UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the year ended December 31, 2013
OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____to _____
Commission File Number: 001-33958

Galena Biopharma, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**20-8099512**
(State of incorporation)	**(I.R.S. Employer Identification No.)**

4640 SW Macadam Ave., Suite 270, Portland, OR 97239
(Address of principal executive office) (Zip code)

Registrant's telephone number: (855) 855-4253

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of Each Class	**Name of Exchange on Which Registered**
Common Stock, $0.0001 Par Value per Share	**The NASDAQ Capital Market**

Securities registered pursuant to Section 12(b) of the Exchange Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ☐ Yes ☒ No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. ☐ Yes ☒ No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐ Yes ☒ No

Indicate by check mark whether the registrant has submitted electronically and posted on it corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for any such shorter time that the registrant was required to submit and post such files). ☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act (Check one):

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): ☐ Yes ☒ No

Based on the closing price of the Registrant's common stock as reported on the NASDAQ Capital Market, the aggregate market value of the Registrant's common stock held by non-affiliates on June 28, 2013 (the last business day of the Registrant's most recently completed second fiscal quarter) was approximately $185,711,000 .

As of February 28, 2014 , Galena Biopharma, Inc. had outstanding 117,879,459 shares of common stock, $0.0001 par value per share, exclusive of treasury shares.

GALENA BIOPHARMA, INC.

FORM 10-K — FISCAL YEAR ENDED DECEMBER 31, 2013

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"SAFE HARBOR" STATEMENT

Some of the information contained in this annual report may include forward-looking statements that reflect our current views with respect to our commercial and development programs, business strategy, business plan, financial performance and other future events. These statements include forward-looking statements both with respect to us, specifically, and our industry, in general. We make these statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Statements that include the words “expect,” “intend,” “plan,” “believe,” “project,” “estimate,” “may,” “should,” “anticipate,” “will” and similar statements of a future or forward-looking nature identify forward-looking statements for purposes of the federal securities laws or otherwise.

Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. There are or will be important factors that could cause actual results to differ materially from those indicated in these statements. These factors include, but are not limited to, those factors set forth in the sections entitled “Business,” “Risk Factors,” “Legal Proceedings,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” “Quantitative and Qualitative Disclosures About Market Risk” and “Controls and Procedures” in this annual report, all of which you should review carefully. Please consider our forward-looking statements in light of those risks as you read this annual report. We undertake no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise, except as required by law.

If one or more of these or other risks or uncertainties materializes, or if our underlying assumptions prove to be incorrect, actual results may vary materially from what we anticipate. All subsequent written and oral forward-looking statements attributable to us or individuals acting on our behalf are expressly qualified in their entirety by this “Safe Harbor” Statement.

PART I.

ITEM 1. BUSINESS

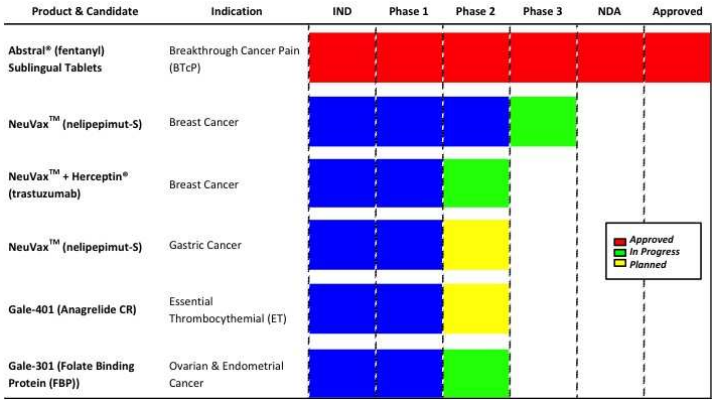
Overview

Galena Biopharma, Inc. (“we,” “us,” “our,” “Galena” or the “company”) is a biopharmaceutical company focused on developing and commercializing innovative, targeted treatments that address major unmet medical needs to advance cancer care.

Our strategy is to build value for patients and shareholders by:

- Achieving revenue goals for Abstral® (fentanyl) sublingual tablets, to which we acquired for the U.S. rights in March 2013 and launched in the fourth quarter of 2013;
- Completing the pivotal Phase 3 randomized, multicenter PRESENT (Prevention of Recurrence in Early-Stage, Node-Positive Breast Cancer with Low-to-Intermediate HER2 Expression with NeuVax Treatment) study of our lead product candidate, NeuVax™ (nelipepimut-S) in 700 patients under a U.S. Food and Drug Administration (FDA)-approved Special Protocol Assessment (SPA);
- Completing the Phase 2b randomized, multicenter clinical trial in 300 patients to study NeuVax in combination with Herceptin® (trastuzumab; Genentech/Roche);
- Completing the Phase 2 clinical trials of GALE-301 (folate binding protein (FBP)) cancer immunotherapy trials in both ovarian and endometrial cancers;
- Initiating a Phase 2 clinical trial with GALE-401 (anagrelide controlled release (CR)), which we acquired in January 2014, in essential thrombocythemia (ET); and
- Pursuing strategic alliances and acquisitions of other cancer treatments to complement our existing product pipeline and commercialization capabilities.

The chart below summarizes the current status of our commercial and development programs:



Establishing Commercial Capabilities

Abstral® (fentanyl) Sublingual Tablets

Our first commercial product, Abstral® (fentanyl) Sublingual Tablets, is an important treatment option for inadequately controlled breakthrough cancer pain (BTcP). Abstral is approved by the FDA as a sublingual (under the tongue) fentanyl tablet only for the management of breakthrough pain in patients with cancer, 18 years of age and older, who are already receiving, and who are tolerant to, opioid therapy for their persistent baseline cancer pain. The innovative Abstral formulation delivers the analgesic power and increased bioavailability of micronized fentanyl in a convenient sublingual tablet which is designed to dissolve under the tongue in seconds, provide relief of breakthrough pain within minutes, and match the duration of the pain episode.

BTcP is defined as a transient exacerbation of pain that occurs either spontaneously, or in relation to a specific predictable or unpredictable trigger, despite relatively stable and adequately controlled background pain. BTcP occurs in an estimated 40%-80% of patients who are already receiving chronic, long-acting opioid pain management and yet have episodes of severe tumor- and treatment-related cancer pain. BTcP occurs frequently in these patients, particularly as they try to conduct normal daily activities, with a mean number of episodes of four per day (average range 1-14 per day) and a median duration of 30 minutes (range 1-240 minutes). The wide range of time to relief of these severe pain episodes leads to high levels of distress and impaired quality of life experienced by patients.

Abstral is now available throughout the United States, with full launch of the product having commenced in the fourth quarter of 2013. Since the acquisition of Abstral, we have made significant, disciplined investments in growing the Abstral commercial infrastructure and franchise. Commercial efforts to date include:

Sales, distribution and marketing – We have established an experienced specialty sales force in the United States, including sales management, account management, managed care and product access management, and field sales personnel. Since the acquisition of Abstral, we have hired a dedicated sales team to support our commercial launch in the fourth quarter of 2013. Our distribution efforts to date have focused on securing contracts with key distributors, group purchasing organizations, managed care organizations, and specialty pharmacies and other institutional dispensaries. We have established and mobilized our field sales force. We have also contracted with a third party logistics provider with significant experience with pharmaceutical industry inventory and supply chain management and logistics.

Manufacturing – We acquired the necessary equipment to produce Abstral and are manufacturing Abstral through our contract manufacturing organizations (CMOs).

Patient Support Services – We launched Galena Patient Services (GPS), a full service support program overseen by a third party vendor, designed to navigate patient access to our products. GPS includes a dedicated team that works with healthcare professionals, their patients, and the insurance providers to guide the benefits investigation and prior authorization process, help manage the appeals and denials process, locate a preferred pharmacy, and execute the Patient Assistance Program for patient reimbursement support.

Regulatory compliance - We have established required internal processes and reporting to ensure the full compliance with applicable Transmucosal Immediate Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy (REMS) requirements.

Patient registry study - We have initiated an institutional review board (IRB)-approved observational registry study, entitled RELIEF (Rapid Evaluation of Lifestyle, Independence and Elimination of BTcP with Freedom from oral discomfort through the use of Abstral® (fentanyl) Sublingual Tablets). RELIEF is a post-marketing, single arm, open label multicenter trial to assess Abstral for BTcP in opioid-tolerant cancer patients. RELIEF is an observational study to be completed by enrolled patients over a 30-day period. The data is collected, monitored and maintained by a contract research organization (CRO) who will objectively evaluate the results. Approximately 2,500 patients are expected to enroll in the study in an estimated 100 sites in the U.S.

Developing Novel Cancer Immunotherapies

We are developing peptide vaccine (off-the-shelf) cancer immunotherapies, which address major patient populations of cancer survivors to prevent recurrence of their cancers. These therapies work by harnessing the patient's own immune system to seek out and attack any residual cancer cells. Using peptide immunogens has many clinical advantages, including an excellent safety profile, as these drugs lack the toxicities typical of most cancer therapies. They also evoke long-lasting protection through immune system activation and convenient mode of delivery.

NeuVax™ (nelipepimut-S)

NeuVax™ (nelipepimut-S), our lead cancer immunotherapy, is being developed for the prevention of cancer recurrence in HER2 expressing cancers. NeuVax is the immunodominant nonapeptide derived from the extracellular domain of the HER2 protein, a well-established target for therapeutic intervention in breast and gastric carcinomas. The NeuVax vaccine, nelipepimut-S peptide, is combined with the immune adjuvant, recombinant human granulocyte macrophage-colony stimulating factor (rhGM-CSF) for administration. Data has shown that an increased presence of circulating tumor cells (CTCs) predict Disease Free Survival (DFS) and Overall Survival (OS) - suggesting a dormancy of isolated micrometastases, which over time, lead to recurrence. After binding to the HLA A2/A3 molecules on antigen presenting cells, the nelipepimut-S sequence stimulates specific cytotoxic T lymphocyte (CTLs). These activated specific CTLs recognize, neutralize and destroy, through cell lysis, HER2 expressing cancer cells, including occult cancer cells and micrometastatic foci. The nelipepimut immune response can also generate CTLs to other immunogenic peptides through inter- and intra-antigenic epitope spreading.

NeuVax is a targeted cancer immunotherapy for approximately 30,000-40,000 of the 230,000 breast cancer patients annually diagnosed in the US who are at high risk of their breast cancer recurring, which we refer to as "disease recurrence," after achieving remission (or becoming a "survivor") with standard therapy (surgery, chemotherapy, radiation). These high-risk patients have a particular molecular signature and disease status: HER2 IHC 1+/2+ (oncoprotein associated with aggressive tumor growth), node positive (disease present in the axillary lymph nodes prior to surgery), and HLA A2/A3 (human leukocyte antigen from A2/A3 patients who have the same loci of genes who which represents 65% of population). Up to 25% of resectable node-positive breast cancer patients, having no radiographic evidence of disease following surgery and adjuvant chemo/radiation therapy, still relapse within three years following diagnosis. These cancer patients presumably still had isolated, undetected tumor cells also known as circulating tumor cells which, over time, led to a recurrence of cancer, either in the breast area (local recurrence) or at a remote location (metastatic disease).

We currently have three ongoing or planned trials with NeuVax:

- Phase 3 Ongoing: Based on our Phase 2 trial, which achieved its primary endpoint of DFS, the U.S. Food and Drug Administration (FDA) granted NeuVax a Special Protocol Assessment (SPA) for its Phase 3 PRESENT (Prevention of Recurrence in Early- Stage, Node-Positive Breast Cancer with Low to Intermediate HER2 Expression with NeuVax Treatment) study. The multinational, multicenter PRESENT trial is ongoing in North America, Western and Eastern Europe, and Israel. Additional information on the study can be found at www.neuvax.com.

- Phase 2b Ongoing: A randomized, multicenter, investigator-sponsored, 300 patient Phase 2b clinical trial is enrolling node-positive and node-negative breast cancer patients to study NeuVax in combination with Herceptin® (trastuzumab; Genentech/Roche).

- Phase 2 Planned: In addition, in January 2014, we partnered NeuVax with Dr. Reddy's in India for the commercialization of NeuVax in that region. Per the agreement, Dr. Reddy's is responsible for running a Phase 2 gastric cancer trial of NeuVax in India that is expected to initiate in 2014.

Breast Cancer: According to the National Cancer Institute, over 230,000 women in the U.S. are diagnosed with breast cancer annually. While improved diagnostics and targeted therapies have decreased breast cancer mortality in the United States, metastatic breast cancer remains incurable. Approximately 75% of breast cancer patients have tissue test positive for some increased amount of the HER2 receptor, which is associated with disease progression and decreased survival. Only approximately 20% to 30% of all breast cancer patients — those with HER2 IHC 3+ disease — have an approved treatment option available. This leaves the majority of breast cancer patients with low-to-intermediate HER2 IHC 1+/2+ ineligible for therapy and without an effective treatment option to prevent cancer recurrence.

Gastric Cancer: Gastric cancer (also known as stomach cancer) is a disease in which the cells forming the inner lining of the stomach become abnormal and start to divide uncontrollably, forming a cancerous tumor mass. Cancer can develop in any of the five sections of the stomach. Symptoms and outcomes of the disease will vary depending on the location of the cancer. Stomach cancer is one of the leading causes of cancer deaths in several areas of the world, most notably Japan and other Asian countries. Annually, almost one million people will be diagnosed worldwide with stomach cancer and over 800,000 will die from the disease. More than 95% of stomach cancers are caused by adenocarcinomas, malignant cancers that originate in glandular tissues. Overexpression of the HER2 receptor occurs in approximately 20% of gastric and gastro-esophageal junction adenocarcinomas, predominantly those of the intestinal type. Overall, only approximately 20% of patients with stomach cancer live at least five years following diagnosis and new adjuvant treatments are needed to prevent disease recurrence.

GALE-301 (folate binding protein (FBP))

Our second immunotherapy product candidate is GALE-301, or Folate Binding Protein (FBP). GALE-301 is derived from a protein that is over-expressed (20-80 fold) in more than 90% of ovarian and endometrial cancers. GALE-301 is highly immunogenic and can stimulate CTLs to recognize and destroy FBP-expressing cancer cells. The FBP vaccine consists of the FBP peptide(s) combined with recombinant human granulocyte macrophage-colony stimulating factor (rhGM-CSF). GALE-301 is currently in a Phase 2 trial in ovarian cancer.

Ovarian and Endometrial Cancer: Ovarian cancer occurs in more than 22,000 patients per year in the U.S. and is the most lethal gynecologic cancer. Despite the incidence of ovarian cancer being only approximately 20% of that of breast cancer, the number of patients who die from ovarian cancer is nearly 50% of that of breast cancer. Due to the lack of specific symptoms, the majority of ovarian cancer patients are diagnosed at later stages of the disease. These patients have their tumors routinely surgically debulked to minimal residual disease, and then are treated with platinum- and/or taxane-based chemotherapy. While most patients respond to this treatment regimen and become clinically free-of-disease, the majority of these patients will relapse, and once the disease recurs, the treatment options and successes drop dramatically. Endometrial cancer is the most common gynecologic cancer and occurs in more than 46,000 women with more than 8,000 deaths in the U.S. annually. There are two basic types of endometrial cancer: endometrioid and papillary serous. The latter has a much more aggressive clinical course and the majority of these patients will die of this form of the disease.

Building the Breadth, Depth and Pace of our Pipeline

Hematology - GALE-401 (anagrelide CR)

On January 13, 2014, we announced the acquisition of the worldwide rights to anagrelide controlled release (CR), which we renamed GALE-401, through our acquisition of Mills Pharmaceuticals, LLC. GALE-401 contains the active ingredient anagrelide, an FDA-approved product, which has been in use since the late 1990s for the treatment of essential thrombocythemia (ET). However, adverse events, such as nausea, diarrhea, abdominal pain, palpitations, tachycardia, and headache are associated with the currently available IR version of anagrelide, and have been shown to be dose and plasma concentration dependent. Therefore, reducing the maximum concentration (Cmax) is hypothesized to reduce the side effects, but preserve efficacy. In Phase 1 clinical studies, GALE-401 has been shown to significantly reduce the Cmax of anagrelide following oral administration. Thus, GALE-401 may reduce the peak plasma exposure to lessen the adverse events while maintaining therapeutic levels for platelet inhibition.

Multiple Phase 1 studies in approximately 90 healthy subjects have shown GALE-401 has a favorable pharmacokinetic profile (i.e. reduced Cmax) and appears to be well tolerated at the doses administered and to be capable of reducing platelet levels. Based on a regulatory meeting with the FDA, Galena believes a 505(b)(2) regulatory filing is an acceptable pathway for approval of GALE-401, with the reference drug Agrylin® (anagrelide; Shire Pharmaceuticals). The Phase 1 program has provided the desired PK/PD (pharmacokinetic/pharmacodynamic) profile to enable the Phase 2 initiation in 2014. The FDA has also indicated that only a single Phase 3 trial would be required for approval.

Essential Thrombocythemia (ET): ET is an acquired disease of the bone marrow, characterized by highly elevated platelet counts, and is associated with vascular complications including increased risk of thrombosis and bleeding events such as heart attack and stroke. We believe ET meets the qualifications of an orphan drug with prevalence in the U.S. of approximately 80,000-100,000 and an annual incidence rate of about 8,000 new diagnoses each year, with similar rates in Europe. Initially, many patients are asymptomatic so the disease goes undiagnosed, but with increased standard blood testing, the diagnoses are increasing as well. Currently, about 75% of diagnosed patients receive therapeutic treatment which highlights the importance of developing better tolerated drugs to this chronically treated, high risk orphan disease patient population.

Alliance Partners in Therapeutic Areas

We are actively seeking to leverage our technology platforms by seeking to work with pharmaceutical and biotechnology partners in a number of therapeutic areas. Our team has experience targeting products in multiple therapeutic areas, and based on this experience, we believe we can discover many more drug candidates by working with partners than we can develop with our own resources. We are seeking to work with partners in the discovery and development of drugs in a number of therapeutic areas and technology platforms.

Intellectual Property

Patents and other intellectual property rights are crucial to our success. It is our policy to protect our intellectual property rights through available means, including filing patent and prosecuting applications in the United States and other countries, protection of trade secrets, and utilizing regulatory protections such as data exclusivity and orphan drug status.. We also develop and protect confidential information and know-how, for example, we include restrictions regarding use and disclosure of our proprietary information in our contracts with third parties. We regularly enter into agreements with our employees, consultants, clinical investigators and scientific advisors to protect our confidential information and know-how. Together with our licensors, we also rely on trade secrets to protect our combined technology especially where we do not believe patent protection is appropriate or obtainable. It is also our policy to operate without infringing on, or misappropriating, the proprietary rights of others. The following chart summarizes our intellectual property rights:

Product	Indication	Scope	Strategic Partner	Estimated Exclusivity Period
Abstral® (fentanyl) Sublingual Tablets	Breakthrough cancer pain	United States Only	Orexo AB	2019
NeuVax™ (nelipepimut-S)	Breast cancer recurrence	Filed and pending or issued worldwide	University of Texas/Henry M. Jackson Foundation	2028
NeuVax™ in combination with Herceptin®	Breast cancer recurrence	Filed and pending or issued worldwide	Henry M. Jackson Foundation, Genetech/Roche	2026
Folate Binding Protein (GALE-301)	Ovarian and endometrial cancer	Filed and pending or issued worldwide	Henry M. Jackson Foundation	2022
Anagrelide Controlled Release (GALE-401)	Essential thrombocythemia	Filed and pending or issued worldwide	BioVascular, Inc.	2029

Out-License Agreements

Teva Pharmaceuticals

Effective December 3, 2012, we entered into a license and supply agreement with ABIC Marketing Limited, a subsidiary of Teva Pharmaceuticals (“ABIC”), under which we granted ABIC exclusive rights to seek marketing approval in Israel for our NeuVax product candidate for intradermal injection for the treatment of breast cancer following its approval by the FDA or the European Medicines Agency, and to market, sell and distribute NeuVax in Israel assuming such approval is obtained. ABIC’s rights also include a right of first refusal in Israel for all future indications for which NeuVax may be approved.

Under the license and supply agreement, ABIC will assume responsibility for regulatory registration of NeuVax in Israel, provide financial support for local development, and commercialize the product in the region in exchange for making royalty payments to us based on future sales of NeuVax. ABIC also agrees in the license and supply agreement to purchase from us all supplies of NeuVax at a price determined according to a specified formula.

Dr. Reddy's Laboratories Ltd.

Effective January 14, 2014, we entered into a strategic development and commercialization partnership with Dr. Reddy's Laboratories Ltd. ("Dr. Reddy's"). We licensed commercial rights in India to Dr. Reddy's for NeuVax in breast and gastric cancers in India. Dr. Reddy's will lead the Phase 2 development of NeuVax in India in gastric cancer, significantly expanding the potential addressable patient population.

Recent Developments (in reverse chronological order)

Abstral Target Revenue Achieved - We achieved our target net revenue from the sale of Abstral for 2013.

On March 17, 2014, we announced our results of operations from the quarter and the fiscal year ended December 31, 2013, including net revenue of $2.5 million from the sale of Abstral. We also announced an increase to approximately $11 million to $15 million in our current 2014 net revenue expectations from the sale of Abstral.

Galena Patient Services Launched - We announced the launch of Galena Patient Services (GPS), a full service program to help manage patient access and reimbursement for patients taking Abstral® (fentanyl) Sublingual Tablets.

On March 3, 2014, we announced the launch of GPS, a full service support program designed to navigate patient access to Abstral coordinated through a third party vendor. The GPS will work with the healthcare professionals, their patients, and the insurance providers to guide the benefits investigation and approval process, manage the appeals and denial process, locate the preferred pharmacy and execute our Patient Assistance Program for patient reimbursement support.

NeuVax Australian Patent - We received a Notice of Acceptance for a patent for NeuVax ™ by the Australian Patent Office.

On February 28, 2014, we announced that the Australian Patent Office had notified us of a Notice of Acceptance for a patent for NeuVax ™ (nelipepimut-S) in Australia. The patent covers the use of NeuVax as a vaccine for the prevention of breast cancer recurrence in patients having low-to-intermediate of HER2, as determined by an IHC score of 1+ or 2+ and a FISH rating of less than 2.0. These patients represent a significant unmet medical need, since as many as 80% of breast cancer patients do not qualify for Herceptin® therapy. The patent protection expires in 2028.

Dr. Reddy's Partnership - We entered into a partnership with Dr. Reddy's Laboratories Ltd., which includes future commercialization of NeuVax in India for breast and gastric cancers.

On January 14, 2014, we announced a strategic development and commercialization partnership on NeuVax (nelipepimut-S) with Dr. Reddy's Laboraties Ltd. in India. We licensed commercial rights to Dr. Reddy's for NeuVax in breast and gastric cancers, in exchange for development and sales milestones, as well as double-digit royalties on sales. Dr. Reddy's is to lead the Phase 2 development of NeuVax in India in gastric cancer, significantly expanding the potential addressable patient population.

GALE-401 Acquisition - We acquired the worldwide rights to GALE-401 (Anagrelide CR), a controlled release formulation of anagrelide.

On January 13, 2014, we announced the acquisition of worldwide rights to GALE-401, (Anagrelide CR), a controlled release (CR) formulation of anagrelide. We expect to pursue the expedited 505(b)b(2) regulatory pathway to seek approval of GALE-401 for the treatment of essential thrombocythemia (ET). The controlled release formulation is expected to decrease the adverse event rate relative to the approved product. We believe GALE-401 meets the qualifications for orphan drug status. GALE-401 has an estimated peak market size of approximately $200 million in the U.S.

First Patient Enrolled in GALE-301 (Folate Binding Protein (FBP) Vaccine) Phase 2 Trial - We enrolled our first patient in the Phase 2 trial for GALE-301.

On January 7, 2014, we announced that the first patient was enrolled in the Phase 2 trial of GALE-301 (Folate Binding Protein (FBP) vaccine) in ovarian cancer. GALE-301 is a folate receptor alpha-derived, peptide-based cancer immunotherapy administered to HLA-A2 positive patients in combination with the adjuvant granulocyte macrophage-colony stimulating factor (GM-CSF) to prevent recurrences in high-risk, endometrial and ovarian cancer patients rendered disease-free after completing standard of care therapy. The optimal biological dose, along with the implementation of a booster regime, will be used in the Phase 2 trial. Initial results from the Phase 1 trial determined an optimal biological dose for further study and showed that GALE-301 was well tolerated and evoked a FBP specific immunological response.

Initial Results from the Phase 1 Trial of GALE-301 (Folate Binding Protein (FBP)) Announced - We announced the encouraging initial results from the Phase 1 trial of GALE-301, shown to be safe and immunogenic.

On November 11, 2013, we announced the initial results from the GALE-301 (Folate Binding Protein (FBP) vaccine) Phase 1 trial. The results of the Phase 1 portion of the trial showed GALE-301 to be both well tolerated and immunogenic. The initial results from the Phase 1 trial indicate that GALE-301 is suitable for further study as a potential cancer immunotherapy for the prevention of disease recurrence in ovarian and endometrial cancer patients rendered disease-free after completing standard of care therapy.

Completion of Public Offering - We announced the closing of our underwritten public offering.

On September 18, 2013, we announced the closing of our underwritten public offering of shares of common stock and warrants. The net proceeds to us were approximately $37.5 million. As of March 14, 2013, we had cash and cash equivalents of approximately $55.3 million, including the net proceeds of the public offering.

NeuVax European Patent - We were issued a Pharmaceutical Use Patent for NeuVax ™ by the European Patent Office.

On August 21, 2013, we announced that the European Patent Office had notified us of an intention to grant a Pharmaceutical Use Patent for NeuVax ™ (nelipepimut-S). The patent, which was granted on November 6, 2013, covers the use of NeuVax as a vaccine for the prevention of breast cancer recurrence in patients having low-to-intermediate of HER2, as determined by an IHC score of 1+ or 2+ and a FISH rating of less than 2.0. These patients represent a significant unmet medical need, with as many as 80% of breast cancer patients not qualifying for Herceptin® therapy. The patent protection is afforded in all of the European Union countries and will expire in April 2028.

Abstral (Fentanyl) License Acquisition and Launch - We acquired Abstral (fentanyl) Sublingual Tables for sale and distribution in the United States for treatment of inadequately controlled breakthrough cancer pain, and officially launched the product in the fourth quarter.

On March 18, 2013, we announced the acquisition of Abstral® (fentanyl) Sublingual Tablets for sale and distribution in the United States from Orexo AB, an emerging pharmaceutical company based in Sweden. Abstral is an important new treatment option for inadequately controlled breakthrough cancer pain in patients who are already receiving, and who are tolerant to, opioid therapy for their persistent baseline cancer pain. The innovative Abstral formulation delivers the analgesic power of fentanyl in a convenient and easy to use sublingual tablet, which dissolves under the tongue within seconds. Abstral provides rapid relief of breakthrough cancer pain, predictable dosing, and is convenient and easy to use.

On October 3, 2013, we announced our official product launch of Abstral (fentanyl) Sublingual Tablets in the U.S. Since acquiring Abstral in March 2013, Galena has scaled its commercial team, manufactured the drug for commercial sale, secured broad access and reimbursement support from commercial and federal health insurance entities, implemented a robust patient assistance program, and developed a broad product distribution network.

Competition

The biotechnology industry, including the cancer therapy vaccines, hematology therapies, and break-through cancer pain management markets, are intensely competitive and involves a high degree of risk. We compete with other companies that have far greater experience and financial, research and technical resources than us. Potential competitors in the United States and worldwide are numerous and include pharmaceutical and biotechnology companies, educational institutions and research foundations, many of which have substantially greater capital resources, marketing experience, research and development staffs and facilities than us. Some of our competitors may develop and commercialize products that compete directly with those incorporating our technology, introduce products to market earlier than our products or on a more cost effective basis. We may be unable to effectively develop our technology or any other applications on a cost effective basis or otherwise. In addition, our technology may be subject to competition from other technology or methods developed using techniques other than those developed by traditional biotechnology methods. Our competitors compete with us in recruiting and retaining qualified scientific and management personnel as well as in acquiring technologies complementary to our technology. Our collaborators or we will face competition with respect to product efficacy and safety, ease of use and adaptability to various modes of administration, acceptance by physicians, the timing and scope of regulatory approvals, availability of resources, reimbursement coverage, price and patent position, including potentially dominant patent positions of others. An inability to successfully complete our product development could lead to us having limited prospects for establishing market share or generating revenue from our technology.

For patients with early stage breast cancer, adjuvant therapy is often given to prevent recurrence and increase the chance of long-term disease free survival. Adjuvant therapy for breast cancer can include chemotherapy, hormonal therapy, radiation therapy, or combinations thereof. In addition, the HER2 targeted drug trastuzumab (Herceptin®) may be given to patients with tumors with high expression of HER2 (IHC 3+), as well as other novel targets such as MUC1 which may be useful in treating breast cancer.

There are a number of cancer vaccines in development for breast cancer, including but not limited to Lapuleucel-T (Dendreon), AE-37 (Antigen Express) and Stimuvax (Merck KgA). While these development candidates are aimed at a number of different targets, and AE-37 has published data in the HER2 breast cancer patient population, there is no guarantee that any of the these compounds will not in the future be indicated for treatment of low-to-intermediate HER2 breast cancer patients and become directly competitive with NeuVax™.

For patients with essential thrombocythemia (ET), current treatment options include Agrylin® and its generic equivalents, hydorxyurea and interferon alpha. Agents currently being studied in patients with ET include investigational JAK2 inhibitors (e.g., LY2784544 (Eli Lily), momelotinib (Gilead Sciences)) and pegylated interferon alfa-2a (Pegasys, Genetech/Roche).

Government Regulation

The United States and other developed countries extensively regulate the preclinical and clinical testing, manufacturing, labeling, storage, record-keeping, advertising, promotion, export, marketing and distribution of drugs and biologic products. The FDA regulates pharmaceutical and biologic products under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and other federal statutes and regulations.

To obtain approval of our future product candidates from the FDA, we must, among other requirements, submit data supporting safety and efficacy for the intended indication as well as detailed information on the manufacture and composition of the product candidate. In most cases, this will require extensive laboratory tests and preclinical and clinical trials. The collection of these data, as well as the preparation of applications for review by the FDA involve significant time and expense. The FDA also may require post-marketing testing to monitor the safety and efficacy of approved products or place conditions on any approvals that could restrict the therapeutic claims and commercial applications of these products. Regulatory authorities may withdraw product approvals if we fail to comply with regulatory standards or if we encounter problems at any time following initial marketing of our products.

The first stage of the FDA approval process for a new biologic or drug involves completion of preclinical studies and the submission of the results of these studies to the FDA. These data, together with proposed clinical protocols, manufacturing information, analytical data and other information submitted to the FDA, in an Investigational New Drug (IND), must become effective before human clinical trials may commence. Preclinical studies generally involve FDA regulated laboratory evaluation of product characteristics and animal studies to assess the efficacy and safety of the product candidate.

After the IND becomes effective, a company may commence human clinical trials. These are typically conducted in three sequential phases, but the phases may overlap. Phase 1 trials consist of testing the product candidate in a small number of patients or healthy volunteers, primarily for safety at one or more doses. Phase 2 trials, in addition to safety, evaluate the efficacy of the product candidate in a patient population somewhat larger than Phase 1 trials. Phase 3 trials typically involve additional testing for safety and clinical efficacy in an expanded population at multiple test sites. A company must submit to the FDA a clinical protocol, accompanied by the approval of the Institutional Review Boards at the institutions participating in the trials, prior to commencement of each clinical trial.

To obtain FDA marketing authorization, a company must submit to the FDA the results of the preclinical and clinical testing, together with, among other things, detailed information on the manufacture and composition of the product candidate, in the form of a new drug application, or NDA, or, in the case of a biologic, a biologics license application, or BLA.

The amount of time taken by the FDA for approval of an NDA or BLA will depend upon a number of factors, including whether the product candidate has received priority review, the quality of the submission and studies presented, the potential contribution that the compound will make in improving the treatment of the disease in question, and the workload at the FDA.

The FDA may, in some cases, confer upon an investigational product the status of a fast track product. A fast track product is defined as a new drug or biologic intended for the treatment of a serious or life threatening condition that demonstrates the potential to address unmet medical needs for this condition. The FDA can base approval of an NDA or BLA for a fast track product on an effect on a surrogate endpoint, or on another endpoint that is reasonably likely to predict clinical benefit. If a preliminary review of clinical data suggests that a fast track product may be effective, the FDA may initiate review of entire sections of a marketing application for a fast track product before the sponsor completes the application.

We anticipate that our products will be manufactured by our strategic partners, licensees or other third parties. Before approving an NDA or BLA, the FDA will inspect the facilities at which the product is manufactured and will not approve the product unless the manufacturing facilities are in compliance with the FDA's current good manufacturing practice ("cGMP"), which are regulations that govern the manufacture, holding and distribution of a product. Manufacturers of biologics also must comply with the FDA's general biological product standards. Our manufacturers also will be subject to regulation under the Occupational Safety and Health Act, the Nuclear Energy and Radiation Control Act, the Toxic Substance Control Act and the Resource Conservation and Recovery Act and other applicable environmental statutes. Following approval, the FDA periodically inspects drug and biologic manufacturing facilities to ensure continued compliance with the good manufacturing practices regulations. Our manufacturers will have to continue to comply with those requirements. Failure to comply with these requirements subjects the manufacturer to possible legal or regulatory action, such as suspension of manufacturing or recall or seizure of product. Adverse patient experiences with the product must be reported to the FDA and could result in the imposition of marketing restrictions through labeling changes or market removal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval.

The labeling, advertising, promotion, marketing and distribution of a drug or biologic product also must be in compliance with FDA and Federal Trade Commission requirements which include, among others, standards and regulations for off-label promotion, industry sponsored scientific and educational activities, promotional activities involving the internet, and direct-to-consumer advertising. We also will be subject to a variety of federal, state and local regulations relating to the use, handling, storage and disposal of hazardous materials, including chemicals and radioactive and biological materials. In addition, we will be subject to various laws and regulations governing laboratory practices and the experimental use of animals. In each of these areas, as above, the FDA has broad regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay issuance of product approvals, seize or recall products, and deny or withdraw approvals.

We will also be subject to a variety of regulations governing clinical trials and sales of our products outside the United States. Whether or not FDA approval has been obtained, approval of a product candidate by the comparable regulatory authorities of foreign countries and regions must be obtained prior to the commencement of marketing the product in those countries. The approval process varies from one regulatory authority to another and the time may be longer or shorter than that required for FDA approval. In the European Union, Canada and Australia, regulatory requirements and approval processes are similar, in principle, to those in the United States.

Financial Condition

We had cash and cash equivalents of approximately $55.3 million as of March 14, 2014. We believe that our existing cash and cash equivalents, along with revenue from Abstral sales, should be sufficient to fund our operations for the foreseeable future. This projection is based on our current planned operations and revenue expectations and is subject to changes in our plans and uncertainties inherent in our business, and we may need to seek to replenish our existing cash and cash equivalents sooner than we project.

We expect to continue to incur operating losses as we commercialize Abstral in the U.S. and continue to advance our product candidates through the drug development and regulatory process. We will need to generate significant revenues to achieve profitability and may never do so. In the absence of profits from the commercialization of Abstral or our product candidates, our potential sources of operational funding are proceeds from the sale of equity and funded research and development payments and payments received under partnership and collaborative agreements.

We also may borrow the remaining $5.0 million tranche of our recent long-term debt financing, subject to certain conditions. There is no guarantee that the remaining $5.0 million tranche will be available to us, or that we will generate sufficient revenue from the sale of Abstral to become profitable or that any debt, additional equity or other funding will be available to us on acceptable terms, or at all. If we fail to generate adequate revenue or obtain additional funding when needed, we would be forced to scale back, or terminate, our operations or to seek to merge with or to be acquired by another company.

Environmental Compliance

Our commercial and development programs involve the controlled use of potentially harmful biological materials as well as hazardous materials, chemicals and various radioactive compounds. We are subject to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specific waste products. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of bio-hazardous materials. The cost of compliance with these laws and regulations could be significant and may adversely affect capital expenditures to the extent we are required to procure expensive capital equipment to meet regulatory requirements.

Human Resources

As of March 17, 2014, the company had 60 full-time employees. None of our employees are represented by a labor union or covered by a collective bargaining agreement, nor have we experienced any work stoppages.

Insurance

We carry insurance for customary property and liability risks of our current commercial and development programs.

Corporate Information

Our principal executive offices are located at 4640 SW Macadam Avenue, Suite 270, Portland, Oregon 97239, and our phone number is (855) 855-4253. Our website address is www.galenabiopharma.com. We do not incorporate the information on our website into this annual report, and you should not consider such information part of this annual report.

We were incorporated as Argonaut Pharmaceuticals, Inc. in Delaware on April 3, 2006 and changed our name to RXi Pharmaceuticals Corporation on November 28, 2006. On September 26, 2011, we changed the name of our company from RXi Pharmaceuticals Corporation to Galena Biopharma, Inc., as described above.

ITEM 1A. RISK FACTORS

Our business is subject to numerous risks. We caution you that the following important factors, among others, could cause our actual results to differ materially from those expressed in statements made by us or on our behalf in filings with the SEC, press releases or communications with investors and others. Any or all of our statements in this annual report and in any other public statements we make may turn out to be wrong. They can be affected by inaccurate assumptions or by known or unknown risks and uncertainties. The factors mentioned in the discussion below will be important in determining future results. Consequently, actual future results may vary materially from those anticipated in this annual report or our other public statements.

Risks Related to Our Commercial Program

We only recently initiated our product launch of Abstral®, our only approved product. We have a history of net losses and negative cash flow from operations, and have not sold any other products, and cannot predict if or when we will become profitable.

In October 2013, we initiated the product launch of Abstral® ("Abstral") sublingual tablets in the United States. Abstral is a sublingual (under the tongue) formulation of fentanyl indicated for the treatment of breakthrough pain in patients with cancer, 18 years of age and older, who are receiving, and are tolerant to, opioid therapy for their persistent baseline cancer pain. Prior to the acquisition of Abstral, we had no commercialization history and had never sold or distributed any other products. As a result, there is no historical basis upon which to assess how we will respond to regulatory, competitive or other challenges to our ability to sell Abstral on a profitable basis. We are unable to predict when, if ever, that we will generate profits from the sale of Abstral.

We have generated substantial operating losses and negative cash flow from operations since our inception. For example, for 2013 and 2012, we incurred net operating losses of $33.8 million and $21.2 million, respectively, and our net cash used in operating activities was $28.9 million and $21.0 million, respectively, and, at December 31, 2013, our accumulated deficit was $178.9 million. Despite our launch of Abstral in the United States, we expect to continue to incur losses and negative cash flow for the foreseeable future.

Our ability to generate sufficient revenues from Abstral and to transition to profitability and generate positive cash flow will depend on numerous factors described in the risk factors that follow, and we may never achieve profitability or positive cash flow. If we are unable to transition to profitability and generate positive cash flow over time, our business, results of operations and financial condition would be materially and adversely affected, which could result in our inability to continue operations.

We are dependent on the commercial success of Abstral to generate revenues.

Although we are in the process of testing and developing other drug candidates and may seek to acquire rights in other approved drugs, we anticipate that our ability to generate revenues and to become profitable in the foreseeable future will depend upon the commercial success of our one approved product, Abstral. In addition to the other risks discussed elsewhere in this section, our ability to generate future revenues from the sale of Abstral will depend on a number of factors, including, but not limited to:

- achievement of market acceptance and coverage by third-party payors for Abstral;
- the effectiveness of our efforts in marketing and selling Abstral;
- our ability to effectively work with physicians to ensure that patients are treated to an effective dose of Abstral;
- our ability to comply with regulatory requirements;
- our contract manufacturers' ability to successfully manufacture commercial quantities of Abstral at acceptable cost levels and in compliance with regulatory requirements;
- our ability to maintain a cost-efficient commercial organization; and

- our ability to successfully maintain intellectual property protection for Abstral.

Because of the numerous risks and uncertainties associated with our commercialization efforts, even if we do achieve significant revenues from Abstral or become profitable, we may not be able to sustain or increase our revenues or maintain profitability on an ongoing basis.

If Abstral does not achieve market acceptance or coverage by third-party payors, the revenues that we generate from that product will be limited.

The commercial success of Abstral will depend upon the acceptance of that product by physicians, patients, healthcare payors and the medical community. Coverage and reimbursement for that product by third-party payors is also necessary for commercial success. The degree of market acceptance of Abstral will depend on a number of factors, including:

- our ability to communicate acceptable evidence of safety and efficacy;
- acceptance by physicians and patients of the product as a safe and effective treatment;
- the relative convenience and ease of administration;
- the prevalence and severity of adverse side effects;
- limitations or warnings contained in Abstral's FDA-approved labeling;
- the clinical indications for which Abstral is approved;
- availability and perceived advantages of alternative treatments;
- any negative publicity related to Abstral or our competitors' products;
- the effectiveness of our or any current or future collaborators' sales, marketing and distribution strategies;
- pricing and cost effectiveness;
- our ability to obtain sufficient third-party payor coverage and reimbursement;
- the effectiveness of our patient assistance efforts; and
- our ability to maintain compliance with regulatory requirements.

