc., which doubled its size, nurtured a successful working relationship with the FDA, and completed key phase I and phase II international clinical trials of novel anti-inflammatory compounds during his tenure.

***Robert E. Kennedy,** Treasurer and Chief Financial Officer*

Robert E. Kennedy co-founded Apthera in 2005, where he served as Director, Secretary, Treasurer and Chief Financial Officer. Previously, Mr. Kennedy served as Director and Chief Financial Officer for Blue Dot Services, Inc., a nationwide heating, ventilation, air-conditioning and plumbing construction and services company. Prior to his work at Blue Dot Services, he was the managing director for Koch Ventures, Inc., the venture capital arm of Koch Industries, Inc., the second largest privately-held company in the United States. Mr. Kennedy has held finance and accounting management roles at

Sterling House Corporation, Thorn Americas, Inc., Raytheon Aircraft Corporation, and F.B. Kubik & Company, CPAs; he serves on the board of directors of Immunologix, Inc. and Arizona BioIndustry Association, and is a member of the American Institute of Certified Public Accountants and the Arizona Society of CPAs.

Hana B. Moran, PhD, VP, Regulatory Affairs & Quality Assurance

Dr. Moran has more than 25 years of pharmaceutical industry experience in research, regulatory affairs, and quality assurance in start-up and high-growth companies including SangStat, Scios, Athena Neurosciences, Intarcia, and Hana Biosciences. She has a long and varied experience in development of pharmaceuticals, including oncology products and led marketing approval activities for nine pharmaceutical products, among them drugs, biologics, medical devices and *in-vitro* diagnostics globally. Dr. Moran earned an MSc in Chemical Engineering from Slovak Technical University, Bratislava, Slovakia and a Ph.D. in Organic Chemistry from the Weizmann Institute of Science, Rehovoth, Israel.

George Peoples, MD, Senior Medical Advisor

Cancer Vaccine Development Program, Deputy Director, United States Military Cancer Institute, Professor, Uniformed Services University Chief, Surgical Oncology, Department of Surgery, Brooke Army Medical Center

INDUSTRY OUTLOOK

Our Outlook For The Biotech Industry Is Positive

We think there are a number of strong secular growth drivers that still power the biotech industry-namely, an aging population and an enormous research and development (R&D) effort to bring new, better drugs to market. People are living longer, and many have prescription pharmaceuticals to thank for it. Recent breakthroughs in oncology, neurology, and cardiology offer sizable market opportunities. Biotechnology research is finally starting to deliver. Expanded knowledge of genomics and proteomics is attracting significant attention from some of the industry's larger players. Drug companies are finding ways to reformulate and enhance current products. This is clearly a positive for the biotech industry. Demand for innovative medicines remains strong and biotechnology should deliver the next wave of pharmaceutical products to the market. This should allow the group to outperform the broader sector.

Licensing/partnership remain the lifeline of biotech industry. We expect to see continued partnership and in-licensing/out-licensing activities for biotech companies in the next few years.

We also expect further consolidation throughout the industry because we believe that current market environment in the Pharma/Biotech industry is favorable for M&A activities. The big pharmaceutical companies have long been faced with big challenges such as patent expiration for blockbusters, low research and development productivity, and generic competition. Platform technology and efficient R&D efforts in smaller biotech companies may be part of the solution to the challenges faced by big Pharma companies. As long as the challenges still exist in the pharmaceutical industry, the buyout of smaller biotech companies by big Pharma/giant biotech companies will continue to make sense.

For individual biotech companies, we think companies with one or more of the following fundamentals will be attractive.

- With approved products on the market which can generate cash for the company;
- With a strong balance sheet and low cash burn rate; huge amount of cash will be needed to provide funds for drug development before it can reach the market;

- With platform technologies with deep, diversified pipeline (from early to late stage drug candidates); platform technology can produce series drug candidates, and is usually worth more than a single drug candidate program. When a drug candidate is moving closer to market, it usually reduces development risks.

Investors should pay attention to those large profitable biotechnology stocks, as well as small-cap biotechnology stocks with promising pipelines.

VALUATION AND RECOMMENDATION

We maintain an Outperform rating on Galena shares and reiterate our 12-month price target of $4.0 per share which reflects the recent progresses the Company has made.

Galena is a late stage clinical development biotech company with a focus on cancer indications. The Company's proprietary platform technology, peptide based cancer vaccine, has broad applications in various clinical settings. Based on the above platform technology, Galena has developed a pipeline targeting various cancer indications.

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 $1.00 per share which values the Company at about $42 million in market cap based on 42 million shares outstanding. This is a huge 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 $200 million in market in market cap. Our price of $4.0 per share corresponds to a $170 million in market cap based on 42 million outstanding shares.

RISKS

Balance Sheet Is Relatively Strong; But Cash Burn Is Still A Concern

Galena had cash and cash equivalents of approximately $15.7 million as of September 30, 2011.

