Galena Biopharma, Inc.
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GALE RESEARCH REPORT:

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COMPANY OVERVIEW AND PIPELINE:

Galena Biopharma, Inc. (GALE), formerly RXi Pharmaceuticals Corporation, is a biopharmaceutical company focused on developing and commercializing oncology treatments. The company is pursuing the development of cancer therapeutics using peptide-based immunotherapy products that seek to prevent the recurrence of cancer in patients. Through their main product candidate – NeuVax (nelipepimut-S, or "E75") – the company intends to reduce the recurrence of breast cancer in low to intermediate HER2-positive breast cancer patients. The company is also testing NeuVax in combination with Herceptin (trastuzumab from Genentech/Roche) in node-positive and node-negative breast cancer patients, and separately for use in treating gastric (stomach) cancer as well. Separately, the company is also developing GALE-301, or Folate Binding Protein (FBP), for the treatment of ovarian and endometrial cancers.

Furthermore, through their acquisition of Mills Pharmaceuticals in January 2014, GALE retained the worldwide rights to anagrelide controlled release (CR), which was renamed GALE-401, for the treatment of essential thrombocythemia (ET). Although anagrelide is already an FDA-approved product and has been in use since the late 1990s, adverse side effects such as nausea, diarrhea, abdominal pain, palpitations, tachycardia and headache have been known to occur. As a result, through clinical trials, GALE has been reducing the maximum concentration (Cmax) to reduce these side effects while preserving efficacy.

Lastly, GALE's first commercial product – Abstral (fentanyl) Sublingual Tablets – is approved by the FDA for the management of breakthrough cancer pain (BTcP) in patients with cancer who are already receiving, and who are tolerant to, opioid therapy for their persistent baseline cancer pain. The tablet is designed to dissolve under the tongue (sublingual) in seconds and provide relief of breakthrough pain within minutes while matching the duration of the pain episode. Abstral was launched commercially by GALE during the fourth quarter of 2013.

The company's full pipeline is shown below:

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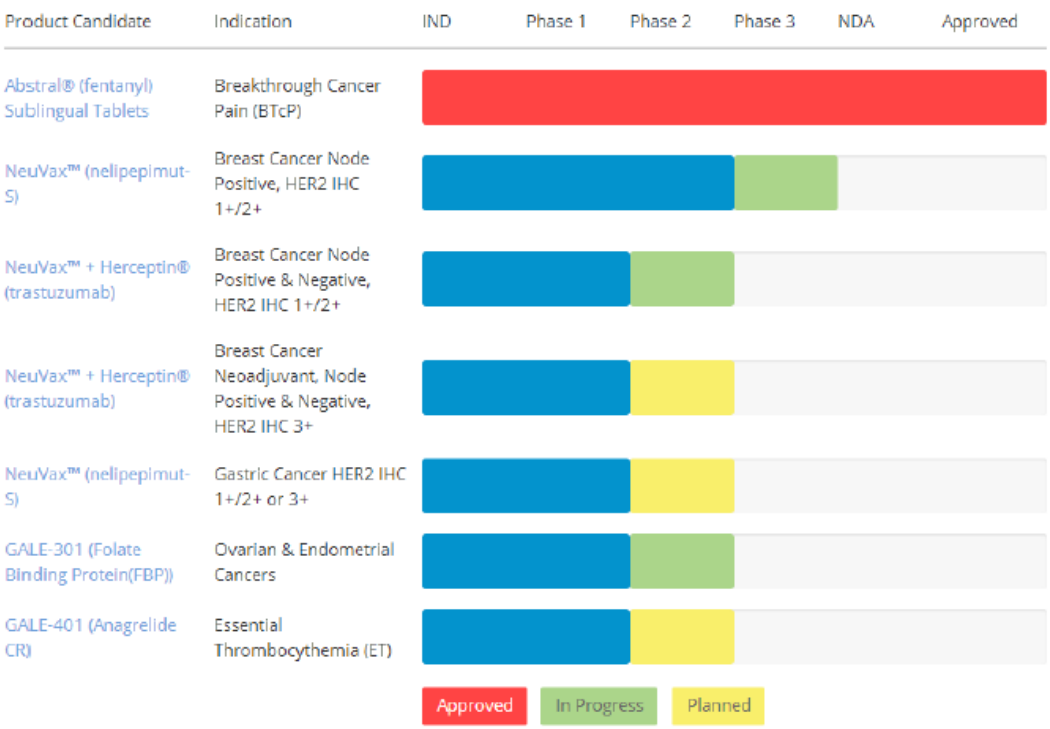
Pipeline