For example, while we believe that our sublingual delivery method for Abstral will appeal to patients, some patients may believe that an under the tongue delivery method is ineffective or may otherwise react unfavorably to sublingual delivery. In accordance with the risk evaluation mitigation strategy ("REMS") protocol for all transmucosal immediate-release fentanyl ("TIRF") products, physicians are advised to begin patients at the lowest dose available for the applicable TIRF product, which for Abstral is 100 mcg. If patients do not experience pain relief at initial low-dose prescriptions of Abstral, they or their physicians may conclude that Abstral is ineffective in general and may discontinue use of Abstral before titrating to an effective dose. In addition, many third-party payors require usage and failure on cheaper generic versions of fentanyl prior to providing reimbursement for Abstral, which would limit Abstral's use as a first-line treatment option.

Products used to treat and manage pain, especially in the case of controlled substances, are from time to time subject to negative publicity, including negative publicity relating to illegal use, overdoses, abuse, diversion, serious injury and death. These events have led to heightened regulatory scrutiny. Controlled substances are classified by the U.S. Drug Enforcement Administration (the "DEA") as Schedule I through V substances, with Schedule I substances being prohibited for sale in the United States, Schedule II substances considered to present the highest risk of abuse and Schedule V substances being considered to present the lowest relative risk of abuse. Abstral contains fentanyl, an opioid, and is regulated as a Schedule II controlled substance. Despite the strict regulations on the marketing, distributing, prescribing and dispensing of such substances, illicit use and abuse of controlled substances is well-documented. Thus, the marketing of Abstral may generate public controversy that may adversely affect market acceptance of Abstral.

Our efforts to educate the medical community and third-party payors on the benefits of Abstral and gain broad market acceptance may require significant resources and may never be successful. If Abstral does not achieve an adequate level of acceptance by physicians, third-party payors and patients, we may not generate sufficient revenue from that product to become or remain profitable.

In addition, fentanyl treatments can be costly to third-party payors and patients. Accordingly, hospitals and physicians may resist prescribing Abstral and third-party payors, and patients may not purchase Abstral due to cost.

We are subject, directly or indirectly, to U.S. federal and state health care fraud and abuse and false claims laws and regulations. Prosecutions under such laws have increased in recent years and we may become subject to such litigation. If we are unable to, or have not fully complied with such laws, we could face substantial penalties.

Our Abstral operations are directly, or indirectly through our customers and health care professionals, subject to various U.S. federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, federal False Claims Act, federal Sunshine Act, and federal Foreign Corrupt Practices Act. These laws may impact, among other things, our Abstral sales, and marketing and education programs.

The federal Anti-Kickback Statue prohibits persons from knowingly and willfully soliciting, offering, receiving, or providing renumeration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal health care program such as the Medicare and Medicaid programs. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving renumeration is to induce referrals of federal health care covered business, the statute has been violated. The Anti-Kickback Statue is broad, and despite a series of narrow safe harbors, prohibits many arrangements and practices that are lawful in businesses outside of the health care industry. Penalties for violations of the federal Anti-Kickback Statute include criminal penalties and civil and administrative sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal health care programs. An alleged violation of the Anti-Kickback Statute may be used as a predicate offense to establish liability pursuant to other federal laws and regulations such as a the federal False Claims Act. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for health care items or services reimbursed by any source, not only Medicare and Medicaid programs.

The federal False Claims Act prohibits persons from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false statements to obtain payment from, the federal government. Suits filed under the False Claims Act, known as " *qui tam* " actions, can be brought by any individual on behalf of the government and such individuals, commonly known as "relators" or "whistleblowers," may share in any amounts paid by the entity to the government in fines or settlement. The frequency of filing *qui tam* actions has increased significantly in recent years, causing greater numbers of health care companies to have to defend a False Claim Act action. The federal Patient Protection and Affordable Care Act includes provisions expanding the ability of certain relators to bring actions that would have been dismissed under prior law. When an entity is determined to have violated the federal False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. The Deficit Reduction Act of 2005 encouraged states to enact or modify their state false claims act to be at least as effective as the federal False Claims Act by granting states a portion of any federal Medicaid funds recovered through Medicaid-related actions. Most states have enacted state false claims laws, and many of those states included laws including qui tam provisions.

The federal Patient Protection and Affordable Care Act include provisions known as the Physician Payments Sunshine Act, which requires manufacturers of drugs, biologics, devices and medical supplies covered under Medicare and Medicaid to record any transfers of value to physicians and teaching hospitals and to report this data beginning in 2013 to the Centers for Medicare and Medicaid Services for subsequent public disclosures. Manufacturers must also disclose investment interest held by physicians and their family members. Failure to submit the required information may result in civil monetary penalties of up to $1 million per year for knowing violations and may result in liability under other federal laws or regulations. Similar reporting requirements have also been enacted on the state level in the U.S., and an increasing number of countries worldwide either have adopted or are considering similar laws requiring transparency of interactions with health care professionals. In addition, some states such as Massachusetts and Vermont imposed an outright ban on certain gifts to physicians. These laws could affect our Abstral promotional activities by limiting the kinds of interactions we could have with hospitals, physicians or other potential purchasers or users of our system. Both the disclosure laws and gift bans also will impose administrative, cost and compliance burdens on us.

We are unable to predict whether we could become subject to actions under any of these laws, or the impact of such actions. If we are found to be in violation of any of the laws described above and other applicable state and federal fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines, or an administrative action of suspension or exclusion from government health care reimbursement programs and the curtailment or restructuring of our commercial operations.

In addition, to the extent we commence commercial operations overseas, we will be subject to the Foreign Corrupt Practices Act and other countries' anti-corruption/anti-bribery regimes, such as the U.K. Bribery Act. The Foreign Corrupt Practices Act prohibits improper payments or offers of payments to foreign governments and their officials for the purpose of obtaining or retaining business. Safeguards we implement to discourage improper payments or offers of payments by our employees, consultants, sales agents or distributors may be ineffective, and violations of the Foreign Corrupt Practices Act and similar laws may result in severe criminal or civil sanctions, or other liabilities or proceedings against us, any of which would likely harm our reputation, business, financial conditions and results of operations.

We have no internal manufacturing capabilities; we rely instead on third parties in our supply chain for the commercial supply of Abstral, and if we fail to maintain our supply and manufacturing relationships with these third parties or develop new relationships with other third parties, we may be unable to continue to commercialize Abstral.

We rely on third parties for the commercial supply of Abstral. Our ability to commercially supply Abstral will depend, in part, on our ability to successfully obtain fentanyl, the active pharmaceutical ingredient ("API") for Abstral, and outsource most, if not all, of the aspects of its manufacture at competitive costs, in accordance with regulatory requirements and in sufficient quantities for commercialization. If we fail to maintain supply relationships with these third parties, we may be unable to continue to commercialize Abstral.

We will purchase the fentanyl API utilized in connection with Abstral from third parties. Our ability to obtain fentanyl API in sufficient quantities and quality, and on a timely basis, is critical to our commercialization of Abstral. There is no assurance that these suppliers will produce the materials in the quantities and quality and at the times they are needed, if at all.

The manufacture of pharmaceutical products generally requires significant expertise and capital investment, often including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production. These problems can include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Additionally, our manufacturers may experience difficulties due to resource constraints, labor disputes, unstable political environments or natural disasters. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations for any reason, our ability to commercially supply Abstral could be jeopardized. Any delay or interruption in our ability to commercially supply Abstral will result in the loss of potential revenues and could adversely affect the market's acceptance of that product.

Manufacturers and suppliers are subject to regulatory requirements including current Good Manufacturing Practices ("cGMPs"), which cover, among other things, manufacturing, testing, quality control and recordkeeping relating to Abstral, and are subject to ongoing inspections by the FDA, the Drug Enforcement Agency (DEA) and other regulatory agencies. If any of our third-party manufacturers cannot successfully manufacture product that conforms to our specifications and the applicable regulatory authorities' strict regulatory requirements, they will not be able to secure or maintain regulatory approval for the manufacturing facilities. In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any other applicable regulatory authorities do not approve these facilities for the manufacture of Abstral or if they withdraw any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to commercially supply Abstral.

We face intense competition, including from generic products, and if our competitors market or develop alternative treatments that are demonstrated to be safer or more effective than Abstral, our commercial opportunities will be reduced or eliminated.

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on developing proprietary therapeutics. We face competition from a number of sources, some of which may target the same indications as Abstral, such as pharmaceutical companies, including generic drug companies, biotechnology companies, drug delivery companies and academic and research institutions, many of which have greater financial resources, marketing capabilities, including well-established sales forces, manufacturing capabilities, research and development capabilities, experience in obtaining regulatory approvals for product candidates and other resources than we have.

Abstral competes against numerous branded and generic products already being marketed and potentially those which are or will be in development. Many of these competitive products are offered in the United States by large, well-capitalized companies. In the breakthrough cancer pain ("BTcP") market, physicians often treat BTcP with a variety of short-acting opioid medications, including morphine, morphine and codeine derivatives and fentanyl. Some currently marketed products against which we directly compete include Teva Pharmaceutical Industries Ltd.'s Fentora and Actiq, Insys's Subsys, Archimedes Pharma Ltd.'s Lazanda and BioDelivery Sciences International, Inc.'s Onsolis. Some generic fentanyl products against which Abstral competes are marketed by Mallinckrodt, Inc., Par Pharmaceutical Companies, Inc. and Actavis, Inc. In addition, we are aware of numerous companies developing other treatments and technologies for rapid delivery of opioids to treat BTcP, including transmucosal, transdermal, nasal spray, and inhaled sublingual delivery systems. If these treatments and technologies are successfully developed and approved, they could represent significant additional competition to Abstral. We will also face competition from third parties in obtaining allotments of fentanyl under applicable DEA annual quotas and recruiting and retaining qualified personnel.

If we are unable to achieve and maintain adequate levels of coverage and reimbursement for Abstral, on reasonable pricing terms, its commercial success may be severely hindered.

Successful sales of Abstral depend on the availability of adequate coverage and reimbursement from third-party payors. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. The reimbursement payment rates for Abstral might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use Abstral unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of Abstral.

In addition, the market for Abstral depends significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available. For example, many third-party payors require usage and failure on cheaper generic versions of rapid acting fentanyl prior to providing reimbursement for Abstral and other branded TIRF products, which limits Abstral's use as a first-line treatment option.

Third-party payors, whether governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of Abstral to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions in the United States. Third-party coverage and reimbursement for Abstral may cease to be available or adequate in the United States, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

We anticipate that the majority of our sales of Abstral will be to wholesale pharmaceutical distributors who, in turn, will sell the products to pharmacies, hospitals and other customers. The loss by us of any of these wholesale pharmaceutical distributors' accounts or a material reduction in their purchases could have a material adverse effect on our business, results of operations, financial condition and prospects.

In addition, these wholesale customers comprise a significant part of the distribution network for pharmaceutical products in the United States. This distribution network has undergone, and may continue to undergo, significant consolidation marked by mergers and acquisitions. As a result, a small number of large wholesale distributors control a significant share of the market. Consolidation of drug wholesalers has increased, and may continue to increase, competitive and pricing pressures on pharmaceutical products. We cannot assure you that we can manage these pricing pressures or that wholesaler purchases will not fluctuate unexpectedly from period to period.

Our sales of Abstral can be greatly affected by the inventory levels our wholesalers carry. We will monitor wholesaler inventory of Abstral using a combination of methods. However, our estimates of wholesaler inventories may differ significantly from actual inventory levels. Significant differences between actual and estimated inventory levels may result in excessive production (requiring us to hold substantial quantities of unsold inventory), inadequate supplies of products in distribution channels, insufficient product available at the retail level, and unexpected increases or decreases in orders from our wholesalers. These changes may cause our revenues to fluctuate significantly from quarter to quarter, and in some cases may cause our operating results for a particular quarter to be below our expectations or the expectations of securities analysts or investors. In addition, at times, wholesaler purchases may exceed customer demand, resulting in reduced wholesaler purchases in later quarters, which may result in substantial fluctuations in our results of operations from period to period. If our financial results are below expectations for a particular period, the market price of our common stock may drop significantly.

We rely on third parties to perform many necessary services for Abstral, including services related to distribution, invoicing, storage and transportation.

We have retained third-party service providers to perform a variety of functions related to the sale and distribution of Abstral, key aspects of which will be out of our direct control. For example, we rely on third parties to provide logistics, warehousing and inventory management, distribution, contract administration and chargeback processing, accounts receivable management, patient assistance program management, and call center management and, as a result, most of our Abstral inventory may be stored at warehouses maintained by the service providers. If these third-party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines, or otherwise do not carry out their contractual duties to us, or encounter physical damage or natural disaster at their facilities, our ability to deliver Abstral to meet commercial demand would be significantly impaired. In addition, we expect to utilize third parties to perform various other services for us relating to sample accountability and regulatory monitoring, including adverse event reporting, safety database management and other product maintenance services. If the quality or accuracy of the data maintained by these service providers is insufficient, our ability to continue to market Abstral could be jeopardized or we could be subject to regulatory sanctions. We do not currently have the internal capacity to perform these important commercial functions, and we may not be able to maintain commercial arrangements for these services on reasonable terms.

We may need to increase the size and complexity of our organization in the future, and we may experience difficulties in managing our growth and executing our growth strategy.

Our management and personnel, systems and facilities currently in place may not be adequate to support our business plan and future growth. The effective management of our commercial program requires that we:

- continue to improve our operational, financial, management and regulatory compliance controls and reporting systems and procedures;
- attract and retain sufficient numbers of talented employees;
- manage our commercialization activities in a cost-effective manner; and
- carry out our contractual obligations to contractors and other third parties.

In addition, historically, we have utilized and continue to utilize the services of part-time outside consultants to perform a number of tasks for us, including tasks related to accounting and finance, compliance programs, clinical trial management, regulatory affairs, formulation development and other drug development functions. Our growth strategy related to Abstral may also entail expanding our use of consultants to implement these and other tasks going forward. Because we rely on consultants for certain functions of our business, we will need to be able to effectively manage these consultants to ensure that they successfully carry out their contractual obligations and meet expected deadlines. There can be no assurance that we will be able to manage our existing consultants or find other competent outside consultants, as needed, on economically reasonable terms, or at all. If we are not able to effectively expand our organization by either hiring new employees and expanding our use of consultants, or both, we may be unable to successfully implement the tasks necessary to effectively execute on our Abstral-related development and commercialization activities and, accordingly, may not achieve our goals.

We face potential product liability exposure relating to Abstral and, if successful claims are brought against us, we may incur substantial liability if our insurance coverage for those claims is inadequate.

The commercial sale of Abstral or other products we succeed in commercializing exposes us to possible product liability claims. This risk exists even if a product is approved for commercial sale by the FDA and manufactured in facilities licensed and regulated by the FDA, such as the case with Abstral. Abstral is designed to affect important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with Abstral could result in injury to a patient or even death. For example, because Abstral is designed to be self-administered by patients, it is possible that a patient could fail to follow instructions and as a result apply a dose in a manner that results in injury. In addition, Abstral is an opioid pain reliever that contains fentanyl, which is regulated as a "controlled substance" under the Controlled Substances Act of 1970 (the "CSA") and could result in harm to patients relating to its potential for abuse. In addition, a liability claim may be brought against us even if Abstral merely appears to have caused an injury. Product liability claims may be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with Abstral. If we cannot successfully defend ourselves against product liability claims we will incur substantial liabilities. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand for Abstral;
- impairment of our business reputation;
- product recall or withdrawal from the market;
- costs of related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants; or
- loss of revenues.

We have obtained product liability insurance coverage for commercial product sales with a $5 million per occurrence and a $5 million annual aggregate coverage limit. We also carry excess product liability insurance coverage for commercial product sales with an additional $5 million per occurrence and an additional $5 million annual aggregate coverage limit. Our insurance coverage may not be sufficient to cover all of our product liability related expenses or losses and may not cover us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at a reasonable cost, in sufficient amounts or upon adequate terms to protect us against losses due to product liability. If we determine that it is prudent to increase our product liability coverage based on sales of Abstral, we may be unable to obtain this increased product liability insurance on commercially reasonable terms or at all. Large judgments have been awarded in class action or individual lawsuits based on drugs that had unanticipated side effects, including side effects that are less severe than those of Abstral. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and have a material adverse effect our business, results of operations, financial condition and prospects.

Our business involves the use of hazardous materials and we and our third-party manufacturers and suppliers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials, including the components of Abstral. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use will be stored at our and our manufacturers' facilities pending use and disposal. We cannot completely eliminate the risk of contamination, which could cause an interruption of our Abstral commercialization efforts, injury to our employees and others, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we expect that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials will generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this will be the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources. We do not currently carry biological or hazardous waste insurance coverage and our property and casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination.

Abstral is subject to ongoing and continued regulatory review, which may result in significant expense and adversely affect our commercialization of Abstral.

Even after U.S. regulatory approval for a product such as Abstral, the FDA may still impose significant restrictions on the approved indicated uses for which the product may be marketed or on the conditions of approval. For example, a product's approval may contain requirements for potentially costly post-approval studies and surveillance, including Phase 4 clinical trials, to monitor the safety and efficacy of the product. We will also be subject to ongoing FDA obligations and continued regulatory review with respect to the manufacturing, processing, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for Abstral. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs, good clinical practices and good laboratory practices.

In the case of Abstral, we and our contract manufacturers are also subject to ongoing DEA regulatory obligations, including, among other things, annual registration renewal, security, recordkeeping, theft and loss reporting, periodic inspection and annual quota allotments for the raw material for commercial production of Abstral. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where, or processes by which, the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturer or us, including requiring product recall, notice to physicians, withdrawal of the product from the market or suspension of manufacturing.

If we, Abstral or the manufacturing facilities for Abstral fail to comply with applicable regulatory requirements, a regulatory agency may:

- impose restrictions on the marketing or manufacturing of Abstral, suspend or withdraw product approvals or revoke necessary licenses;
- issue warning letters, show cause notices or untitled letters describing alleged violations, which may be publicly available;
- commence criminal investigations and prosecutions;
- impose injunctions, suspensions or revocations of necessary approvals or other licenses;
- impose fines or other civil or criminal penalties;
- deny or reduce quota allotments for the raw material for commercial production of Astral;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize Abstral or require us to initiate a product recall.

In addition, our product labeling, advertising and promotion are subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription drug products. In particular, a drug product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling, although the FDA does not regulate the prescribing practices of physicians. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including substantial monetary penalties and criminal prosecution.

The FDA's regulations, policies or guidance may change and new or additional statutes or government regulations may be enacted that could further restrict or regulate post-approval activities relating to Abstral. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to market Abstral, which would adversely affect our ability to generate revenue and achieve or maintain profitability.

Abstral may cause undesirable side effects or have other unexpected properties that could result in post-approval regulatory action.

If we or others identify undesirable side effects, or other previously unknown problems, caused by Abstral or other products with the same or related active ingredients, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of Abstral;
- regulatory authorities may require us to recall Abstral;
- regulatory authorities may require the addition of warnings in the product label or narrowing of the indication in the product label;
- we may be required to create a Medication Guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way Abstral is administered or modify Abstral in some other way;
- the FDA may require us to conduct additional clinical trials or costly post-marketing testing and surveillance to monitor the safety or efficacy of the product;
- we could be sued and held liable for harm caused to patients; and
- our business and results of operations and our reputation may suffer.

Any of the above events resulting from undesirable side effects or other previously unknown problems could prevent us from achieving or maintaining market acceptance of Abstral and could substantially increase the costs of commercializing Abstral.

We are subject to numerous complex regulations and failure to comply with these regulations, or the cost of compliance with these regulations, may harm our business.

The research, testing, development, manufacturing, quality control, approval, labeling, packaging, storage, recordkeeping, promotion, advertising, marketing, distribution, possession and use of Abstral are subject to regulation by numerous governmental authorities in the United States. The FDA regulates drugs under the Federal Food, Drug and Cosmetic Act (the "FDCA") and implementing regulations. Noncompliance with any applicable regulatory requirements can result in refusal to approve products for marketing, warning letters, product recalls or seizure of products, total or partial suspension of production, prohibitions or limitations on the commercial sale of products or refusal to allow the entering into of federal and state supply contracts, fines, civil penalties and/or criminal prosecution. Additionally, the FDA and comparable governmental authorities have the authority to withdraw product approvals that have been previously granted. Moreover, the regulatory requirements relating to Abstral may change from time to time, and it is impossible to predict what the impact of any such changes may be.

Abstral is a controlled substance as defined in the CSA, which establishes, among other things, certain registration, production quotas, security, recordkeeping, reporting, import, export and other requirements administered by the DEA. The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have high potential for abuse, no currently accepted medical use in the United States and lack accepted safety for use under medical supervision, and may not be marketed or sold in the United States. Except for research and industrial purposes, a pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances. Fentanyl is listed by the DEA as a Schedule II substance under the CSA.

The manufacture, shipment, storage, sale and use, among other things, of controlled substances that are pharmaceutical products are subject to a high degree of regulation. For example, generally all Schedule II substance prescriptions, such as prescriptions for fentanyl, must be written and signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription.

The DEA also conducts periodic inspections of certain registered establishments that handle controlled substances. Facilities that conduct research, manufacture, distribute, import or export controlled substances must be registered to perform these activities and have the security, control and inventory mechanisms required by the DEA to prevent drug loss and diversion. Failure to maintain compliance, particularly non-compliance resulting in loss or diversion, can result in regulatory action that could have a material adverse effect on our business, results of operations, financial condition and prospects. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to restrict, suspend or revoke those registrations. In certain circumstances, violations could lead to criminal proceedings.

Individual states also have controlled substances laws. Though state controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule Abstral. While some states automatically schedule a drug when the DEA does so, other states schedule drugs through rulemaking or a legislative action. State scheduling may delay the commercial sale of Abstral even though we have federal regulatory approval of Abstral, and adverse scheduling could have a material adverse effect on the commercial attractiveness of Abstral. We or our partners must also obtain separate state registrations, permits or licenses in order to be able to obtain, handle, and distribute Abstral for commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions by the states in addition to those from the DEA or otherwise arising under federal law.

Controlled substances are also regulated pursuant to several international drug control treaties. These treaties are enforced by the United Nations Commission on Narcotic Drugs. The United States is a signatory to these treaties and thus must conform its laws and regulations to the international requirements, which generally include licensing, recordkeeping and reporting requirements. Fentanyl is currently classified under the international treaties, and current U.S. controls adequately address international requirements. Any change in the international treaties regarding classification of that product could affect regulation of the substance in the United States.

Annual DEA quotas on the amount of Abstral allowed to be produced in the United States and our specific allocation of fentanyl by the DEA could significantly limit the production or sale of Abstral.

The DEA limits the availability and production of all Schedule II substances through a quota system, which includes a national aggregate quota and individual quotas. Because fentanyl is subject to the DEA's production and procurement quota scheme, the DEA establishes annually an aggregate quota for how much fentanyl may be produced in total in the United States based on the DEA's estimate of the quantity needed to meet legitimate scientific and medicinal needs. This limited aggregate amount of fentanyl that the DEA allows to be produced in the United States each year is allocated among individual companies, which must submit applications annually to the DEA for individual production and procurement quotas. The DEA requires substantial evidence and documentation of expected legitimate medical and scientific needs before assigning quotas to manufacturers. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments.

Moreover, we do not know what amounts of fentanyl other companies developing product candidates containing fentanyl may request for future years. The DEA, in assessing factors such as medical need, abuse and diversion potential and other policy considerations, may choose to set the aggregate fentanyl quota lower than the total amount requested by the companies. We are permitted to petition the DEA to increase the annual aggregate quota after it is initially established, but there is no guarantee that the DEA would act favorably upon such a petition. Our production and procurement quota of fentanyl may not be sufficient to meet our commercial demand or clinical development needs. Any delay or refusal by the DEA in establishing the production and/or procurement quota or a reduction in our quota for fentanyl or a failure to increase it over time as we anticipate could delay or stop the commercial sale of Abstral or cause us to fail to achieve our expected operating results, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

Health care reform measures and changes in policies, funding, staffing and leadership at the FDA and other agencies could hinder or prevent the commercial success of Abstral.

In the United States, there have been a number of legislative and regulatory changes to the healthcare system in ways that could affect our future results of operations and the future results of operations of our potential customers. For example, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 established a new Part D prescription drug benefit, which became effective January 1, 2006. Under the prescription drug benefit, Medicare beneficiaries can obtain prescription drug coverage from private sector plans that are permitted to limit the number of prescription drugs that are covered in each therapeutic category and class on their formularies. If Abstral is not widely included on the formularies of these plans, our ability to market Abstral may be adversely affected.

Furthermore, there have been and continue to be a number of initiatives at the federal and state levels that seek to reduce healthcare costs. In March 2010, President Obama signed into law the Patient Protection and Affordable Health Care Act of 2010, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 (jointly, the "PPACA"), which includes measures to significantly change the way health care is financed by both governmental and private insurers. Among the provisions of the PPACA of importance to the pharmaceutical industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23% and 13% of the average manufacturer price for most branded and generic drugs, respectively;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing both the volume of sales and manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report certain financial arrangements with physicians and teaching hospitals, as defined in the PPACA and its implementing regulations, including reporting any "transfer of value" made or distributed to teaching hospitals, prescribers, and other healthcare providers and reporting any ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations during the preceding calendar year, with data collection required and reporting to the Centers for Medicare & Medicaid Services (the "CMS") required by the 90th day of each calendar year;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians;
- expansion of health care fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a licensure framework for follow-on biologic products;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- creation of the Independent Payment Advisory Board which, beginning in 2014, will have authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs and those recommendations could have the effect of law even if Congress does not act on the recommendations; and
- establishment of a Center for Medicare Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012 (the "ATRA"), which, among other things, delayed for another two months the budget cuts mandated by these sequestration provisions of the Budget Control Act of 2011. The ATRA also reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other health care funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

Additionally, individual states have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally-mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects.

In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This can reduce demand for Abstral or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

The commercial success of Abstral will depend, in part, upon the availability of coverage and reimbursement from third-party payors at the federal, state and private levels. Third-party payors include governmental programs such as Medicare or Medicaid, private insurance plans and managed care plans. These third-party payors may deny coverage or reimbursement for a product or therapy in whole or in part if they determine that the product or therapy was not medically appropriate or necessary. Also, third-party payors have attempted to control costs by limiting coverage through the use of formularies and other cost-containment mechanisms and the amount of reimbursement for particular procedures or drug treatments.

Additionally, given recent federal and state government initiatives directed at lowering the total cost of healthcare, Congress and state legislatures will likely continue to focus on healthcare reform, the cost of prescription drugs and the reform of the Medicare and Medicaid programs. While we cannot predict the full outcome of any such legislation, it may result in decreased reimbursement for prescription drugs, which may further exacerbate industry-wide pressure to reduce prescription drug prices. This could harm our ability to market Abstral and generate revenues. In addition, legislation has been introduced in Congress that, if enacted, would permit more widespread importation or re-importation of pharmaceutical products from foreign countries into the United States, including from countries where the products are sold at lower prices than in the United States. Such legislation, or similar regulatory changes, could lead to a decision to decrease our prices to better compete, which, in turn, could adversely affect our business, results of operations, financial condition and prospects. It is also possible that other legislative proposals having similar effects will be adopted.

Furthermore, regulatory authorities' assessment of the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, changing policies and agency funding, staffing and leadership. We cannot be sure whether future changes to the regulatory environment will be favorable or unfavorable to our business prospects.

If we fail to comply with federal and state healthcare laws, including fraud and abuse and health information privacy and security laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected.

As a biopharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which constrains our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, by prohibiting, among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual or the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under the U.S. federal Anti-Kickback Statute, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If we or our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in U.S. federal or state health care programs, and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could materially adversely affect our ability to operate our business and our financial results.

The FDA provides guidelines with respect to appropriate promotion and continuing medical and health education activities. Although we endeavor to follow these guidelines, the FDA or the Office of the Inspector General: U.S. Department of Health and Human Services may disagree, and we may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions. In addition, management's attention could be diverted, and our reputation could be damaged.

Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

Risks Relating to Our Development Programs

Our drug candidates may not receive regulatory approval or be successfully commercialized.

Before they can be marketed, our products in development must be approved by the FDA or similar foreign governmental agencies. The process for obtaining FDA approval is both time-consuming and costly, with no certainty of a successful outcome. Before obtaining regulatory approval for the sale of any drug candidate, we must conduct extensive preclinical tests and clinical trials to demonstrate the safety and efficacy in humans of our product candidates. Although our drug candidates have exhibited no serious adverse events ("SAEs") in the Phase 1 and 1/2 clinical trial, SAEs or other unexpected side effects may arising during further testing and development. A failure of any preclinical study or clinical trial can occur at any stage of testing. The results of preclinical and initial clinical testing of these products may not necessarily indicate the results that will be obtained from later or more extensive testing. It also is possible to suffer significant setbacks in advanced clinical trials, even after obtaining promising results in earlier trials.

Clinical trial designs that were discussed with the authorities prior to their commencement may subsequently be considered insufficient for approval. Thus, our special protocol assessment with the FDA for our PRESENT trial does not guarantee marketing approval or approval of NeuVax for the treatment of breast cancer.

We reached agreement with the FDA regarding the special protocol assessment, or SPA, for the design of our NeuVax Phase 3 PRESENT trial as an adjuvant in the treatment of patients with Node positive HER2 negative breast cancer. An SPA agreement with the FDA provides a trial sponsor with an agreement that the clinical trial protocol design and analyses are adequate to support an efficacy claim. The SPA is documented as part of the administrative record, and is binding on the FDA and may not be changed unless we fail to follow the agreed upon protocol, data supporting the test are found to be false or incomplete, or the FDA determines that a substantial scientific issue essential to determining the safety or effectiveness of the drug was identified after the testing began. In June 2013, the FDA agreed to an amendment to the SPA to account for the use of a companion diagnostic. Even if an SPA is agreed to, approval of an NDA or a biological license application is not guaranteed because a final determination that an agreed upon protocol satisfies a specific objective, such as the demonstration of efficacy, or supports an approval decision, will be based on a complete review of all the data submitted to the FDA. There is no assurance, therefore, that NeuVax will be approved by the FDA.

A number of different factors could prevent us from obtaining regulatory approval or commercializing our product candidates on a timely basis, or at all.

We, the FDA or other applicable regulatory authorities, an Independent Data Safety Monitoring Board or "IDSMB" governing our clinical trials, or an institutional review board, or " IRB ," which is an independent committee registered with and overseen by the U.S. Department of Health and Human Services, or " HHS ," that functions to approve, monitor and review biomedical and behavioral research involving humans, may suspend clinical trials of a drug candidate at any time for various reasons, including if we or they believe the subjects or patients participating in such trials are being exposed to unacceptable health risks. Among other reasons, adverse side effects of a drug candidate on subjects or patients in a clinical trial could result in the FDA or other regulatory authorities suspending or terminating the trial and refusing to approve a particular drug candidate for any or all indications of use.

Clinical trials of a new drug candidate require the enrollment of a sufficient number of patients, including patients who are suffering from the disease the drug candidate is intended to treat and who meet other eligibility criteria. Rates of patient enrollment are affected by many factors, and delays in patient enrollment can result in increased costs and longer development times than we expect at present. For example, breast cancer patients can be enrolled in our Phase 3 PRESENT study of NeuVax as early as the time they are prescribed standard of care treatment, which typically lasts approximately eight to nine months, but under the SPA can be treated in the Phase 3 PRESENT study only after completing standard of care treatment and being screened for HER2 and haplotype (HLA) status. A significant percentage of patients who are potentially eligible for the study may fail screening and not be treated with NeuVax, because of differences between their local and central diagnoses on the basis of HER2 status, haplotype or imaging requirements under the SPA, which requires that patients be in remission at the time of initiating the NeuVax inoculation series. Other patients who are enrolled at the outset of their standard of care also may eventually choose for personal reasons not to participate in the study. We also compete for eligible patients with other breast cancer trials underway from time to time, and we may experience delays in patient enrollment due to the pendency of other large trials underway in the same patient population.

Clinical trials also require the review and oversight of IRBs, which approve and continually review clinical investigations to protect the rights and welfare of human subjects. An inability or delay in obtaining IRB approval could prevent or delay the initiation and completion of clinical trials, and the FDA may decide not to consider any data or information derived from a clinical investigation not subject to initial and continuing IRB review and approval.

In addition, cancer vaccines are a relatively new form of therapeutic and a very limited number of such products have received regulatory approval. Therefore, the FDA or other regulatory authority may apply standards for approval of a new cancer vaccine that is different from past experience.

Numerous factors could affect the timing, cost or outcome of our drug development efforts, including the following:

- difficulties or delays in enrolling patients in our Phase 3 PRESENT study of NeuVax or our Phase 1/2 clinical trials of GALE-301 (folate binding protein (FBP) vaccine), our Phase 2 clinical trial of GALE-401 (anagrelide controlled release) or other clinical trials in conformity with required protocols or projected timeline or in our other NeuVax clinical trials;
- conditions imposed on us by the FDA, including the possibility that the FDA would require an additional Phase 3 trial of NeuVax, or comparable foreign authorities regarding the scope or design of our clinical trials;
- difficulties or delays in arranging for third parties to conduct clinical trials of our product candidates;
- problems in engaging IRBs to oversee trials or problems in obtaining or maintaining IRB approval of studies;
- third-party contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner;
- our drug candidates having very different chemical and pharmacological properties in humans than in laboratory testing and interacting with human biological systems in unforeseen, ineffective or harmful ways, and the possibility that our previous Phase 2 trials will not be indicative of our drug candidates' performance in larger patient populations;
- the need to suspend or terminate our clinical trials if the participants are being exposed to unacceptable health risks;
- insufficient or inadequate supply or quality of our drug candidates or other necessary materials necessary to conduct our clinical trials;
- disruption at our foreign clinical trial sites resulting from local social or political unrest or other geopolitical factors;
- effects of our drug candidates not being the desired effects or including undesirable side effects or the drug candidates having other unexpected characteristics;
- negative or inconclusive results from our clinical trials or the clinical trials of others for drug candidates similar to our own or inability to generate statistically significant data confirming the efficacy of the product being tested;
- adverse results obtained by other companies developing similar drugs;
- modification of the drug during testing;
- changes in the FDA's requirements for our testing during the course of that testing; and
- reallocation of our financial and other resources to other clinical programs.

It is possible that none of the product candidates that we develop will obtain the appropriate regulatory approvals necessary for us to begin selling them or that any regulatory approval to market a product may be subject to limitations on the indicated uses for which we may market the product. The time required to obtain FDA and other approvals is unpredictable but often can take years following the commencement of clinical trials, depending upon the complexity of the drug candidate. Any analysis we perform of data from clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. Any delay or failure in obtaining required approvals could have a material adverse effect on our ability to generate revenue from the particular drug candidate.

We are also subject to numerous foreign regulatory requirements governing the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process includes all of the risks associated with the FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Approval by the FDA does not assure approval by regulatory authorities outside of the United States.

We are dependent upon contract manufacturers for clinical supplies of our product candidates, including our sole source of supply of a key component of our Phase 3 PRESENT study of NeuVax.

We do not have the facilities or expertise to manufacture supplies of any of our product candidates for clinical trials. Accordingly, we are dependent upon contract manufacturers for these supplies. There can be no assurance that we will be able to secure needed supply arrangements on attractive terms, or at all. Our failure to secure these arrangements as needed could have a materially adverse effect on our ability to complete the development of our product candidates or, if we obtain regulatory approval for our product candidates, to commercialize them.

Our current plans call for the manufacture of our compounds by contract manufacturers offering research grade, Good Laboratory grade and Good Manufacturing Practices grade materials for preclinical studies (e.g., toxicology studies) and for clinical use. Certain of our product candidates are complex molecules requiring many synthesis steps, which may lead to challenges with purification and scale-up. These challenges could result in increased costs and delays in manufacturing.

NeuVax is administered in combination with Leukine® , a "GM-CSF" available in both liquid and lyopholyzed forms exclusively from Genzyme Corporation, or "Genzyme," a subsidiary of Sanofi-Aventis.

We will continue to be dependent on Genzyme by us for our supply of Leukine ® in connection with the ongoing NeuVax trials and the eventual commercial manufacture of NeuVax. Any future interruptions in the availability of Leukine ® , or any determination by us to change the GM-CSF used with NeuVax, may have a material adverse effect on our NeuVax trials and any commercialization of NeuVax.

We may not be able to establish or maintain the third-party relationships that are necessary to develop or potentially commercialize some or all of our product candidates.

We expect to depend on collaborators, partners, licensees, clinical research organizations and other third parties to support our discovery efforts, to formulate product candidates, to manufacture our product candidates, and to conduct clinical trials for some or all of our product candidates. We cannot guarantee that we will be able to successfully negotiate agreements for or maintain relationships with collaborators, partners, licensees, clinical investigators, vendors and other third parties on favorable terms, if at all. Our ability to successfully negotiate such agreements will depend on, among other things, potential partners' evaluation of the superiority of our technology over competing technologies and the quality of the preclinical and clinical data that we have generated, and the perceived risks specific to developing our product candidates. If we are unable to obtain or maintain these agreements, we may not be able to clinically develop, formulate, manufacture, obtain regulatory approvals for or commercialize our product candidates. Under certain license agreements that we have already entered into, we have minimum dollar amounts per year that we are obligated to spend on the development of the technology we have licensed from our contract partners and other obligations to maintain certain licenses. If we fail to meet this requirement under any of our licenses that contain such requirements or any other obligations under these licenses, we may be in breach of our obligations under such agreement, which may result in the loss of the technology licensed. We cannot necessarily control the amount or timing of resources that our contract partners will devote to our research and development programs, product candidates or potential product candidates, and we cannot guarantee that these parties will fulfill their obligations to us under these arrangements in a timely fashion. We may not be able to readily terminate any such agreements with contract partners even if such contract partners do not fulfill their obligations to us.

In addition, we may receive notices from third parties from time to time alleging that our technology or product candidates infringe upon the intellectual property rights of those third parties. Any assertion by third parties that our activities or product candidates infringe upon their intellectual property rights may adversely affect our ability to secure strategic partners or licensees for our technology or product candidates or our ability to secure or maintain manufacturers for our compounds.

Even if we obtain regulatory approvals, our marketed drugs will be subject to ongoing regulatory review. If we fail to comply with ongoing regulatory requirements, we could lose our approvals to market drugs and our business would be materially adversely affected.

Following regulatory approval of any drugs we may develop, we will remain subject to continuing regulatory review, including the review of adverse drug experiences and clinical results that are reported after our drug products are made available to patients. This would include results from any post marketing tests or vigilance required as a condition of approval. The manufacturer and manufacturing facilities we use to make any of our drug products will also be subject to periodic review and inspection by the FDA.

The discovery of any new or previously unknown problems with the product, manufacturer or facility may result in restrictions on the drug or manufacturer or facility, including withdrawal of the drug from the market. We would continue to be subject to the FDA requirements governing the labeling, packaging, storage, advertising, promotion, recordkeeping, and submission of safety and other post-market information for all of our product candidates, even those that the FDA had approved. If we fail to comply with applicable continuing regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approval, product recalls and seizures, operating restrictions and other adverse consequences.

Even if we receive regulatory approval to market our product candidates, our product candidates may not be accepted commercially, which may prevent us from becoming profitable.

NeuVax and our other product candidates may not achieve market acceptance. Factors that we believe will materially affect market acceptance of our product candidates include:

- timing of our receipt of any marketing approvals, the terms of any approvals and the countries in which approvals are obtained;
- safety, efficacy and ease of administration of our product candidates;
- advantages of our product candidates over those of our competitors;
- willingness of patients to accept relatively new therapies;
- success of our physician education programs;
- availability of government and third-party payor reimbursement;
- pricing of our products, particularly as compared to alternative treatments; and
- availability of effective alternative treatments and the relative risks and/or benefits of the treatments.

We will be subject to competition and may not be able to compete successfully.

The biotechnology industry, including the cancer therapy vaccines market, is intensely competitive and involves a high degree of risk. We compete with other companies that have far greater experience and financial, research and technical resources than us. Potential competitors in the United States and worldwide are numerous and include pharmaceutical and biotechnology companies, educational institutions and research foundations, many of which have substantially greater capital resources, marketing experience, research and development staffs and facilities than us. Some of our competitors may develop and commercialize products that compete directly with those incorporating our technology, introduce products to market earlier than our products or on a more cost effective basis. We may be unable to effectively develop our technology or any other applications on a cost effective basis or otherwise. In addition, our technology may be subject to competition from other technology or methods developed using techniques other than those developed by traditional biotechnology methods. Our competitors compete with us in recruiting and retaining qualified scientific and management personnel as well as in acquiring technologies complementary to our technology. Our collaborators or we will face competition with respect to product efficacy and safety, ease of use and adaptability to various modes of administration, acceptance by physicians, the timing and scope of regulatory approvals, availability of resources, reimbursement coverage, price and patent position, including potentially dominant patent positions of others. An inability to successfully complete our product development could lead to us having limited prospects for establishing market share or generating revenues from our technology.

For patients with early stage breast cancer, adjuvant therapy is often given to prevent recurrence and increase the chance of long-term disease free survival. Adjuvant therapy for breast cancer can include chemotherapy, hormonal therapy, radiation therapy, or combinations thereof. In addition, the HER2 targeted drug trastuzumab (Herceptin ®) may be given to patients with tumors with high expression of HER2 (IHC 3+), as well as other novel targets such as MUCI which may be useful in treating breast cancer.