However, we understand that, research and development expenses are expected to soar in connection with the Phase III and Phase II clinical trial for NeuVax and Phase I trial for FBP. Expenses will increase significantly from historic levels for the foreseeable future. We believe existing cash and cash equivalents should be sufficient to fund operations through the first quarter of 2012. Therefore, we expect Galena will tap the capital market soon.

We remind investors that Galena has not generated revenue to date and may not generate product revenue in the foreseeable future. In the absence of product revenues, the potential sources of operational funding are expected to be the proceeds from the sale of equity, funded research and development payments and payments received under partnership and collaborative agreements. We

think equity financing will be the main source of funding for the near future. Issuance of new shares will dilute existing shareholder base and share value will suffer as a result.

Clinical And Regulatory Risks Remain High

Although the acquisition of Apthera has transformed Galena into a late stage development company, both clinical and regulatory risks remain high. NeuVax has demonstrated good efficacy and safety profile in Phase II clinical trials; however, there is no guarantee that NeuVax will achieve the same results in the following Phase III clinical trials.

The Company's FBP vaccine is still in IND stage. Clinical risk for FBP is even higher than that for NeuVax. We remind investors that drug candidates, even in their late stage of development, are always exposed to both clinical and regulatory risks.

We have seen many clinical trial failures in the past, and will continue to see a lot in the future. Besides the long process of drug development, regulatory hurdle for drug development is also big at present. Drug companies must face a more conservative health authority nowadays more than ever before. We have seen many cases in which drug candidates with positive clinical data are still denied by the FDA.

With these in mind, we cannot rule out completely the possible failure of any of Galena's clinical programs, even for the late stage programs.

PROJECTED INCOME STATEMENT

	2010A (Dec)					2011E (Dec)					2012E (Dec)	2013E (Dec)	2014E (Dec)	2015E (Dec)
$ in million except per share data	Q1A	Q2A	Q3A	Q4A	FYA	Q1A	Q2A	Q3A	Q4E	FYE	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**	**$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	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**	**$0.00**
Gross Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
R&D	$1.93	$2.26	$1.94	$1.75	$7.87	$2.16	$2.67	$3.00	$2.50	$10.33	$8.50	$10.00	$12.00	$15.00
% R&D	-	-	-	-	-	-	-	-	-	-	-	-	-	-
SG&A	$2.53	$2.49	$1.78	$1.95	$8.75	$3.12	$1.95	$2.07	$3.50	$10.64	$4.50	$5.50	$7.00	$8.50
% 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	$0.00
% Other	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Operating Income	**($4.5)**	**($4.8)**	**($3.7)**	**($3.7)**	**($16.6)**	**($5.3)**	**($4.6)**	**($5.1)**	**($6.0)**	**($21.0)**	**($13.0)**	**($15.5)**	**($19.0)**	**($23.5)**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Net	$0.6	$2.6	($0.42)	$1.9	$4.6	$1.4	$3.2	($0.4)	$1.0	$5.3	($0.8)	($0.8)	($1.0)	($1.0)
Pre-Tax Income	**($3.9)**	**($2.1)**	**($4.1)**	**($1.8)**	**($12.0)**	**($3.8)**	**($1.4)**	**($5.5)**	**($5.0)**	**($15.7)**	**($13.8)**	**($16.3)**	**($20.0)**	**($24.5)**
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	$0.0
Tax Rate	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Reported Net Income	**($3.9)**	**($2.1)**	**($4.1)**	**($1.8)**	**($12.0)**	**($3.8)**	**($1.4)**	**($5.5)**	**($5.0)**	**($15.7)**	**($13.8)**	**($16.3)**	**($20.0)**	**($24.5)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Shares Out	*16.4*	*18.4*	*18.4*	*18.4*	*17.9*	*20.3*	*38.6*	*42.0*	*42.0*	*35.7*	*45.0*	*50.0*	*55.0*	*60.0*
Reported EPS	**($0.24)**	**($0.12)**	**($0.23)**	**($0.10)**	**($0.67)**	**($0.19)**	**($0.04)**	**($0.13)**	**($0.12)**	**($0.44)**	**($0.31)**	**($0.33)**	**($0.36)**	**($0.41)**
YOY Growth	-	-	-	-	-					-	-	-	-	-
One time charge	$0.00	*($2.61)*	*$0.00*	*($2.02)*	*($4.63)*	*($1.40)*	*($3.24)*	*$0.00*	*$0.00*	*($4.64)*	*$0.00*	*$0.00*	*$0.00*	*$0.00*
Non GAAP Net Income	**($3.9)**	**($4.8)**	**($4.1)**	**($3.8)**	**($16.6)**	**($5.2)**	**($4.6)**	**($5.5)**	**($5.0)**	**($20.3)**	**($13.8)**	**($16.3)**	**($20.0)**	**($24.5)**
Non GAAP EPS	**($0.24)**	**($0.26)**	**($0.23)**	**($0.21)**	**($0.93)**	**($0.26)**	**($0.12)**	**($0.13)**	**($0.12)**	**($0.57)**	**($0.31)**	**($0.33)**	**($0.36)**	**($0.41)**

Source: Company filings and Zacks estimates

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HISTORICAL ZACKS RECOMMENDATIONS



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