Source: http://galenabiopharma.com/pipeline/

MARKET AND COMPETITION:

BREAST CANCER:

According to GLOBOCAN 2012, breast cancer was the second most commonly diagnosed form of cancer in 2012 with 1.7 million new cases, and accounting for nearly 12% of all new cancer cases. Since the 2008 estimates, breast cancer incidence has increased by more than 20% while mortality has increased by 14%. With approximately 522,000 deaths in 2012, breast cancer is now the most common cause of cancer death among women.[1]

Overall, incidence rates of breast cancer remain the highest in more developed regions, while mortality is relatively higher in less developed countries due to a lack of early detection and access to treatment. In the US specifically, over 230,000 women are diagnosed with breast cancer annually.[2] Approximately 75% of breast cancer patients have tissue test positive for an increased amount of the HER2 receptor, which is associated with disease progression and decreased survival.[3] Since the majority of breast cancer patients with low to intermediate HER2 IHC 1+/2+ do not have an approved and effective treatment option to prevent cancer recurrence, GALE believes it can capitalize on this unmet need.

Currently, treatment options for early stage breast cancer typically include chemotherapy, hormonal therapy, radiation therapy, or any combination of these options. For patients with tumors with high

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expressions of HER2 (IHC 3+), which account for approximately 20% to 30% of all breast cancer patients, the HER2-targeted drug Herceptin (trastuzumab) may be administered as well as other novel targets such as MUC1.

In addition, there are a number of cancer treatment options in development for breast cancer, including Lapuleucel-T (Dendreon), AE-37 (Antigen Express), ONT-380 (Oncothyreon) and others such as Merck's failed Stimuvax drug that the company just re-launched in a phase III trial for lung cancer. While these drug candidates are aimed at a number of different targets, perhaps AE-37 is the closest competitor to GALE's NeuVax with Oncothyreon (who is also combining their drug with trastuzumab) close behind. Each of these drug candidates, however, are currently at different trial phases with NeuVax the furthest along at phase III, AE-37 at phase II and ONT-380 at phase I. However, despite NeuVax's progression, the estimated completion date of the study is in 2024 with an estimated primary completion date in 2017. Compare that to AE-37, which has an estimated study completion date of December 2015 – albeit for phase II.

GASTRIC (STOMACH) CANCER:

Meanwhile, it is reported that each year almost one million people are diagnosed with stomach cancer worldwide. More importantly, GLOBOCAN 2012 reported that stomach (gastric) cancer was the third leading cause of cancer death in 2012, accounting for about 8.8% of cancer deaths – roughly 700,000.[4] Overall, only approximately 20% of patients with stomach cancer live at least five years following diagnosis,[5] thereby reinforcing the need for new treatments to prevent disease recurrence.

Similar to breast cancer, the typical treatments for earlier stage stomach cancer include surgery, chemotherapy, radiation, or a combination of these treatments. For patients whose tumors are HER2-positive, trastuzumab can be added to chemotherapy, while ramucirumab (Cyramza) may also be an option if chemotherapy stops working. Ultimately, however, treatment options for stomach cancer are somewhat limited, with NeuVax possibly being a legitimate contender in the space.

OVARIAN AND ENDOMETRIAL CANCER:

According to the World Cancer Research Fund International, ovarian and endometrial cancers combined account for about 4% of all cancer cases worldwide with over 550,000 new cases reported in 2012.[6] In the US, ovarian cancer occurs in more than 22,000 patients per year and is the most lethal gynecologic cancer.[7] Tumors are removed through surgery with patients undergoing platinum- and/or taxane-based chemotherapy soon after. Although most patients respond to these treatment options, a majority of them relapse, which significantly decreases their treatment options and success rates. Meanwhile, endometrial cancer is the most common gynecologic cancer and occurs in more than 46,000 women (resulting in about 8,000 deaths) in the US each year.[8] As with ovarian cancer, treatment options for endometrial cancer are also limited, ultimately favoring GALE's Folate Binding Protein (GALE-301) drug candidate, currently in a phase II trial.