There are a number of cancer vaccines in development for breast cancer, including but not limited to Lapuleucel-T (Dendreon), AE-37 (Antigen Express) and Stimuvax (Merck KgA). While these development candidates are aimed at a number of different targets, and AE-37 has published data in the HER2 breast cancer patient population, there is no guarantee that any of the these compounds will not in the future be indicated for treatment of low to intermediate HER2 breast cancer patients and become directly competitive with NeuVax.

We are dependent on technologies we license, and if we lose the right to license such technologies or we fail to license new technologies in the future, our ability to develop new products would be harmed.

We currently are dependent on licenses from third parties for technologies relating to our product candidates. Our current licenses impose, and any future licenses we enter into are likely to impose, various development, funding, royalty, diligence, sublicensing, insurance and other obligations on us. If our license with respect to any of these technologies is terminated for any reason, the development of the products contemplated by the licenses would be delayed, or suspended altogether, while we seek to license similar technology or develop new non-infringing technology. The costs of obtaining new licenses are high.

Risks associated with operating in foreign countries could materially adversely affect our product development.

We conduct our Phase 3 PRESENT study of NeuVax in countries outside of the United States. Consequently, we are, and will continue to be, subject to risks related to operating in foreign countries. Risks associated with conducting operations in foreign countries include:

- differing regulatory requirements for drug approvals and regulation of approved drugs in foreign countries;
- unexpected changes in tariffs, trade barriers and regulatory requirements; economic weakness, including inflation, or political instability in particular foreign economies and markets; compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses or reduced revenues, and other obligations incident to doing business or operating in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism.

In addition, there may be political instability, including war, terrorism, riots, civil insurrection or social unrest, and natural or man-made disasters, including famine, flood, fire, earthquake, storm or disease, which could seriously harm the progress of our clinical trials at sites in particular foreign countries or regions. For example, approximately 10% of our Phase 3 PRESENT trial sites are in The Ukraine, and the recent occupation of Ukrainian territory by Russian military forces and political and civil unrest there could disrupt activities at these trial sites, which could adversely affect patient enrollment or other activities at these sites.

Any drugs we develop may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could have a material adverse effect on our business.

We intend to sell our products primarily to hospitals, oncologists, clinics, and practices which receive reimbursement for the health care services they provide to their patients from third-party payors, such as Medicare, Medicaid and other domestic and international government programs, private insurance plans and managed care programs. Most third-party payors may deny reimbursement if they determine that a medical product was not used in accordance with cost-effective treatment methods, as determined by the third-party payor, was used for an unapproved indication or if they believe the cost of the product outweighs its benefits. Third-party payors also may refuse to reimburse for experimental procedures and devices. Furthermore, because our clinical programs are still in clinical development, we are unable at this time to determine their cost-effectiveness and the level or method of reimbursement for them. Increasingly, the third-party payors who reimburse patients are requiring that drug companies provide them with predetermined discounts from list prices, and are challenging the prices charged for medical products. If the price we are able to charge for any products we develop is inadequate in light of our development and other costs, our profitability could be adversely affected.

We currently expect that the drugs we are currently developing will need to be administered under the supervision of a physician. Under currently applicable law, drugs that are not usually self-administered may be eligible for coverage by the Medicare program if:

- they are “incidental” to a physician’s services;

- they are “reasonable and necessary” for the diagnosis or treatment of the illness or injury for which they are administered according to accepted standard of medical practice;
- they are not excluded as immunizations; and
- they have been approved by the FDA.

Insurers may refuse to provide insurance coverage for newly approved drugs, or insurance coverage may be delayed or be more limited than the purpose for which the drugs are approved by the FDA. Moreover, eligibility for insurance coverage does not imply that any drug will be reimbursed in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement may be based on payments for other services and may reflect budgetary constraints or imperfections in Medicare data. Net prices for drugs may be reduced by mandatory discounts or rebates required by government health care programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Private third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for new drugs that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to develop products, and our overall financial condition.

Additionally, third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for medical products and services. Levels of reimbursement may decrease in the future, and future legislation, regulation or reimbursement policies of third-party payors may adversely affect the demand for and price levels of our products. If our customers are not reimbursed for our products, they may reduce or discontinue purchases of our products, which could have a material adverse effect on our business, financial condition and results of operations.

Comprehensive health care reform legislation, which was recently adopted by Congress and was subsequently signed into law, could adversely affect our business and financial condition. Among other provisions, the legislation provides that a “biosimilar” product may be approved by the FDA on the basis of analytical tests and certain clinical studies demonstrating that such product is highly similar to an existing, approved product and that switching between an existing product and the biosimilar product will not result in diminished safety or efficacy. This abbreviated regulatory approval process may result in increased competition if we are able to bring a product to market. The legislation also includes more stringent compliance programs for companies in various sectors of the life sciences industry with which we may need to comply and enhanced penalties for non-compliance with the new health care regulations. Complying with new regulations may divert management resources, and inadvertent failure to comply with new regulations may result in penalties being imposed on us.

Some states and localities have established drug importation programs for their citizens, and federal drug import legislation has been introduced in Congress. The Medicare Prescription Drug Plan legislation, which became law in December 2003, required the Secretary of Health and Human Services to promulgate regulations for drug reimportation from Canada into the United States under some circumstances, including when the drugs are sold at a lower price than in the United States. The Secretary, however, retained the discretion not to implement a drug reimportation plan if he finds that the benefits do not outweigh the costs, and has so far declined to approve a reimportation plan. Proponents of drug reimportation may attempt to pass legislation that would directly allow reimportation under certain circumstances. Legislation or regulations allowing the reimportation of drugs, if enacted, could decrease the price we receive for any products that we may develop and adversely affect our future revenues and prospects for profitability.

If our management team is not effective or if we fail to attract, hire and retain qualified personnel, we may not be able to design, develop, market or sell our products or successfully manage our business.

Our business prospects are dependent on our management team. The loss of Dr. Ahn, our President and Chief Executive Officer, or our other executive officers, or our inability to identify, attract, retain and integrate additional qualified key personnel, could make it difficult for us to manage our business successfully and achieve our business objectives.

Competition for skilled research, product development, regulatory and technical personnel also is intense, and we may not be able to recruit and retain the personnel we need. The loss of the services of any key research, product development, regulatory, and technical personnel, or our inability to hire new personnel with the requisite skills, could restrict our ability to develop our product candidates.

We use biological and hazardous materials, and we may be liable for any contamination or injury we cause.

Our research and development activities involves or may involve the controlled use of potentially harmful biological materials as well as hazardous materials, chemicals and various radioactive compounds. We cannot completely eliminate the risk of accidental contamination or injury; we may be liable for any damages that result, and any liability could exceed our resources.

We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of biohazardous materials. We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of these materials. State laws mandate the limits of our workers' compensation insurance, and our workers' compensation liability is capped at these state-mandated limits. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate any of these laws or regulations.

Risks Relating To Our Financial Position and Capital Requirements

We may not be able to obtain sufficient financing, and may not be able to develop our product candidates.

We believe that our existing cash and cash equivalents along with revenue from sale of Abstral, should be sufficient to fund our operations for the foreseeable future. This projection is based on our current planned operations and revenue expectations and is subject to changes in our plans and uncertainties inherent in our business, and we may need to seek to replenish our existing cash and cash equivalents sooner than we project. In the future, we may be dependent on obtaining further financing from third parties in order to maintain our operations and to meet our financial obligations. We cannot assure that additional funding to maintain our operations and to meet our obligations to our licensors will be available to us in the future on acceptable terms, or at all. If we fail to obtain additional funding when needed, we would be forced to scale back, or terminate, our operations, or to seek to merge with or to be acquired by another company.

We expect to continue to incur significant research and development expenses, which may make it difficult for us to attain profitability, and may lead to uncertainty about or as to our ability to continue as a going concern.

Substantial funds were expended to develop our technologies and product candidates, and additional substantial funds will be required for further preclinical testing and clinical trials of our product candidates, and to manufacture and market any products that are approved for commercial sale. Because the successful development of our products is uncertain, we are unable to precisely estimate the actual funds we will require to develop and potentially commercialize them. In addition, we may not be able to generate enough revenue, even if we are able to commercialize any of our product candidates, to become profitable.

In the event that we are unable to achieve or sustain profitability or to secure additional financing, we may not be able to meet our obligations as they come due, raising substantial doubts as to our ability to continue as a going concern. Any such inability to continue as a going concern may result in our common stock holders losing their entire investment. There is no guaranty that we will become profitable or secure additional financing. Our financial statements contemplate that we will continue as a going concern and do not contain any adjustments that might result if we were unable to continue as a going concern. Changes in our operating plans, our existing and anticipated working capital needs, the acceleration or modification of our expansion plans, increased expenses, potential acquisitions or other events will all affect our ability to continue as a going concern. Future financing may be obtained through, and future development efforts may be paid for by, the issuance of debt or equity, which may have an adverse effect on our security holders or may otherwise adversely affect our business.

If we raise funds through the issuance of debt or equity, any debt securities or preferred stock issued will have rights, preferences and privileges senior to those of holders of our common stock in the event of a liquidation. In such event, there is a possibility that once all senior claims are settled, there may be no assets remaining to pay out to the holders of common stock. In addition, if we raise funds through the issuance of additional equity, whether through private placements or additional public offerings, such an issuance would dilute your ownership in us.

The terms of debt securities may also impose restrictions on our operations, which may include limiting our ability to incur additional indebtedness, to pay dividends on or repurchase our capital stock, or to make certain acquisitions or investments. In addition, we may be subject to covenants requiring us to satisfy certain financial tests and ratios, and our ability to satisfy such covenants may be affected by events outside of our control.

You may have difficulty evaluating our business, because we only recently commenced commercial sales of our first product, Abstral, and our historical financial information may not be representative of our future results.

We may be unable to comply with our reporting and other requirements under federal securities laws.

As a publicly traded company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the " Exchange Act ," and the Sarbanes-Oxley Act of 2002, or the " Sarbanes-Oxley Act ." In addition, the Exchange Act requires that we file annual, quarterly and current reports. Our failure to prepare and disclose this information in a timely manner could subject us to penalties under federal securities laws, expose us to lawsuits and restrict our ability to access financing. The Sarbanes-Oxley Act requires that we, among other things, establish and maintain effective internal controls and procedures for financial reporting. From time to time we evaluate our existing internal controls in light of the standards adopted by the Public company Accounting Oversight Board. It is possible that we or our independent registered public accounting firm may identify significant deficiencies or material weaknesses in our internal control over financial reporting in the future. Any failure or difficulties in implementing and maintaining these controls could cause us to fail to meet the periodic reporting obligations or result in material misstatements in our financial statements.

Section 404 of the Sarbanes-Oxley Act requires annual management assessments of the effectiveness of our internal control over financial reporting. Our failure to satisfy the requirements of Section 404 on a timely basis could result in the loss of investor confidence in the reliability of our financial statements, which in turn could have a material adverse effect on our business and our common stock.

Risks Related to Our Intellectual Property

We may not be able to obtain and enforce patent rights or other intellectual property rights that cover our commercial product or product candidates and that are of sufficient breadth to prevent third parties from competing against us.

Our success with respect to our commercial product and product candidates will depend in part on our ability to obtain and maintain patent protection in the United States and abroad, to preserve our trade secrets, and to prevent third parties from infringing upon our proprietary rights. Our patents and patent applications, however, may not be sufficient to provide protection for Abstral, NeuVax, or our other products and product candidates against commercial competition.

NeuVax . The active peptide found in NeuVax, the E75 peptide, has been known and studied for many years. We have one issued U.S. patent, US 6,514,942, covering the composition of matter of the E75 peptide, which is expected to expire in 2015, prior to any potential commercialization of NeuVax. We do not have and will not be able to obtain any composition of matter patent protection for E75, the active peptide in NeuVax outside the United States. We also have a license from The Henry M. Jackson Foundation to an issued U.S. and European method of use patents, which expire in 2028, that are directed to a method of inducing immunity against breast cancer recurrence by administering a composition comprising the E75 peptide to a patient, that patent covers administration to patients who have both an immunohistochemistry (IHC) rating of 1+ or 2+ for HER2/neu protein expression and a fluorescence in situ hybridization (FISH) rating of less than about 2.0 for HER2/neu gene expression. Thus, our method of use patent may not prevent competitors from seeking to develop and market NeuVax for use in breast cancer patients who do not meet these criteria or for any other indications. If any such alternative uses were approved, this could lead to off-label use and price erosion for our NeuVax product. We may seek FDA approval for use of NeuVax to treat cancer patients who fall outside the claimed IHC and FISH ranges and for other cancers as well. Although we are pursuing additional patent protection for NeuVax through pending patent applications, we may not be able to obtain additional patent protection that would provide us with a significant commercial advantage.

GALE- 401. Anagrelide hydrochloride, the sole active pharmaceutical ingredient, or "API," in GALE-401, has been approved for many years and, thus, it is not possible to obtain composition of matter patents that cover anagrelide hydrochloride. As a result, competitors who obtain the requisite regulatory approval can offer products with the same API as GALE-401, so long as the competitors do no infringe any formulation patents that we may have or may obtain or license, if any. The only patent protection that we have or are likely to obtain covering GALE-401 are patents relating to very specific formulations, methods using these formulations, and methods of manufacturing and packaging. We have two granted patents in the United Kingdom that expire in 2019 and we are prosecuting pending patent applications in other territories including but not limited to the United States and Europe, which may not issue prior to any potential commercialization of GALE-401. We may seek FDA approval for use of GALE-401 to treat patients with essential thrombocythemia and for other hermatological disorders as well. Although we are pursuing additional patent protection for GALE-401 through pending patent applications, we may not be able to obtain additional patent protection that would provide us with a significant commercial advantage.

Orexo AB filed an action in the U.S. District Court of New Jersey on June 30, 2011 asserting infringement by Mylan Pharmaceuticals Inc., of one of our licensed U.S. patents, US 6,761,910, covering Abstral. This patent is directed to pharmaceutical compositions for the treatment of acute disorders by sublingual administration. The claims of the patent cover formulations for other products in addition to Abstral, including Ambien (and generic forms of Ambien, which is the subject of the infringement action). Validity of the patent is being challenged as part of the court proceeding, and the patent could be held invalid or unenforceable as a result. We do not believe the invalidity or unenforceability of this patent would affect our license under the other Abstral patents or our ability to market, sell, distribute or manufacture Abstral in the United States.

GALE-301. The active peptides found in GALE-301 are derived from Folate Binding Protein. One of the active peptides, E39, has been known and studied for many years. The other active peptide(s) in GALE-301 are derivatives of E39. We have a license from The Henry Jackson Foundation to issued and granted patents in the U.S., Canada, and Japan, as well as a recently allowed European patent application, covering composition of matter for the E39 derivative peptides alone and in combination with E39. The issued patents in Canada and Japan, and the allowed European patent application, further contain claims to the use of these compositions for the treatment of cancer. These patents are expected to expire in 2022, prior to any potential commercialization of GALE-301. We do not have and will not be able to obtain any composition of matter patent protection for the E39 peptide in any territory. Thus, although, the have a license from The Henry M. Jackson Foundation grants us the right to develop and market GALE-301 for any use, including methods of treating cancer, our patents may not prevent competitors from seeking to develop and market the E39 peptide alone. If any such alternative uses of compositions containing the E39 peptide were approved, this could lead to off-label use and price erosion for GALE-301. We may seek FDA approval for use of GALE-301 to treat cancer patients with ovarian and endometrial cancers and for other cancers as well. Although we are pursuing additional patent protection for GALE-301 through pending patent applications, we may not be able to obtain additional patent protection that would provide us with a significant commercial advantage.

Our ability to obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions. Accordingly, rights under any patents we have or may obtain or license may not provide us with sufficient protection for our commercial product and product candidates to afford a commercial advantage against competitive products or processes, including those from branded and generic pharmaceutical companies. In addition, we cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to us. Nor can we guarantee that the claims of these patents will be held valid or enforceable by the courts or will provide us with any significant protection against competitive products or otherwise be commercially valuable to us.

Changes in either the patent laws or in the interpretations of patent laws in the United States or abroad may diminish the value of our intellectual property. In addition, on September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to the United States patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The United States Patent Office is currently developing regulations and procedures to govern administration of the Leahy-Smith Act, and many substantive changes to patent law associated with the Leahy-Smith Act have not yet become effective. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act, in particular the first-to-file provision and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement of or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents.

While we intend to take actions reasonably necessary to enforce our patent rights, we may not be able to detect infringement of our own or in-licensed patents, which may be especially difficult for methods of manufacturing or formulation products, and we depend, in part, on our licensors and collaborators to protect a substantial portion of our proprietary rights. In addition, third parties may challenge our in-licensed patents and any of our own patents that we may obtain, which could result in the invalidation or unenforceability of some or all of the relevant patent claims. Litigation or other proceedings to enforce or defend intellectual property rights is very complex, expensive, and may divert our management's attention from our core business and may result in unfavorable results that could adversely affect our ability to prevent third parties from competing with us.

If another party has reason to assert a substantial new question of patentability against any of our claims in our own and in-licensed patents, the third party can request that the patent claims be reexamined, which may result in a loss of scope of some claims or a loss of the entire patent. In addition to potential infringement suits and, interference and reexamination proceedings, we may become a party to patent opposition proceedings where either the patentability of the inventions subject of our patents are challenged, or we are challenging the patents of others. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful.

As the medical device, biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that others may assert our commercial product and/or product candidates infringe their patent rights. If a third-party's patents were found to cover our commercial product and product candidates, proprietary technologies or their uses, we or our collaborators could be enjoined by a court and required to pay damages and could be unable to continue to commercialize our products or use our proprietary technologies unless we or they obtained a license to the patent. A license may not be available to us or our collaborators on acceptable terms, if at all. In addition, during litigation, the patent holder could obtain a preliminary injunction or other equitable relief which could prohibit us from making, using or selling our commercial product and product candidates pending a trial on the merits, which could be years away.

Proprietary trade secrets and unpatented know-how are also very important to our business. Although we have taken steps to protect our trade secrets and unpatented know-how, by entering into confidentiality agreements with third parties, and proprietary information and invention agreements with certain employees, consultants and advisors, third parties may still obtain this information or we may be unable to protect our rights. We also have limited control over the protection of trade secrets used by our licensors, collaborators and suppliers. There can be no assurance that binding agreements will not be breached, that we would have adequate remedies for any breach, or that our trade secrets and unpatented know-how will not otherwise become known or be independently discovered by our competitors. If trade secrets are independently discovered, we would not be able to prevent their use. Enforcing a claim that a third party illegally obtained and is using our trade secrets or unpatented know-how is expensive and time consuming, and the outcome is unpredictable.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed to us alleged trade secrets of their other clients or former employers. As is common in the biotechnology and pharmaceutical industry, certain of our employees were formerly employed by other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Moreover, we engage the services of consultants to assist us in the development of our commercial product and product candidates, many of whom were previously employed at or may have previously been or are currently providing consulting services to, other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees and consultants or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or their former or current customers. Litigation may be necessary to defend against these types of claims. Even if we are successful in defending against any such claims, any such litigation would likely be protracted, expensive, a distraction to our management team, not viewed favorably by investors and other third parties, and may potentially result in an unfavorable outcome.

Our NeuVax product candidate for which we intend to seek approval as a biological product may face competition sooner than expected after the expiration of our composition of matter patent protection for such product in 2015.

We intend to seek data exclusivity or market exclusivity provided under the Federal Food, Drug and Cosmetic Act, or FDCA, and similar laws in other countries. We believe that NeuVax will qualify for 12 years of data exclusivity under the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which was enacted as part of the Patient Protection and Affordable Care Act and the Health Care and Education Affordability Reconciliation Act of 2010 (collectively, the Affordable Care Act or ACA) enacted in March 2010. Under the BPCIA, an application for a biosimilar product cannot be submitted to the FDA until four years, or approved by the FDA until 12 years, after the original brand product identified as the reference product is approved under a BLA, The BPCIA provides an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The new abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. The new law is complex and is only beginning to be interpreted and implemented by the FDA. While it is uncertain when any such processes may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products. There is also a risk that the U.S. Congress could amend the BPCIA to shorten this exclusivity period as proposed by President Obama, potentially creating the opportunity for biosimilar competition sooner than anticipated after the expiration of our patent protection. Moreover, the extent to which a biosimilar, once approved, will be substituted for any reference product in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

If NeuVax is not considered a biologic that would qualify for exclusivity under the BPCIA, it may be eligible for market exclusivity as a drug under the FDCA, which could delay approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the U.S. to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA, submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by FDA to be essential to the approval of the application, for example, for new indications, dosages, or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent.

Even if, as we expect, NeuVax is considered to be a reference product eligible for 12 years of exclusivity under the BPCIA or five years of exclusivity under the FDCA, another company could market a competing product if the FDA approves a full BLA or full NDA for such product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product.

In some countries outside of the U.S., peptide vaccines, such as NeuVax are regulated as chemical drugs rather than as biologics and may or may not be eligible for non-patent exclusivity.

Risks Relating to Ownership of Our Common Stock

The market price and trading volume of our common stock may be volatile.

The market price of our common stock has exhibited substantial volatility recently. Between January 1, 2014 and March 14, 2014, the sale price of our common stock as reported on The NASDAQ Capital Market ranged from a low of $3.15 to a high of $7.77. The market price of our common stock could continue to fluctuate significantly for many reasons, including the following factors:

- reports of the results of our clinical trials regarding the safety or efficacy of our product candidates and surrogate markers;
- announcements of regulatory developments or technological innovations by us or our competitors;
- announcements of business or strategic transactions;

- announcements of legal or regulatory actions against us or any adverse outcome of any such actions;
- changes in our relationship with our licensors, licensees and other strategic partners;
- our quarterly operating results;
- developments in patent or other technology ownership rights;
- public concern regarding the safety of our Abstral product or our product candidates;
- additional funds may not be available on terms that are favorable to us and, in the case of equity financings, may result in dilution to our stockholders;
- government regulation of drug pricing; and
- general changes in the economy, the financial markets or the pharmaceutical or biotechnology industries.

Factors beyond our control may also have an impact on the price of our stock. For example, to the extent that other companies within our industry experience declines in their stock price, our stock price may decline as well.

We are, and in the future may be, subject to legal or administrative actions that could adversely affect our results of operations and our business.

In February and March 2014, two purported shareholder derivative complaints- *Fagin v. Ahn* , No. 140202384 (Or. Cir. Ct.), and *Werbowsky v. Hillsberg* , No. 3:14-cv-382 (D. Or.)-were filed against our company, as nominal defendant, and certain of our officers and directors in the Circuit Court of Oregon for the County of Multnomah and in the United States District Court for the District of Oregon. The complaints allege, among other things, breaches of fiduciary duties and abuse of control by the officers and directors in connection with various public statements purportedly issued by us or on our behalf and sales of our common stock by the officers and directors in January and February of this year.

In March 2014, three purported securities class action complaints- *Deering v. Galena Biopharma, Inc.* , No. 3:14-cv-367 (D. Or.), *Hau v. Galena Biopharma, Inc.* , No. 3:14-cv-389 (D. Or.), and *Clavijo v. Galena Biopharma, Inc.* , No. 3:14-cv-410 (D. Or.)-were filed against our company and certain of our officers in the United States District Court for the District of Oregon. The complaints allege that the defendants violated the federal securities laws by making materially false and misleading statements in press releases and in filings with the SEC arising out of the same circumstances that are the subject of the derivative actions described above.

We intend to vigorously defend against the foregoing complaints. Based on the very early stage of the litigation, it is not possible to estimate the amount or range of possible loss that might result from an adverse judgment or a settlement of these matters.

In February 2014 **,** we learned that the SEC is investigating certain matters relating to our company and an outside investor-relations firm that we retained in 2013. We have been in contact with the SEC staff through our counsel and are cooperating with the investigation.

Litigation is inherently uncertain, and there is no assurance as to the outcome of the complaints or the SEC investigation described above. We could incur substantial legal fees and other expenses in connection with these matters, which could adversely affect our results of operations. These matters also may distract the time and attention of our officers and directors or divert our other resources away from our ongoing commercial and development programs. An unfavorable outcome in any of these matters could damage our business and reputation or result in additional claims or proceedings against us.

Our outstanding contingent value rights and the achievement milestones related to our acquisition of GALE 401 may result in substantial future payments by us, and any payments made in shares of our common stock would result in dilution to our stockholders.

In conjunction with our acquisition of Apthera, Inc., or Apthera, in April 2011 we issued to the former Apthera shareholders contingent value rights entitling them to future payments of a total of up to $32 million of contingent consideration based on the achievement of specified development and commercial milestones relating to NeuVax™ of which a total of $2 million has been paid. We may pay the remaining $30 million of future contingent consideration, at our option, in either cash or in shares of our common stock valued for this purpose at the market price of our common stock when the contingent consideration becomes payable. We may determine to pay any contingent consideration that may become payable in the future in shares of our common stock rather than cash, depending upon our cash and cash requirements and the market price of our common stock at the time and other relevant factors. To the extent we pay any future contingent consideration in shares of our common stock, it would have a dilutive effect on our stockholders.

To the extent we pay any contingent consideration in shares of our common stock, we will be obliged to file a registration statement with the SEC covering the resale of such shares by the contingent value rights holders.

On January 12, 2014, we acquired exclusive worldwide license to develop and commercialize GALE−401 (anagrelide CR), a patented, controlled-release formulation of anagrelide, through our acqusition of Mills Pharmaceuticals, LLC (“Mills”) under the Unit Purchase Agreement ("Purchase Agreement"). Under the terms of the Purchase Agreement, we made an up-front cash payment to the former Mills owners and also agreed to make additional contingent payments to the former owners upon the achievement of certain development milestones relating to GALE−401, including 2,000,000 shares of our common stock upon initiating the first clinical trial of GALE−401 in patients with essential thrombocythemia, or “ET,” which we plan to do during 2014, and an additional 2,000,000 shares upon initiating a Phase 3 clinical study of GALE−401. The number of shares issuable upon the milestones is subject to increase based on a formula specified in the purchase agreement, up to a maximum of 3,000,000 shares for each milestone, in the event the five−day average trailing closing price of our common stock (the “Average Price”) is less than $4.84 at the time the applicable milestone is achieved. Similarly, the number of shares issuable upon achievement of the milestones is subject to decrease based on such formula if the Average Price exceeds $6.84 at the time of achievement of the applicable milestone.

We and the owners also entered into a registration rights agreement, pursuant to which we agreed to file, on or before April 14, 2014, a registration statement under the Securities Act of 1933 covering the resale by the owners of the shares of our common stock issuable upon achievement of the milestones, and to use commercially reasonable efforts to cause such registration statement to become effective by the earlier of July 11, 2014, or the achievement of the first milestone under the purchase agreement.

We cannot predict if future issuances or sales of our common stock issued to our contingent value rights holders or the former owners of Mills, or the availability of our common stock for issuance or sale, will harm the market price of our common stock or our ability to raise capital.

Future sales of substantial amounts of our common stock, or the possibility that such sales could occur, could adversely affect the market price of our common stock.

Future sales in the public market of our common stock, including shares referred to in the foregoing risk factors or shares issued upon exercise of our outstanding stock options, or the perception by the market that these issuances or sales could occur, could lower the market price of our common stock or make it difficult for us to raise additional capital.

As of March 14, 2014, we had reserved for issuance 10,009,601 shares of our common stock issuable upon the exercise of outstanding stock options at a weighted-average exercise price of $3.18 per share. Subject to applicable vesting requirements, upon exercise of these options the underlying shares may be resold into the public market. In the case of outstanding options that have exercise prices that are below the market price of our common stock from time to time, our stockholders would experience dilution upon the exercise of these options.

We cannot predict if future issuances or sales of our common stock to our contingent value rights holders or the availability of our common stock for issuance or sale will harm the market price of our common stock or our ability to raise capital.

Some of our outstanding warrants may result in dilution to our stockholders.

Our outstanding March 2011 and April 2011 warrants to purchase a total of 891,398 shares of common stock as of March 14, 2014 at a current exercise price of $0.65 per share contain so-called full-ratchet anti-dilution provisions. Our outstanding March 2010 and December 2012 warrants to purchase a total of 3,035,111 shares of common stock as of March 14, 2014 at current exercise prices of $2.18 per share and $1.90 per share, respectively, contain so-called weighted-average anti-dilution provisions. These anti-dilution provisions also will be triggered upon any future issuance by us of shares of our common stock or common stock equivalents at a price per share below the then-exercise price of the warrants, subject to some exceptions.

To the extent that these anti-dilution provisions are triggered in the future, we would be required to reduce the exercise price of all of the warrants on either a full-ratchet or weighted-average basis, which would have a dilutive effect on our stockholders.

We may issue preferred stock in the future, and the terms of the preferred stock may reduce the value of our common stock.

We are authorized to issue up to 5,000,000 shares of preferred stock in one or more series. Our board of directors may determine the terms of future preferred stock offerings without further action by our stockholders. If we issue preferred stock, it could affect your rights or reduce the market value of our outstanding common stock. In particular, specific rights granted to future holders of preferred stock may include voting rights, preferences as to dividends and liquidation, conversion and redemption rights, sinking fund provisions, and restrictions on our ability to merge with or sell our assets to a third party.

Anti-takeover provisions of our amended and restated certificate of incorporation and amended and restated bylaws and provisions of Delaware law could delay or prevent a change of control that you may favor.

Anti-takeover provisions of our amended and restated certificate of incorporation and amended and restated bylaws may discourage, delay or prevent a merger or other change of control that security holders may consider favorable or may impede the ability of the holders of our common stock to change our management. These provisions of our amended and restated certificate of incorporation and amended and restated bylaws, among other things:

- divide our board of directors into three classes, with members of each class to be elected for staggered three-year terms;
- limit the right of security holders to remove directors;
- prohibit stockholders from acting by written consent;
- regulate how stockholders may present proposals or nominate directors for election at annual meetings of stockholders; and
- authorize our board of directors to issue preferred stock in one or more series, without stockholder approval.

In addition, Section 203 of the Delaware General Corporation Law provides that, subject to limited exceptions, persons that acquire, or are affiliated with a person that acquires, more than 15% of the outstanding voting stock of a Delaware corporation such as our company shall not engage in any business combination with that corporation, including by merger, consolidation or acquisitions of additional shares for a three-year period following the date on which that person or its affiliate crosses the 15% stock ownership threshold. Section 203 could operate to delay or prevent a change of control of our company.

Our amended and restated by-laws designate the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our amended and restated by-laws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, or (iv) any action asserting a claim that is governed by the internal affairs doctrine. Any person purchasing or otherwise acquiring any interest in any shares of our capital stock shall be deemed to have notice of and to have consented to this provision of our amended and restated by-laws. This choice-of-forum provision may limit our stockholders' ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits. Alternatively, if a court were to find this provision of our amended and restated by-laws inapplicable or unenforceable with respect to one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition. For example, in late February 2014, two purported stockholder derivative complaints were filed in Oregon against us, as nominal defendant, and certain of our directors i.

We have never declared or paid cash dividends on our capital stock and we do not anticipate paying cash dividends in the foreseeable future.

Our business requires significant funding. We currently plan to invest all available funds and future earnings in the development and growth of our business and do not anticipate paying any cash dividends on our common stock in the foreseeable future, and are prohibited by the terms of our outstanding indebtedness from paying dividends on any common stock, except with the prior consent of our lenders. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of potential gain for the foreseeable future.

The terms of our outstanding indebtedness may inhibit potential acquirors.

We are prohibited by the terms of our outstanding indebtedness from disposing of any of our business or property, except with the consent of our lenders. Our outstanding indebtedness may inhibit potential acquirors or other interested parties from seeking to acquire all or a part of our business or assets, and there is no assurance that our lenders would consent to any proposed future transaction that might be beneficial to our stockholders.

ITEM 1B. UNRESOLVED STAFF COMMENTS

We have received no written comments from the staff of the SEC regarding our periodic or current reports that (1) we believe are material; (2) were issued not less than 180 days before the end of our 2013 fiscal year; and (3) remain unresolved.

ITEM 2. PROPERTIES

On May 10, 2013, we entered into a lease with Cameron Oregon Properties, LLC and Luca Oregon Properties, LLC for our facility located at 4640 SW Macadam Ave., Portland, Oregon, 97239. The facility is approximately 3,400 square feet and is used for our general and administrative offices. The monthly rent is approximately $6,500.

We believe that our facility is suitable for our current needs.

ITEM 3. LEGAL PROCEEDINGS

In February and March 2014, two purported shareholder derivative complaints- *Fagin v. Ahn* , No. 140202384 (Or. Cir. Ct.), and *Werbowsky v. Hillsberg* , No. 3:14-cv-382 (D. Or.)-were filed against our company, as nominal defendant, and certain of our officers and directors in the Circuit Court of Oregon for the County of Multnomah and in the United States District Court for the District of Oregon. The complaints allege, among other things, breaches of fiduciary duties and abuse of control by the officers and directors in connection with various public statements purportedly issued by us or on our behalf and sales of our common stock by the officers and directors in January and February of this year.

In March 2014, three purported securities class action complaints- *Deering v. Galena Biopharma, Inc.* , No. 3:14-cv-367 (D. Or.), *Hau v. Galena Biopharma, Inc.* , No. 3:14-cv-389 (D. Or.), and *Clavijo v. Galena Biopharma, Inc.* , No. 3:14-cv-410 (D. Or.)-were filed against our company and certain of our officers in the United States District Court for the District of Oregon. The complaints allege that the defendants violated the federal securities laws by making materially false and misleading statements in press releases and in filings with the SEC arising out of the same circumstances that are the subject of the derivative actions described above.

We intend to vigorously defend against the foregoing complaints. Based on the very early stage of the litigation, it is not possible to estimate the amount or range of possible loss that might result from an adverse judgment or a settlement of these matters.

In February 2014 **,** we learned that the SEC is investigating certain matters relating to our company and an outside investor-relations firm that we retained in 2013. We have been in contact with the SEC staff through our counsel and are cooperating with the investigation.

From time to time, we also are subject to other legal claims and proceedings in the ordinary course of our business. We are currently not aware of any such claims or proceedings.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II.

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is listed on The NASDAQ Capital Market under the symbol "GALE " The following table shows the high and low per-share sale prices of our common stock for the periods indicated:

	High	Low
2012		
First Quarter	$ 3.54	$ 0.43
Second Quarter	2.24	1.04
Third Quarter	2.30	1.45
Fourth Quarter	2.43	1.23
2013		
First Quarter	$ 2.18	$ 1.55
Second Quarter	3.00	1.92
Third Quarter	2.53	1.65
Fourth Quarter	5.30	2.01

Holders

As of March 1, 2014, there were approximately 629 holders of record of our common stock. Because many of our shares are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of individual stockholders represented by these holders of record.

Dividends

We have never paid any cash dividends and do not anticipate paying any cash dividends on our common stock in the foreseeable future. We expect to retain future earnings, if any, for use in our development activities and the operation of our business. The payment of any future dividends will be subject to the discretion of our board of directors and will depend, among other things, upon our results of operations, financial condition, cash requirements, prospects and other factors that our board of directors may deem relevant. Additionally, our ability to pay future dividends may be restricted by the terms of any debt financing.

Equity Compensation Plans

The following table sets forth certain information as of December 31, 2013, regarding securities authorized for issuance under our equity compensation plans:

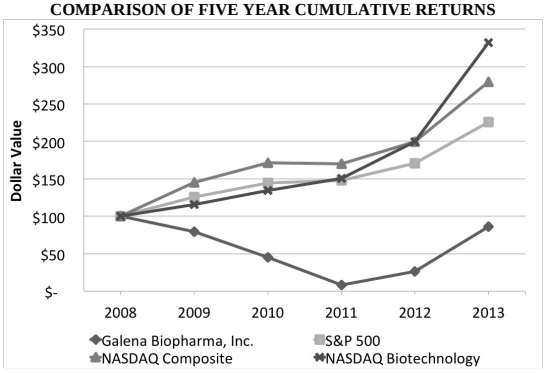
Plan Category	(a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	(b) Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
Equity compensation plans approved by our security holders:			
Amended and Restated 2007 Incentive Plan	13,159,033	$ 2.26	1,926,750
Equity compensation plans not approved by our security holders:			
Employee Stock Purchase Plan	NA	NA	756,491
Outstanding warrants [1]	889,061	$ 3.20	—
Total	14,048,094	$ 2.67	2,683,241

[1] The warrants shown were issued in discreet transactions from time to time as compensation for services rendered by consultants, advisers or other third parties, and do not include warrants sold in private placement or public offering transactions. The material terms of such warrants were determined based upon arm's-length negotiations with the services providers. The warrant exercise prices approximated the market price of our common stock at or about the date of grant, and the warrant terms range from three to ten years from the grant date.

Performance Graph

The following graph shows the value of an investment of $100 on December 31, 2008 in each of Galena Biopharma, Inc. common stock, the NASDAQ Composite Index, the NASDAQ Biotechnology Index, and Standard & Poor's Index (S&P 500). All values assume reinvestment of pretax value of dividends and are calculated as of December 31 of each year. The historical stock price performance of the our common stock shown in the performance graph is not necessarily indicative of future stock performance.

COMPARISON OF FIVE YEAR CUMULATIVE RETURNS



	As of December 31,					
	2008	2009	2010	2011	2012	2013
Galena Biopharma, Inc. [1]	$ 100.00	$ 79.65	$ 44.87	$ 8.17	$ 26.61	$ 86.26
S&P 500	100.00	125.92	144.58	147.60	171.04	225.85
NASDAQ Composite	100.00	145.05	171.14	169.83	199.89	279.63
NASDAQ Biotechnology	100.00	115.93	134.42	150.63	199.91	331.72

[1] The cumulative return depicted above for Galena Biopharma, Inc. does not include the value of our former subsidiary, RXi Pharmaceuticals Corporation ("RXi"), which we spun off to our stockholders in April 2012. See Note 4 of the notes to the consolidated financial statements for additional information about the spin-off.

Recent Sales of Unregistered Securities

Set forth below is information regarding any unregistered sales by us of common stock, preferred stock, options and warrants during the period covered by this annual report that were not previously reported by us in a Quarterly Report on Form 10-Q or Current Report on Form 8-K:

Preferred Stock

None.

Common Stock

None.

Common Stock Options and Warrants

None.

ITEM 6. SELECTED FINANCIAL DATA

	Years Ended December 31,				
	2013	2012	2011	2010	2009
Net revenue [1]	$ 2,487	$ —	$ —	$ —	$ —
Operating expenses:					
Research and development [1]	21,076	14,614	3,851	7,873	8,892
Selling, general, and administrative [1]	14,600	6,585	8,635	8,752	8,628
Other income (loss) [1]	(41,786)	(13,145)	9,079	4,632	(867)
Loss from continuing operations [1]	(76,678)	(33,325)	(3,407)	(11,993)	(18,387)
Loss from continuing operations per share [1]	(0.85)	(0.53)	(0.09)	(0.67)	(1.24)
	As of December 31,				
	2013	2012	2011	2010	2009
Total assets [1]	$ 87,976	$ 54,986	$ 30,968	$ 7,476	$ 6,252
Total debt [1]	9,892	—	—	—	—
Other long-term obligations [1]	11,900	11,311	9,654	20	36
Total stockholders' equity [1]	5,886	27,756	10,112	2,430	741

[1] See Note 4 of the notes to the consolidated financial statements for discussion of our spin-off of RXi activities being classified as discontinued operations in the consolidated statements of expenses for 2012 and 2011. The net assets of RXi were removed from the consolidated balances sheet as of the date of the spin-off and were recorded as an equity distribution. The selected financial data referenced for the years ended December 31, 2012 and 2011 are exclusive of RXi activities.

See "Management's Discussion and Analysis of Financial Condition and Results of Operations" below, and the consolidated financial statements and accompanying notes and previously filed Annual Reports on Form 10-K for further information regarding our consolidated results and financial position for periods reported herein and for known factors that will impact comparability of future results.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion in conjunction with the consolidated financial statements and the notes to consolidated financial statements included elsewhere in this annual report. This "Management's Discussion and Analysis of Financial Condition and Results of Operations" section contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. For a discussion of indicators of forward-looking statements and specific important factors that could cause actual results to differ materially from those contained in forward-looking statements, see "Risk Factors" under Part I — Item 1A of this annual report. This "Management's Discussion and Analysis of Financial Condition and Results of Operations" section should be read and interpreted in light of such factors. Our actual results and the timing of certain events could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including those discussed below and elsewhere in this annual report.

You may have difficulty evaluating our business, because we completed a partial spin off of RXi on April 26, 2012. Since the partial spin-off, our financial statements have no longer reflected the consolidated financial condition and results of operations of RXi, and we have accounted for our partial ownership of RXi based on the cost method of accounting. For these reasons, the historical consolidated financial information included in this annual report do not necessarily reflect the financial condition, results of operations or cash flows that we will achieve in the future.

Overview

Galena Biopharma, Inc. (“we,” “us,” “our,” “Galena” or the “company”) is a biopharmaceutical company focused on developing and commercializing innovative, targeted oncology treatments that address major unmet medical needs to advance cancer care.

Our strategy is to build value for patients and shareholders by:

- Achieving revenue goals for Abstral® (fentanyl) sublingual tablets, to which we acquired for the U.S. rights in March 2013 and launched in the fourth quarter of 2013;
- Completing the pivotal Phase 3 randomized, multicenter PRESENT (Prevention of Recurrence in Early-Stage, Node-Positive Breast Cancer with Low-to-Intermediate HER2 Expression with NeuVax Treatment) study of our lead product candidate, NeuVax™ (nelipepimut-S) in 700 patients under a U.S. Food and Drug Administration (FDA)-approved Special Protocol Assessment (SPA);
- Completing the Phase 2b randomized, multicenter clinical trial in 300 patients to study NeuVax in combination with Herceptin® (trastuzumab; Genentech/Roche);
- Completing the Phase 2 clinical trials of GALE-301 (folate binding protein (FBP)) cancer immunotherapy trials in both ovarian and endometrial cancers;
- Initiating a Phase 2 clinical trial with GALE-401 (anagrelide controlled release (CR)), which we acquired in January 2014, in essential thrombocythemia (ET); and
- Pursuing strategic alliances and acquisitions of other cancer treatments to complement our existing product pipeline and commercialization capabilities.

Galena is developing peptide vaccine (off-the-shelf) cancer immunotherapies, which address patient populations of cancer survivors to prevent disease recurrence by harnessing the patient's own immune system to seek out and attack any residual cancer. In this case, 25% of resectable node-positive breast cancer patients, despite having no evidence of disease following surgery and chemo/radiation therapy, will still relapse within three years. Increased presence of circulating tumor cells (CTCs) predict Disease Free Survival (DFS) and Overall Survival (OS) - suggesting a dormancy of isolated micrometastases, which over time, leads to recurrence. Our lead product, NeuVaxTM (nelipepimut-S) elicits a robust, specific and durable killer CD8+ cytotoxic T lymphocyte (CTLs) response to lyse HER2 expressing tumor cells.

NeuVax™ (nelipepimut-S) is the immunodominant nonapeptide derived from the extracellular domain of the HER2 protein, a well-established target for therapeutic intervention in breast carcinoma. The nelipepimut sequence stimulates specific CTLs following binding to HLA-A2/A3 molecules on antigen presenting cells (APC). These activated specific CTLs recognize, neutralize and destroy, through cell lysis, HER2 expressing cancer cells, including occult cancer cells and micrometastatic foci. The nelipepimut immune response can also generate CTLs to other immunogenic peptides through inter- and intra-antigenic epitope spreading. Based on a successful Phase 2 trial, which achieved its primary endpoint of DFS, the Food and Drug Administration (FDA) granted NeuVax a Special Protocol Assessment (SPA) for its Phase 3 PRESENT (Prevention of Recurrence in Early-Stage, Node-Positive Breast Cancer with Low-to-Intermediate HER2 Expression with NeuVax Treatment) study. The PRESENT trial is ongoing and additional information on the study can be found at www.neuvax.com. A randomized, multicenter, investigator-sponsored, 300 patient Phase 2b clinical trial is also enrolling patients to study NeuVax in combination with Herceptin® (trastuzumab; Genentech/Roche).

Our second product candidate, GALE-301 (Folate Binding Protein, or “FBP”), is derived from a protein that is over-expressed (20-80 fold) in more than 90% of ovarian and endometrial cancers. FBP is a highly immunogenic peptide that can stimulate CTLs to recognize and destroy preclinical FBP-expressing cancer cells. The FBP vaccine consists of the FBP peptide(s) combined with the immune adjuvant, recombinant human granulocyte macrophage-colony stimulating factor (rhGM-CSF). Galena’s FBP vaccine is currently in a Phase 1/2 trial in two gynecological cancers: ovarian and endometrial adenocarcinomas.

Our third product candidate, GALE-401 (anagrelide controlled release (CR)) was acquired on January 13, 2014. GALE-401 contains the active ingredient anagrelide, an FDA-approved product, which has been in use since the late 1990s for the treatment of Essential Thrombocythemia (ET). GALE-401 is a reformulated, controlled release version of anagrelide that is currently only given as an immediate release (IR) version. Multiple Phase 1 studies in approximately 90 patients have shown the drug to be effective at lowering platelet levels while reducing side effects that prevent patients from taking their therapy regularly. Based on a regulatory meeting with the FDA, Galena believes a 505(b)(2) regulatory filing is an acceptable paradigm for approval of GALE-401, with the reference drug Agrylin® (anagrelide; Shire Pharmaceuticals). The Phase 1 program has provided the desired PK/PD (pharmacokinetic/pharmacodynamic) profile to enable the Phase 2 initiation in 2014.

Our first commercial product, Abstral® (fentanyl) Sublingual Tablets, is an important treatment option for inadequately controlled breakthrough cancer pain (BTcP), which affects an estimated 40%-80% of all cancer patients. Abstral is approved by the FDA as a sublingual (under the tongue) tablet for the management of breakthrough pain in patients with cancer, 18 years of age and older, who are already receiving, and who are tolerant to, opioid therapy for their persistent baseline cancer pain. The innovative Abstral formulation delivers the analgesic power and increased bioavailability of micronized fentanyl in a convenient sublingual tablet which is designed to dissolve under the tongue in seconds, provide relief of breakthrough pain within minutes, and match the duration of the pain episode.

In the future, we may pursue selective strategic alliances and acquisitions of other cancer treatments to complement or add to our existing cancer product pipeline.

Critical Accounting Policies and Estimates

Use of Estimates

The preparation of our financial statements requires management to make estimates, allocations and judgments that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, management evaluates its estimates, including those related to impairment of goodwill and long-lived assets, accrued liabilities, net revenue, and certain expenses. Our estimates about the carrying values of assets and liabilities that are not readily apparent from other sources are based on historical experience and on other assumptions believed to be reasonable under the circumstances. Actual results may differ materially from these estimates under different assumptions or conditions. Additionally, the financial information included here may not necessarily reflect the financial position, operating results, changes in our invested equity and cash flows in the future.

Our significant accounting policies are summarized in the notes to our consolidated financial statements. We believe the following critical accounting policies involve significant judgments and estimates used in the preparation of our financial statements.

Net Revenue

The company recognizes revenue from the sale of Abstral. Revenue is recognized when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title has passed, (iii) the price is fixed or determinable and (iv) collectability is reasonably assured.

We sell Abstral product in the United States to wholesale pharmaceutical distributors and retail pharmacies, or collectively, our "customers," subject to rights of return. During the year ended December 31, 2013 , we began recognizing Abstral product sales at the time title transfers to our customer, and providing for an estimate of future product returns. Revenue from product sales is recorded net of provisions for estimated returns, prompt pay discounts, wholesaler discounts, rebates, chargebacks, patient assistance program rebates and other deductions as needed. Refer to Note 1 of the notes to the consolidated financial statements for a detailed description of these reserves.

Research and Development Expenses

Research and development costs are expensed as incurred. Included in research and development costs are wages, benefits and other operating costs, facilities, supplies, external services and overhead related to our research and development departments, and clinical trial expenses.

Clinical trial expenses include direct costs associated with contract research organizations ("CROs"), as well as well as patient-related costs at sites at which our trials are being conducted.

Direct costs associated with our CROs are generally payable on a time and materials basis, or when certain enrollment and monitoring milestones are achieved. Expense related to a milestone is recognized in the period in which the milestone is achieved or in which we determine that it is more likely than not that it will be achieved.

The invoicing from clinical trial sites can lag several months. We accrue these site costs based on our estimate of upfront set-up costs upon the screening of the first patient at each site, and the patient related costs based on our knowledge of patient enrollment status at each site.

Stock-Based Compensation

We follow the provisions of the Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) Topic 718, “Compensation — Stock Compensation” (“ASC 718”), which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees, non-employee directors, and consultants, including employee stock options. Stock compensation expense based on the grant date fair value estimated in accordance with the provisions of ASC 718 is recognized as an expense over the requisite service period.

For stock options granted as consideration for services rendered by non-employees, we recognize compensation expense in accordance with the requirements of FASB ASC Topic 505-50 (“ASC 505-50”), “Equity Based Payments to Non—Employees.” Non-employee option grants that do not vest immediately upon grant are recorded as an expense over the vesting period of the underlying stock options. At the end of each financial reporting period prior to vesting, the value of these options, as calculated using the Black-Scholes option-pricing model, will be re-measured using the fair value of our common stock and the non-cash compensation recognized during the period will be adjusted accordingly. Since the fair market value of options granted to non-employees is subject to change in the future, the amount of the future compensation expense will include fair value re-measurements until the stock options are fully vested.

The fair value of each option grant is estimated using the Black-Scholes option-pricing model, with the following weighted average assumptions to determine the fair value of all its stock options granted:

	2013	2012
Risk free interest rate	1.57%	1.05%
Volatility	77.98%	75.76%
Expected lives (years)	6.25	6.13
Expected dividend yield	0.00%	0.00%

The company’s expected common stock price volatility assumption is based upon the volatility of a basket of companies that we consider comparable to us. The expected life assumptions for employee grants were based upon the simplified method provided for under ASC 718-10, which averages the contractual term of the options of ten years with the average vesting term of four years for an average of six years. The expected life assumptions for non-employees were based upon the contractual terms of the options. The dividend yield assumption of zero is based upon the fact that the company has never paid cash dividends and presently has no intention of paying cash dividends in the future. The risk-free interest rate used for each grant was also based upon prevailing short-term interest rates.

The company has an estimated annualized forfeiture rate of 15.0% for options granted to employees, and 8.0% for options granted to senior management and no forfeiture rate for directors. The company will record additional expense if the actual forfeitures are lower than estimated and will record a recovery of prior expense if the actual forfeiture rates are higher than estimated.

Derivative Financial Instruments

During the normal course of business, from time to time, we issue warrants and options to vendors as consideration to perform services. We may also issue warrants as part of a debt or equity financing. We do not enter into any derivative contracts for speculative purposes.

We recognize all derivatives as assets or liabilities measured at fair value with changes in fair value of derivatives reflected as current period income or loss unless the derivatives qualify for hedge accounting and are accounted for as such. During the years ended December 31, 2013 and 2012, we issued warrants to purchase approximately 7,000,000 and 7,500,000 shares of common stock, respectively, in connection with equity transactions. In accordance with ASC Topic 815-40, "Derivatives and Hedging — Contracts in Entity's Own Stock" ("ASC 815-40"), the value of these warrants is required to be recorded as a liability, as the holders have an option to put the warrants back to us in certain events, as defined, and the warrants are determined not to be indexed to the company's own stock.

The derivative liabilities are remeasured each period end to the estimated fair value. The fair value of our derivative liabilities is estimated using the Black-Scholes option-pricing model, with the following assumptions at December 31:

	2013	2012
Risk free interest rate	0.11% – 1.61%	0.21% – 0.72%
Volatility	66.85% – 73.45%	69.79% – 82.48%
Expected lives (years)	0.59 – 4.72	1.59 – 4.98
Expected dividend yield	0.00%	0.00%

The company's expected common stock price volatility assumption is based upon the volatility of a basket of companies that we consider comparable to us. The expected life assumptions for the warrants is estimated to coincide with the contractual terms of the warrants.

Business Combinations and Asset Purchases

We allocate the purchase price of our acquisitions to the assets and liabilities acquired, including identifiable intangible assets, based on their respective fair values at the date of acquisition. Some of the items, including property and equipment, other intangible assets, certain accrued liabilities and other reserves require a degree of management judgment. Certain estimates may change as additional information becomes available. Management finalizes the purchase price allocation within 12 months of the acquisition date as certain initial accounting estimates are resolved.

Goodwill, Other Intangible Assets and Impairment of Long-Lived Assets

Goodwill and Intangible Assets — Goodwill and indefinite-lived intangible assets are not amortized but are tested annually for impairment at the reporting unit level, or more frequently if events and circumstances indicate impairment may have occurred. Factors the company considers important that could trigger an interim review for impairment include, but are not limited to, the following:

- significant changes in the manner of its use of acquired assets or the strategy for its overall business;
- significant negative industry or economic trends;
- significant decline in stock price for a sustained period; and
- significant decline in market capitalization relative to net book value.

Goodwill and other intangible assets with indefinite lives are evaluated for impairment first by a qualitative assessment to determine the likelihood of impairment. If it is determined that impairment is more likely than not, the company will then proceed to the two step impairment test. The first step is to compare the fair value of the reporting unit to the carrying amount of the reporting unit (the "First Step"). If the carrying amount exceeds the fair value, a second step must be followed to calculate impairment (the "Second Step"). Otherwise, if the fair value of the reporting unit exceeds the carrying amount, the goodwill is not considered to be impaired as of the measurement date. In its review of the carrying value of the goodwill for its single reporting unit and its indefinite-lived intangible assets, the company determines fair values of its goodwill using the market approach, and its indefinite-lived intangible assets using the income approach.

Intangible assets not considered indefinite-lived are reviewed for impairment when facts or circumstances suggest that the carrying value of these assets may not be recoverable. The company's policy is to identify and record impairment losses, if necessary, on intangible product rights when events and circumstances indicate that the assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amounts of those assets.

The company performed its review for impairment using the qualitative assessment for both goodwill and indefinite-lived intangible assets, and has determined that there has been no impairment to these assets as of December 31, 2013 .

Acquisitions and In-Licensing — For all in-licensed products and technologies, we perform an analysis to determine whether we hold a variable interest or a controlling financial interest in a variable interest entity. On the basis of our interpretations and conclusions, we determine whether the acquisition falls under the purview of variable interest entity accounting and if so, consider the necessity to consolidate the acquisition. As of December 31, 2013 , we determined there were no variable interest entities required to be consolidated.

The acquisition of the Abstral U.S. rights has been accounted for as an asset acquisition and not a business combination. The purchase price, including transaction costs, was recorded as an intangible asset related to the license and distribution rights acquired in the transaction. No other significant assets or liabilities were acquired or assumed in the transaction. The license and distribution rights will be amortized over ten years in a pattern based on our Abstral sales projections. Amortization expense, related to the Abstral rights, of $130,000 was recorded in cost of revenue for the year ended December 31, 2013 . There was no amortization recorded prior to the rear ended December 31, 2013 . Refer to Note 15 of the notes to the consolidated financial statements for further information regarding the acquisition of Abstral U.S. rights.

Valuation of Contingent Purchase Price Consideration

Acquisitions may include contingent consideration payments based on the achievement of certain future financial performance measures of the acquired company (earn-out). Contingent consideration is required to be recognized at fair value as of the acquisition date. We estimate the fair value of these liabilities based on financial projections of the acquired companies and estimated probabilities of achievement. We believe our estimates and assumptions are reasonable; however, there is significant judgment involved. We evaluate, on a routine, periodic basis, the estimated fair value of the contingent consideration and changes in estimated fair value, subsequent to the initial fair value estimate at the time of the acquisition, are reflected in income or expense in the consolidated statements of expenses. Changes in the fair value of contingent consideration obligations may result from changes in discount periods and rates, changes in the timing of development milestones achieved and changes in probability assumptions with respect to the likelihood of achieving the various earnout criteria. Any changes in the estimated fair value of contingent consideration may have a material impact on our operating results.

Results of Operations for the Years Ended December 31, 2013 , 2012 and 2011

For the year ended December 31, 2013 our loss from operations was $33.8 million compared with a loss from operations of $21.2 million and $12.5 million for the years ended December 31, 2012 and 2011, respectively. For the year ended December 31, 2013 , our net loss was $76.7 million compared with a net loss of $35.0 million and $11.5 million for the years ended December 31, 2012 and 2011, respectively.

Abstral is our first commercial product and revenue was recorded for the first time during the year ended December 31, 2013 . We expect to continue to incur significant costs and expenses in connection with our commercialization of Abstral in the U.S. before realizing a profit from the sale and distribution of Abstral. For these reasons, we expect our future results of operation to differ materially from our historical results.

Further analysis of the changes and trends in our operating results are discussed below.

Net Revenue

The company recognize revenue from the sale of Abstral to wholesale pharmaceutical distributors and retail pharmacies, net of product-related discounts, allowances, product returns, rebates, chargebacks, and patient assistance benefits, as applicable.

Net revenue for the years ended December 31, 2013 and 2012 were as follows (in thousands):

	Twelve Months Ended December 31,		
	2013	2012	$ Change
Net revenue	$ 2,487	$ —	$ 2,487

There was no revenue or net revenue in prior years given the launch of Abstral, our first and only commercial product, during 2013. We expect to net revenue to increase throughout 2014 based on anticipated increases in number of Abstral prescriptions fulfilled, combined with the execution of programs which are expected to significantly reduce our gross-to-net revenue adjustments. Our current expectations for 2014 net revenue from the sale of Abstral is approximately $11 milltion to $15 million, but there is no assurance we will achieve our expectations.

Cost of Revenue and Amortization of Certain Acquired Intangible Assets

Cost of revenue and amortization of certain acquired intangible assets for the years ended December 31, 2013 and 2012 were as follows (dollars in thousands):

	Year Ended December 31,			
	2013	% of net revenue	2012	% of net revenue
Cost of revenue (excluding amortization of certain acquired intangible assets:				
Abstral royalties	$ 298	12%	$ —	—
Direct product costs and related overhead	91	4%	—	—
Other cost of revenue	131	5%	—	—
Total cost of revenue (excluding amortization of certain acquired intangible assets	$ 520	21%	$ —	—
Amortization of certain acquired intangible assets	$ 130	5%	$ —	—

There was no cost of revenue or amortization of certain acquired intangible assets in prior years given the launch of Abstral, our first and only commercial product, during 2013. Cost of revenue, which excludes the amortization of certain acquired intangible assets, was $0.5 million for the year December 31, 2013 and zero for all prior years. Variable cost of revenue includes the royalty due to Orexo and product costs. Product related overhead and other cost of revenue are fixed in nature, and will decrease or increase as a percentage of net revenue as net revenue increases or decreases, respectively.

Amortization of certain acquired intangible assets was $0.1 million for the year ended December 31, 2013 and zero for all prior years. Amortization of certain acquired intangible assets is a non-cash variable cost based on net revenue during the period.

Research and Development Expense

Research and development expense consists primarily of clinical trial expenses and compensation-related costs for our employees dedicated to research and development activities, compensation paid to our Scientific Advisory Board (“SAB”) members, and licensing fees and patent prosecution costs. Research and development expenses also consist of costs related to the Abstral registry trial as described above. Research and development expense for the years ended December 31, 2013 and 2012 were as follows (dollars in thousands):

	Year Ended December 31,		
	2013	2012	% Change
Research and development expense	$ 21,076	$ 14,614	44%

The increase in research and development expense in 2013 was primarily related to the ramp-up of our Phase 3 PRESENT clinical trial and the related enrollment efforts. We expect research and development expense related to our PRESENT trial to remain at current levels through the first part of 2014, and then begin to decrease in the second half of 2014 as we complete the enrollment phase of the trial and transition to the monitoring and follow-up phase. The expected decrease in costs could be at partially offset by the increase in research and development expense related to the GALE-401 program, which we expect to complete enrollment in a Phase 2 clinical trial during 2014, and our Abstral Registry trial, which we also expect to complete enrollment during 2014.

Research and development expense for the years ended December 31, 2012 and 2011 were as follows (dollars in thousands):

	Year Ended December 31,		
	2012	2011	% Change
Research and development expense	$ 14,614	$ 3,851	279%

The increase in research and development expense was primarily related to the significant efforts in preparation for our Phase 3 PRESENT clinical trial of NeuVax.

Selling, General and Administrative Expense

Selling, general and administrative expense includes compensation-related costs for our employees dedicated to sales and marketing, general and administrative activities, legal fees, audit and tax fees, consultants and professional services, and general corporate expenses. Selling, general and administrative expense for the years ended December 31, 2013 and 2012 were as follows (dollars in thousands):

	Year Ended December 31,		
	2013	2012	% Change
Selling, general and administrative expense	$ 14,600	$ 6,585	122%

Selling, general and administrative expense increased during the year ended December 31, 2013 , primarily due to the establishment of our Abstral commercial sales force and marketing team, as well as other expenses related to the commencement of our commercial efforts and the launch of Abstral in the fourth quarter of 2013 and related corporate support.

Selling, general and administrative expense for the years ended December 31, 2012 and 2011 was as follows (dollars in thousands):

	Year Ended December 31,		
	2012	2011	% Change
Selling, general and administrative expense	$ 6,585	$ 8,635	(24)%

The decrease was primarily due to a decrease in cash-based expense due to the costs related to the spin-off of RXi, and a decrease for employee stock based compensation expense, largely due to the lower strike prices and volatility assumptions used to calculate stock based compensation using the Black Scholes pricing model. These decreases were partially offset by an increase in warrants and other stock based compensation issued to non-employees for business advisory and other services.

Non-Operating Income (Expense)

Non-operating expense for the year ended December 31, 2013 and 2012 was as follows (dollars in thousands):

	Year Ended December 31,		
	2013	2012	% Change
Non-operating expense	$ (41,786)	$ (13,178)	217%

The increase to our non-operating expense in 2013 was primarily due to a $33.2 million increase in the fair value of warrants accounted for as liabilities. This increase in the estimated fair value of our warrant liabilities was primarily due to the increase in our common stock price, rising from $1.59 per share as of January 1, 2013 to $4.96 per share as of December 31, 2013, which is one of the most impactful inputs into the pricing model we use to estimate the fair value of our warrant liabilities. We also incurred $0.8 million in interest expense related to the debt financing we completed in May 2013, an expense not incurred in prior years.

The increases to the warrant liabilities and interest expense were partially offset by realized gains on the sale of marketable securities of $3.9 million , with no such sales occurring in prior years, and a decrease to the loss on the change in the fair value of our contingent purchase price consideration.

Non-operating income (expense) for the year ended December 31, 2012 and 2011 was as follows (dollars in thousands):

	Year Ended December 31,		
	2012	2011	% Change
Non-operating income (expense)	$ (13,178)	$ 9,079	(245)%

The overall decrease in non-operating income was primarily due to a $19.8 million increase in the fair value of warrants accounted for as liabilities. This increase in the estimated fair value of our warrant liabilities was primarily due to the increase in our common stock price, rising from $0.47 per share as of January 1, 2012 to $1.57 per share as of December 31, 2012, which is one of the most impactful inputs into the pricing model we use to estimate the fair value of our warrant liabilities. We also incurred an additional non-cash expense of $2.5 million in the estimated fair value of the contingent purchase price consideration due to a shorter amount of time and a lower discount related to the time value of money, to the estimated date that some of the larger milestones will be reached.

Income Taxes

For the years ended December 31, 2013 and 2012, we recognized an income tax expense of $1.1 million and an income tax benefit of $1.1 million , respectively. This expense (benefit) offsets the tax impact related to the unrealized loss (gain) on our marketable securities, which is presented as other comprehensive income, net of tax, on our condensed consolidated statement of comprehensive loss. During 2013, we reclassified the entire amount of unrealized gain on marketable securities into net loss as we liquidated all of our marketable securities. There was no income tax expense or benefit during the year ended December 31, 2011. We continue to maintain a full valuation allowance against our net deferred tax assets.

Loss from Discontinued Operations

There is no loss from discontinued operations for the year ended December 31, 2013 due to the fact that the RXi spin-off that completed as of April 26, 2012, and RXi has operating as a separate unrelated entity since that date.

Liquidity and Capital Resources

We had cash and cash equivalents of approximately $47.8 million as of December 31, 2013 , compared with $32.8 million as of December 31, 2012.

The increase of approximately $15.0 million in cash and cash equivalents from December 31, 2012 to December 31, 2013 was attributable to $37.5 million of net proceeds from the issuance of common stock and warrants in our September 2013 underwritten public offering, $9.9 million of net proceeds from the issuance of long-term debt, $8.5 million proceeds from the exercise of common stock warrants and stock-based compensation awards, and $3.9 million in net proceeds from sale of marketable securities, partially offset by $31.4 million in net cash operating loss (exclusive of the $2.5 million change in working capital accounts), $15.7 million spent to purchase the U.S. commercialization rights to Abstral and the related inventory and equipment, and $0.5 million spent in finance charges paid with respect to our long-term debt.

We expect to continue to incur operating losses as we grow our commercial presence for Abstral in the U.S. and continue to advance our product candidates through the drug development and regulatory process. We will need to generate significant revenues to achieve profitability and may never do so. In the absence of profits from the commercialization of Abstral or our product candidates, our potential sources of operational funding are proceeds from the sale of equity and funded research and development payments and payments received under partnership and collaborative agreements.

We believe that our existing cash and cash equivalents, along with revenue from Abstral sales, should be sufficient to fund our operations into the foreseeable future. We also may borrow the remaining $5.0 million tranche of our recent long-term debt financing, subject to certain conditions. There is no guarantee that the remaining $5.0 million tranche will be available to us, or that we will generate sufficient revenue from the sale of Abstral to become profitable or that any debt, additional equity or other funding will be available to us on acceptable terms, or at all. If we fail to generate adequate revenues or obtain additional funding when needed, we would be forced to scale back, or terminate, our operations or to seek to merge with or to be acquired by another company.

Net Cash Flow from Operating Activities

Net cash used in operating activities was approximately $ 28.9 million for the year ended December 31, 2013 , compared with $21.0 million for the year ended December 31, 2012 . The increase of approximately $7.9 million resulted primarily from an increase in research and development activities related to our Phase 3 PRESENT trial, as well as approximately $12.5 million associated with the Abstral pre-launch activities.

Net Cash Flow from Investing Activities

Net cash used in investing activities was $ 12.0 million for the year ended December 31, 2013 , compared with $ 0.1 million for the year ended December 31, 2012 . The increase was primarily due to acquisition of Abstral for $15 million during the year ended December 31, 2013, partially offset by the realized gain from marketable securities.

Net Cash Flow from Financing Activities

Net cash provided by financing activities was $ 55.9 million for the year ended December 31, 2013 , compared with $42.4 million for the year ended December 31, 2012 . The increase was primarily due to net proceeds from the issuance of common stock in September 2013 of $37.5 million , compared with $36.4 million from the issuance of common stock in 2012, as well as to $ 9.9 million of net proceeds from the first tranche of our long-term debt financing in the second quarter of 2013, compared to no long-term debt in 2012. The increase from the prior year was partially offset by a decrease in proceeds from the exercise of warrants with $ 5.7 million from the exercise of warrants in 2012 compared to $ 7.8 million in the year ended December 31, 2013 .

Contractual Obligations

The following table sets forth our contractual obligations as of December 31, 2013 (in thousands):

	Payment Due by Period			
	Less than 1 Year	1 to 3 Years	3 to 5 Years	Total
Long-term debt [1]	$ 2,648	$ 4,451	$ 5,001	$ 12,100
Cancelable license agreements [2]	325	700	7,215	8,240
Non-cancelable employment agreements [2]	450	400	—	850
Non-cancelable operating leases [2]	72	157	152	381
Total	$ 3,495	$ 5,708	$ 12,368	$ 21,571

[1] Long-term debt payments presented are comprised of principle and interest payments. See Note 7 of the notes to the consolidated financial statements for additional information on the debt issued in May 2013.

[2] See Note 8 of the notes to the consolidated financial statements for additional information on the referenced contractual obligations.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet financing arrangements other than operating leases.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

The primary objective of our investment activities is to preserve capital. We do not utilize hedging contracts or similar instruments.

We are exposed to certain market risks relating primarily to (1) interest rate risk on our cash and cash equivalents, and (2) risks relating to the financial viability of the institutions which hold our capital and through which we have invested our funds. We manage such risks by investing primarily in money market mutual funds.

In addition, we are exposed to foreign currency exchange rate fluctuations relating to payments we make to certain vendors and suppliers and license partners using foreign currencies. We do not hedge against foreign currency risks. Consequently, changes in exchange rates could adversely affect our operating results and stock price. Such losses have not been significant to date.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

GALENA BIOPHARMA, INC.

FORM 10-K — FISCAL YEAR ENDED DECEMBER 31, 2013

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Galena Biopharma, Inc.

We have audited the accompanying consolidated balance sheets of Galena Biopharma, Inc. (the "Company") as of December 31, 2013, and the related consolidated statements of comprehensive loss, stockholders' equity, and cash flows for the year then ended. We also have audited the Company's internal control over financial reporting as of December 31, 2013, based on criteria established in *Internal Control - Integrated Framework (1992)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on these consolidated financial statements and an opinion on the Company's internal control over financial reporting based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audit of the consolidated financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall consolidated financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Galena Biopharma, Inc. as of December 31, 2013, and the consolidated results of its operations and its cash flows for the year ended December 31, 2013, in conformity with generally accepted accounting principles in the United States of America. Also in our opinion, Galena Biopharma, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2013, based on criteria established in Internal Control - Integrated Framework (1992) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

/s/ Moss Adams LLP

Portland, Oregon
March 17, 2014

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Galena Biopharma, Inc.
Portland, Oregon

We have audited the accompanying consolidated balance sheet of Galena Biopharma, Inc. (the "Company") as of December 31, 2012, and the related consolidated statements of comprehensive loss, stockholders' equity, and cash flows for the years ended December 31, 2012 and 2011. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Galena Biopharma, Inc. as of December 31, 2012 and the results of its operations and its cash flows for the years ended December 31, 2012 and 2011, in conformity with accounting principles generally accepted in the United States of America.

/s/ BDO USA, LLP

March 12, 2013
Seattle, Washington

GALENA BIOPHARMA, INC.
CONSOLIDATED BALANCE SHEETS
(Amounts in thousands, except share and per share data)

	December 31, 2013	December 31, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	$ 47,787	$ 32,807
Restricted cash	200	101
Marketable securities	—	2,678
Accounts receivable	3,683	—
Inventories	386	—
Prepaid expenses	1,399	535
Total current assets	53,455	36,121
Equipment and furnishings, net	665	29
Abstral rights, net	14,979	—
In-process research and development	12,864	12,864
Goodwill	5,898	5,898
Deposits and other assets	115	74
Total assets	$ 87,976	$ 54,986
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,660	$ 1,976
Accrued expenses and other current liabilities	8,667	2,038
Current maturities of capital lease obligations	6	6
Fair value of warrants potentially settleable in cash	48,965	10,964
Current portion of contingent purchase price consideration	—	935
Current portion of long-term debt	2,149	—
Total current liabilities	62,447	15,919
Capital lease obligations, net of current maturities	26	51
Deferred tax liability	5,053	5,053
Contingent purchase price consideration, net of current portion	6,821	6,207
Long-term debt, net of current portion	7,743	—
Total liabilities	82,090	27,230
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized, 110,100,701 shares issued and 109,425,701 shares outstanding at December 31, 2013; 125,000,000 shares authorized, 83,595,837 shares issued and 82,920,837 outstanding at December 31, 2012	10	8
Additional paid-in capital	188,600	132,168
Accumulated other comprehensive income	—	1,626
Accumulated deficit	(178,875)	(102,197)
Less treasury shares at cost, 675,000 shares	(3,849)	(3,849)
Total stockholders' equity	5,886	27,756
Total liabilities and stockholders' equity	$ 87,976	$ 54,986

See accompanying notes to consolidated financial statements.

GALENA BIOPHARMA, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(Amounts in thousands, except share and per share data)

	For the Year Ended December 31,		
	2013	2012	2011
Net revenue	$ 2,487	$ —	$ —
Costs and expenses:			
Cost of revenue (excluding amortization of certain acquired intangible assets)	520	—	—
Research and development	21,076	14,614	3,851
Selling, general and administrative	14,600	6,585	8,635
Amortization of certain acquired intangible assets	131	—	—
Total costs and expenses	36,327	21,199	12,486
Operating loss	(33,840)	(21,199)	(12,486)
Non-operating income (expense):			
Interest income (expense), net	(807)	(33)	(7)
Other income (expense)	(40,979)	(13,145)	9,086
Total non-operating income (expense), net	(41,786)	(13,178)	9,079
Loss from continuing operations before income taxes	(75,626)	(34,377)	(3,407)
Income tax expense (benefit)	1,052	(1,052)	—
Loss from continuing operations	(76,678)	(33,325)	(3,407)
Loss from discontinued operations	—	(1,644)	(8,078)
Net loss	$ (76,678)	$ (34,969)	$ (11,485)
Net loss per common share:			
Basic and diluted per share, continuing operations	$ (0.85)	$ (0.53)	$ (0.09)
Basic and diluted loss per share, discontinued operations	$ —	$ (0.03)	$ (0.22)
Basic and diluted net loss per share	$ (0.85)	$ (0.56)	$ (0.32)
Weighted-average common shares outstanding: basic and diluted	90,181,501	62,480,666	36,334,413
Comprehensive loss			
Net loss	$ (76,678)	$ (34,969)	$ (11,485)
Reclassification of unrealized gain upon sale of marketable securities	(2,678)	—	—
Unrealized gain on marketable securities	—	2,678	—
Tax effect of reclassification of unrealized gain upon sale of marketable securities	1,052	—	—
Tax effect of unrealized gain on marketable securities	—	(1,052)	—
Total comprehensive loss	$ (78,304)	$ (33,343)	$ (11,485)

See accompanying notes to consolidated financial statements.

GALENA BIOPHARMA, INC.
CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY
(Amounts in thousands, except share amounts)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Treasury Stock	Total
	Shares Issued	Amount					
Balance at December 31, 2010	19,047,759	$ 2	$ 62,020	$ —	$ (55,743)	$ (3,849)	$ 2,430
Issuance of common stock	18,650,000	2	18,613	—	—	—	18,615
Common stock warrants issued in connection with 2011 common stock offering	—	—	(12,709)	—	—	—	(12,709)
Issuance of stock in lieu of cash bonus	147,040	—	171	—	—	—	171
Issuance of restricted stock units	220,729	—	256	—	—	—	256
Issuance of common stock in exchange for services	53,558	—	73	—	—	—	73
Issuance of common stock upon exercise of warrants	4,301,000	—	3,270	—	—	—	3,270
Issuance of common stock related to acquisition of Apthera, Inc.	4,974,090	1	6,366	—	—	—	6,367
Issuance of common stock subject to employee termination agreements	398,453	—	350	—	—	—	350
Issuance of common stock in connection with employee stock purchase plan	18,824	—	15	—	—	—	15
Stock based compensation for directors and employees	—	—	2,774	—	—	—	2,774
Stock based compensation for services	—	—	(15)	—	—	—	(15)
Net loss	—	—	—	—	(11,485)	—	(11,485)
Balance at December 31, 2011	47,811,453	$ 5	$ 81,184	$ —	$ (67,228)	$ (3,849)	$ 10,112
Issuance of common stock	25,486,960	2	36,376	—	—	—	36,378
Common stock warrants issued in connection with 2012 common stock offering	—	—	(7,286)	—	—	—	(7,286)
Issuance of common stock in exchange for services	288,285	—	364	—	—	—	364
Issuance of common stock upon the exchange and exercise of warrants including reclassification of $10,843 in warrant liability upon exercise	8,433,003	1	16,550	—	—	—	16,551
Repurchase of common stock warrants	—	—	(266)	—	—	—	(266)
Issuance of common stock in connection with employee stock purchase plan	234,350	—	93	—	—	—	93
Stock based compensation for directors and employees	—	—	794	—	—	—	794
Stock based compensation for services	—	—	600	—	—	—	600
Exercise of stock options	25,937	—	21	—	—	—	21
Issuance of common stock in settlement of contingent purchase price consideration	1,315,849	—	1,579	—	—	—	1,579
Net liabilities distributed in connection with the RXi spin-off	—	—	2,159	—	—	—	2,159
Unrealized gain on marketable securities, net of tax benefit of $1,052	—	—	—	1,626	—	—	1,626
Net loss	—	—	—	—	(34,969)	—	(34,969)
Balance at December 31, 2012	83,595,837	$ 8	$ 132,168	$ 1,626	$ (102,197)	$ (3,849)	$ 27,756

GALENA BIOPHARMA, INC.
CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY
(Amounts in thousands, except share amounts)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Treasury Stock	Total
	Shares Issued	Amount					
Issuance of common stock	20,125,000	$ 2	$ 37,537	$ —	$ —	$ —	$ 37,539
Common stock warrants issued in connection with September 2013 common stock offering	—	—	(8,238)	—	—	—	(8,238)
Issuance of common stock upon exercise of warrants	5,320,669	—	22,064	—	—	—	22,064
Issuance of common stock in settlement of contingent purchase price consideration	492,988	—	1,247	—	—	—	1,247
Issuance of common stock warrants with long-term debt financing	—	—	351	—	—	—	351
Issuance of common stock in exchange for services	99,998	—	211	—	—	—	211
Issuance of common stock in connection with employee stock purchase plan	52,532	—	163	—	—	—	163
Stock based compensation for directors and employees	—	—	1,886	—	—	—	1,886
Stock based compensation for services	—	—	644	—	—	—	644
Reclassification of unrealized gain upon the sale of marketable securities, net of tax of $1,052	—	—	—	(1,626)	—	—	(1,626)
Exercise of stock options	413,677	—	567	—	—	—	567
Net loss	—	—	—	—	(76,678)	—	(76,678)
Balance at December 31, 2013	110,100,701	$ 10	$ 188,600	$ —	$ (178,875)	$ (3,849)	$ 5,886

See accompanying notes to consolidated financial statements.

GALENA BIOPHARMA, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Amounts in thousands)

	For the Year Ended December 31,		
	2013	**2012**	**2011**
Cash flows from operating activities:			
Net loss	$ (76,678)	$ (34,969)	$ (11,485)
Adjustment to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization expense	452	49	163
Loss on disposal of equipment	—	—	7
Gain on sale of marketable securities	(3,911)	—	—
Deferred taxes	1,052	(1,052)	—
Non-cash stock-based compensation	2,530	1,394	3,001
Fair value of common stock warrants issued in exchange for services	—	—	108
Fair value of common stock issued in exchange for services	211	364	73
Change in fair value of common stock warrants	44,001	10,775	(8,981)
Change in fair value of contingent consideration	926	2,370	(109)
Changes in operating assets and liabilities:			
Accounts receivable	(3,683)	—	—
Inventories	(386)	—	—
Prepaid expenses and other assets	(832)	(396)	(99)
Accounts payable	684	641	500
Accrued expenses and other current liabilities	6,726	(139)	2,154
Net cash used in operating activities	(28,908)	(20,963)	(14,668)
Cash flows from investing activities:			
Change in restricted cash	(99)	—	(101)
Cash paid for acquisition of Abstral rights	(15,143)	—	—
Cash received in Apthera acquisition	—	—	168
Proceeds from sale of marketable securities	3,911	—	—
Cash paid for purchase of equipment and furnishings	(705)	—	(53)
Cash transferred with the RXi spin-off	—	(87)	—
Net cash provided by (used in) investing activities	(12,036)	(87)	14
Cash flows from financing activities:			
Net proceeds from issuance of common stock	37,539	36,378	18,615
Cash paid for repurchase of warrants	—	(266)	—
Net proceeds from exercise of stock options	567	21	—
Proceeds from exercise of warrants	7,815	5,708	150
Proceeds from common stock issued in connection with ESPP	163	93	15
Net proceeds from issuance of RXi convertible notes payable	—	500	500
Net proceeds from issuance of long-term debt	9,865	—	—
Repayments of capital lease obligations	(25)	(10)	(84)
Net cash provided by financing activities	55,924	42,424	19,196
Net increase in cash and cash equivalents	14,980	21,374	4,542
Cash and cash equivalents at the beginning of period	32,807	11,433	6,891
Cash and cash equivalents at end of period	$ 47,787	$ 32,807	$ 11,433

	For the Year Ended December 31,		
	2013	**2012**	**2011**
Supplemental disclosure of cash flow information:			
Cash received during the periods for interest	$ 19	$ 1	$ 2
Cash paid during the periods for interest	$ 547	$ 1	$ 6
Supplemental disclosure of non-cash investing and financing activities:			
Fair value of warrants issued in connection with common stock recorded as cost of equity	$ 8,238	$ 7,286	$ 12,709
Issuance of common stock in exchange of outstanding warrants	$ —	$ —	$ 3,120
Net liabilities distributed to common stock holders in the RXi spin-off, net of cash transferred	$ —	$ 2,246	$ —
Reclassification of warrant liabilities upon exercise	$ 14,249	$ 10,843	$ —
Common stock issued in settlement of contingent purchase price consideration	$ 1,247	$ 1,579	$ —
Change in fair value of marketable securities before settlement	$ (2,678)	$ 2,678	$ —
NeuVax acquisition:			
Fair value of shares issued to acquire NeuVax	$ —	$ —	$ 6,367
Fair value of contingent purchase price consideration in connection with NeuVax acquisition	—	—	6,460
Net assets acquired, excluding cash of $168	$ —	$ —	$ 12,827

See accompanying notes to consolidated financial statements.

GALENA BIOPHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Business and Basis of Presentation

Galena Biopharma, Inc. (“we,” “us,” “our,” “Galena” or the “company”) is a biopharmaceutical company focused on developing and commercializing innovative, targeted treatments that address major unmet medical needs to advance cancer care.

Galena is developing peptide vaccine (off-the-shelf) cancer immunotherapies, which address patient populations of cancer survivors to prevent disease recurrence by harnessing the patient's own immune system to seek out and attack any residual cancer. In this case, 25% of resectable node-positive breast cancer patients, despite having no evidence of disease following surgery and chemo/radiation therapy, will still relapse within three years. Increased presence of circulating tumor cells (CTCs) predict Disease Free Survival (DFS) and Overall Survival (OS) - suggesting a dormancy of isolated micrometastases, which over time, leads to recurrence. Our lead product, NeuVaxTM (nelipepimut-S) elicits a robust, specific and durable killer CD8+ cytotoxic T lymphocyte (CTLs) response to lyse HER2 expressing tumor cells.