ESSENTIAL THROMBOCYTHEMIA (ET):

Essential Thrombocythemia is a rare chronic blood disorder characterized by the overproduction of platelets in the bone marrow, which may develop into acute myeloid leukemia or myelofibrosis. Galena

believes ET meets the qualifications of an orphan drug given the fact there are currently 80,000-100,000 people with ET in the US and an annual incidence rate of about 8,000 new cases each year, with similar rates in Europe.

Current treatment options for ET include Agrylin and its generic equivalents – hydorxyurea and interferon alpha. Other investigational drug candidates include JAK2 inhibitors (LY2784544 from Eli Lily and momelotinib from Gilead Sciences) and pegylated interferon alfa-2a (Pegasys from Genetech/Roche).

BREAKTHROUGH CANCER PAIN (BTcP):

Lastly, breakthrough cancer pain occurs in an estimated 40%-80% of patients who are already receiving chronic, long-acting opioid pain management and still have episodes of severe tumor- and treatment-related cancer pain. Breakthrough cancer pain occurs frequently in these patients (i.e. average range of 1-14 episodes per day) with a wide range of duration (between 1-240 minutes).[9]

Galena's commercial launch of Abstral in the fourth quarter of 2013 joins several other approved medications for BTcP including morphine, morphine and codeine derivatives and fentanyl. The company directly competes with Fentora and Actiq (Teva Pharmaceutical); Subsys (Insys); Lazanda (Archimedes Pharma); and Onsolis (BioDelivery Sciences International). Abstral also competes against some generic fentanyl products from Mallinckrodt, Inc., Par Pharmaceutical Companies, Inc. and Actavis, Inc. Further, there are a variety of other companies developing other treatments and technologies for the rapid delivery of opioids to treat BTcP, such as transmucosal, transdermal, nasal sprays and inhaled sublingual delivery systems.[10]

RECENT CONTROVERSY:

The recent controversy surrounding GALE can be traced back to evidence linking the company to a stock promotions firm called the DreamTeam Group, who was hired by GALE in July 2013 for $50,000 for a period of 240 days to publish promotional information with the intention of boosting the company's share price. This promotional information included "analyst" articles on websites, message boards, social media, etc. This information was brought to light following the removal of two articles in February 2014 posted on Seeking Alpha that were published by the DreamTeam Group under two different aliases in August 2013 and November 2013. Both of the pro-GALE articles were made to look as if they were written by individual investors while failing to disclose a financial relationship with the DreamTeam Group or GALE.

In a document obtained by TheStreet, it was disclosed that "by December 20, 2013, the DreamTeam Group had published a total of 50 unique GALE-centered blogs that were distributed throughout the DTG network and a number of investor-oriented community sites on the internet such as StockHouse, StockTwits, Seeking Alpha and Wall Street Cheat Sheet."[11] While it is not illegal for companies to pay firms for promotional purposes, these arrangements must be disclosed and must not be an attempt to manipulate the market. More importantly, it should be noted that although it has been denied by GALE's CEO Mark Ahn, several insiders including Ahn profited directly from this promotional campaign by selling shares of GALE in January 2014 after the stock rose from under $2/share in July 2013 to over

$7/share in January 2014. Moreover, the sales below accounted for a significant percentage of the total shares owned by these individuals.