NeuVax™ (nelipepimut-S) is the immunodominant nonapeptide derived from the extracellular domain of the HER2 protein, a well-established target for therapeutic intervention in breast carcinoma. The nelipepimut sequence stimulates specific CTLs following binding to HLA-A2/A3 molecules on antigen presenting cells (APC). These activated specific CTLs recognize, neutralize and destroy, through cell lysis, HER2 expressing cancer cells, including occult cancer cells and micrometastatic foci. The nelipepimut immune response can also generate CTLs to other immunogenic peptides through inter- and intra-antigenic epitope spreading. Based on our Phase 2 trial, which achieved its primary endpoint of DFS, the Food and Drug Administration (FDA) granted NeuVax a Special Protocol Assessment (SPA) for its Phase 3 PRESENT (Prevention of Recurrence in Early-Stage, Node-Positive Breast Cancer with Low-to-Intermediate HER2 Expression with NeuVax Treatment) study. The PRESENT trial is ongoing and additional information on the study can be found at www.neuvax.com. A randomized, multicenter, investigator-sponsored, 300 patient Phase 2b clinical trial is also enrolling patients to study NeuVax in combination with Herceptin® (trastuzumab; Genentech/Roche).

Our second product candidate, GALE-301 (Folate Binding Protein, or “FBP”), is derived from a protein that is over-expressed (20-80 fold) in more than 90% of ovarian and endometrial cancers. FBP is a highly immunogenic peptide that can stimulate CTLs to recognize and destroy preclinical FBP-expressing cancer cells. The FBP vaccine consists of the FBP peptide(s) combined with the immune adjuvant, recombinant human granulocyte macrophage-colony stimulating factor (rhGM-CSF). Galena’s FBP vaccine is currently in a Phase 1/2 trial in two gynecological cancers: ovarian and endometrial adenocarcinomas.

Our third product candidate, GALE-401 (anagrelide controlled release (CR)) was acquired on January 13, 2014. GALE-401 contains the active ingredient anagrelide, an FDA-approved product, which has been in use since the late 1990s for the treatment of essential thrombocythemia (ET). GALE-401 is a reformulated, controlled release version of anagrelide that is currently only given as an immediate release (IR) version. Multiple Phase 1 studies in an aggregate 90 patients have shown the drug to be effective at lowering platelet levels while reducing side effects that prevent patients from taking their therapy regularly. Based on a regulatory meeting with the FDA, Galena believes a 505(b)(2) regulatory filing is an acceptable paradigm for approval of GALE-401, with the reference drug Agrylin® (anagrelide; Shire Pharmaceuticals). The Phase 1 program has provided the desired PK/PD (pharmacokinetic/pharmacodynamic) profile to enable the Phase 2 initiation in 2014.

Our first commercial product, Abstral® (fentanyl) Sublingual Tablets, is an important treatment option for inadequately controlled breakthrough cancer pain (BTcP) which affects an estimated 40%-80% of all cancer patients. Abstral is approved by the FDA, as a sublingual (under the tongue) tablet for the management of breakthrough pain in patients with cancer, 18 years of age and older, who are already receiving, and who are tolerant to, opioid therapy for their persistent baseline cancer pain. The innovative Abstral formulation delivers the analgesic power and increased bioavailability of micronized fentanyl in a convenient sublingual tablet which is designed to dissolve under the tongue in seconds, provide relief of breakthrough pain within minutes, and match the duration of the pain episode.

GALENA BIOPHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - Continued

Basis of Presentation and Significant Accounting Policies

The accompanying consolidated financial statements included herein have been prepared by Galena pursuant to the rules and regulations of the Securities and Exchange Commission (SEC). Unless the context otherwise indicates, references in this these notes to the "company," "we," "us" or "our" refer (i) to Galena, our wholly owned subsidiary, Apthera, Inc., or "Apthera," and our former subsidiary, RXi Pharmaceuticals Corporation, or "RXi," collectively, prior to our partial spin-off of RXi in April 2012; and (ii) to Galena and Apthera, together, after the partial spin-off.

Based on the product launch of Abstral and the significant commercial operations during the second half of 2013, Galena is no longer a development stage entity in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 915, *"Development Stage Entities,"* and the financial statements for the period ended December 31, 2013 will no longer reflect financial information since inception.

Uses of Estimates in Preparation of Financial Statements — The preparation of these consolidated financial statements in accordance with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ materially from those estimates.

Principles of Consolidation — The consolidated financial statements include the accounts of Galena and its wholly owned subsidiary. All material intercompany accounts have been eliminated in consolidation.

Reclassifications — Certain prior year amounts have been reclassified to conform to current year presentation. These reclassifications had no effect on net loss per share.

Cash and Cash Equivalents — The company considers all highly liquid debt instruments with an original maturity of 90 days or less to be cash equivalents. Cash equivalents consist primarily of amounts invested in money market accounts and demand deposits.

Restricted Cash — Restricted cash consists of certificates of deposit on hand with the company's financial institutions as collateral for its corporate credit cards.

Marketable Securities — Marketable securities consist of shares of common stock of our former subsidiary, RXi Pharmaceuticals Corporation, a publicly traded company, and are classified as available-for-sale and carried at fair value on the balance sheet. Changes in the fair value of marketable securities are recorded as other comprehensive income (loss).

Fair Value of Financial Instruments — The carrying amounts reported in the balance sheet for cash equivalents, marketable securities, accounts receivable, accounts payable, and capital leases approximate their fair values due to their short-term nature and market rates of interest.

Accounts Receivable - The company maintains credit limits for all customers based upon several factors, including but not limited to financial condition and stability, payment history, published credit reports and use of credit references. Management performs analysis to evaluate accounts receivables to ensure recorded amounts reflect estimate net realizable value.

Inventories — Inventories are stated at the lower of cost or market value and are determined using the first-in, first-out ("FIFO") method. Inventories consist of Abstral work-in-process and finished goods. The company has entered into manufacturing and supply agreements for the manufacture and packing of Abstral finished goods. As of December 31, 2013 , the company had inventories of $386,000 , consisting of $270,000 of work-in-process and $116,000 of finished goods. The company had no inventory as of December 31, 2012.

Equipment and Furnishings — Equipment and furnishings are stated at cost and depreciated using the straight-line method based on the estimated useful lives (generally three to five years for equipment and furniture) of the related assets.

GALENA BIOPHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - Continued

Goodwill and Intangible Assets — Goodwill and indefinite-lived intangible assets are not amortized but are tested annually for impairment at the reporting unit level, or more frequently if events and circumstances indicate impairment may have occurred. Factors the company considers important that could trigger an interim review for impairment include, but are not limited to, the following:

- Significant changes in the manner of its use of acquired assets or the strategy for its overall business;
- Significant negative industry or economic trends;
- Significant decline in stock price for a sustained period; and
- Significant decline in market capitalization relative to net book value.

Goodwill and other intangible assets with indefinite lives are evaluated for impairment first by a qualitative assessment to determine the likelihood of impairment. If it is determined that impairment is more likely than not, the company will then proceed to the two step impairment test. The first step is to compare the fair value of the reporting unit to the carrying amount of the reporting unit (the “First Step”). If the carrying amount exceeds the fair value, a second step must be followed to calculate impairment (the “Second Step”). Otherwise, if the fair value of the reporting unit exceeds the carrying amount, the goodwill is not considered to be impaired as of the measurement date. In its review of the carrying value of the goodwill for its single reporting unit and its indefinite-lived intangible assets, the company determines fair values of its goodwill using the market approach, and its indefinite-lived intangible assets using the income approach.

Intangible assets not considered indefinite-lived are reviewed for impairment when facts or circumstances suggest that the carrying value of these assets may not be recoverable. The company’s policy is to identify and record impairment losses, if necessary, on intangible product rights when events and circumstances indicate that the assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amounts of those assets.

The company performed its review for impairment using the qualitative assessment for both goodwill and indefinite-lived intangible assets, and has determined that there has been no impairment to these assets as of December 31, 2013 .

Revenue Recognition - The company recognizes revenue from the sale of Abstral. Revenue is recognized when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title has passed, (iii) the price is fixed or determinable and (iv) collectability is reasonably assured.

We sell Abstral product in the United States to wholesale pharmaceutical distributors and retail pharmacies, or collectively, our "customers," subject to rights of return. During the year ended December 31, 2013 , we began recognizing Abstral product sales at the time title transfers to our customer, and providing for an estimate of future product returns. Revenue from product sales is recorded net of provisions for estimated returns, prompt pay discounts, wholesaler discounts, rebates, chargebacks, patient assistance program rebates and other deductions as needed.

Returns - The company estimates future returns based on historical return information, as well as information regarding prescription information and sell-through trends, in relation to the estimated amount of product in the sales channels and product expiration dates. No reserve for future returns was deemed necessary at December 31, 2013.

Product Sales Discounts and Allowances - The company recognizes revenue at the point of sale to its wholesale pharmaceutical distributors and retail pharmacies and the allowances for product returns, rebates and allowances are recognized at the point of sale. The company is required to make significant judgments and estimates in determining some of these allowances. If actual results differ from its estimates, the company will be required to make adjustments to these allowances in the future.

Prompt Pay Discounts - As an incentive for prompt payment, the company offers a cash discount to customers, generally 2% of gross sales. The company expects that all customers will comply with the contractual terms to earn the discount. The company records the discount as an allowance against accounts receivable and a reduction of revenue.

Wholesaler Discounts - The company offers discounts to certain wholesalers and distributors based on contractually determined rates. The company accrues the discount as a reduction of receivables due from the wholesalers upon shipment to the respective wholesale distributors and retail pharmacies and recognizes the discount as a reduction of revenue in the same period the related revenue is recognized.

Rebates - The company participates in certain rebate programs, which provide discounted prescriptions to members of group purchasing organization and specialty pharmacies. Under these rebate programs, the company pays a rebate to the third-party administrator of the program, generally two to the three months after the quarter in which prescriptions subject to the rebate are filled. The company estimates and accrues these rebates based on current contract prices, historical and estimated future percentages of product sold to qualifying member pharmacies and estimated levels of inventory in the distribution channel. Rebates are recognized as a reduction in the period that the related revenue is recognized.

Chargebacks - The company provides discounts primarily to authorized users of the Federal Supply Schedule (FSS) of the General Services Administration under an FSS contract negotiated by the Department of Veterans Affairs and various organizations under Medicaid or Medicare contracts and regulations. These entities purchase products from the wholesale distributors at a discounted price, and the wholesale distributors then charge back to the company the difference between the current retail price and the price the entity paid for the product. The company estimates and accrues chargebacks based on estimated wholesaler inventory levels, current contract prices and historic chargeback activity. Chargebacks are recognized as a reduction of revenue in the period the related revenue is recognized.

Patient Assistance Programs - The company offers discount card programs to patients for Abstral in which patients receive discounts on their Abstral prescriptions that are reimbursed by the company. The company estimates the total amount that will be recognized based on a percentage of actual redemption applied to inventory in the distribution and retail channel and recognizes the discount as a reduction of revenue and as an other current liability (see Note 6) in the same period the related revenue is recognized.

Acquisitions and In-Licensing — For all in-licensed products and technologies, we perform an analysis to determine whether we hold a variable interest or a controlling financial interest in a variable interest entity. On the basis of our interpretations and conclusions, we determine whether the acquisition falls under the purview of variable interest entity accounting and if so, consider the necessity to consolidate the acquisition. As of December 31, 2013 , we determined there were no variable interest entities required to be consolidated.

We also perform an analysis to determine if the assets and liabilities acquired in an acquisition qualify as a "business." The excess of the purchase price over the fair value of the net assets acquired can only be recognized as goodwill in a business combination.

The acquisition of the Abstral U.S. rights has been accounted for as an asset acquisition and not a business combination. The purchase price, including transaction costs, was recorded as an intangible asset related to the license and distribution rights acquired in the transaction. No other significant assets or liabilities were acquired or assumed in the transaction. The license and distribution rights will be amortized over ten years in a pattern based on our Abstral sales projections. Amortization expense, related to the Abstral rights, of $131,000 was recorded in amortization of certain acquired intangible assess in the statement of comprehensive loss for the year ended December 31, 2013 . There was no amortization recorded prior to the year ended December 31, 2013 . Refer to Note 15 for further information regarding the acquisition of Abstral U.S. rights.

Contingent Purchase Price Consideration — Contingent consideration is recorded at the estimated fair value as of the acquisition date. The fair value of the contingent consideration is remeasured at each reporting period with any adjustments in fair value included in our consolidated statement of comprehensive loss.

Patents and Patent Application Costs — Although the company believes that its patents and underlying technology have continuing value, the amount of future benefits to be derived from the patents is uncertain. Patent costs are, therefore, expensed as incurred.

GALENA BIOPHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - Continued

Share-based Compensation — The company follows the provisions of the FASB ASC Topic 718, " *Compensation — Stock Compensation"* ("ASC 718"), which requires the measurement and recognition of compensation expense for all stock-based payment awards made to employees, non-employee directors, and consultants, including stock options and warrants. Stock compensation expense based on the grant date fair value estimated in accordance with the provisions of ASC 718 is recognized as an expense over the requisite service period.

For stock options and warrants granted as consideration for services rendered by non-employees, the company recognizes compensation expense in accordance with the requirements of FASB ASC Topic 505-50 ("ASC 505-50"), " *Equity Based Payments to Non- Employees* ." Non-employee option and warrant grants that do not vest immediately upon grant are recorded as an expense over the vesting period. At the end of each financial reporting period prior to vesting, the value of these options and warrants, as calculated using the Black-Scholes option-pricing model, will be re-measured using the fair value of the company's common stock and the non-cash compensation recognized during the period will be adjusted accordingly. Since the fair market value of options and warrants granted to non-employees is subject to change in the future, the amount of the future compensation expense will include fair value re-measurements until the stock options are fully vested.

Research and Development Expenses — Research and development costs are expensed as incurred. Included in research and development costs are wages, benefits and other operating costs, facilities, supplies, external services and overhead related to our research and development departments, and clinical trial expenses.

Clinical trial expenses include direct costs associated with contract research organizations ("CROs"), as well as well as patient-related costs at sites at which our trials are being conducted.

Direct costs associated with our CROs are generally payable on a time and materials basis, or when certain enrollment and monitoring milestones are achieved. Expense related to a milestone is recognized in the period in which the milestone is achieved or in which we determine that it is more likely than not that it will be achieved.

The invoicing from clinical trial sites can lag several months. We accrue these site costs based on our estimate of upfront set-up costs upon the screening of the first patient at each site, and the patient related costs based on our knowledge of patient enrollment status at each site.

Income Taxes — The company recognizes liabilities or assets for the deferred tax consequences of temporary differences between the tax basis of assets or liabilities and their reported amounts in the financial statements in accordance with FASB ASC 740-10, " *Accounting for Income Taxes" ("ASC 740-10").* These temporary differences will result in taxable or deductible amounts in future years when the reported amounts of the assets or liabilities are recovered or settled. *ASC 740-10* requires that a valuation allowance be established when management determines that it is more likely than not that all or a portion of a deferred asset will not be realized. The company evaluates the realizability of its net deferred income tax assets and valuation allowances as necessary, at least on an annual basis. During this evaluation, the company reviews its forecasts of income in conjunction with other positive and negative evidence surrounding the realizability of its deferred income tax assets to determine if a valuation allowance is required. Adjustments to the valuation allowance will increase or decrease the company's income tax provision or benefit. The recognition and measurement of benefits related to the company's tax positions requires significant judgment, as uncertainties often exist with respect to new laws, new interpretations of existing laws, and rulings by taxing authorities. Differences between actual results and the company's assumptions or changes in the company's assumptions in future periods are recorded in the period they become known.

For the year ended December 31, 2013 , we recognized an income tax expense of $1,052,000 , which offsets the tax impact related to the unrealized gain on our marketable securities that were reclassified to realized gain on the sale of marketable securities during the year. We continue to maintain a full valuation allowance against our net deferred tax assets.

Concentrations of Credit Risk — Financial instruments that potentially subject the company to significant concentrations of credit risk consist principally of cash and cash equivalents. The company maintains cash balances in several accounts with two banks, which at times are in excess of federally insured limits. As of December 31, 2013 , the company's cash equivalents were invested in money market mutual funds. The company's investment policy does not allow investment in any debt securities rated less than "investment grade" by national ratings services. The company has not experienced any losses on its deposits of cash and cash equivalents. As of December 31, 2013 , we had approximately $47,240,000 in interest-bearing accounts above federally insured limits.

Comprehensive Loss — Comprehensive loss consists of our net loss and other comprehensive income related to the unrealized gain (loss), net of tax, on our marketable securities, which are classified as available-for-sale.

2. Recently Adopted Accounting Pronouncements

In February 2013, the FASB issued ASU No. 2013-02, *Comprehensive Income (Topic 220): Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income* , a new accounting pronouncement intended to improve the reporting of reclassifications out of accumulated other comprehensive income. The new standard requires an entity to provide information about the amounts reclassified out of accumulated other comprehensive income by component. The new standard also requires an entity to present, either on the face of the statement where net income is presented or in the notes, significant amounts reclassified out of accumulated other comprehensive income by the respective line items of net income if the amount reclassified is required to be reclassified to net income in its entirety in the same reporting period. For amounts not required to be reclassified in their entirety in the same reporting period, an entity is required to cross-reference to other required disclosures that provide additional detail about those amounts. The new standard was effective for reporting periods beginning after December 31, 2012. Adoption of this new standard for the year ended December 31, 2013 did not have a material impact on the company's consolidated financial statements.

Note 3. NeuVax™ Acquisition

On April 13, 2011 , the company acquired its late stage product candidate, NeuVax, through a merger acquisition of Apthera, Inc., a Delaware corporation ("Apthera"), with Apthera surviving as a wholly-owned subsidiary of the company. At the closing of the merger, the company issued to Apthera's stockholders approximately 5.0 million shares of common stock of the company and agreed to pay to the former Apthera shareholders future contingent consideration of up to $32 million based on the achievement of specified development and commercial milestones relating to the NeuVax, of which $2 million had been paid as of December 31, 2013. The remaining $30 million of contingent consideration is payable, at the election of the company, in cash or in additional shares of common stock valued for this purpose at the market price of the company common stock when the contingent consideration becomes payable.

The goodwill associated with the acquisition is not deductible for tax purposes.

The purchase price consideration and allocation of purchase price were as follows (in thousands):

Calculation of allocable purchase price:			
Fair value of shares issued at closing including escrowed shares expected to be released	$	6,367	(i)
Estimated value of earn-out		6,460	
Total allocable purchase price	$	12,827	
Allocation of purchase price:			
Cash	$	168	
Prepaid expenses and other current assets		14	
Equipment and furnishings		11	
Goodwill		5,898	
In-process research and development		12,864	
Accounts payable		(931)	
Accrued expenses and other current liabilities		(143)	
Notes payable		(1)	
Deferred tax liability, non-current		(5,053)	
	$	12,827	

(i) The value of the company's common stock was based upon a per share value of $1.28 , the closing price of the company's common stock as of the close of business on April 13, 2011.

The company recorded the estimated fair value of the contingent consideration at $6.5 million based on the expected probability of achieving the specified development and commercial milestones relating to the company's NeuVax product candidate and then applying a discount rate, based on a corporate debt interest rate index publicly issued, to the expected future payments. The expected timing and probability of achieving each milestone and the discount rates applied are reviewed quarterly using the most current information to measure the contingent consideration as of the reporting date. On January 19, 2012, the first milestone was achieved, and the company issued into escrow in favor of the former Apthera shareholders $1,000,000 , or 1,315,849 shares, of common stock in payment of the related contingent consideration. The number of shares was based on the $0.76 closing price of the company's common stock as reported on The NASDAQ Capital Market on January 18, 2012, the day prior to achievement of the first milestone. In September 2012, the escrowed shares were released to the former Apthera shareholders from escrow, and the company paid to the former Apthera shareholders cash of $35,016 , representing an interest factor of ten percent 10% per annum on the $1,000,000 amount of the milestone payment from February 10, 2012 through the day immediately prior to the release of the escrowed shares. During the year ended December 31, 2012, the company recorded additional other expense of $579,000 , related to the change in the fair value of the escrowed shares up to the date of release from escrow. In June 2013, the company achieved another milestone under the contingent value rights agreement, resulting in a $1,247,000 milestone payment that was paid by issuing 492,988 shares of our common stock.

The increase in the fair value of the contingent liability during the years ended December 31, 2013 and 2012, was $926,000 and $2,370,000 , respectively, and the decrease in the fair value of the contingent liability during the year ended December 31, 2011 was $109,000 . The changes in the fair value of the contingent liability are included in other income (expense) in the accompanying consolidated statements of expenses. The fair value of the contingent liability at December 31, 2013 and 2012 was $6,821,000 and $7,142,000 , of which $0 and $935,000 is recorded as a current contingent liability, respectively.

The following presents the unaudited, pro forma net loss and pro forma net loss per common share of the company for year ended December 31, 2011 as if the company's acquisition of Apthera occurred as of January 1, 2011 (in thousands expect for per share data):

	For the Year Ended December 31, 2011
Net loss from continuing operations	$ (4,700)
Net loss from discontinued operations	$ (8,078)
Net loss per common share, continuing operations	$ (0.12)
Net loss per common share, discontinued operations	$ (0.21)
Net loss per common share	$ (0.34)

4. RXi Spin-off

On September 24, 2011, the company entered into a contribution agreement with our former subsidiary, RXi Pharmaceuticals Corporation, or "RXi," pursuant to which we assigned and contributed to RXi substantially all of the company's RNAi-related technologies and assets. The contributed assets consisted primarily of our novel RNAi compounds and licenses relating to our RNAi technologies, as well as the lease of our Worcester, Massachusetts laboratory facility, fixed assets and other equipment located at the facility and our employment arrangements with certain scientific, corporate and administrative personnel who became employees of RXi. The company also contributed $1.5 million of cash to the capital of RXi.

Pursuant to the contribution agreement, RXi assumed certain accrued expenses of our former RXI-109 development program and all subsequent obligations under the contributed licenses, employment arrangements and other agreements. RXi also has agreed to make future milestone payments to us of up to $45 million , consisting of two one-time payments of $15 million and $30 million , respectively, if RXi achieves annual net sales equal to or greater than $500 million and $1 billion , respectively, of any covered products that may be developed with the contributed RNAi technologies.

The company agreed in the securities purchase agreement to distribute to our stockholders on a share-for-share basis a total of approximately 66,959,894 RXi shares, which distribution was made in April 2012. The company retained 33,476,595 shares of common stock of RXi, which were subject to a one -year lock-up period that expired on April 27, 2013 . On July 24, 2013, RXi effected a 1-for- 30 reverse stock split of its outstanding shares of common stock, including RXi shares held by the company. During the year ended December 31, 2013 , the company sold 1,115,887 RXi shares, on a post-split basis, for total proceeds of $3,911,000 , which is included in other income as realized gains on sale of marketable securities. There were no shares sold during the year ended December 31, 2012 .

The company fully liquidated its position in RXi common stock during the year ended December 31, 2013. The value of RXi shares held by the company at December 31, 2012 was $2,678,000 , based on the closing price of RXi shares on the last trading day of the year of $2.40 per share, on a post-split basis, as reported on the OTCQX marketplace.

The company classified the RXi activities for previously reported periods as discontinued operations in the accompanying condensed consolidated statements of comprehensive loss retroactively for all periods presented. The net assets of RXi were removed from the condensed consolidated balance sheet as of the date of the spin-off, and were recorded as an equity distribution.

5. Fair Value Measurements

The company follows ASC 820, “Fair Value Measurements and Disclosures,” (“ASC 820”) for the company’s financial assets and liabilities that are re-measured and reported at fair value at each reporting period, and are re-measured and reported at fair value at least annually using a fair value hierarchy that is broken down into three levels. Level inputs are as defined as follows:

Level 1 — quoted prices in active markets for identical assets or liabilities.
Level 2 — other significant observable inputs for the assets or liabilities through corroboration with market data at the measurement date.
Level 3 — significant unobservable inputs that reflect management’s best estimate of what market participants would use to price the assets or liabilities at the measurement date.

The company categorized its cash equivalents and marketable securities as Level 1 inputs. The valuations for Level 1 were determined based on a “market approach” using quoted prices in active markets for identical assets. Valuation of these assets does not require a significant degree of judgment. The company categorized its warrants potentially settleable in cash as Level 2 inputs. The warrants are measured at market value on a recurring basis and are being marked to market each quarter-end until they are completely settled. The warrants are valued using an appropriate pricing model, using assumptions consistent with our application of ASC 718. The contingent purchase price consideration is categorized as Level 3 inputs and is measured at its estimated fair value on a recurring basis and is adjusted at each quarter-end until it is completely settled. The contingent price consideration is valued based on the expected timing of milestones, the expected probability of success for each milestone and discount rates based on a corporate debt interest rate index publicly issued.

The following tables present information about our assets and liabilities measured at fair value on a recurring basis in the condensed consolidated balance sheets (in thousands):

Description	December 31, 2013	Quoted Prices In Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$ 42,349	$ 42,349	$ —	$ —
Marketable securities	—	—	—	—
Total assets measured and recorded at fair value	$ 42,349	$ 42,349	$ —	$ —
Liabilities:				
Warrants potentially settleable in cash	$ 48,965	$ —	$ 48,965	$ —
Contingent purchase price consideration	6,821	—	—	6,821
Total liabilities measured and recorded at fair value	$ 55,786	$ —	$ 48,965	$ 6,821

Description	December 31, 2012	Quoted Prices In Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$ 32,431	$ 32,431	$ —	$ —
Marketable securities	2,678	2,678	—	—
Total assets measured and recorded at fair value	$ 35,109	$ 35,109	$ —	$ —
Liabilities:				
Warrants potentially settleable in cash	$ 10,964	$ —	$ 10,964	$ —
Contingent purchase price consideration	7,142	—	—	7,142
Total liabilities measured and recorded at fair value	$ 18,106	$ —	$ 10,964	$ 7,142

The company has not transferred any financial instruments into or out of Level 3 classification during the years ended December 31, 2013 or 2012. A reconciliation of the beginning and ending Level 3 liabilities for the years ended December 31, 2013 and 2012 is as follows (in thousands):

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3)
Balance, January 1, 2012	$ 6,351
Milestone payment	(1,579)
Change in the estimated fair value of the contingent purchase price consideration	2,370
Balance, December 31, 2012	7,142
Milestone payment	(1,247)
Change in the estimated fair value of the contingent purchase price consideration	926
Balance at December 31, 2013	$ 6,821

The fair value of the contingent purchase price consideration is measured at the end of each reporting period using Level 3 inputs in a probability-weighted, discounted cash-outflow model. The significant unobservable assumptions include the probability of achieving each milestone, the date we expect to reach the milestone, and a determination of present value factors used to discount future expected cash outflows.

6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following (in thousands):

	December 31, 2013	December 31, 2012
Clinical development expense	$ 3,109	$ 1,705
Patient assistance programs	2,618	—
Compensation and related benefits	1,999	217
Professional fees	713	116
Royalties	158	—
Interest expense	70	—
Accrued expenses and other current liabilities	$ 8,667	$ 2,038

7. Long-term Debt

On May 8, 2013 we entered into a loan and security agreement with Oxford Finance LLC, as collateral agent, and related lenders under which we may borrow up to $15 million (the "Loan") in two tranches. We borrowed the first tranche of $10 million on May 8, 2013, and may borrow the second tranche of $5 million on or before May 31, 2014, subject to our achievement of certain operational and financial conditions. There is no assurance these conditions will be achieved. The Loan payments will include 12 months of interest-only payments at the fixed coupon rate of 8.45% , followed by 30 months of amortization of principal and interest until maturity in November 2016. In connection with the Loan, we paid the lender a 1% cash facility fee and a 5.5% cash final payment and granted to the lenders seven -year warrants to purchase up to 182,186 shares of our common stock at an exercise price of $2.47 , which equaled a 20 -day average market price of our common stock prior to the date of the grant.

As of December 31, 2013, future schedule principal payments to be made on long-term debt are as follows (in thousands):

For the year ending December 31, 2014	$ 2,149
2015	3,938
2016	3,913
Total future principal payments	10,000
Unamortized debt issuance costs (net of fair value of warrants issued)	(108)
Total debt	9,892
Less current portion	(2,149)
Total long-term debt, net	$ 7,743

8. Commitments and Contingencies

The company acquires assets still in development and enters into research and development arrangements with third parties that often require milestone and royalty payments based on the progress of the asset through development stages. Milestone payments may be required, for example, upon approval of the product for marketing by a regulatory agency. In certain agreements, the company is required to make royalty payments based upon a percentage of the sales. Because of the contingent nature of these payments, they are not included in the table of contractual obligations shown below.

These arrangements may be material individually, and in the unlikely event that milestones for multiple products covered by these arrangements were reached in the same period, the aggregate charge to expense could be material to the results of operations. In addition, these arrangements often give the company the discretion to unilaterally terminate development of the product, which would allow the company to avoid making the contingent payments; however, the company is unlikely to cease development if the compound successfully achieves clinical testing objectives. The company's contractual obligations that will require future cash payments as of December 31, 2013 are as follows (in thousands):

	Operating Leases [1]	Non-Cancelable Employment Agreements [2]	Subtotal	Cancelable License Agreements [3]	Total
2014	$ 72	$ 450	$ 522	$ 325	$ 847
2015	74	300	374	350	724
2016	83	100	183	350	533
2017	82	—	82	350	432
2018	70	—	70	6,865	6,935
Total	$ 381	$ 850	$ 1,231	$ 8,240	$ 9,471

[1] Operating leases are primarily facility and equipment related obligations with third party vendors. Operating lease expenses during the years ended December 31, 2013, 2012, and 2011 were approximately $77,000 , $139,000 and $233,000 , respectively.

(2) Employment agreement obligations include management contracts, as well as scientific advisory board member compensation agreements. Certain agreements, which have been revised from time to time, provide for minimum salary levels, adjusted annually at the discretion of the Compensation Committee, as well as for minimum bonuses that are payable.

(3) License agreements generally relate to the company's obligations with The Board of Regents, University of Texas and Henry Jackson Foundation for our oncology therapies. The company continually assesses the progress of its licensed technology and the progress of its research and development efforts as it relates to its licensed technology and may terminate with notice to the licensor at any time. In the event these licenses are terminated, no amounts will be due.

The company applies the disclosure provisions FASB ASC Topic 460 ("ASC 460"), " *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others* ", to its agreements that contain guarantee or indemnification clauses. The company provides (i) indemnifications of varying scope and size to certain investors and other parties for certain losses suffered or incurred by the indemnified party in connection with various types of third-party claims and (ii) indemnifications of varying scope and size to officers and directors against third party claims arising from the services they provide to us. These indemnifications give rise only to the disclosure provisions of ASC 460. To date, the company has not incurred costs as a result of these obligations and does not expect to incur material costs in the future. Accordingly, the company has not accrued any liabilities in its financial statements related to these indemnifications.

9. Stockholders' Equity

Preferred Stock — The company has authorized up to 5,000,000 shares of preferred stock, $0.0001 par value per share, for issuance. The preferred stock will have such rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, as shall be determined by the company's board of directors upon its issuance. To date, the company has not issued any preferred shares.

Common Stock — The company has authorized up to 200,000,000 shares of common stock, $0.0001 par value per share, for issuance. Shares of common stock are reserved as follows:

April 2012 Registered Direct Offering — On April 13, 2012, the company completed an underwritten public offering of 9,751,000 shares of common stock for gross proceeds of approximately $14.6 million , resulting in approximately $13.5 million of net proceeds to the company after deducting the underwriting discounts and commissions and offering expenses.

December 2012 Registered Direct Offering — On December 18, 2012, the company closed an underwritten public offering of 15,156,250 units at a price to the public of $1.60 per unit for gross proceeds of $24.3 million (the "December 2012 Offering"). The offering provided approximately $22.5 million to the company after deducting the underwriting discounts and commissions and offering expenses. Each unit consists of (i) one share of common stock, and (ii) a five -year warrant to purchase 0.50 of a share of common stock at an exercise price of $1.90 per share (subject to anti-dilution adjustment provisions).

September 2013 Underwritten Public Offering - On September 18, 2013 the company closed an underwritten public offering of 17,500,000 units at a price to the public of $2.00 per unit for gross proceeds of $35 million (the "September 2013 Offering"). Each unit consists of one share of common stock, and a warrant to purchase 0.35 of a share of common stock at an exercise price of $2.50 per share. The offering included an over-allotment option for the underwriters to purchase an additional 2,625,000 shares of common stock and/or warrants up to 918,750 share of common stock. On September 23, 2013, the underwriters exercised their over-allotment option in full. The additional gross proceeds to the company as a result of the full exercise of the over-allotment option were approximately $5.2 million . The total net proceeds of the September 2013 offering, including the exercise of the over-allotment option, were $37.5 million , after deducting underwriting discounts and commissions and offering expenses payable by the company.

Other Equity Transactions — On January 20, 2012, The company sold 579,710 shares of our common stock for $400,000 , the fair market value on the date of issuance, to Kwang Dong Pharmaceuticals Company, as part of an existing license agreement for NeuVax covering territorial rights for the compound in South Korea that the company acquired in its merger acquisition with Apthera. During 2013, the company issued a total of 492,988 shares of common stock to the holders of the company's outstanding contingent value rights holders for a milestone payment with a total fair market value of $1,247,000 .

GALENA BIOPHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - Continued

10. Warrants

The following is a summary of warrant activity for the years ended December 31, 2013 and 2012 (in thousands):

	September 2013 Warrants	December 2012 Warrants	April 2011 Warrants	March 2011 Warrants	March 2010 Warrants	August 2009 Warrants	Consultant and Oxford Warrants	Total
Outstanding, January 1, 2012	—	—	9,470	2,400	540	978	733	14,121
Granted	—	7,578	—	—	—	—	400	7,978
Exercised	—	—	(6,624)	(2,039)	(180)	—	(40)	(8,883)
Outstanding, December 31, 2012	—	7,578	2,846	361	360	978	1,093	13,216
Granted	7,044	—	—	—	—	—	182	7,226
Exercised	(602)	(2,661)	(1,688)	(185)	(70)	—	(196)	(5,402)
Expired	—	—	—	—	—	—	(190)	(190)
Outstanding, December 31, 2013	6,442	4,917	1,158	176	290	978	889	14,850
Expiration	September 2018	December 2017	April 2017	March 2016	March 2016	August 2014	Varies 2014-2020	

Warrants consist of warrants potentially settleable in cash, which are liability-classified warrants, and equity-classified warrants.

Warrants classified as liabilities

Liability-classified warrants consist of warrants to purchase common stock issued in connection with equity financings in September 2013, December 2012, April 2011, March 2011, March 2010 and August 2009. These warrants are potentially settleable in cash and were determined not to be indexed to our common stock.

The estimated fair value of outstanding warrants accounted for as liabilities is determined at each balance sheet date. Any decrease or increase in the estimated fair value of the warrant liability since the most recent balance sheet date is recorded in the condensed consolidated statement of comprehensive loss as other income (expense). The fair value of the warrants is estimated using an appropriate pricing model with the following inputs:

	As of December 31, 2013					
	September 2013 Warrants	December 2012 Warrants	April 2011 Warrants	March 2011 Warrants	March 2010 Warrants	August 2009 Warrants
Strike price	$ 2.50	$ 1.90	$ 0.65	$ 0.65	$ 2.15	$ 4.50
Expected term (years)	4.72	3.98	3.31	2.18	2.24	0.59
Volatility %	71.97%	71.38%	71.71%	73.45%	73.36%	66.85%
Risk-free rate %	1.61%	1.25%	0.93%	0.45%	0.47%	0.11%

	As of December 31, 2012					
	September 2013 Warrants	December 2012 Warrants	April 2011 Warrants	March 2011 Warrants	March 2010 Warrants	August 2009 Warrants
Strike price	—	$ 1.90	$ 0.65	$ 0.65	$ 2.18	$ 4.50
Expected term (years)	0.00	4.98	4.30	3.18	3.24	1.59
Volatility %	—	80.93%	82.48%	69.90%	69.79%	74.13%
Risk-free rate %	—	0.72%	0.59%	0.39%	0.40%	0.21%

The company's expected volatility is based on a combination of implied volatilities of similar publicly traded entities. The expected life assumption is based on the remaining contractual terms of the warrants. The risk-free rate is based on the zero coupon rates in effect at the time of valuation. The dividend yield used in the pricing model is zero, because the company has no present intention to pay cash dividends.

The changes in fair value of the warrant liability for the years ended December 31, 2013 and 2012 were as follows (in thousands):

	September 2013 Warrants	December 2012 Warrants	April 2011 Warrants	March 2011 Warrants	March 2010 Warrants	August 2009 Warrants	Total
Warrant liability, January 1, 2012	$ —	$ —	$ 3,145	$ 421	$ 116	$ 64	$ 3,746
Fair value of warrants granted	—	7,286	—	—	—	—	7,286
Fair value of warrants exercised	—	—	(8,130)	(2,456)	(257)	—	(10,843)
Change in fair value of warrants	—	(332)	8,295	2,413	328	71	10,775
Warrant liability, December 31, 2012	—	6,954	3,310	378	187	135	10,964
Fair value of warrants granted	8,238	—	—	—	—	—	8,238
Fair value of warrants exercised	(1,931)	(8,482)	(3,455)	(260)	(121)	—	(14,249)
Change in fair value of warrants	16,643	19,588	5,214	645	879	1,043	44,012
Warrant liability, December 31, 2013	$ 22,950	$ 18,060	$ 5,069	$ 763	$ 945	$ 1,178	$ 48,965

Warrants classified as equity

Equity-classified warrants consist of warrants issued in connection with consulting services provided to us. Additionally, on May 8, 2013 as a part of our Loan financing, we granted Oxford Financial LLC warrants to purchase 182,186 shares of common stock at an exercise price of $2.47 , which equaled to the 20 -day average market price of our common stock prior to the date of the grant. The warrants were valued using the Black Scholes model. The fair value assumptions for the grant included a volatility of 75.34% , expected term of seven years, risk free rate of 1.20% , and a dividend rate of 0.00% . The fair value of the warrants granted was $1.93 per share. These warrants are recorded in equity at fair value upon issuance, and not as liabilities, and are not subject to adjustment to fair value in subsequent reporting periods.

11. Stock-Based Compensation

Options to Purchase Shares of Common Stock — The company follows the provisions ASC 718, which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees, non-employee directors and consultants, including employee stock options. Stock compensation expense based on the grant date fair value estimated in accordance with the provisions of ASC 718 is recognized as an expense over the requisite service period.

For stock options and warrants granted in consideration for services rendered by non-employees, the company recognizes compensation expense in accordance with the requirements of ASC Topic 505-50. Non-employee option and warrant grants that do not vest immediately upon grant are recorded as an expense over the vesting period. At the end of each financial reporting period prior to vesting, the value of these options and warrants, as calculated using the Black-Scholes option-pricing model, is being re-measured using the fair value of the company's common stock and the non-cash compensation recognized during the period will be adjusted accordingly. Since the fair market value of options and warrants granted to non-employees is subject to change in the future, the amount of the future compensation expense will include fair value re-measurements until the stock options and warrants are fully vested.

The following table summarizes the components of stock-based compensation expense in the Consolidated Statements of Comprehensive Loss for the years ended December 31, 2013 , 2012, and 2011 (in thousands):

	2013	2012	2011
Research and development	$ 754	$ 580	$ 139
Selling, general, and administrative	2,150	1,179	2,386
Total stock-based compensation	$ 2,904	$ 1,759	$ 2,525

The company uses the Black-Scholes option-pricing model and the following weighted-average assumptions to determine the fair value of all its stock options granted:

	2013	2012
Risk free interest rate	1.57%	1.05%
Volatility	77.98%	75.76%
Expected lives (years)	6.25	6.13
Expected dividend yield	0.00%	0.00%

The weighted-average fair value of options granted during the years ended December 31, 2013 and 2012 was $1.98 and $0.70 per share, respectively.

The company's expected common stock price volatility assumption is based upon the volatility of a basket of comparable companies. The expected life assumptions for employee grants were based upon the simplified method provided for under ASC 718-10, which averages the contractual term of the company's options of ten years with the average vesting term of four years for an average of six years . The expected life assumptions for non-employees were based upon the contractual term of the option. The dividend yield assumption is zero, because the company has never paid cash dividends and presently has no intention of paying cash dividends in the future. The risk-free interest rate used for each grant was also based upon prevailing short-term interest rates. The company has estimated an annualized forfeiture rate of 15% for options granted to its employees, 8% for options granted to senior management and zero for non-employee directors. The company will record additional expense if the actual forfeitures are lower than estimated and will record a recovery of prior expense if the actual forfeiture rates are higher than estimated.

As of December 31, 2013 , there was $12,033,000 of unrecognized compensation cost related to outstanding options that is expected to be recognized as a component of the company's operating expenses over a weighted-average period of 2.78 years.

As of December 31, 2013 , an aggregate of 16,500,000 shares of common stock were reserved for issuance under the company's 2007 Incentive Plan, including 13,159,000 shares subject to outstanding common stock options granted under the plan and 1,927,000 shares available for future grants. The administrator of the plan determines the times when an option may become exercisable. Vesting periods of options granted to date have not exceeded four years . The options generally will expire, unless previously exercised, no later than ten years from the grant date.

The following table summarizes option activity of the company:

	Total Number of Shares (In Thousands)	Weighted Average Exercise Price
Outstanding at December 31, 2012	7,672	$ 2.54
Granted	7,113	2.87
Exercised	(289)	1.21
Cancelled	(1,337)	2.80
Outstanding at December 31, 2013	13,159	$ 2.73
Options exercisable at December 31, 2013	6,557	$ 2.63

The weighted average remaining contractual life of options outstanding as of December 31, 2013, 2012, and 2011 was 8.09 , 7.87 , and 7.56 , respectively. The weighted average remaining contractual life of options exercisable as of December 31, 2013, 2012, and 2011 was 6.76 , 7.38 , and 6.87 , respectively.

The aggregate intrinsic value of outstanding options as of December 31, 2013 and 2012 was $30,537,000 and $2,288,000 , respectively. The aggregate intrinsic value of exercisable options as of December 31, 2013 and 2012 was $16,376,000 and $1,394,000 , respectively. There was no aggregate intrinsic value of exercisable or outstanding options as of December 31, 2011. The aggregate intrinsic value is calculated based on the positive difference between the closing fair market value of the company's common stock and the exercise price of the underlying options.

The aggregate intrinsic value of options exercised during the years ended December 31, 2013 and 2012 was $890,000 and $18,000 , respectively. There were no options exercised during the year ended December 31, 2011.

Employee Stock Purchase Plan — The company also has an employee stock purchase plan (“ESPP”) which allows employees to contribute up to 15% of their cash earnings, subject to certain maximums, to be used to purchase shares of our common stock on each semi-annual purchase date. The purchase price is equal to 85% of the market value per share on either the first or last day of the semi-annual period, whichever is lower. Our ESPP is non-compensatory pursuant to the provisions of generally accepted accounting principles for share-based compensation expense. The ESPP contains an “evergreen provision” with annual increases in the number of shares available for issuance on the first day of each year through January 1, 2015 equal to the lesser of: (a) 250,000 shares increased on each anniversary of the adoption of the Plan by 1% of the total shares of stock then outstanding and (b) 1,000,000 shares. As of December 31, 2013, an aggregate of 756,490 shares of common stock were authorized and available for future issuance under the ESPP. The company has issued 243,510 shares under the ESPP through December 31, 2013.

Restricted Stock Units — In addition to options to purchase shares of common stock, the company may grant restricted stock units (“RSU”) as part of its compensation package. If granted, each RSU would be granted at the fair market value of the company's common stock on the date of grant. Vesting is determined on a grant-by-grant basis.

In 2011, the company granted a total of 220,729 RSUs. The RSUs granted in 2011 had an aggregate intrinsic value of $256,000 and fully vested during 2012. There were no RSU's granted in 2012 and 2013.

Note 12. Other Income (Expense)

Other income (expense) is summarized as follows (in thousands):

	Year Ended December 31,		
	2013	2012	2011
Change in fair value of warrants potentially settleable in cash	$ (44,001)	$ (10,775)	$ 8,986
Realized gain on sale of marketable securities	3,911	—	—
Change in fair value of the contingent purchase price liability	(926)	(2,370)	109
Miscellaneous other income	37	—	(9)
Total other income (expense)	$ (40,979)	$ (13,145)	$ 9,086

13. Net Loss Per Share

The company accounts for and discloses net loss per common share in accordance with FASB ASC Topic 260 " *Earnings per Share."* Basic net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding. Diluted net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common shares that would have been outstanding during the period assuming the issuance of common shares for all potential dilutive common shares outstanding. Potential common shares consist of shares issuable upon the exercise of stock options and warrants.

The following table sets forth the potentially dilutive common shares excluded from the calculation of net loss per common share because their inclusion would be anti-dilutive (in thousands):

	December 31,	
	2013	2012
Warrants to purchase common stock	14,850	13,216
Options to purchase common stock	13,159	7,672
Total	28,009	20,888

Note 14. Income Taxes

The components of federal and state income tax expense (benefit) are as follows (in thousands):

	As of December 31,	
	2013	2012
Current		
Federal	$ —	$ —
State	—	—
Total current	—	—
Deferred expense (benefit)		
Federal	894	(894)
State	158	(158)
Total deferred	1,052	(1,052)
Total income tax expense (benefit)	$ 1,052	$ (1,052)

The components of net deferred tax assets are as follows (in thousands):

	As of December 31,	
	2013	2012
Net operating loss carryforwards	$ 33,539	$ 23,632
Tax credit carryforwards	3,549	3,201
Unrealized gain on marketable securities	—	(1,052)
Stock based compensation	8,322	7,944
Other	12	(328)
Licensing deduction deferral	8,682	8,194
Gross deferred tax assets	54,104	41,591
Valuation allowance	(54,104)	(41,591)
Net deferred tax asset	$ —	$ —

The components of net deferred tax liabilities are as follows (in thousands):

	As of December 31,	
	2013	2012
In-process research and development not subject to future amortization for tax purposes	$ 5,053	$ 5,053
Gross deferred tax liability	$ 5,053	$ 5,053

The provision for income taxes differs from the provision computed by applying the federal statutory rate to net loss before income taxes as follows (in thousands):

	As of December 31,	
	2013	2012
Expected federal income tax benefit	$ (25,713)	$ (11,688)
State income taxes after credits	(3,676)	(1,067)
Unrealized gain on marketable securities	1,052	(1,052)
Changes in warrant value	17,283	3,664
Stock compensation	813	152
Effect of change in valuation allowance	11,408	8,939
Income tax credits	(240)	—
Other	125	—
	$ 1,052	$ (1,052)

The company has incurred net operating losses from inception. At December 31, 2013, the company had domestic federal and state net operating loss carryforwards of approximately $83.9 million and $49.8 million , respectively, available to reduce future taxable income, which expire at various dates beginning in 2013 through 2033. The company also had federal and state research and development tax credit carryforwards of approximately $2.2 million and $2.0 million , respectively, available to reduce future tax liabilities and which expire at various dates beginning in 2023 through 2032. The income tax expense for the year ended December 31, 2013 relates to the realized gain on sale of marketable securities.

Approximately $280,000 of the company's net operating loss carryforwards were generated as a result of deductions related to the exercises of stock options and disqualifying dispositions. If utilized, this portion of the Company's carrforwards, as tax effected, will be accounted for as a direct increase to contributed capital rather than as a reduction of that year's provision for income taxes. Net operating loss carryforwards created by excess tax benefits from the exercise of stock options are not recorded as deferred tax assets. The deferred tax assets related to net operating losses have been accordingly reduced by $109,000 for the year ended December 31, 2013.

Under the provisions of the Internal Revenue Code, certain substantial changes in the company’s ownership may result in a limitation on the amount of net operating loss carryforwards and research and development credit carryforwards which could be utilized annually to offset future taxable income and taxes payable.

Based on an assessment of all available evidence including, but not limited to the company's limited operating history in its core business and lack of profitability, uncertainties of the commercial viability of its technology, the impact of government regulation and healthcare reform initiatives, and other risks normally associated with biotechnology companies, the company has concluded that it is more likely than not that these net operating loss carryforwards and credits will not be realized and, as a result, a 100% deferred income tax valuation allowance has been recorded against these assets. The valuation allowance increased by $12.5 million and $5.1 million for the years ended December 31, 2013 and 2012, respectively.

The company files income tax returns in the U.S. federal, Massachusetts, Colorado, California and Oregon jurisdictions. The company is subject to tax examinations for the 2009 tax year and beyond. The company does not believe there will be any material changes in its unrecognized tax positions over the next 12 months. The company has not incurred any interest or penalties. In the event that the company is assessed interest or penalties at some point in the future, they will be classified in the financial statements as general and administrative expense.

15. License Agreements

As part of its business, the company enters into licensing agreements with third parties that often require milestone and royalty payments based on the progress of the licensed asset through development and commercial stages. Milestone payments may be required, for example, upon approval of the product for marketing by a regulatory agency, and the company may be required to make royalty payments based upon a percentage of net sales of the product. The expenditures required under these arrangements in any period may be material and are likely to fluctuate from period to period.

These arrangements sometimes permit the company to unilaterally terminate development of the product and thereby avoid future contingent payments; however, the company is unlikely to cease development if the compound successfully achieves clinical testing objectives.

In conjunction with the acquisition of NeuVax ™, the company acquired rights and assumed obligations under a license agreement among Apthera and The University of Texas M. D. Anderson Cancer Center ("MDACC") and The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. ("HJF") which grants exclusive worldwide rights to a U.S. patent covering the nelipepimut-S peptide and several U.S. and foreign patents and patent applications covering methods of using the peptide as a vaccine. Under the terms of this license, we are required to pay an annual maintenance fee of $200,000 , we paid a milestone payment of $200,000 upon commencing the Phase 3 PRESENT trial of NeuVax and other clinical milestone payments, as well as royalty payments based on sales of NeuVax or other therapeutic products developed from the licensed technologies.

Effective December 3, 2012, we entered into a license and supply agreement with ABIC Marketing Limited, a subsidiary of Teva Pharmaceuticals ("ABIC"), under which we granted ABIC exclusive rights to seek marketing approval in Israel for our NeuVax product candidate for intradermal injection for the treatment of breast cancer following its approval by the FDA or the European Medicines Agency, and to market, sell and distribute NeuVax in Israel assuming such approval is obtained. ABIC's rights also include a right of first refusal in Israel for all future indications for which NeuVax may be approved. Under the license and supply agreement, ABIC will assume responsibility for regulatory registration of NeuVax in Israel, provide financial support for local development, and commercialize the product in the region in exchange for making royalty payments to us based on future sales of NeuVax. ABIC also agrees in the license and supply agreement to purchase from us all supplies of NeuVax at a price determined according to a specified formula.

On March 18, 2013, we acquired Abstral ® (fentanyl) sublingual tablets for sale and distribution in the United States from Orexo AB (ORX.ST), an emerging specialty pharmaceutical company based in Sweden. Abstral has been approved by the U.S. Food and Drug Administration (FDA) and is a transmucosal immediate-release fentanyl (TIRF) product.

Under our agreement with Orexo, we assumed responsibility for the U.S. commercialization of Abstral and for all regulatory and reporting matters in the U.S. We also agreed to establish and maintain through 2015 a specified minimum commercial field force to market, sell and distribute Abstral and to use commercially reasonable efforts to reach the specified sales milestones. Orexo is entitled to reacquire the U.S. rights to Abstral from us for no consideration if we breach our obligations to establish and maintain the requisite sales force throughout the marketing period. We recently launched U.S. commercial sales of Abstral.

In exchange for the U.S. rights to Abstral, (1) we paid Orexo $10 million in March 2013 and a $5 million milestone payment in cash in October 2013 upon the approval by the FDA of a specified U.S. manufacturer of Abstral; and (2) we agreed to pay to Orexo: (a) three one-time future cash milestone payments based on our net sales of Abstral; and (b) a low double-digit royalty on future net sales. No further milestone or royalty payments will be due after the date on which all claims of the last remaining licensed patents expire (currently 2019) or become invalidated by a governmental agency.

On January 12, 2014, we acquired worldwide rights to anagrelide controlled release (CR), which we renamed GALE-401, through our acquisition of Mills Pharmaceuticals, LLC ("Mills"). GALE-401 contains the active ingredient anagrelide, an FDA-approved product, which has been in use since the late 1990s for the treatment of essential thrombocythemia (ET). Under the terms of the acquisition agreement, we paid $2 million to the former owners of Mills. Additionally, the former owners are entitled to receive one-time payments of up to an aggregate of 4,000,000 shares of the company's common stock upon the achievement of specified regulatory milestones and $3 million upon FDA approval of a new drug application in respect to GALE-401. Mills holds an exclusive license to develop and commercialize anagrelide CR, pursuant to a license agreement with BioVascular, Inc. Under the terms of the license agreement, Mills agreed to pay BioVascular, Inc. a mid-to-low single digit royalty on net revenue from the sale of licensed products and future cash milestone payments based on specified regulatory milestones. Mills is also responsible for patent prosecution and maintenance.

16. Significant Customers and Concentration of Credit Risk

The company is engaged in the business of developing and commercializing pharmaceutical products. The company has one commercial product, Abstral, available in six dosing strengths, and all sales reported are in the United States.

The company had product sales to three customers that represented more than 10% of revenue for the three months ended December 31, 2013 . Customers A, B, and C had product shipments that accounted for 34% , 26% , and 25% , respectively, of sales for the year ended December 31, 2013 . No revenue was recognized prior to the year ended December 31, 2013 .

The company had accounts receivable from three customers that represented more than 10% of total accounts receivable balance as of December 31, 2013 . Customers A, B, and C had accounts receivable of 54% , 11% , and 25% , respectively, of the total accounts receivable balance as of December 31, 2013 . There was no accounts receivable balance as of December 31, 2012 .

17. Related Party Transactions

Since 2011, the company has retained TroyGould PC as outside corporate counsel. Sanford J. Hillsberg, the Chairman of the company, is a senior lawyer with TroyGould PC. The company incurred $577,000 for services provided by TroyGould PC during the year ended December 31, 2013, as wells as $100,000 for services related to our underwritten public offering in September 2013, which is recorded as reduction of gross proceeds from the issuance of common stock as of December 31, 2013. At December 31, 2013, Galena owed $177,000 to TroyGould PC.

18. Employee Benefit Plan

The company sponsors a 401(k) retirement savings plan (the “Plan”). Participation in the Plan is available to full-time employees who meet eligibility requirements. Eligible employees may defer a portion of their salary as defined by Internal Revenue Service regulations. The company may make matching contributions on behalf of all participants in the 401(k) Plan in an amount determined by the company’s board of directors. The company may also make additional discretionary profit sharing contributions in amounts as determined by the board of directors, subject to statutory limitations. Matching and profit-sharing contributions, if any, are subject to a vesting schedule; all other contributions are at all times fully vested. The company intends the 401(k) Plan, and the accompanying trust, to qualify under Sections 401(k) and 501 of the Internal Revenue Code so that contributions by employees to the 401(k) Plan, and income earned (if any) on plan contributions, are not taxable to employees until withdrawn from the 401(k) Plan, and so that the company will be able to deduct its contributions, if any, when made. The trustee under the 401(k) Plan, at the direction of each participant, invests the assets of the 401(k) Plan in any of a number of investment options. For the year ending December 31, 2013, the company made matching contributions totaling $35,000 . There were no contributions to the plan in 2012 or 2011.

Note 19. Selected Quarterly Financial Data (Unaudited)

The following amounts are in thousands, except per share amounts:

	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
2013				
Net revenue	$ —	$ —	$ 1,170	$ 1,317
Gross profit on net revenue [1]	$ —	$ —	$ 869	$ 967
Net loss	$ (9,293)	$ (9,597)	$ (9,287)	$ (48,501)
Net loss per share	$ (0.11)	$ (0.11)	$ (0.11)	$ (0.46)
2012				
Net revenue	$ —	$ —	$ —	$ —
Gross profit on net revenue	$ —	$ —	$ —	$ —
Net loss	$ (24,761)	$ (196)	$ (6,261)	$ (3,751)
Net loss per share	$ (0.52)	$ —	$ (0.09)	$ (0.05)

[1] Gross profit for the quarter ended December 31, 2013 is calculated by taking net revenue less cost of revenue and amortization of certain acquired intangible assets, which is consistent with the gross profit reported for the quarter ended September 30, 2013.

20. Subsequent Events

The company evaluated all events or transactions that occurred after December 31, 2013 up through the date these financial statements were issued. Other than as disclosed elsewhere in the notes to the condensed consolidated financial statements, the company did not have any material recognizable or unrecognizable subsequent events, except as described below.

For the period of January 1, 2014 through March 14, 2014, we issued an additional 5,072,900 shares of our common stock as a result of 5,095,616 warrant exercises. Cash proceeds from the warrant exercises during this period were $9,371,000 . As of March 14, 2014, we had 9,753,815 warrants outstanding.

For the period of January 1, 2014 through March 14, 2014, we issued an additional 3,158,338 shares of our common stock as a result of 3,182,764 stock option exercises. Cash proceeds from the stock option exercises during this period were $3,889,000 . As of March 14, 2014 we had 9,335,403 stock options outstanding.

Effective January 14, 2014, we entered into a strategic development and commercialization partnership with Dr. Reddy's Laboratories Ltd. ("Dr. Reddy's"). We licensed commercial rights to Dr. Reddy's for NeuVax in breast and gastric cancers in India. Dr. Reddy's will lead the Phase 2 development of NeuVax in gastric cancer, significantly expanding the potential addressable patient population.

In February and March 2014, two purported shareholder derivative complaints- *Fagin v. Ahn* , No. 140202384 (Or. Cir. Ct.), and *Werbowsky v. Hillsberg* , No. 3:14-cv-382 (D. Or.)-were filed against our company, as nominal defendant, and certain of our officers and directors in the Circuit Court of Oregon for the County of Multnomah and in the United States District Court for the District of Oregon. The complaints allege, among other things, breaches of fiduciary duties and abuse of control by the officers and directors in connection with various public statements purportedly issued by us or on our behalf and sales of our common stock by the officers and directors in January and February of this year.

In March 2014, three purported securities class action complaints- *Deering v. Galena Biopharma, Inc.* , No. 3:14-cv-367 (D. Or.), *Hau v. Galena Biopharma, Inc.* , No. 3:14-cv-389 (D. Or.), and *Clavijo v. Galena Biopharma, Inc.* , No. 3:14-cv-410 (D. Or.)-were filed against our company and certain of our officers in the United States District Court for the District of Oregon. The complaints allege that the defendants violated the federal securities laws by making materially false and misleading statements in press releases and in filings with the SEC arising out of the same circumstances that are the subject of the derivative actions described above.

In February 2014 **,** we learned that the SEC is investigating certain matters relating to our company and an outside investor-relations firm that we retained in 2013. We have been in contact with the SEC staff through our counsel and are cooperating with the investigation.

Based on the very early stage of the litigation, it is not possible to estimate the amount or range of possible loss that might result from an adverse judgment or a settlement of these matters.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURES

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Rule 13a-15(e) under the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), defines the term "disclosure controls and procedures" as those controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms and that such information is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Our Chief Executive Officer and Chief Financial Officer have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined under Rules 13a-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this report. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures are effective.

Evaluation of Disclosure Controls and Procedure Management's report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Under the supervision and with the participation of our management, including our Chief Executive Officer and Principal Accounting Officer, we conducted evaluations of the effectiveness of our internal control over financial reporting based on the framework in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based on our evaluations under the framework in Internal Control-Integrated Framework issued by the COSO, our Chief Executive Officer and Chief Financial Officer concluded that our internal control over financial reporting was effective as of December 31, 2013.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

This annual report includes an attestation report of the company's registered public accounting firm regarding internal control over financial reporting.

There have been no changes in our internal controls over financial reporting during the fourth quarter of the year ended December 31, 2013 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

ITEM 9B. OTHER INFORMATION

Appointment of Director

On March 14, 2014, the company's board of directors appointed Irving M. Einhorn agreed to serve as a Class II director of the company, with a term expiring at the 2015 annual stockholder meeting, and as a member of the special committee of the board of directors formed to investigate certain allegations contained in the purported derivative complaint recently filed against the company and certain of its directors. Mr. Einhorn will be compensated for his services as director and member of the special committee in the same manner as other directors and special committee members.

Mr. Einhorn, started his career in 1972 as a SEC Staff attorney. He rose to increasingly more responsible positions culminating in his appointment as Regional Administrator of the Commission's Los Angeles Regional Office where he was responsible for overseeing in excess of 100 staff members whose function was to implement the SEC's regulatory and law enforcement mandates principally in the Western United States. Subsequent to leaving the SEC in 1989, Mr. Einhorn has engaged in the private practice of law focused exclusively on federal, state and self-regulatory organization securities enforcement and securities compliance matters. Our board of directors believes that Mr. Einhorn has unique experience in SEC enforcement, SEC regulation, SEC compliance, and SEC disclosure requirements based on 17 years of service as an SEC attorney and over 40 years of experience as an attorney whose practice has been devoted exclusively to securities related compliance and enforcement matters.

Appointment of Chief Medical Officer

On November 7, 2013, we entered into an employment agreement with Brian Hamilton, M.D., Ph.D., pursuant to which Dr. Hamilton will serve as our Executive Vice President and Chief Medical Officer.

Under the employment agreement, Dr. Hamilton is entitled to (i) receive an annual base salary of $385,000 and (ii) a grant under our Amended and Restated 2007 Incentive Plan of stock options to purchase 300,000 shares of our common stock, subject to the approval of our board of directors. The stock options will vest and become exercisable in 12 equal quarterly installments beginning on the first quarterly anniversary of the effective date of his employment, provided, in each case, that Dr. Hamilton remains in our continuous employment through such vesting date, and will be determined on the other terms set forth in our standard form of stock option agreement. The exercise price of the stock options will be equal to the market price of our common stock on the date of grant.

Additionally, Dr. Hamilton will be eligible under the employment letter agreement to: (i) receive an annual bonus (as determined by the Compensation Committee of our board of directors) of up to 30% of his annual base salary; and (ii) participate in all employee benefit plans in effect for our employees from time to time. We also will pay Dr. Hamilton, under the employment letter agreement, a $70,000 sign-on bonus.

Dr. Hamilton has extensive academic and pharmaceutical experience in immunology, hematopoietic stem cell transplantation, and oncology. Having worked at both large pharmaceutical companies such as AstraZeneca and Wyeth, as well as at biotech companies such as BioVex, Soligenix, and Onyx. He has experience with drug development across multiple therapeutic indications and platforms, including small molecules, biologics, oncolytic viruses, and vaccines. He has been a partner and Vice President of Biopharm Solutions, a private consulting firm in the life sciences industry, since 2001. Dr. Hamilton received his M.D. and Ph.D. from the University of Washington School of Medicine, trained in Pediatrics at the Children's Medical Center in Dallas, Texas, with specialty training in Immunology at the Children's Hospital Medical Center and Sidney Farber Cancer Center and in Allergy at the University of California-San Francisco. He has held academic appointments at the University of Washington and the University of Miami.

Dr. Hamilton, 66 years old, has no family relationship with any of our officers or directors.

Frequency of Stockholder Advisory Vote on Executive Compensation

On June 28, 2013, at our annual meeting of stockholders, our stockholders voted on, among other matters, an advisory proposal on the frequency with which we will hold an advisory vote on the compensation of our named executive officers. As previously reported on July 3, 2013, our stockholders recommended, on an advisory basis, that the company include a stockholder advisory vote on executive compensation in the company's proxy materials every year, which was consistent with the recommendation of our board of directors. In light of the foregoing, the company has determined to follow the stockholders' recommendation and to include in future proxy statements an annual stockholder advisory vote on the compensation of our named executive officers until the next required vote on the frequency of stockholder votes on the compensation of executives.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

We will file with the SEC a definitive Proxy Statement, which we refer to herein as the "Proxy Statement," not later than 120 days after the fiscal year ended December 31, 2013. The information required by this item is incorporated herein by reference to the information to be contained in the Proxy Statement.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated herein by reference to the information to be contained in the Proxy Statement.

ITEM 12. SECURITY OWENERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDERS

The information required by this item is incorporated herein by reference to the information to be contained in the Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated herein by reference to the information to be contained in the Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated herein by reference to the information to be contained in the Proxy Statement.

PART IV.

ITEM 15. EXHIBITS

Exhibit Number	Description
1.1	Underwriting Agreement dated as of September 13, 2013 by and between Galena Biopharma, Inc. and Oppenheimer & Co. Inc. as representative of the several underwriters named in Schedule I thereto. (1)
1.2	Underwriting Agreement dated as of April 5, 2012 by and between Galena Biopharma, Inc. and Roth Capital Partners, LLC, as representative of the several underwriters named therein.(2)
1.3	Purchase Agreement dated as of December 18, 2012 by and between Galena Biopharma, Inc. and Piper Jaffray & Co.(24)
2.1	Unit Purchase Agreement, dated as of January 12, 2014, between Galena Biopharma, Inc. and Mills Pharmaceuticals, LLC.+**
3.1	Amended and Restated Certificate of Incorporation of Galena Biopharma, Inc. (formerly RXi Pharmaceuticals Corporation), as amended as of June 28, 2013.(2)
3.2	Certificate of Ownership and Merger.(13)
3.3	Amended and Restated By-Laws of Galena Biopharma, Inc., as amended as of August 6, 2013. (2)
4.1	Form of Warrant Agreement by and Galena Biopharma, Inc., Computershare Inc. and Computershare Trust Company, N.A. (1)
4.2	Warrant No. A-1 in favor of J.P. Turner Partners, LP, dated August 7, 2008. (19)
4.3	Form of Common Stock Purchase Warrant issued in August 2009.(20)
4.4	Form of Common Stock Purchase Warrant issued in March 2010.(21)
4.5	Form of Five-Year Common Stock Purchase Warrant issued in March 2011.(22)
4.6	Form of Common Stock Purchase Warrant issued in April 2011.(23)
4.7	Warrant No. 2012-1 in favor of Legend Securities, Inc. issued in February 2012.(4)
4.8	Form of December 2012 Warrant.(24)
4.9	Registration Rights Agreement, dated January 12, 2014, between Galena Biopharma, Inc. and each former owner of membership units of Mills Pharmaceuticals, LLC.**
10.1	Employment letter agreement, effective July 1, 2013, between Galena Biopharma, Inc. and Ryan M. Dunlap.*(2)
10.2	Employment letter agreement, effective November 7, 2013, between Galena Biopharma, Inc. and Brian Hamilton, M.D., Ph.D.* **
10.3	Form of Contingent Value Rights Agreement among Galena Biopharma, Inc. (formerly RXi Pharmaceuticals Corporation), Computershare Trust Company, N.A., Computershare Inc., and Robert E Kennedy, dated April 13, 2011.(3)
10.4	First Amendment to Contingent Value Rights Agreement among Galena Biopharma, Inc. (formerly RXi Pharmaceuticals Corporation), Computershare Trust Company, N.A., Computershare Inc., and Robert E Kennedy, dated February 15, 2012.(4)
10.5	Employment Agreement between Galena Biopharma, Inc. (formerly RXi Pharmaceuticals Corporation) and Mark W. Schwartz, Ph.D., dated April 13, 2011.*(5)
10.6	Amendment No. 1 to Employment Agreement made as of September 23, 2011 between Galena Biopharma, Inc. (formerly RXi Pharmaceuticals) and Mark W. Schwartz, Ph.D.*(6)
10.7	Amendment No. 2 to Employment Agreement made as of March 11, 2013 between Galena Biopharma, Inc. and Mark W. Schwartz, Ph.D.*(7)
10.8	Employment Agreement between Galena Biopharma, Inc. (formerly RXi Pharmaceuticals Corporation) and Mark Ahn, Ph.D., dated March 31, 2011.*(8)
10.9	Galena Biopharma, Inc. (formerly RXi Pharmaceuticals Corporation) Amended and Restated 2007 Incentive Plan.*(9)

10.10	Amendment to Galena Biopharma, Inc. (formerly RXi Pharmaceuticals Corporation) Amended and Restated 2007 Incentive Plan.*(10)
10.11	Form of Incentive Stock Option.*(11)
10.12	Form of Non-qualified Stock Option.*(11)
10.13	Patent and Technology License Agreement, dated September 11, 2006, by and among the Board of Regents of the University of Texas System, the University of Texas M.D. Anderson Cancer Center, the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., and Apthera, Inc. (formerly Advanced Peptide Therapeutics, Inc.).+(5))
10.14	Amendment No. 1 to Patent and Technology License Agreement, dated December 21, 2007, by and among the Board of Regents of the University of Texas System, the University of Texas M.D. Anderson Cancer Center, the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., and Apthera, Inc. (formerly Advanced Peptide Therapeutics, Inc.).(5)
10.15	Amendment No. 2 to Patent and Technology License Agreement, dated September 3, 2008, by and among the Board of Regents of the University of Texas System, the University of Texas M.D. Anderson Cancer Center, the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., and Apthera, Inc. (formerly Advanced Peptide Therapeutics, Inc.).(5)
10.16	Amendment No. 3 to Patent and Technology License Agreement, dated July 8, 2009, by and among the Board of Regents of the University of Texas System, the University of Texas M.D. Anderson Cancer Center, the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., and Apthera, Inc. (formerly Advanced Peptide Therapeutics, Inc.).(5)
10.17	Amendment No. 4 to Patent and Technology License Agreement, dated February 11, 2010, by and among the Board of Regents of the University of Texas System, the University of Texas M.D. Anderson Cancer Center, the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., and Apthera, Inc. (formerly Advanced Peptide Therapeutics, Inc.).+(5)
10.18	Amendment No. 5 to Patent and Technology License Agreement, dated January 10, 2011, by and among the Board of Regents of the University of Texas System, the University of Texas M.D. Anderson Cancer Center, the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., and Apthera, Inc. (formerly Advanced Peptide Therapeutics, Inc.).+(5)
10.19	Scientific Advisory Agreement between Galena Biopharma, Inc. (formerly RXi Pharmaceuticals Corporation) and George E. Peoples, Ph.D., dated May 1, 2011.(7)
10.20	Form of Amendment to Stock Options Granted under Galena Biopharma, Inc. (formerly RXi Pharmaceuticals Corporation) 2007 Incentive Plan, entered into in April 2011 by Galena Biopharma, Inc. with all directors of Galena Biopharma, Inc., as of April 1, 2011, and Mark J. Ahn, Ph.D.*(5)
10.21	Exclusive License Agreement, dated as of July 11, 2011, by and among The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., Galena Biopharma, Inc. (formerly RXi Pharmaceuticals Corporation) and its wholly-owned subsidiary, Apthera, Inc.+(5)
10.22	Agreement and Plan of Merger by and among Galena Biopharma, Inc. (formerly RXi Pharmaceuticals Corporation), Diamondback Acquisition Corp., Apthera, Inc. and Robert E. Kennedy, in his capacity as the Stockholder Representative, dated March 31, 2011.(8)
10.23	Exclusive License Agreement, dated effective as of September 16, 2011, by and among The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., Galena Biopharma, Inc. (formerly RXi Pharmaceuticals Corporation), The Board of Regents of the University of Texas System and The University of Texas M.D. Anderson Cancer Center.+(12)
10.24	Galena Biopharma, Inc. (formerly RXi Pharmaceuticals Corporation) Employee Stock Purchase Plan.*
10.25	License Agreement, effective as of April 30, 2009, between Kwangdong Pharmaceutical Co., Ltd. and Apthera, Inc.+(14)
10.26	Amendment No. 1 to License Agreement, dated as of January 13, 2012, by and among Apthera, Inc., Kwangdong Pharmaceutical Co., Ltd., and Galena Biopharma, Inc.(14)
10.27	Employment letter agreement, effective July 16, 2012, between Galena Biopharma, Inc. and Ryan M. Dunlap.* (16)
10.28	Amendment to Galena Biopharma, Inc. (formerly RXi Pharmaceuticals Corporation) Amended and Restated 2007 Incentive Plan.* (17)
10.29	License and Supply Agreement, effective December 3, 2012, between Galena Biopharma, Inc. and ABIC Marketing Limited, a subsidiary of Teva Pharmaceuticals.+(7)
10.30	Asset Purchase Agreement dated March 15, 2013 between Galena Biopharma, Inc. and Orexo AB.+(25)

10.31	License Agreement dated March 15, 2013 between Galena Biopharma, Inc. and Orexo AB.(25)
10.32	Loan and Security Agreement dated May 8, 2013 among Galena Biopharma, Inc., Apthera, Inc., Oxford Finance LLC and the Lenders listed on Schedule 1.1 thereto.(25)
10.33	Form of warrants granted on May 8, 2013 under the Loan and Security Agreement set forth as Exhibit 10.6.(25)
10.34	Amendment No. 1 to Employment Agreement made as of May 8, 2013 between Galena Biopharma, Inc. and Mark J. Ahn, Ph.D.*(25)
10.35	Lease between Galena Biopharma, Inc. and Cameron Oregon properties LLC and Lucas Oregon Properties, LLC for Suite 270 in the Willamette Wharf Building at 4640 Macadam Avenue in Portland, Oregon dated April 25, 2013.(2)
10.36	License and Development Agreement, dated January 13, 2014, between Galena Biopharma, Inc. and Dr. Reddy's Laboratories, Ltd.+ **
10.37	Exclusive License Agreement, dated as of December 20, 2013, between Mills Pharmaceuticals, LLC and BioVascular, Inc.+**
14.1	Code of Ethics and Conduct.(18)
21.1	Subsidiaries of the Registrant.**
23.1	Consent of Moss Adams LLP, Independent Registered Public Accounting Firm.**
23.2	Consent of BDO USA LLP, Independent Registered Public Accounting Firm.**
31.1	Sarbanes-Oxley Act Section 302 Certification of Mark J. Ahn, Ph.D.**
31.2	Sarbanes-Oxley Act Section 302 Certification of Ryan M. Dunlap.**
32.1	Sarbanes-Oxley Act Section 906 Certification of Mark J. Ahn, Ph.D., and Ryan M. Dunlap.**
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema.
101.CAL	XBRL Taxonomy Extension Calculation.
101.DEF	XBRL Taxonomy Extension Definition.
101.LAB	XBRL Taxonomy Extension Label.
101.PRE	XBRL Taxonomy Extension Presentation.
101.PRE	XBRL Taxonomy Extension Presentation.

(1) Previously filed as an Exhibit to the Company's Form 8-K filed on September 13, 2013 (File No. 001-33958) and incorporated herein by reference.

(2) Previously filed as an Exhibit to the Company's Form 10-Q filed on August 9, 2013 (File No. 001-33958) and incorporated herein by reference.

(3) Previously filed as an Exhibit to the Company's Form 8-K filed on April 14, 2011 (File No. 001-33958) and incorporated by reference herein.

(4) Previously filed as an Exhibit to the Company's Form 10-K filed on March 28, 2012 (File No. 001-33958) and incorporated by reference herein.

(5) Previously filed as an Exhibit to the Company's Form 10-Q filed on August 15, 2011 (File No. 001-33958) and incorporated by reference herein.

(6) Previously filed as an Exhibit to the Company's Form 10-Q filed on November 14, 2011 (File No. 001-33958) and incorporated by reference herein.(7) Previously filed as an Exhibit to the Company's Form 10-K filed on March 12, 2013 (File No. 001-33958) and incorporated by reference herein

(8) Previously filed as an Exhibit to the Company's Form 8-K filed on April 5, 2011 (File No. 001-33958) and incorporated by reference herein.

(9) Previously filed as Annex A to the Company's Proxy Statement on Schedule 14A filed on April 23, 2010 (File No. 001-33958) and incorporated by reference herein.

(10) Previously filed as Annex A to the Company's Proxy Statement on Schedule 14A filed on May 31, 2011 (File No. 001-33958) and incorporated by reference herein.

(11) Previously filed as an Exhibit to the Company's Registration Statement on Form S-1 filed on October 30, 2007 (File No. 333-147009) and incorporated by reference herein.

(12) Previously filed as an Exhibit to the Company's Form 8-K filed on September 21, 2011 (File No. 001-33958) and incorporated by reference herein.

(13) Previously filed as an Exhibit to the Company's Form 8-K filed on September 26, 2011 (File No. 001-33958) and incorporated by reference herein.

(14) Previously filed as an Exhibit to the Company's Form 10-K filed on March 28, 2012 (File No. 001-33958) and incorporated by reference herein.

(15) Previously filed as Annex B to the Company's Proxy Statement on Schedule 14A, filed on April 23, 2010 (File No. 001-33958) and incorporated by reference herein.

(16) Previously filed as an Exhibit to the Company's Form 10-Q filed on August 14, 2012 (File No. 001-33958) and incorporated by reference herein.

(17) Previously filed as Annex A to the Company's Proxy Statement on Schedule 14A filed on April 23, 2010 (File No. 001-33958). and incorporated by reference herein.

(18) Previously filed as an Exhibit to the Company's Form 10-K filed on April 15, 2008 (File No. 001-33958) incorporated by reference herein.

(19) Previously filed as an Exhibit to the Company's Form 10-Q filed on November 14, 2008 (File No. 001-33958) and incorporated by reference herein.

(20) Previously filed as an Exhibit to the Company's Form 8-K filed on July 31, 2009 (File No. 001-33958) and incorporated by reference herein.

(21) Previously filed as an Exhibit to the Company's Form 8-K filed on March 23, 2010 (File No. 001-33958) and incorporated by reference herein.

(22) Previously filed as an Exhibit to the Company's Form 8-K filed on March 1, 2011 (File No. 001-33958) and incorporated by reference herein.

(23) Previously filed as an Exhibit to the Company's Form 8-K filed on April 15, 2011 (File No. 001-33958) and incorporated by reference herein.

(24) Previously filed as an Exhibit to the Company's Form 8-K filed on December 19, 2012 (File No. 001-33958) and incorporated by reference herein.

(25) Previously filed as an Exhibit to the Company's Form 10-Q filed on May 9, 2013 (File No. 001-33958) and incorporated by reference herein.

* Indicates a management contract or compensatory plan or arrangement.

** Filed herewith.

+ This exhibit was filed separately with the Commission pursuant to an application for confidential treatment. The confidential portions of the exhibit have been omitted and have been marked by an asterisk.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Annual Report to be signed on its behalf by the undersigned thereunto duly authorized.

GALENA BIOPHARMA, INC.

By: /s/ *Mark J. Ahn*

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

Date: March 17, 2014

By: /s/ *Ryan M. Dunlap*

Ryan M. Dunlap
Vice President, Chief Financial Officer

Date: March 17, 2014

Dated: March 17, 2014

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report has been signed by the following persons on behalf of the Registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ Mark J. Ahn Mark J. Ahn, Ph. D.	President, Chief Executive Officer and Director (Principal Executive Officer)	March 17, 2014
/s/ Ryan M. Dunlap Ryan M. Dunlap	Vice President, Chief Financial Officer (Principal Financial and Accounting Officer)	March 17, 2014
/s/ Sanford J. Hillsberg Sanford J. Hillsberg	Director, Chairman of the Board	March 17, 2014
/s/ William L. Ashton William L. Ashton	Director	March 17, 2014
/s/ Richard Chin Richard Chin, M.D.	Director	March 17, 2014
/s/ Stephen S. Galliker Stephen S. Galliker	Director	March 17, 2014
/s/ Steven A. Kriegsman Steven A. Kriegsman	Director	March 17, 2014
/s/ Rudolph Nisi Rudolph Nisi, M.D.	Director	March 17, 2014

TEXT MARKED BY [* * *] HAS BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

Execution Version

UNIT PURCHASE AGREEMENT

THIS UNIT PURCHASE AGREEMENT (this " *Agreement* ") is made and entered into as of January 12, 2014, by and among Mills Pharmaceuticals, LLC, a Delaware limited liability company (the " *Company* "), the members of the Company as identified on the signature pages attached to this Agreement (each such party, an " *Owner* " and collectively, the " *Owners* "), Galena Biopharma, Inc., a Delaware corporation (" *Buyer* "), and Aceras Partners, LLC, a Delaware limited liability company (the " *Representative* "), solely in its capacity as Representative. The Company, the Owners, Buyer and the Representative may be referred to individually as a " *Party* " and collectively as the " *Parties* ." Capitalized terms used but not defined herein shall have the meanings given in Article VIII hereof.

RECITALS

The Owners own beneficially and of record all of the Units (as defined below), which constitute all of the issued and outstanding membership interests of the Company;

The Owners desire to sell to Buyer, and Buyer desires to purchase from the Owners, the Units upon the terms and conditions set forth herein; and

The Company and the Owners acknowledge that Buyer would not enter into this Agreement but for the Owners agreeing to the terms of Section 3.5 hereof.

AGREEMENTS

In consideration of the mutual covenants, agreements and understandings contained herein and intending to be legally bound, the Parties agree as follows:

ARTICLE I- PURCHASE AND SALE OF UNITS

1.1 Purchase and Sale of the Units . Upon the terms and subject to the conditions contained herein, on the Closing Date, each Owner agrees to sell, and hereby sells, assigns and transfers, to Buyer, free and clear of all Liens, and Buyer agrees to purchase, and hereby purchases from each Owner, all of such Owner's issued and outstanding membership interests in the Company, which membership interests are as set forth on Schedule 1.1 hereto (the " *Units* "). Any other unit or membership interest held in the treasury of the Company, each unit of any other class of membership interests of the Company (other than the Units), and any debt or other securities convertible into or exercisable for the purchase of units of the Company, issued and outstanding immediately prior to the Closing, shall be cancelled without payment of any consideration therefor and without any conversion thereof.

1.2 Purchase Price.

(a) **Purchase Price** . The total purchase price for the Units will be an amount equal to the sum of: (i) One Million Seven Hundred and Twenty Thousand Dollars ($1,720,000) (the " *Cash Amount* "), plus (ii) the Milestone Payments, if any (collectively, the " *Purchase Price* "), as adjusted pursuant to Article VII below.

(b) **Closing Payment and Assumptions** . At Closing, Buyer will:

(i) direct payment of an amount equal to the Company's Indebtedness as set forth on Schedule 1.2(b)(i) hereof as of the Closing Date pursuant to payoff letter(s) in form reasonably acceptable to Buyer which will cause the release of all Liens (if any) on the Assets (the " *Indebtedness Amount* ");

(ii) direct payment of an amount equal to the Company's legal fees incurred in connection with the consummation of the transactions contemplated by this Agreement (the " *Legal Fees Amount* ") up to a maximum aggregate amount of $40,000 pursuant to payoff letter(s) in form reasonably acceptable to Buyer; and

(iii) pay to the Owners via check or wire transfer of immediately available funds to the accounts or addresses designated by the Representative the sum of the following (the " *Closing Cash Payment* "), which shall be paid to the Owners pro rata based on their ownership of the Units reflected on Schedule 1.1 :

a. the Cash Amount, minus

b. the Indebtedness Amount, minus

c. the Legal Fees Amount in excess of $40,000.