Date*	Name/Title	Shares	Transaction	Value
02/12/2014	Richard Chin Independent Director	187,500	Sale at $4.333 per share.	812,437
02/03/2014	Stephen S. Galliker Independent Director	300,000	Sale at $4.177 per share.	1,253,040
01/30/2014	Mark W. Schwartz Executive Vice President and Chief Operating Officer	100,000	Sale at $5.565 per share.	556,500
01/30/2014	Richard Chin Independent Director	50,000	Sale at $5.57 per share.	278,500
01/30/2014	Richard Chin Independent Director	25,000	Sale at $5.61 per share.	140,255
01/30/2014	Sanford J. Hillsberg Chairman of the Board	250,000	Sale at $5.41 per share.	1,352,500
01/29/2014	Rudolph Nisi Independent Director	250,000	Sale at $5.28 per share.	1,320,000
01/27/2014	Mark J. Ahn Director, Chief Executive Officer and President	796,765	Sale at $4.83 per share.	3,848,374
01/23/2014	Steven A. Kriegsman Independent Director	150,000	Sale at $5.924 per share.	888,540
01/22/2014	Steven A. Kriegsman Independent Director	250,000	Sale at $6.13 per share.	1,532,500
01/17/2014	Sanford J. Hillsberg Chairman of the Board	200,000	Sale at $6.925 per share.	1,385,000
01/17/2014	Steven A. Kriegsman Independent Director	200,000	Sale at $7 per share.	1,400,000
01/17/2014	Rudolph Nisi Independent Director	200,000	Sale at $6.9 per share.	1,380,000

Source: Morningstar

Furthermore, as a result of GALE's activities surrounding DreamTeam and its insider sales, the company disclosed that the SEC is investigating "certain matters relating to [their] company and an outside investor-relations firm that [they] retained in 2013" in their annual report filed in March 2014.[12] Coming on the heels of several lawsuits against the company, the SEC's investigation further cements the legal troubles that will surely plague the company in the near future. While an unfavorable outcome is not certain, the uncertainty associated with the investigation will surely weigh on shares for the time being. If GALE is found to be guilty by the SEC and/or in the investor lawsuits, the company will likely face stiff penalties that could drain their monetary resources. Moreover, any legal action against the company will most certainly adversely impact GALE's ability to access the capital markets.

OUTLOOK:

Personally, while the appearance of impropriety by the company's management coupled with an SEC investigation are enough to dissuade me from investing in shares of GALE, there are other aspects to consider before making an investment decision regarding the company.

ABSTRAL:

Beginning with the company's one commercially available product (Abstral), GALE – unlike most other developmental stage biotechnology companies – is actually able to generate revenues. In fact, in the

first quarter of 2014, the company reported $2.2 million in revenue while guiding in the range of $11 million to $15 million in full year sales for 2014. At a current market cap of approximately $340 million, that puts GALE's price to sales (P/S) ratio in the range of roughly 31 to 23, respectively. Additionally, although gross margin was favorable in Q1 around 85%, the trend going forward should be monitored closely for consistency and any expansion or contraction.

Moreover, of the product sales that GALE generated in Q1 2014, more than half came from one customer (51%), while two other customers represented 15% and 12% of total sales. As of March 31, 2014, the company also had accounts receivable of 63%, 21% and 5% from those same three customers. Going forward, the company's reliance on one or more customers should be watched as GALE should not become too dependent on one customer for the majority of their revenues.

In addition, since GALE acquired the rights to Abstral from Orexo AB, they will need to make three one-time future cash milestone payments based on their net sales of the product, as well as a low double-digit royalty of future net sales until the last remaining licensed patents expire in 2019. These payments are in addition to the amount GALE has already paid Orexo upfront – $10 million initially plus a $5 million milestone payment made in October 2013 following the FDA approval of Abstral.

Furthermore, while sales of Abstral are expected to increase in the future, the company anticipates sales peaking at around $40 million to $60 million in the next three to five years. Not exactly what I would call a home run. Although these sales should help the company fund their operating expenses in the future, it is uncertain when, or even if, GALE will become profitable. For the most part, the company's success or failure rides on their other drug candidates – especially NeuVax.

One last note about Abstral that I came across was in looking at the company's aforementioned competitors in the BTcP market. A quick search on WebMD found the following list and accompanying reviews. Upon reading the reviews of the various treatment options, it appears as though the top four all had mostly positive reviews while Abstral's three reviews were decidedly poor. Obviously this is an extremely small sample size and should not be the basis for a negative view towards Abstral, but it is something else to consider in addition to all of the above points.