(c) **Milestone Payments** . Following Closing, to the extent that the Milestones described in Section 1.3 hereof are achieved such that a payment is due and payable, Buyer shall pay to the Owners, pro rata based on their ownership of the Units reflected on Schedule 1.1 , the payments in respect of the Milestones (" *Milestone Payments* ") as described in Section 1.3. Notwithstanding the foregoing, in the event a Milestone Payment becomes payable due to a Change of Control, then Buyer may, at its option, and in lieu of actually issuing the shares of Buyer Common Stock to which the Owners would be entitled upon the achievement of the First Milestone or Second Milestone, as applicable (the " Milestone Shares "), satisfy such Milestone Payments by providing each Owner with the right to receive the same amount and kind of securities, cash or property as each Owner would have been entitled to receive upon the occurrence of such Change of Control as if such Owner had been, immediately prior to such Change of Control, the holder of the Milestones Shares.

(d) **Purchase Price Obligations** . Upon payment of the respective portion of the Purchase Price (including any Milestone Payments) to the accounts or addresses designated by the Representative, as applicable, Buyer shall have no further liability or

obligation to distribute such respective portion of the Purchase Price to any Owner, and the Representative shall be solely responsible for distribution thereof to the Owners and for the payment of any costs and expenses related to such distribution.

1.3 Milestones.

(a) **First Milestone** . Upon the earlier to occur of (i) the later of (A) six (6) months following the Closing Date, and (B) the Date of Enrollment of the first patient in the first Clinical Trial, (ii) a Change of Control, (iii) entry into of a Strategic Collaboration Agreement by Buyer or an Affiliate thereof, or (iv) termination of the BioVascular License Agreement, Buyer shall issue to the Owners, in the case of a Change of Control, immediately prior to closing of such Change of Control, and otherwise within one (1) business day of the occurrence of such event, an aggregate of two million (2,000,000) shares of Buyer Common Stock, subject to adjustments in accordance with Section 1.3(c) hereof, as applicable (the " *First Milestone* ").

(b) **Second Milestone** . Upon the earlier to occur of (i) the Date of Enrollment of the first patient in the first Phase 3 Clinical Trial, (ii) the acceptance for filing by the FDA of a New Drug Application submitted by or on behalf of Buyer or an Affiliate or licensee or development partner thereof in respect of the Product Candidate, (iii) a Change of Control, so long as Buyer or an Affiliate has not terminated the development of the Product Candidate and terminated the BioVascular License Agreement, or (iv) entry into of a Strategic Collaboration Agreement by Buyer or an Affiliate thereof, Buyer shall issue to the Owners, in the case of a Change of Control, immediately prior to closing of such Change of Control, and otherwise within one (1) business day of the occurrence of such event, an aggregate of two million (2,000,000) shares of Buyer Common Stock, subject to adjustments in accordance with Section 1.3(c) hereof, as applicable (the " *Second Milestone* ").

(c) **Stock Consideration Adjustments** .

(i) The aggregate number of shares issued to the Owners in respect of the First Milestone or the Second Milestone, as applicable, shall in each case, be increased or decreased, as applicable, if, and only if: (x) the Average Closing Price of one share of Buyer Common Stock (1) with respect to a Change of Control, on the day of the first public announcement or public filing relating to such Change of Control, or (2) with respect to any other event resulting in the corresponding Milestone Payment becoming due and payable, the day on which the applicable Milestone is achieved, is less than $4.84 per share (as appropriately adjusted pursuant to Section 1.3(c)(ii) below), then Buyer shall issue to the Owners the number of shares of Buyer Common Stock equal to, in the aggregate, Nine Million Six Hundred and Eighty Thousand Dollars ($9,680,000) divided by such Average Closing Price (rounded to the nearest whole share); or (y) the Average Closing Price of one share of Buyer Common Stock (1) with respect to a Change of Control, on the day of the first public announcement or public filing relating to such Change of Control, or (2) with respect to any other event resulting in the corresponding Milestone Payment

becoming due and payable, the day on which the applicable Milestone is achieved, is greater than $6.84 per share (as appropriately adjusted pursuant to Section 1.3(c)(ii) below), then the Buyer shall issue to the Owners the number of shares of Buyer Common Stock equal, in the aggregate, to Thirteen Million Six Hundred and Eighty Thousand Dollars ($13,680,000) divided by such Average Closing Price (rounded to the nearest whole share). Notwithstanding the foregoing, in no event shall the aggregate number of shares of Buyer Common Stock issuable with respect to each of the First Milestone or Second Milestone exceed 3,000,000 shares of Buyer Common Stock.

(ii) The number of shares issuable or issued to the Owners pursuant to any provision hereunder and any determination of Average Closing Price shall be subject to appropriate adjustment by virtue of any stock split, stock dividend, combination, recapitalization or similar event affecting Buyer Common Stock generally.

(iii) Notwithstanding anything to the contrary contained herein, under no circumstances shall Buyer be permitted to satisfy any Milestone Payment with shares of Buyer Common Stock unless such issuance of Buyer Common Stock has been approved by the requisite vote of Buyer's stockholders in accordance with Rule 5635(a) of the NASDAQ Listing Rules. If Buyer is prohibited or otherwise restricted from distributing Buyer Common Stock, or Buyer otherwise determines that an issuance of Buyer Common Stock is not desirable, it shall not be relieved of its obligation to make the applicable Milestone Payment and such payment shall be made all in cash or in a combination of cash and Buyer Common Stock, as determined by Buyer in its sole discretion. The amount of any cash payment required to be made pursuant to this Section 1.3(c)(iii) shall be determined by multiplying (1) the number of shares of Buyer Common Stock in lieu of which such cash payment is being made, by (2) the Fair Market Value of one share of Buyer Common Stock with respect to the business day on which the applicable cash payment will be made (or the next succeeding business day, if such cash payment will be made other than on a business day).

(d) **Registration Rights** . Any shares of Buyer Common Stock received by the Owners pursuant to the First Milestone or Second Milestone hereunder, as applicable, shall be subject to the rights and obligations set forth in a Registration Rights Agreement by and between Buyer and the Owners (the " ***Registration Rights Agreement*** ").

(e) **Non-Transferability of Rights** . None of the rights of any Owner to receive the First Milestone Payment or the Second Milestone Payment shall be assignable or transferable except through a testamentary disposition, by the laws of descent and distribution upon the death of such Owner, as applicable, or as otherwise permitted in the Registration Rights Agreement. Any attempted assignment, transfer, conveyance, or other disposition (other than as aforesaid) of any interest in the rights of any Owner to receive the First Milestone Payment or the Second Milestone Payment shall be void.

(f) **Third Milestone** . Upon the FDA's written approval of a New Drug Application in respect of the Product Candidate submitted by or on behalf of Buyer or an Affiliate or licensee or development partner thereof, Buyer shall pay to the Owners an aggregate amount equal to Three Million Dollars ($3,000,000) in cash by check or wire transfer of immediately available funds to one or more accounts or addresses designated by the Representative (the " *Third Milestone* ").

(g) **Acknowledgements with Respect to Milestones** . From and after the Closing and continuing for so long as any payments may become payable under this Section 1.3, Buyer shall, or Buyer shall cause one or more of its Affiliates to, (i) use its (or their) Commercially Reasonable Efforts to achieve the First Milestone on or before the first anniversary of the Closing Date, and (ii) otherwise use its (or their) Commercially Reasonable Efforts to develop the Product Candidate, including, without limitation, with respect to the Company's performance under the BioVascular License Agreement. In the event that the Buyer, or one or more of its Affiliates, has not achieved the First Milestone on or before the first anniversary of the Closing Date (the " *First Milestone Deadline* "), Buyer shall be required to make the Milestone Payment in respect of the First Milestone on such date; provided, however, that in the event of **[**********]** (each, a " *Delay Event* "), the First Milestone Deadline will be extended by an amount of time equal to the duration of such Delay Event. Subject to the execution of a confidentiality agreement in form and substance reasonably satisfactory to Buyer, for so long as any payments may become due under this Section 1.3, Buyer shall provide the Representative a copy of the portions of the development plans and progress reports and any updates thereto required to be delivered pursuant to Section 4.7 of the BioVascular License Agreement which relate solely to the development of the Product Candidate, such documents to be delivered within ten (10) days of being provided to BioVascular.

(h) **Withholding** . Buyer will be entitled to deduct and withhold from the final Purchase Price including, for the avoidance of doubt, any Milestone Payment, any withholding taxes or other amounts required under the Code or any applicable Law to be deducted and withheld. To the extent that any such amounts are so properly deducted or withheld, such amounts will be treated for all purposes of this Agreement as having been paid to the Person in respect of which such deduction and withholding was made.

1.4 Post-Closing Cooperation . Each Owner agrees from time to time after the Closing Date, at Buyer's reasonable request, to execute, acknowledge, and deliver to Buyer such other instruments of conveyance and transfer and will take such other actions and execute and deliver such other documents, certifications, and further assurances as Buyer may reasonably require in order to vest more effectively in Buyer, or to put Buyer more fully in possession of, all membership or other equity interests of the Company and any of the Company's rights or assets used in the Business. Each of the Parties hereto will cooperate with the other and execute and deliver to the other Parties hereto such other instruments and documents and take such other actions as may be

reasonably requested from time to time by any other Party hereto as necessary to carry out, evidence, and confirm the intended purposes of this Agreement.

1.5 Representative.

(a) The Owners, by the approval and adoption of this Agreement, authorize the Representative to (i) take all action necessary to consummate the transactions contemplated hereunder, or to defend and/or settle any claims for which the Owners may be required to indemnify Buyer or any other Indemnified Party pursuant to Article VII, (ii) give and receive all notices required to be given under this Agreement, and (iii) take any and all additional action as is contemplated to be taken by or on behalf of the holders of Units by the terms of this Agreement.

(b) All decisions and actions by the Representative, including without limitation, (i) any agreement between the Representative and Buyer relating to the defense or settlement of any claims for which the Owners may be required to indemnify Buyer or any other Indemnified Party pursuant to Article VII, and (ii) any agreement between the Representatives and Buyer relating to the determination of the achievement of an event triggering Buyer's payment obligations under Section 1.3 or any other matter relating to Article I, shall be binding upon all of the Owners, and no Owner shall have the right to object, dissent, protest or otherwise contest the same.

(c) The Representative shall not have any liability to any of the parties hereto or to the Owners for any act done or omitted hereunder as Representative while acting in good faith and in the exercise of reasonable judgment, and any act done or omitted pursuant to the advice of counsel shall be conclusive evidence of such good faith. The Owners shall severally indemnify the Representative and hold it harmless against any loss, liability or expense incurred without gross negligence or bad faith on the part of the Representative and arising out of or in connection with the acceptance or administration of its duties hereunder.

(d) The Representative shall have full power and authority on behalf of each Owner to take any and all actions on behalf of, execute any and all instruments on behalf of, and execute or waive any and all rights of, the Owners under this Agreement.

(e) By his, her or its approval of this Agreement and the transactions contemplated hereby and thereby, each Owner agrees, in addition to the foregoing, that:

(i) Buyer shall be entitled to rely conclusively on the instructions and decisions of the Representative as to (i) the settlement of any claims for indemnification by Buyer pursuant to Article VII, (ii) actions taken in respect of the determination of the achievement of an event triggering Buyer's payment obligations under Section 1.3 or any other matter relating to Article I, (iii) written instructions provided to Buyer by the Representative relating to the Milestone Payments among the Owners from the amounts set forth on Schedule 1.1 , or (iv) any other actions required or permitted to be taken by the Representative hereunder, and no Owner

shall have any cause of action against Buyer for any action taken by Buyer in reliance upon the instructions or decisions of the Representative;

(ii) all actions, decisions and instructions of the Representative shall be conclusive and binding upon all of the Owners and no Owner shall have any cause of action against the Representative for any action taken, decision made or instruction given by the Representative under this Agreement except for fraud or willful misconduct by the Representative in connection with the matters described in this Section 1.5;

(iii) the provisions of this Section 1.5 are independent and severable, are irrevocable and coupled with an interest and shall be enforceable notwithstanding any rights or remedied that any Owner may have in connection with the transactions contemplated by this Agreement; and

(iv) the provisions of this Section 1.5 shall be binding upon the executors, heirs, legal representatives, personal representatives, successor trustees and successors of each Owner, and any reference in this Agreement to an Owner or the Owners shall mean and include the successors to the rights of the Owners hereunder, whether pursuant to testamentary disposition, the laws of descent and distribution or otherwise.

(f) The Representative may resign at any time by giving prior written notice to Buyer and the Owners, and the Representative may be removed, with or without cause, by the Owners previously holding at least a majority of the Units reflected on Schedule 1.1 (or their respective successors and assigns), at any time by giving prior written notice to Buyer and the Representative. Such resignation or removal shall take effect upon the appointment of a successor Representative by the Owners previously holding at least a majority of the Units reflected on Schedule 1.1 (or their respective successors and assigns). Upon the acceptance in writing of any appointment as Representative hereunder by a successor Representative, such successor Representative shall thereupon succeed to and become vested with all the rights, powers, privileges and duties of the retiring Representative, and the retiring Representative shall be discharged from its duties and obligations under this Agreement, but shall not be discharged from any liability for actions taken as Representative hereunder prior to such succession. After any retiring Representative's resignation or removal, the provisions of this Agreement shall inure to its benefit as to any actions taken or omitted to be taken by it while it was Representative under this Agreement.

(g) The Representative shall not be compensated for its services hereunder.

ARTICLE II- CLOSING

2.1 Closing . The closing of the transactions contemplated by this Agreement (the " *Closing* ") will take place on the date of this Agreement (the " *Closing Date* ") at the Representative's

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office at 325 East 41st Street, Suite 107, New York, New York 10017 and the Closing will be deemed effective as of 12:01 a.m. Eastern time on the Closing Date.

2.2 Closing Deliveries of the Company and the Owners . The Company and the Owners will deliver or cause to be delivered to Buyer the following at the Closing:

(i) Consulting Agreements by and between Buyer and Daniel DiPietro (" *DiPietro* "), and by and between Buyer and Peter Barber (" *Barber* "), in the forms of Exhibit A attached hereto (the " *Consulting Agreements* "), executed by DiPietro and Barber, respectively;

(j) a Manager's Certificate executed on behalf of the Company by its Manager, certifying that the Company's (i) organizational documents, and (ii) manager and member resolutions authorizing the execution, delivery and performance of the Transaction Documents, none of which have been modified, rescinded, or revoked;

(k) certificate for the Company from the Secretary of State of Delaware, certifying that the Company is validly existing and in good standing in Delaware;

(l) payoff letters acceptable to Buyer on all Indebtedness and lien releases with respect to all Liens (if any) relating to the Assets;

(m) evidence of the Legal Fees Amount in a form reasonably acceptable to Buyer;

(n) the Registration Rights Agreement executed by the Owners; and

(o) such other documents reasonably necessary for the consummation of the transactions contemplated by this Agreement as Buyer may reasonably request.

2.3 Closing Deliveries of Buyer . Buyer will deliver or cause to be delivered the following:

(a) the Closing Cash Payment by check or wire transfer of immediately available funds to one or more accounts or addresses specified by the Representative;

(b) the Consulting Agreements, executed with Buyer;

(c) the Registration Rights Agreement, executed by Buyer; and

(d) such other documents reasonably necessary for the consummation of the transactions contemplated by this Agreement as the Representative may reasonably request.

ARTICLE III- COVENANTS

3.1 Public Announcements. No Party will issue any press release or otherwise make any public statement with respect to the Closing of the purchase of the Units contemplated by this Agreement (a " *Closing Press Release* ") without the prior written consent of the Representative, in

the case of Buyer, or Buyer, in the case of the Representative or Owners, except as required by any Laws (including rules of any exchange). Each Party shall have the right to review any Closing Press Release and the Party making such Closing Press Release shall make such changes as are reasonably requested by the reviewing Party. In addition, neither the Owners nor the Representative will issue any press release or otherwise make any public statement regarding the transactions contemplated by this Agreement without the prior written consent of Buyer.

3.2 Preservation of Records . Buyer, each of Buyer's Affiliates and each Owner agrees that it shall preserve and keep the records held by it for a period of two (2) years from the Closing Date and shall make such records and personnel available to any Party as may be reasonably required by such Party in order to enable such Party to comply with its obligations under this Agreement and each other agreement, document or instrument contemplated hereby or thereby.

3.3 Tax Matters.

(h) **Tax Periods Ending on or Before the Closing Date** . Buyer shall prepare or cause to be prepared and timely file or cause to be timely filed all Tax Returns for the Company for all Tax periods ending on or prior to the Closing Date that are filed after the Closing Date (" *Pre-Closing Tax Periods* ").

(i) **Tax Periods Beginning Before and Ending After the Closing Date** . Buyer shall prepare or cause to be prepared and timely file or cause to be timely filed any Tax Returns of the Company for Tax periods that begin before the Closing Date and end after the Closing Date (" *Straddle Tax Periods* ").

(j) **Payment of Taxes** . The Owners shall be responsible for and shall indemnify Buyer from and against, any Tax of the Company that is attributable to a Pre-Closing Tax Period or to that portion of Straddle Tax Period that ends on the Closing Date, in each case to the extent that such Tax exceeds the amount (if any) reflected as a current liability for such Tax in the Unaudited Balance Sheet (as defined below). Within five (5) days prior to the due date for the payment of any such Tax, if the amount of such Tax for which the Owners are responsible pursuant to this Section 3.3 exceeds the amount reflected as a current liability for such Tax in the Unaudited Balance Sheet, the Owners shall pay to Buyer an amount equal to such excess. For purposes of this Section 3.3, in the case of any Taxes that are imposed on a periodic basis and are payable for a Straddle Tax Period, the portion of such Tax that relates to the portion of such Taxable period ending on the Closing Date shall be deemed to be the amount of such Tax for the entire Tax period multiplied by a fraction the numerator of which is the number of days in the Tax period ending on the Closing Date and the denominator of which is the number of days in the entire Tax period.

(k) **Sales and Transfer Taxes** . All sales, use, excise, value-added, goods and services, transfer, recording, documentary, registration, conveyancing and similar Taxes that may be imposed on the sale and transfer of the Units, together with any and all penalties, interest and additions to Tax with respect thereto shall be allocated among and paid in equal amounts by Buyer and the Owners; provided, that notwithstanding the foregoing [and in

accordance with the Registration Rights Agreement], all costs and expenses associated with the registration of Buyer Common Stock shall be paid by Buyer.

(l) **Cooperation on Tax Matters** . Buyer, the Company and the Owners shall cooperate as and to the extent reasonably requested by the other party, in connection with the filing of Tax Returns pursuant to this Section 3.3 and any audit, litigation or other proceeding with respect to Taxes. Such cooperation shall include the retention, until 30 days after the expiration of the applicable statute of limitations, and (upon the other Party's request) the provision of records and information that are reasonably relevant to any such audit, litigation or other proceeding and making employees available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder. In addition, the Parties shall cooperate in the preparation, execution and filing of all returns, questionnaires, applications and other documents regarding Taxes and all transfer, recording, registration and other fees that become payable in connection with the transactions contemplated hereby that are required or permitted to be filed at or prior to the Closing.

(m) **Representative Review** . To the extent any tax shown as due on any Tax Return filed after the Closing Date could reasonably be expected to be payable by Owners (taking into account the indemnification obligations hereunder), (a) such Tax Return shall be provided to Representative at least thirty (30) days prior to the filing deadline (or, if required to be filed within thirty (30) days of the Closing, as soon as possible following the Closing), (b) the Representative shall have the right to review and comment on such Tax Return and (c) Buyer shall make such revisions to such Tax Return as are reasonably requested by the Representative and consistent with applicable Laws.

(n) **Schedule K - 1** . Buyer shall, or cause one of its Affiliates to, deliver to each Owner the final Schedule K-1 for such Owner for the Company's partnership tax years ended December 31, 2013 and on the Closing Date within 90 days after the expiration of each such tax year.

3.4 Non-Competition and Non-Solicitation by the Owners .

(a) **Non-Competition** . For a period of **[***]** years after the Closing Date, each Owner (except with respect to performance of an Owner's obligations under the Consulting Agreements and any other agreements between an Owner and the Company or Buyer, as applicable) will not, directly or indirectly, (i) engage in **[***]** (a " *Competing Business* ") , or (ii) invest in, own, manage, operate, finance, control, advise, render services to or guarantee the obligations of any Person engaged in or planning to become engaged in any Competing Business; provided , however , that each Owner may purchase or otherwise acquire up to (but not more than) **[***]** % of any class of the securities of any Person engaged in or planning to become engaged in a Competing Business (but may not otherwise participate in the activities of such Person).

(b) **Non-Solicitation and Non-Hire.** For a period of five (5) years after the Closing Date, each Owner will not, directly or indirectly:

(i) solicit the business of any Person who is a customer of Buyer or its Affiliates with respect to a Competing Business;

(ii) cause, induce or attempt to cause or induce any customer, supplier, licensee, licensor, franchisee, employee, consultant or other business relation of Buyer or its Affiliates (A) to cease doing business with such parties, (B) to deal with any competitor of Buyer or its Affiliates, or (C) in any way interfere with its relationship with such parties, in the case of (B) and (C), in connection with a Competing Business;

(iii) cause, induce or attempt to cause or induce any customer, supplier, licensee, licensor, franchisee, employee, consultant or other business relation of the Company on the Closing Date or within the year preceding the Closing Date (A) to cease doing business with Buyer or its Affiliates, (B) to deal with any competitor of Buyer or its Affiliates, or (C) in any way interfere with its relationship with such parties, in the case of (B) and (C), in connection with a Competing Business; or

(iv) hire, retain or attempt to hire or retain any employee of Buyer or its Affiliates or in any way interfere with the relationship between Buyer and its Affiliates and any of their respective employees.

(c) **Modification of Covenant** . If a final judgment of a court or tribunal of competent jurisdiction determines that any term or provision contained in this Section 3.4 is invalid or unenforceable, then the Parties agree that the court or tribunal will have the power to reduce the scope, duration or geographic area of the term or provision, to delete specific words or phrases or to replace any invalid or unenforceable term or provision with a term or provision that is valid and enforceable and that comes closest to expressing the intention of the invalid or unenforceable term or provision. This Section 3.4 will be enforceable as so modified after the expiration of the time within which the judgment may be appealed. Each Owner acknowledges this Section 3.4 is reasonable and necessary to protect and preserve Buyer's and its Affiliates' legitimate business interests and that such party will not challenge the enforceability of such restrictions.

3.5 Confidentiality by Owners. Each Owner will (i) for a period of five (5) years from the Closing Date, keep confidential and not disclose to others, all proprietary, non-public information of Buyer and the Company (collectively, the " ***Protected Information*** ") and (ii) not use any of the Protected Information for such Owner's own direct or indirect benefit, or the direct or indirect benefit of any third party, except that such Owner may use such information to the extent necessary to perform its duties and obligations, or to enforce such Owner's rights, under this Agreement or any other agreement between an Owner and Buyer, as applicable. The foregoing shall not prohibit disclosures compelled to be made by any requirement of Law or pursuant to any legal, regulatory or investigative proceeding before any court, or governmental or regulatory authority, agency or

commission so long as such Owner provides prior written notice to Buyer so that Buyer may seek a protective order or other remedy to protect the confidentiality of the Protected Information and/or waive such Owner's compliance with this Section 3.5, provided that all such information so disclosed (other than in a way which makes it generally available to the public) shall remain Protected Information for all other purposes. If such protective order, other remedy or waiver is not obtained by the time such Owner is required to comply, such Owner may furnish only that portion of the Protected Information that it is legally compelled, in the opinion of counsel, to disclose and shall request, at Buyer's expense, that such Protected Information be accorded confidential treatment (if such procedure is available), including redaction of any payment terms specified herein. Each Owner further agrees to take appropriate measures to prevent any such prohibited disclosure of Protected Information by his, her or its present and future employees, officers, agents, subsidiaries, or consultants. Notwithstanding the foregoing, no data or information constitutes "Protected Information" if such data or information is publicly known and in the public domain through means that do not involve a breach by an Owner of any covenant or obligation set forth in this Agreement or any other agreement between an Owner and the Buyer, as applicable.

3.6 Confidentiality by Buyer . Except as required pursuant to any applicable Laws, from and after the Closing Date, Buyer shall not intentionally disclose, and shall not permit any of its Affiliates to disclose intentionally, any documents or other information related to a Third-Party Claim, the defense of which has been assumed by an Owner pursuant to Section 7.3 (a).

3.7 Enforcement of Covenants . The Parties agree that the remedy of damages at law for the breach of any of the covenants contained in Section 3.4 and Section 3.5 is an inadequate remedy and that each Owner will not challenge the enforceability or reasonableness of the covenants set forth in Section 3.4 or Section 3.5 hereof. In recognition of the irreparable harm that a violation by the Owner of any of the covenants, agreements or obligations arising under Section 3.4 or Section 3.5 would cause Buyer or its Affiliates, each Owner agrees that in addition to any other remedies or relief afforded by law, an injunction against a violation or violations may be issued against the Owner without posting a bond or other security. In the event of an action to enforce the covenants in Sections 3.4 and 3.5, the prevailing party as finally determined by a court of competent jurisdiction will be entitled to be reimbursed for actual attorney's fees incurred by such party with respect to such action. Should any Owner violate any of the terms of the restrictive covenant obligations set forth in Section 3.4 or Section 3.5 hereof, the period of the obligation at issue will be extended by the period of time that such Owner (as applicable) was in violation of such obligation.

ARTICLE IV- REPRESENTATIONS OF THE COMPANY AND THE OWNERS

The Company and the Owners, jointly and severally, represent and warrant to Buyer that the statements contained in this Article IV are true and correct as of the date hereof except as set forth in the disclosure schedules attached hereto (the " *Disclosure Schedules* "). Notwithstanding anything to the contrary herein, (1) the representations and warranties set forth in this Article IV are made for the purpose of allocating contractual risk between the Parties hereto and shall not constitute or be deemed to be an admission of fact to any third party concerning any item set forth herein and (2) the use and meaning of the term "material" (and variations thereof) herein may be different from the use and meaning of such term under applicable securities laws.

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4.1 Organization and Qualification . The Company is a limited liability company duly organized and existing in good standing under the laws of Delaware. The Company has full corporate power and authority to carry on its business as it is now being conducted and to own or lease its properties and assets. The Company is duly qualified to conduct business as a foreign corporation and is in good standing in each jurisdiction wherein the nature of its activities requires such qualification, except where the failure to be so qualified would not have a material adverse effect on the Company's business, financial condition or results of operations.

4.2 Power and Authority; Enforceability . The Company has all power and authority to enter into and consummate the transactions contemplated by this Agreement and the agreements contemplated herein (collectively, the " *Transaction Documents* ") to which it is a party. The Transaction Documents to which it is a party have been duly executed and delivered by the Company and such Transaction Documents constitute the legal, valid and binding obligations of the Company, enforceable against the Company in accordance with their respective terms except that the enforceability thereof may be subject to or limited by bankruptcy, insolvency, reorganization, arrangement, moratorium, or other similar Laws relating to or affecting rights of creditors and general equitable principles.

4.3 Indebtedness . The Company is not in default of its obligations under its Indebtedness. The Company has not received any notice of default nor is the Company aware of any circumstances that could give rise to such notice.

4.4 No Conflicts . The execution, delivery and performance of this Agreement and the Transaction Documents by the Company and the consummation of the transactions contemplated herein and therein will not: (a) result in a violation of Law, (b) result in a breach of the terms and conditions of, constitute a default under or violation of, terminate or modify, or give any party the right to terminate or modify, the articles of incorporation, bylaws or other organizational documents of the Company or any agreement, mortgage, note, bond, indenture, license or other instrument or obligation to which the Company is a party or by which the Company or any of its assets (including, without limitation, the Business) may be bound or affected; (c) result in the creation of any Lien upon any asset of the Company; or (d) require any authorization, consent, approval, exemption or other action by or notice to any person or entity.

4.5 Capitalization . The capitalization of the Company is as set forth on Schedule 1.1 . The membership interests set forth on Schedule 1.1 constitute all of the Company's outstanding membership interests and are validly issued, fully paid and non-assessable. Except as set forth on Schedule 1.1, there are no (i) outstanding subscriptions, options, calls, contracts, commitments, understandings, restrictions, arrangements, rights or warrants, including any rights plan, and any right of conversion or exchange under any outstanding security, instrument or other agreement, obligating the Company to issue, deliver or sell, or cause to be issued, delivered or sold, additional membership interests of the Company or obligating the Company to grant, extend or enter into any such agreement or commitment, and (ii) no voting trusts, proxies or other agreements or understandings to which the Company is a party or is bound with respect to the voting of any of the membership interests. There are no outstanding or authorized equity appreciation rights, phantom equity payments based on the consideration payable to the Owners, payments based on a

change of control of the Company, or other similar rights with respect to the Company. The Company does not have any subsidiaries and does not hold any equity or membership interest of any Person.

4.6 Listing of Certain Assets and Data .

(a) **Real Property** . The Company does not own, lease or have any options relating to, of record or beneficially, any real property. The Company does not use any real property in the conduct of the Business.

(b) **Equipment** . The Company does not own, lease or use any material items of machinery, equipment, tools, furniture, fixtures, vehicles or other similar property and assets.

(c) **Permits** . The Company has not obtained any permits, licenses, approvals, registrations, authorizations, certificates, exemptions and/or approvals of any Governmental Entity relating to the Business or the Product Candidate (collectively, the " *Permits* ").

(d) **Indebtedness Agreements** . Schedule 4.6 (d) sets forth a list of all outstanding mortgages, promissory notes, evidences of Indebtedness, deeds of trust, indentures, loan or credit agreements or similar instruments for money borrowed, excluding normal trade credit, to which the Company is a party (as lender or borrower), written or otherwise, and all amendments or modifications, if any, thereof. Prior to the date of this Agreement, the Company has delivered to Buyer true and complete copies of all documents identified in Schedule 4.6(d) .

(e) **Insurance Policies and Claims** . The Company has never and does not currently maintain any policies of insurance.

(f) **Employees** . The Company has two managers, Daniel DiPietro and Peter Barber, and one consultant, Paul Glidden. The Company has no employees.

(g) **Benefit Plans** . The Company does not maintain any Benefit Plans.

(h) **Powers of Attorney** . The Company has granted no powers of attorneys.

(i) **Tax Returns** . The Company has never filed a Tax Return.

(j) **Inventory** . The Company has no inventory.

(k) **Banks and Depositories** . Schedule 4.6(k) sets forth a list of each bank, broker or other depository with which the Company has an account or safe deposit box, the names and numbers of such accounts or boxes and the names of all persons authorized to draw or execute transactions on such accounts.

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(l) **Accounts Receivable and Accounts Payable** . The Company has no accounts or notes receivable. Other than the Indebtedness and the Legal Fees Amount, the Company has no accounts payable.

(m) **Business Documentation.** The Company has made available to Buyer all of the following information and documentation in the Company's possession (1) research and development materials, study protocols, reports and records of the Company related to the Business or the Product Candidate, (2) production reports and records related to the Business or the Product Candidate, (3) all filings, submissions, records and correspondence with Governmental Entities, including the FDA, (4) testing, maintenance and validation records and other documents relating to the Product Candidate, (5) safety reports, logs and vigilance records (collectively, " ***Business Documentation*** ").

(n) **Intangibles** . The Company has no telephone numbers, facsimile numbers, e-mail addresses, social media accounts, or websites.

4.7 Compliance with Laws .

(a) The Company is not in material default or violation of any applicable federal, state, local, or foreign Laws, ordinances, regulations, interpretations, judgments, decrees, injunctions, permits, licenses, certificates, governmental requirements, orders, codes, standards or other similar items of any court or other Governmental Entity. No written notice has been received by the Company from any Governmental Entity or any Person alleging a violation of or liability under any applicable Law.

(b) The Company has not received any notice or other communication from the FDA or any other Governmental Entity alleging any violation by the Company with respect to work performed for the benefit of the Company, of any applicable Laws within the jurisdiction of the FDA or any comparable state or foreign Governmental Entity, including any failure to maintain systems and programs adequate to ensure compliance with any applicable Law. Neither the Company nor, to the Knowledge of the Company, anyone acting on behalf of the Company, has received any notice that the FDA or any other Governmental Entity or institutional review board has initiated, or threatened to initiate, any clinical hold or other action to suspend any clinical trial or suspend or terminate any NDA, Investigational New Drug (" ***IND*** ") (or foreign equivalent thereof) sponsored by the Company.

(c) The Company has not conducted, nor engaged any Company Partner to conduct on its behalf, any clinical trials.

(d) None of the Company, nor to the Knowledge of the Company, any manager, employee or agent of the Company has been convicted of any crime or engaged in any conduct that would reasonably be expected to result in or that has resulted in (i) debarment under 21 U.S.C. Section 335a or any similar Law, or (ii) exclusion from participating in the federal health care programs under Section 1128 of the Social Security Act or any similar Law. In addition, to the Knowledge of the Company, the Company is in substantial

compliance with all applicable registration and listing requirements promulgated by the FDCA.

(e) None of the Company or, to the Knowledge of the Company, any manager, employee or agent of the Company, has made an untrue statement of a material fact or fraudulent statement to the FDA or any other Governmental Entity, failed to disclose a material fact required to be disclosed to the FDA or any other Governmental Entity, or committed any act, made any statement, or failed to make any statement, that would reasonably be expected to provide a basis for the FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Fact, Bribery, and Illegal Gratuities", set forth in 56 Fed. Reg. 46191 (September 10, 1991) or any similar policy.

(f) To the Knowledge of the Company, there are no lawsuits or other legal proceedings, whether judicial or administrative, pending or threatened against the Company with respect to any alleged injuries to a participant in any clinical trial conducted by the Company.

(g) The Company has no investigational new drug applications, biologics license applications or other product license applications or product licenses. The Company has no biological materials in its possession or control.

(h) Neither the Company, nor any of its managers, is: (i) a person or entity that appears on the Specially Designated Nationals and Blocked Persons List (the SDN List) maintained by the Office of Foreign Assets Control of the U.S. Department of the Treasury (OFAC); or (ii) a person, country, or entity with whom a U.S. person (as defined by the laws and regulations administered by OFAC, 31 C.F.R. Parts 500-598 (the "OFAC Regulations")) or a person subject to the jurisdiction of the United States (as defined by the OFAC Regulations) is otherwise prohibited from dealing under the OFAC Regulations (a " ***Sanctions Target*** "). The Company is not, directly or indirectly, owned or controlled by, or under common control with, or acting for the benefit of or on behalf of any Sanctions Target. The Company is not located in or incorporated in Iran, Sudan, Syria, Cuba, the Union of Myanmar or North Korea. The Company has materially complied, and is in material compliance, with all national and international laws, statutes, orders, rules, regulations and requirements promulgated by any Governmental Entity with regard to the exportation of goods, technology or software. Specifically, the Company has not, during the past five (5) years, exported or reexported any goods or technology or software in any manner that violates any applicable national or international export control regulations or sanctions, including, but not limited to, the United States Export Administration Regulations, 15 C.F.R. Parts 730-774, and the OFAC Regulations.

(i) Neither the Company nor any of its managers, employees or officers, and to the Company's Knowledge, no agents, consultants or distributors engaged by the Company (a) has used or is using any corporate funds for any illegal contributions, gifts, entertainment or other unlawful expenses relating to political activity, (b) has used or is using any corporate funds for any direct or indirect unlawful payments to any foreign or domestic Government

Official or employee, (c) has violated or is violating any provision of the US Foreign Corrupt Practices Act of 1977, as amended (including the rules and regulations issued thereunder) or any other law, rule, regulation, or other legally binding measure of any jurisdiction that relates to bribery or corruption (collectively, " *Anti-Bribery Laws* "), (d) has established or maintained, or is maintaining, any unlawful fund of corporate monies or other properties, (e) has made any bribe, unlawful rebate, unlawful payoff, influence payment, kickback or other unlawful payment of any nature in furtherance of an offer, payment, promise to pay, authorization, or ratification of the payment, directly or indirectly, of any gift, money or anything of value to a Government Official to secure any improper advantage (within the meaning of such term under any applicable Anti-Bribery Law) or to obtain or retain business, or (f) has otherwise taken any action that has caused, or would reasonably be expected to cause the Company to be in violation of any applicable Anti-Bribery Law.

(j) The Company is and at all times has been in material compliance with federal or state criminal or civil Laws (including the federal Anti-Kickback Statute (42 U.S.C. §1320a-7b), Stark Law (42 U.S.C. §1395nn), Federal False Claims Act (31 U.S.C. §3729 et seq.), Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. §1320d et seq., and any comparable state or local laws), and the regulations promulgated pursuant to such Laws, or which are cause for civil or criminal penalties or mandatory or permissive exclusion from Medicare (Title XVIII of the Social Security Act), Medicaid (Title XIX of the Social Security Act) or any other state or federal health care program (each, a " *Program* "). To the Knowledge of the Company, there is no civil, criminal, administrative or other action, suit, demand, claim, hearing, investigation, proceeding, notice or demand (a " *Proceeding* ") (i) excluding any sealed Proceeding, pending or received, (ii) in the case of a sealed Proceeding, pending or received, or (iii) in the case of any Proceeding, threatened, in each case against the Company, that could reasonably be expected to result in its exclusion from participation in any Program or other third party payment programs in which the Company participates.

(k) The Company is not the subject of any pending or, to the Knowledge of the Company, threatened investigation in respect of the Company or the Company's products by the FDA pursuant to its "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" Final Policy set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto. Neither the Company, nor any manager, employee, or to the Knowledge of the Company, any agent of the Company, or any other person acting on such agent's behalf, has directly or indirectly, given or agreed to give any gift or similar benefit to any customer, supplier, governmental employee or other person who is or may be in a position to help or hinder the business of the Company (or assist the Company in connection with any actual or proposed transaction) in violation of any applicable law or regulation.

4.8 Litigation . There is no litigation or proceeding outstanding or pending to which the Company is a party which relates to or could reasonably potentially impact the Business.

4.9 Financial Statements; Undisclosed Liabilities . Schedule 4.9 contains a copy of the unaudited balance sheet of the Company dated as of December 31, 2013 (the " *Unaudited Balance*

Sheet "). The Unaudited Balance Sheet has been prepared from and is in accordance with, the books and records of the Company and the Business and present fairly, in all material respects, the financial position of the Company as of December 31, 2013. There are no Liabilities of the Company other than (i) the Legal Fees Amount, (ii) the Indebtedness, (iii) as are reflected or reserved against on the Unaudited Balance Sheet, or (ii) those incurred after December 31, 2013 in the ordinary course of business.

4.10 Absence of Changes . Since December 10, 2013, there has been no Material Adverse Effect, and the Company has conducted the Business only in the ordinary course of business, and has not, with respect to the Business and except as set forth on the Disclosure Schedule:

(a) discharged or satisfied any Liens or paid any material obligation or Liability, other than current Liabilities paid in the ordinary course of business, or cancelled, compromised, waived or released any material right or material claim;

(b) sold, assigned, licensed or transferred any of its assets, except for sales in the ordinary course of business, or mortgaged, pledged or subjected its assets to any Lien;

(c) sold, assigned, transferred, abandoned or permitted to lapse any licenses or Permits;

(d) made changes in employment terms for any employee, officer or director other than in the ordinary course of business;

(e) suffered any material loss, damage, destruction or casualty loss or waived any rights of material value, whether or not covered by insurance and whether or not in the ordinary course of business;

(f) borrowed any amount or incurred or become subject to any material Liabilities, except amounts borrowed and current Liabilities incurred in the ordinary course of business and Liabilities under contracts entered into in the ordinary course of business;

(g) commenced any litigation or binding dispute resolution process or settled or compromised any pending or threatened suit, action or claim;

(h) commenced any product recall or investigation;

(i) except where incidental to the sale of products or services, granted any license or sublicense of any rights under or with respect to any Intellectual Property Rights; or

(j) entered into any other material transaction, other than in the ordinary course of business.

4.11 Prior Activities . Other than (1) entering into, and performing its obligations under, the Material Contracts and arrangements identified in Schedule 4.6(d) , (2) issuing the Units to the Owners, (3) undertaking activities in connection with the transactions contemplated by the

Transaction Documents, and (4) opening the bank and depository accounts listed on Schedule 4.6(k) , the Company has engaged in no other material business or activities.

4.12 Contracts .

(a) Schedule 4.12 contains an accurate list of all Material Contracts.

(b) Except as set forth on Schedule 4.12, the Company has performed all material obligations required to be performed by it to date under the Material Contracts, and there are no defaults, to the Knowledge of the Company, by any other party thereto, and, no event has occurred (or failed to occur) that, with the passing of time or the giving of notice or both would constitute a default by the Company under any such Material Contract, including the consummation of the transactions contemplated by this Agreement.

(c) No consent, permission, waiver or approval is required to be obtained from, and no penalty, assessment or special payment is required to be paid to, and no notice is required to be sent to, any third party or Government Entity in order to preserve for Buyer the benefits of the Material Contracts after the consummation of the transactions contemplated by this Agreement.

(d) Each Material Contract is in full force and effect and constitutes a legal, valid, binding agreement of the Company, except that the enforceability thereof may be subject to or limited by bankruptcy, insolvency, reorganization, arrangement, moratorium, or other similar Laws relating to or affecting rights of creditors and general equitable principles.