DRUG NAME	INDICATION	TYPE	USER REVIEWS
Actiq buccal			66 User Reviews
Fentora buccal			29 User Reviews
fentanyl citrate buccal			12 User Reviews
Subsys sublingual			6 User Reviews
Abstral sublingual			3 User Reviews
fentanyl citrate sublingual			2 User Reviews
fentanyl sublingual			2 User Reviews
fentanyl nasal			Be the first to review it
Lazanda nasal			Be the first to review it

Source: WebMD[13]

TRIAL COMPLETIONS ARE NOT EXPECTED FOR SOME TIME:

Although some have questioned the validity of the data presented throughout the clinical trials of NeuVax, management stands behind the results and if the data had been poor, the company would not have progressed further into the process. However, given management's recent questionable behavior, it would not be shocking if the data were not as favorable as they have claimed.

More importantly, it is the time frame of the eventual completion dates for the company's drug trials that is most worrisome to me. For example, according to clinicaltrials.gov, the estimated study completion date for nelipepimut-S (NeuVax by itself) is June 2024 with an estimated primary completion date of June 2017. Even though interim results are expected within the next year, that is also just an estimate.

Additionally, GALE's combination study of NeuVax + Herceptin has an estimated completion date of December 2017 and an estimated primary completion date of December 2015. Further, the company's other drug candidates (GALE-301 and GALE-401) have estimated completion dates for their respective trials of April 2017 and July 2016, respectively.

Ultimately, it will be some time before GALE has another commercialized product for sale – if ever. Even their main phase III trial candidate, NeuVax, is not expected for several more years mostly due to the large size of their patient enrollment (700). Add to that the fact that GALE's other drug candidates are only in phase I or phase II trials at the moment. Considering the expenses involved in performing these clinical trials, it is highly likely the company will use up their existing cash and will have to raise additional capital through future equity offerings despite the company's newfound revenue stream in Abstral.

CASH BALANCE:

As of March 31, 2014, the company had approximately $52.4 million in cash and cash equivalents on its balance sheet, which should be sufficient to fund their operations for greater than one year. While the sales of Abstral should help offset the need to use these existing resources to some degree, the company is expected to continue to incur net losses and negative cash flow for the foreseeable future, especially as efforts to sell Abstral commercially are increased and GALE pursues additional clinical trials in each of their drug candidates.

BOTTOM LINE:

While it is true that GALE operates in some very desirable parts of the oncology market and even has a commercially available product in Abstral, there are a multitude of risks surrounding this so-called battleground stock. When an investment is made in a company, you not only buy into the company's product(s) or potential product(s) you buy into the company's management. Given the recent events surrounding GALE's management, an investment in the company is too risky at the moment especially in the face of several investor lawsuits and an SEC investigation. A large fine or settlement could cripple the company and send shares sharply lower. Moreover, long lead times between trial results leave the company with little to no catalysts in the short-term. Ultimately, for the time being, the risk to the

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company's shareholders is to the downside, and as a result I would suggest staying away from shares of GALE for now.

Additional Information:
FDA Calendar Link: http://www.biopharmcatalyst.com/fda-calendar/

SOURCES:

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[1] World Health Organization (WHO). International Agency for Research on Cancer. Press Release: "Latest World Cancer Statistics." 12 December 2013.
[2] National Cancer Institute. GALE Form 10-K. 31 December 2013. Page 5.
[3] GALE Form 10-K. 31 December 2013. Page 5.
[4] World Health Organization (WHO). International Agency for Research on Cancer. Press Release: "Latest World Cancer Statistics." 12 December 2013.
[5] GALE Form 10-K. 31 December 2013. Page 6.
[6] World Cancer Research Fund International. Cancer Statistics Worldwide. http://www.wcrf.org/cancer_statistics/world_cancer_statistics.php
[7] GALE Form 10-K. 31 December 2013. Page 6.
[8] Ibid.
[9] Ibid. Page 4.
[10] Ibid. Page 17.
[11] Feuerstein, Adam. "Galena Biopharma Pays for Stock-Touting Campaign While Insiders Cash Out Millions." TheStreet. 12 February 2014.
[12] GALE Form 10-K. 31 December 2013. Page 37.
[13] http://www.webmd.com/drugs/condition-14092-Breakthrough+Cancer+Pain+in+Opioid+Tolerant+Patient.aspx?diseaseid=14092&diseasename=Breakthrough+Cancer+Pain+in+Opioid+Tolerant+Patient

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