(e) Buyer has been supplied with (i) true and correct copies of all Material Contracts, together with all amendments, waivers or other changes thereto, (ii) true and correct copy copies of any form contracts relating to the Business as identified on Schedule 4.12 , and (iii) true and correct written summaries of all oral contracts or agreements relating to the Business as set forth on Schedule 4.12 .

4.13 Title; Sufficiency of Assets . The Company has good and marketable title to, or a valid leasehold or subleasehold interest in, all of its assets (the " *Assets* "), free and clear of Liens (if any) except as set forth on Schedule 4.13 .

4.14 Tax Matters .

(a) Subject to Section 3.3 hereof, the Company has timely filed all Tax Returns that it was required to file. Other than payment of annual Taxes to the State of Delaware, all Taxes owed by the Company (whether or not shown or required to be shown on any Tax Return) have been paid. The Company is not currently the beneficiary of any extension of time within which to file any Tax Return. No claim has been made by an authority in a jurisdiction that the Company is or may be subject to taxation by that jurisdiction. There are no Liens that arose in connection with any failure (or alleged failure) to pay any Tax. The Company has not waived any statute of limitations in respect of Taxes nor has agreed to nor is subject to any extension of time with respect to a Tax assessment or deficiency.

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(b) To the Company's Knowledge, all Taxes required to have been withheld and paid in connection with any amounts paid or owing by the Company to any employee, independent contractor, creditor, member, or other third party have been withheld and paid, and all Forms W-2 and 1099 required with respect thereto have been properly completed and timely filed other than any forms that are required to be completed and filed by Buyer pursuant to Section 3.3 hereof. To the Company's Knowledge, all Persons providing services have been properly classified as employees or independent contractors for Tax and other purposes.

(c) There is no dispute or claim concerning any Tax Liability of the Company either (i) claimed or raised by any Government Entity or (ii) as to which the Company has Knowledge.

(d) The Company is not a party to any Tax allocation or sharing agreement. The Company has no Liability for the Taxes of any Person, as a transferee or successor, by contract, or otherwise.

4.15 Service Providers. The Company has not received any notice from any consultant or service provider to the effect that any such party will stop, materially decrease the rate of, or materially change the terms (whether related to payment, price or otherwise) with respect to providing services to the Company (whether as a result of the consummation of the transactions contemplated hereby or otherwise).

4.16 Product Sales. The Company has never made any sales or otherwise realized any revenue relating to its sale of any product or performance of any service.

4.17 Brokerage and Finder's Fees. The Company has not incurred any brokerage, finder's fee or similar fee in connection with the transactions contemplated hereby.

4.18 Affiliate Transactions. Other than the Material Contracts, arrangements set forth on Schedule 4.6(d) , and the issuance and ownership of the Units, there are no transactions or relationships amongst the Company, on the one hand, and its Affiliates, on the other, including, without limitation, with respect to shared assets, shared personnel, shared services, shared facilities, shared equipment, and shared systems.

4.19 Software . The Company does not own or use any Software except for commercially-available, non-customized off-the-shelf software.

4.20 Intellectual Property Rights .

(a) Except for the BioVascular License Agreement, the Company has no Intellectual Property Rights.

(b) To the Knowledge of the Company, the BioVascular License Agreement contains all of the Intellectual Property Rights necessary to enable the Company to conduct the Business in the manner in which the Business has been conducted, is currently being

conducted, and is proposed to be conducted. The Company has not transferred ownership of, or granted any interest in, the BioVascular License Agreement. To the Knowledge of the Company, there are no royalties, honoraria, fees or other payments payable by the Company as a result of the ownership, use, possession, license, sale, marketing, advertising or disposition of any Intellectual Property Rights other than as set forth in the BioVascular License Agreement.

(c) To the Knowledge of the Company, there is no unauthorized use or disclosure, infringement or misappropriation of any Intellectual Property Rights covered by the BioVascular License Agreement, by any third party. To the Knowledge of the Company, the Company has not infringed or misappropriated any third-party Intellectual Property Rights. To the Knowledge of the Company, the operation of the Business does not and will not infringe or misappropriate any third-party Intellectual Property Right, and does not constitute unfair competition or unfair trade practices under any Laws.

4.21 Privacy.

(a) The Company has materially complied with all applicable Laws relating to the use, collection, storage, disclosure and transfer of any personally identifiable information collected in connection with the Business by the Company or by third parties (other than Buyer and its Affiliates, employees, service providers, agents and representatives) that have been granted access by the Company to the records of the Company. The execution, delivery and performance of this Agreement, will comply in all material respects with all applicable Laws relating to privacy. The Company has not received any complaint regarding the collection, use or disclosure of personally-identifiable information in connection with the Business.

(b) The Company is in compliance, in all material respects, with all applicable Laws relating to patient data (" ***Data*** "), including without limitation, Health Insurance Portability and Accountability Act of 1996, as amended. There have been (i) no material losses or thefts of Data or security breaches relating to Data used or accessed in the Business; (ii) violations of any privacy or security policy or any agreement regarding any such Data; (iii) any unauthorized access or unauthorized use of any Data; and (iv) no unintended or improper disclosure of any personally identifiable information in the possession, custody or control of the Company or, to the Knowledge of the Company, a contractor or agent acting on behalf of the Company.

4.22 Disclosure . No representation or warranty by the Company contained in this Agreement, and no statement contained in the Disclosure Schedules or any other document, certificate or other instrument delivered to or to be delivered by or on behalf of the Company pursuant to this Agreement, contains or will contain any untrue statement of material fact or omits to state any material fact necessary, in the light of the circumstances under which it was or will be made, in order to make the statements herein and therein not misleading.

ARTICLE V- REPRESENTATIONS OF THE OWNERS

Each Owner, severally and not jointly, represents and warrants to Buyer that the statements contained in this Article V with respect to such Owner are true and correct as of the date hereof. Notwithstanding anything to the contrary herein, (1) the representations and warranties set forth in this Article V are made for the purpose of allocating contractual risk between the Parties hereto and shall not constitute or be deemed to be an admission of fact to any third party concerning any item set forth herein and (2) the use and meaning of the term "material" (and variations thereof) herein may be different from the use and meaning of such term under applicable securities laws.

5.1 Power and Authority; Enforceability . Such Owner has all power and authority to enter into and consummate the transactions contemplated by this Agreement and the Transaction Documents to which it is a party. The Transaction Documents to which it is a party have been duly executed and delivered by such Owner and such Transaction Documents constitute the legal, valid and binding obligations of such Owner, enforceable against the Owner in accordance with their respective terms except that the enforceability thereof may be subject to or limited by bankruptcy, insolvency, reorganization, arrangement, moratorium, or other similar Laws relating to or affecting rights of creditors and general equitable principles.

5.2 No Conflicts . The execution, delivery and performance of this Agreement and the Transaction Documents by such Owner and the consummation of the transactions contemplated herein and therein will not: (a) result in a violation of Law, or (b) require any authorization, consent, approval, exemption or other action by or notice to any person or entity.

5.3 Capitalization .

(a) Such Owner is the record and beneficial owner of the Units shown as owned by such Owner on Schedule 1.1. Such Owner has good and valid title to the Units to be sold by such Owner hereunder, free and clear of all Liens.

(b) There are no voting trusts, proxies or other agreements or understandings to which such Owner is a party or is bound with respect to the voting of any of the membership interests. There are no outstanding or authorized equity appreciation rights, phantom equity payments based on the consideration payable to such Owner, payments based on a change of control of the Company, or other similar rights with respect to the Company.

5.4 Litigation . There is no litigation or proceeding outstanding or pending to which such Owner is a party which relates to or could reasonably potentially impact the Business.

5.5 Brokerage and Finder's Fees. Such Owner has not incurred any brokerage, finder's fee or similar fee in connection with the transactions contemplated hereby.

5.6 Disclosure . No representation or warranty by such Owner contained in this Agreement, and no statement contained in any document, certificate or other instrument delivered to or to be delivered by or on behalf of such Owner pursuant to this Agreement, contains or will contain any untrue statement of material fact or omits to state any material fact necessary, in the

light of the circumstances under which it was or will be made, in order to make the statements herein and therein not misleading.

ARTICLE VI- REPRESENTATIONS OF BUYER

Buyer represents and warrants to the Company and the Owners that the statements contained in this Article V are true and correct as of the date hereof. Notwithstanding anything to the contrary herein, (1) the representations and warranties set forth in this Article IV are made for the purpose of allocating contractual risk between the Parties hereto and shall not constitute or be deemed to be an admission of fact to any third party concerning any item set forth herein and (2) the use and meaning of the term "material" (and variations thereof) herein may be different from the use and meaning of such term under applicable securities laws.

6.1 Authorization; Enforceability . The execution and delivery by Buyer of Transaction Documents to which it is a party and the consummation by Buyer of the transactions contemplated by the Transaction Documents have been duly authorized by all necessary corporate action on the part of Buyer. The Transaction Documents to which it is a party have been duly executed and delivered by Buyer and such Transaction Documents constitute the legal, valid and binding obligations of Buyer, enforceable against Buyer in accordance with their respective terms except that the enforceability thereof may be subject to or limited by bankruptcy, insolvency, reorganization, arrangement, moratorium, or other similar Laws relating to or affecting rights of creditors and general equitable principles.

6.2 Organization . Buyer is a corporation duly organized, validly existing and in good standing under the Laws of Delaware. Buyer has all requisite power and authority to own its properties and to carry on its business as now being conducted, to execute and deliver the Transaction Documents to which it is a party and to perform its obligations under the Transaction Documents. Buyer has delivered to the Company (or made publicly available via EDGAR) complete and correct copies of the certificate of incorporation and bylaws of Buyer, in each case as amended through the date of this Agreement. Buyer is duly qualified to conduct business as a foreign corporation and is in good standing in each jurisdiction wherein the nature of its activities requires such qualification, except where the failure to be so qualified would not have a material adverse effect on Buyer's business, financial condition or results of operations.

6.3 Buyer Common Stock . The shares of Buyer Common Stock to be issued pursuant to this Agreement have been duly and validly authorized and when issued will be validly issued, fully paid and non-assessable, free and clear of all Liens and not subject to any preemptive rights created by statute, the certificate of incorporation or bylaws of Buyer or any contracts to which Buyer is or shall at such time be a party or by which it is or may at such time be bound.

6.4 No Conflicts. The execution, delivery and performance of this Agreement and the Transaction Documents by Buyer and the consummation of the transactions contemplated herein and therein will not: (i) result in a violation of Law, (ii) result in a breach of the terms and conditions of, constitute a default under or violation of, terminate or modify, or give any party the right to terminate or modify, the articles of incorporation, bylaws or other organizational documents of

Buyer; or (iii) require any authorization, consent, approval, exemption or other action by or notice to any person or entity.

6.5 Litigation . There is no litigation, suit, proceeding, claim, arbitration or investigation pending, or as to which Buyer has received any notice of assertion, against Buyer, nor is there any injunction, order, judgment, ruling or decree imposed upon Buyer by or before any Governmental Entity that would, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect on Buyer, impair in any material respect the ability of Buyer to perform its obligations hereunder or prevent, enjoin, alter or materially delay any of the transactions contemplated by this Agreement.

6.6 Buyer Reports.

(a) Buyer has filed all Buyer Reports required to be filed with the SEC on or prior to the date hereof. Each Buyer Report has complied in all material respects with the applicable requirements of the Securities Act, and the rules and regulations promulgated thereunder, and the Exchange Act, and the rules and regulations promulgated thereunder, as applicable, each as in effect on the date so filed. The Buyer Reports have been made available to the Company or are readily available for download from the SEC's online EDGAR system. None of the Buyer Reports (including any financial statements or schedules included or incorporated by reference therein) contained when filed (or, if amended or superseded by a subsequent filing, as of the date of the last such amendment or superseding filing prior to the date hereof) any untrue statement of a material fact or omitted or omits, as the case may be, to state a material fact required to be stated or incorporated by reference therein or necessary to make the statements therein, in the light of the circumstances under which they were or are made, not misleading.

(b) The consolidated financial statements of Buyer included in the Buyer Reports (the " ***Buyer Financial Statements*** ") comply as to form in all material respects with the published rules and regulations of the SEC with respect thereto, have been prepared in accordance with GAAP and Regulation S-X of the SEC (except, in the case of unaudited interim statements, as indicated in the notes thereto or, in the case of unaudited financial statements, as permitted by Form 10-Q under the Exchange Act) applied on a consistent basis during the periods involved (except as may be indicated in the notes thereto or, in the case of unaudited financial statements, as permitted by Form 10-Q under the Exchange Act) and fairly present in all material respects the consolidated financial position of Buyer and its subsidiaries as of the dates thereof and the consolidated results of their operations and cash flows for the periods then ended (subject, in the case of unaudited interim statements, to normal year-end audit adjustments). There has been no change in Buyer's accounting policies except as described in the notes to the Buyer Financial Statements. The Buyer Financial Statements fully and accurately accrue all actual and contingent liabilities for Taxes with respect to all periods through the dates thereof in accordance with GAAP.

(c) Since January 1, 2013, except for publicly disclosed matters and actions taken in connection with this Agreement and the transactions contemplated hereby, (i) Buyer has

conducted its business in the ordinary course, and (ii) there has not been any Material Adverse Effect or any change, event, development, condition, occurrence or effect that has had or would reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect on Buyer. Between January 1, 2013 and the date hereof, no event has occurred (other than the execution of this Agreement) that requires or will require Buyer to file a Form 8-K with the SEC that has not been filed prior to the date hereof by Buyer.

6.7 Compliance with Legal Requirements . Buyer is in compliance with all Laws applicable to it, except for such non-compliance as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect on Buyer. Buyer hold all Permits necessary for the lawful conduct of its business, and all such Permits are valid and in full force and effect, except where the failure to hold the same or of the same to be valid and in full force and effect would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect on Buyer. Buyer is in compliance with the terms of all Permits, except for such non-compliance as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect on Buyer.

6.8 Brokerage and Finder's Fees. Buyer has not incurred any brokerage, finder's fee or similar fee in connection with the transactions contemplated hereby.

6.9 Disclosure . No representation or warranty by Buyer contained in this Agreement, and no statement contained in any document, certificate or other instrument delivered to or to be delivered by or on behalf of Buyer pursuant to this Agreement, contains or will contain any untrue statement of material fact or omits to state any material fact necessary, in the light of the circumstances under which it was or will be made, in order to make the statements herein and therein not misleading.

ARTICLE VII- SURVIVAL AND INDEMNIFICATION

7.1 Survival of Representations, Warranties, Covenants and Agreements . The representations, warranties, and covenants in this Agreement and the Disclosure Schedules attached hereto or in any writing delivered by any Party to any of the other Parties in connection with this Agreement will be continuing and will survive the Closing Date as set forth below.

(c) **Representations and Warranties** . No Indemnifying Party will be liable with respect to any breach or alleged breach of the representations or warranties set forth in Articles IV, V or VI unless written notice of a possible claim for indemnification with respect to such breach is given by the Indemnified Party to the Owners or to Buyer, as applicable, on or before expiration of the survival period applicable thereto and as described below (the " *Survival Period* "), it being understood that so long as such written notice is given on or prior to the expiration of the Survival Period, such representations and warranties, as applicable, will continue to survive until such matter is resolved, but only with respect to the matter(s) identified in such notice(s) of possible claim(s). Other than as expressly set forth below, no claims for indemnification will be allowed if such claim is brought following the expiration of such representation and warranty.

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(v) The representations and warranties of the Company and the Owners will survive for twelve (12) months after the Closing Date, except that the representations and warranties with respect to Sections 4.1 (Organization and Qualification), 4.2 (Power and Authority; Enforceability), 4.5 (Capitalization), 4.13 (Title; Sufficiency of Assets), 5.1 (Power and Authority; Enforceability), and 5.3 (Capitalization) (collectively, the " *Fundamental Reps* "), will survive indefinitely and (B) the representations with respect to Sections 4.7 (Compliance with Laws) and 4.20 (Intellectual Property Rights) (the " *SOL Reps* "), will survive until thirty (30) days after the expiration of applicable statutes of limitation.

(vi) The representations and warranties of Buyer will survive for twelve (12) months after the Closing Date, except that the representations and warranties with respect to Sections 6.1 (Authority; Enforceability) and 6.2 (Organization), will survive indefinitely.

(vii) Notwithstanding anything in this Section 7.1 to the contrary, in the event of any breach of any representation or warranty by any Party hereto that constitutes fraud or intentional misrepresentation, the representation or warranty will survive the consummation of the transactions contemplated in this Agreement and continue in full force and effect without any time limitation with respect to such breach or alleged breach.

(d) **Covenants and Agreements** . All covenants and agreements which by their terms contemplate performance after the Closing Date will survive the Closing indefinitely, unless specified otherwise by their terms.

7.2 General Indemnification.

(a) **Indemnification by Buyer** . Buyer agrees that it will indemnify, defend and hold harmless the Owners and their representatives, successors and assigns (collectively, the " *Company Indemnified Parties* "), from, against and in respect of any and all losses, liabilities, damages, fees, and damages (excluding consequential, incidental and punitive damages except to the extent such types of damages are actually awarded to a third party in connection with a Third Party Claim), and costs and expenses (including reasonable fees and expenses of lawyers, experts and other professionals) (collectively, " *Losses* ") arising out of, resulting from or in connection with: (i) any breach of any representation or warranty made by Buyer contained in this Agreement or in any certificate delivered on behalf of Buyer in connection herewith; or (ii) the breach of any covenant or agreement of Buyer contained in this Agreement.

(b) **Indemnification by the Owners** .

(viii) Each Owner, severally and not jointly, agrees that it will indemnify, defend and hold harmless Buyer, and its Affiliates, managers, officers, directors, shareholders, partners, and their representatives, successors and assigns (the " *Buyer*

Indemnified Parties " and, collectively with the Company Indemnified Parties, the " *Indemnified Parties* ") from, against and in respect of any Losses arising out of, resulting from or in connection with: (i) any breach of any representation or warranty made by such Owner contained in Article V of this Agreement or in any certificate delivered on behalf of such Owner in connection herewith; and (ii) the breach of any covenant or agreement of such Owner made in this Agreement.

(ix) The Owners, severally and not jointly (based on each such Owner's pro rata ownership of the Units reflected on Schedule 1.1), agree that they will indemnify, defend and hold harmless the Buyer Indemnified Parties from, against and in respect of any Losses arising out of, resulting from or in connection with: (i) any breach of any representation or warranty made by the Company or the Owners contained in Article IV of this Agreement or in any certificate delivered on behalf of the Company in connection herewith; (ii) the breach of any covenant or agreement of the Company made in this Agreement; and (iii) any Taxes owed by the Company that are the responsibility of the Owners pursuant to Section 3.3 hereof.

(c) **Limitations on Indemnification** . Notwithstanding anything to the contrary herein:

(i) No Owner will be liable for indemnification under either Section 7.2(b)(i) and 7.2(b)(ii) unless the aggregate amount of Losses under such Sections exceeds Thirty-Seven Thousand and Five Hundred Dollars ($37,500) (the " *Threshold* "), at which time the Owner or Owners, as applicable, will be obligated to indemnify the Buyer Indemnified Parties, with respect to the aggregate amount of all such Losses under such Sections from the first dollar. Notwithstanding the foregoing, the Threshold will not apply to any claim arising out of a breach of a Fundamental Rep, a SOL Rep or fraud or intentional misrepresentation.

(ii) The total amount of indemnification payments that an Owner can be required to make to the Buyer Indemnified Parties pursuant to this Agreement shall not exceed, at any time, the amount of fifty percent (50%) of the value of any unpaid Milestone Payments which then become due and payable by Buyer to such Owner in accordance with the terms of this Agreement (the " *Cap* "). For purposes of the preceding sentence, the value of any cash payments to such Owner shall be the dollar amount thereof, and the value of a share of Buyer Common Stock issued to such Owner shall be the Fair Market Value of one share of Buyer Common Stock with respect to the business day on which the Milestone that resulted in the obligation to issue such Buyer Common Stock to such Owner is achieved (or the next succeeding business day, if such Milestone is achieved other than on a business day). Notwithstanding the foregoing, the Cap will not apply to any claim arising out of fraud or intentional misrepresentation.

(iii) An Indemnified Party's ability to seek indemnity will not be affected by any investigation, inquiry, knowledge, or examination (whether actual,

constructive or imputed) by the Party seeking indemnification with respect to the accuracy or inaccuracy of or compliance with or performance of, any representation, warranty, covenant, agreement or obligation.

(iv) The amount of any Losses for which indemnification is provided for under this Agreement shall be reduced by (i) any amounts actually received by an Indemnified Party as a result of any indemnification, contribution or other payment by any third party, (ii) Tax benefits actually realized by an Indemnified Party in respect of the Losses giving rise to such indemnification, and (iii) any insurance proceeds or other amounts actually recovered or received by the Indemnified Party from third parties with respect to such Losses. If an Indemnified Party recovers any amount with respect to any Loss that was previously satisfied by an Indemnifying Party such Indemnified Party shall promptly pay such amount to the Indemnifying Party.

7.3 Indemnification Procedures .

(o) **Third Party Claims.**

(i) If the facts that give rise to any indemnification hereunder will involve any actual or threatened claim or demand (hereinafter referred to as a " *Third-Party Claim* ") by a party other than a Party hereto, its affiliates, or their respective successors or assigns, the Party entitled to indemnification (the " *Indemnified Party* ") will give the Party obligated to provide indemnification hereunder (the " *Indemnifying Party* ") written notice of such claim (the " *Third-Party Notice* "), including the nature and basis of such Third-Party Claim and the amount of Losses thereof to the extent known, promptly after the Indemnified Party will have received notice thereof from the third-party making such claim. Such Third-Party Notice shall be accompanied by copies of all relevant documentation with respect to such Third-Party Claim, including any summons, complaint or other pleading that may have been served, any written demand or any other document or instrument. The Indemnified Party's failure or delay in providing the Third-Party Notice will not relieve the Indemnifying Party of its obligations under this Article VII (provided that such Third-Party Notice is received by the Indemnifying Party prior to the expiration of the Survival Period applicable to the underlying claims) except to the extent that the Indemnifying Party is materially prejudiced as a result thereof.

(ii) The Indemnifying Party will have twenty (20) business days from receipt of the Third-Party Notice to provide the Indemnified Party with notice that it wishes to assume the defense of the Third-Party Claim, in which event the Indemnified Party will have the right to participate in the defense at its own expense. If the Indemnifying Party fails to give the Indemnified Party timely notice, the Indemnified Party will have the right to defend against the Third-Party Claim.

(iii) If the Indemnifying Party assumes the defense of a Third-Party Claim, the Indemnifying Party will not agree to any settlement, compromise or discharge of the Third-Party Claim without the Indemnified Party's prior written consent (not to be unreasonably conditioned, withheld or delayed), unless such settlement, compromise or discharge includes an unconditional release of the Indemnified Party from all liability in respect of such claim. If the Indemnifying Party does not assume the defense of the Third-Party Claim, the Indemnified Party may make any settlement, compromise or discharge of the Third-Party Claim without the Indemnifying Party's prior written consent and seek indemnification pursuant to this Article VII for Losses resulting from such Third-Party Claim in accordance with the provisions, and subject to the limitations, of this Article VII.

(iv) Notwithstanding anything herein to the contrary, Indemnifying Party will not have the right to assume or continue the defense or handling of such Third-Party Claim unless: (i) the Indemnifying Party will unconditionally agree in writing that it is liable for indemnifying the Indemnified Party for all Losses arising out of such Third-Party Claim in accordance with the provisions, and subject to the limitations, of this Article VII, (ii) the claim does not relate to taxes, criminal or regulatory action, and (iii) the Indemnifying Party conducts the defense actively and diligently.

(v) The parties shall, in connection with the defense of any Third-Party Claim, make available to each other and their counsel and accountants all books and records and information reasonably related to such Third-Party Claim, keep each other fully apprised as to the details and progress of all proceedings relating thereto and render to each other such assistance as may be reasonably required for the proper and adequate defense of any Third-Party Claim; provided, that the covenants and agreements contained in this Section 7.3(a) shall in no event be, or be deemed to be, a waiver by any party of any right to assert the attorney-client or other applicable privilege.

(p) **Direct Claims**

(i) Any Indemnified Party seeking indemnification hereunder (the " ***Claimant*** ") (other than for a Third-Party Claim which is governed by Section 7.3(a) above) must give the Indemnifying Party from whom indemnification is claimed prompt written notice of the claim for Losses (a " ***Demand*** ") stating the aggregate amount of the Losses or a good faith estimate thereof, in each case to the extent known or determinable at such time. The Indemnified Party's failure or delay in providing the Demand will not relieve the Indemnifying Party of its obligations under this Article VII (provided that such Demand is received by the Indemnifying Party prior to the expiration of the Survival Period applicable to the underlying claims) except to the extent that the Indemnifying Party is materially prejudiced as a result thereof.

(ii) Upon receipt of a Demand by an Indemnifying Party, such Indemnifying Party shall have twenty (20) business days (the " *Indemnity Notice Period* "), to review and respond by written notice to such Demand (the " *Return Notice* ") to the Claimant. If the Return Notice does not contest the Demand, or if no Return Notice is delivered to the Claimant by the expiration of the Indemnity Notice Period, then, the Demand shall be conclusively determined in the Indemnified Party's favor for purposes of this Article VII, and the Indemnified Party shall be indemnified by the Indemnifying Party for the amount of the Losses stated in such Demand on demand or, in the case of any notice in which the Losses (or any portion thereof) are estimated, on such later date when the amount of such Losses (or such portion thereof) becomes finally determined.

(iii) If the Return Notice given by the Indemnifying Party disputes the claim or claims asserted in a Demand or the amount of Losses thereof (a " *Disputed Claim* "), then the Claimant and the Indemnifying Parties shall make a reasonable good faith effort to resolve their differences for a period of twenty (20) business days following the receipt by the Claimant of the Return Notice asserting a Disputed Claim. If the Indemnifying Party and the Indemnified Party should so agree, a memorandum setting forth such agreement shall be prepared and signed by both such parties. If no such agreement can be reached after good faith negotiation within twenty (20) business days after delivery of a Return Notice, the matter set forth in the applicable Demand will be resolved in accordance with Section 9.7 hereof.

7.4 Offset . Buyer will have the right to set off the indemnification obligations of the Owners pursuant to, and subject to the limitations of, this Article VII against the Milestone Payments; *provided* , that in the event that Buyer proposes to offset any such amount or right against the Milestone Payments, (a) Buyer shall provide prior written notice of the proposed offset to the Representative specifying in reasonable detail the actual amount of Losses, or Buyer's good faith, reasonable estimate of such Losses, and the proposed offset and basis thereof and (b) Buyer shall be obligated to pay to the Owners any such amount that is not subject to a pending, or finally determined, offset claim pursuant to this Section 7.4. Upon final determination of the actual amount of Losses and corresponding offset permitted pursuant to this Article VII, Buyer promptly, but in any event within five (5) business days, shall pay to the Owners the excess of the value of any amounts previously withheld pursuant to this Section 7.4 over the actual amount of Losses subject to indemnification hereunder. The maximum number of shares subject to offset pursuant to this Section 7.4 shall be equal to 50% of the aggregate number of shares issuable to the Owners upon achievement of the applicable Milestone then subject to offset as determined in accordance with Section 1.3 hereof. For purposes of determining the number of shares of Buyer Common Stock required to satisfy any indemnifiable Losses of Indemnified Parties, each share of Buyer Common Stock shall be valued at the Fair Market Value of one share of Buyer Common Stock with respect to the business day on which Buyer makes such offset following final determination of the actual amount of Losses (or the next succeeding business day, if such offset is to be made other than on a business day). The Owner's indemnification obligations pursuant to this Article VII shall be satisfied exclusively by set off against the Milestone Payments pursuant to this Section 7.4. Unless and until

any shares of Buyer Common Stock subject to offset pursuant to this Section 7.4 actually are issued to the Owners and no longer subject to offset, such shares shall remain the property of Buyer.

7.5 Sole and Exclusive Remedy . Except with respect to claims based on fraud or intentional misrepresentation and the right of a Party to seek specific performance for a breach or threatened breach of covenant, the indemnification rights of the Indemnified Parties under this Article VII shall be the sole and exclusive remedy of the Indemnified Parties with respect to claims resulting from or relating to this Agreement.

7.6 Characterization of Indemnification Payments . The Parties agree to treat any payment made under this Article VII as an adjustment to the Purchase Price.

ARTICLE VIII-DEFINITIONS

8.1 Definitions . For the purposes of this Agreement, capitalized terms not otherwise defined in the Agreement will have the meanings set forth below:

" *Affiliate* " of any particular Person means any other Person controlling, controlled by or under common control with such particular Person, where " control " means the possession, directly or indirectly, of the power to direct the management and policies of a Person whether through the ownership of voting securities, contract or otherwise.

" *Average Closing Price* " means, with respect to a given security, the average of the last reported trade price of such security on the five (5) trading days immediately preceding the date such value is required to be determined on the exchange where it is primarily traded or, if such security is not traded on an exchange, such security shall be valued by taking the average of the last reported closing bid price of such security on the five (5) trading days immediately preceding the date such value is required to be determined as reported by an established quotation service for over-the-counter securities.

" *Benefit Plan* " means any employee benefit plan as defined in Section 3(3) of ERISA and any other material employee plan, program, agreement or arrangement, including any material employment, consulting or deferred compensation agreement or plan, executive compensation, bonus, incentive, pension, profit sharing, savings, retirement, stock option, stock purchase, severance pay plan or policy, life, health, disability or accident insurance plan or any holiday, vacation, PTO policy or practice, whether or not qualified under applicable Law, funded or unfunded, insured or self-insured that is maintained (or contributed to or required to be contributed to) by the Company for the benefit of any current or former employee, director, officer or unit holder of the Company or for which the Company could reasonably be expected to have any material direct or indirect, actual or contingent Liability.

" *BioVascular License Agreement* " means that certain Exclusive License Agreement by and between the Company and BioVascular dated December 20, 2013.

" *Business* " means the Company's business of researching, developing and commercializing the Product Candidate.

" *Buyer Common Stock* " means shares of Buyer's Common Stock, par value $0.0001 per share.

" *Buyer Reports* " shall mean all forms, reports, statements, information and other documents (including schedules and exhibits and all other information incorporated by reference), as supplemented and amended since the time of filing, filed or required to be filed by Buyer with the SEC pursuant to the Exchange Act since January 1, 2012.

" *Change of Control* " shall mean any of the following events:

(d) a sale of all or substantially all of the assets of the Buyer and its subsidiaries taken as a whole (in a single transaction or in a series of related transactions);

(e) a sale, exclusive license grant or other exclusive transfer of all or substantially all of the Intellectual Property Rights of the Buyer and its subsidiaries taken as a whole (in a single transaction or in a series of related transactions);

(f) a sale or other transfer of all or substantially all of the rights under the BioVascular License Agreement by Buyer or an Affiliate thereof (in a single transaction or in a series of related transactions, including, without limitation, in a transaction or transactions that otherwise would be a Change of Control hereunder);

(g) a merger or consolidation involving the Buyer or any Affiliate thereof with rights under the BioVascular License Agreement after the completion of which: (1) in the case of a merger (other than a triangular merger) or a consolidation involving such Person, the shareholders of such Person immediately prior to the completion of such merger or consolidation beneficially own (within the meaning of Rule 13d-3 promulgated under the Exchange Act of 1934, as amended (the " *Exchange Act* ") or comparable successor rules), directly or indirectly, outstanding voting securities representing equal to or less than fifty percent (50%) of the combined voting power of the surviving entity in such merger or consolidation, and (2) in the case of a triangular merger involving such Person or a subsidiary of such Person, the shareholders of such Person immediately prior to the completion of such merger beneficially own (within the meaning of Rule 13d-3 promulgated under the Exchange Act, or comparable successor rules), directly or indirectly, outstanding voting securities representing equal to or less than fifty percent (50%) of the combined voting power of the surviving entity in such merger or equal to or less than fifty percent (50%) of the combined voting power of the parent of the surviving entity in such merger; and

(h) an acquisition by any Person or "group" of affiliated Persons (within the meaning of Section 13(d) or 14(d) of the Exchange Act or any comparable successor provisions), other than any employee benefit plan, or related trust, sponsored or maintained by the Buyer or an Affiliate thereof with rights under the BioVascular License Agreement and other than in a merger or consolidation of the type referred to in clause "(d)" of this

definition, of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Exchange Act, or comparable successor rules) of outstanding voting securities of such Person representing more than fifty percent (50%) of the combined voting power of such Person (in a single transaction or series of related transactions). Notwithstanding the foregoing, a Change in Control shall not be deemed to occur for purposes of the foregoing on account of the acquisition of securities of such Person in a transaction or series of related transactions the primary purpose of which is to obtain financing for the ongoing operations of such Person through the issuance of equity securities.

" *Clinical Trial* " means the first human clinical trial of the Product Candidate in patients with essential thrombocythemia, sponsored by Buyer or an Affiliate or licensee or partner thereof.

" *Code* " means the Internal Revenue Code of 1986, as amended.

" *Commercially Reasonable Efforts* " means with respect to the development of the Product Candidate, efforts that are consistent with those utilized by companies of size and type similar to Buyer, for products or product candidates with similar commercial potential at a similar stage, taking into consideration their cost to develop, the competitiveness of alternative products, the nature and extent of their market exclusivity, the likelihood of regulatory approval, their profitability, and all other relevant factors.

" *Company Partner* " means any third party that tests, develops or manufactures products or product candidates of the Company pursuant to a development, contract research, clinical study, license, manufacturing, supply or other arrangement with the Company. For the avoidance of doubt, the term "Company Partner" does not include BioVascular.

" *Date of Enrollment* " means, with respect to a human subject's participation in a clinical trial of the Product Candidate, the date on which the subject receives a dose of the Product Candidate or placebo in accordance with the terms of the clinical trial protocol governing such clinical trial.

" *Fair Market Value* " means, with respect to a share of the Buyer Common Stock, the Average Closing Price if the Buyer Common Stock is freely tradable on the Nasdaq Global Market or another securities exchange or public market, and otherwise, the fair market value as determined in good faith by the board of directors of Buyer, provided that if the Representative, on behalf of the Owners, disagrees with such determination of the fair market value such value shall be determined by an independent third party appraiser of national standing agreed to by Buyer and the Representative. If Buyer and the Representative fail to agree on such appraiser, then each of Buyer and the Representative shall promptly engage a nationally or internationally recognized investment banking firm, certified public accounting firm or business appraisal firm not providing services to any Party or their Affiliates at the time of the engagement to determine such fair market value within a 30-day period. If the higher appraisal is no more than 10% greater than the lower appraisal, the average of the appraisals will be

deemed to be the fair market value of such securities. If the higher appraisal is more than 10% greater than the lower appraisal, Buyer and the Representative agree to negotiate in good faith for an additional fifteen (15) days to determine such fair market value. If at the end of such 15-day period, the parties are unable to reach agreement with respect to a mutually acceptable fair market value, then the two appraisers shall promptly thereafter select a third appraiser not providing services to any Party or their Affiliates at the time of the engagement to complete an appraisal within thirty (30) days. The average of the two closest appraisals shall be the fair market value and shall be binding on all Parties. The cost of any such appraisers would be shared equally among Buyer, on the one hand, and the Owners, on the other hand. Notwithstanding the foregoing, in no event shall the Fair Market Value of a share of Buyer Common Stock be less than $4.84.

" *FDA* " means the United States Food and Drug Administration or any successor agency.

" *FDCA* " means the Federal Food, Drug and Cosmetic Act of 1938, as amended, and all rules, Laws and regulations promulgated pursuant thereto or in connection therewith.

" *GAAP* " means United States generally accepted accounting principles consistently applied, as in effect from time to time.

" *Governmental Entity* " means a supranational, national, foreign, federal, state or local government or subdivision thereof, or governmental, judicial, legislative, executive, administrative or regulatory authority, agency, commission, tribunal or body.

" *Indebtedness* " means, with respect to any Person at any date, without duplication: (i) all obligations of such Person for borrowed money or in respect of loans or advances; (ii) all obligations of such Person evidenced by bonds, debentures, notes or other similar instruments (including, without limitation, any the Company notes issued in connection with any acquisition undertaken by the Company or any of its subsidiaries); (iii) all obligations of such Person that are not characterized as current liabilities under GAAP; (iv) all obligations in respect of letters of credit, whether or not drawn, and bankers' acceptances issued for the account of such Person; (v) all capital lease liabilities of such Person determined in accordance with GAAP; (vi) all obligations of such Person secured by a contractual lien; (vii) all guarantees of such Person in connection with any of the foregoing; or (viii) any accrued interest, prepayment premiums or penalties or other costs or expenses related to any of the foregoing.

" *Intellectual Property Rights* " means all of the following in any jurisdiction throughout the world, whether or not filed, perfected, registered or recorded and whether now or hereafter existing, filed, issued or acquired: (i) inventions, patents, patent applications, inventions, industrial designs, and patent disclosures; (ii) trademarks, service marks, trade dress, trade names (and all translations, adaptations, derivations and combinations of the foregoing) and Internet domain names, together with all goodwill associated with each of the foregoing; (iii) copyrights, copyright registrations, and copyrightable works; computer programs, software; (iv) advertising and promotional materials; (v) trade secrets, confidential

information, and know-how; (vi) registrations, applications, and renewals for any of the foregoing; and (vii) claims for past infringement of any of the foregoing.

" *Knowledge* " or knowledge with respect to the Company means the actual knowledge of the Owners the Company after reasonable inquiry.

" *Laws* " means all statutes, laws, codes, ordinances, regulations, rules, orders, judgments, writs, injunctions, acts or decrees of any Governmental Entity.

" *Liability* " or " *Liabilities* " means any liability or obligation of whatever kind or nature (whether known or unknown, whether asserted or unasserted, whether absolute or contingent, whether accrued or unaccrued, whether liquidated or unliquidated, and whether due or to become due).

" *Lien* " or " *Liens* " means any mortgage, pledge, security interest, right of first refusal, option, encumbrance, lien or charge of any kind (including any conditional sale or other title retention agreement or lease in the nature thereof), any sale of receivables with recourse against the Company, any filing or agreement to file a financing statement as debtor under the Uniform Commercial Code or any similar statute, or any subordination arrangement in favor of another Person.

" *Material Adverse Effect* " means any event, change, circumstance, effect, or state of facts that, when considered individually or in the aggregate, is, or is reasonably likely to be, materially adverse to (1) the business, financial condition or results of operations of a Party, taken as a whole or (2) the ability of a Party to perform its obligations under the Transaction Documents or to consummate the transactions contemplated therein; provided that "Material Adverse Effect" will not include the effect of any circumstance, change, development, event, or state of facts arising out of the following: (i) general business or economic conditions, including such conditions related to the business of a Party which such conditions do not disproportionately impact such business as compared to other entities engaged in such business, (ii) acts of war (whether or not declared), sabotage or terrorism, military actions or the escalation thereof, or other force majeure events occurring after the date hereof, or (iii) any changes in applicable laws or GAAP which such conditions do not disproportionately impact such business as compared to other entities engaged in such business.

" *Material Contracts* " means the following types of contracts related to or involved with the Business:

(i) any contract for the acquisition or sale of any securities or any substantial portion of the Assets or Business of or to any other Person whether completed or pending;

(ii) any continuing contract for the purchase of materials, supplies, equipment, services or data involving the purchase of more than $10,000 over the life of the contract;

(iii) any contract that expires or may be renewed at the option of any Person other than the Company so as to expire more than 6 months after the date of this Agreement, or which is not terminable by the Company on 30 or fewer days' notice at any time without penalty, and involves the receipt or payment by the Company of more than $10,000;

(iv) any contract for capital expenditures in excess of $10,000 individually, or $30,000 in the aggregate with other similar contracts;

(v) any contract limiting the freedom of the Company to engage in any line of business or to compete with any other Person, or any confidentiality, secrecy or non-disclosure covenant or agreement;

(vi) any contract pursuant to which the Company is a lessor or lessee of any tangible personal property;

(vii) any contract with any Person with whom the Company does not deal at arm's length;

(viii) any contract of guarantee, support, indemnification, reimbursement, contribution, assumption or endorsement of, or any similar commitment with respect to, the obligations, liabilities (whether accrued, absolute, contingent or otherwise) or Indebtedness of any other Person;

(ix) any investment banking, placement, broker or similar contract;

(x) any contract involving the use or license by the Company of any Intellectual Property Rights owned by a third party, including any Intellectual Property Rights covering the Product Candidate;

(xi) any contract involving the joint development of the Product Candidate or technology with a third party;

(xii) any contract involving the supply of material components, materials, services, or products to the Company;

(xiii) any contract relating to the sale, distribution or marketing of any of the Company's products or services;

(xiv) any contract relating to the sale, distribution or marketing by the Company of any third party's products;

(xv) any contract with a group purchasing organization (GPO), integrated delivery network (IDN) or other similar organization or network relating to products or services of the Company;

(xvi) any contract with a Governmental Entity or government official;

(xvii) any contract with a health care provider or health care professional; and

(xviii) any other contract that may have a material effect on the Business or the Company which is not in the ordinary course of business.

" *Milestone* " means each of the First Milestone, the Second Milestone, and the Third Milestone.

" *New Drug Application* " or " *NDA* " shall mean an application submitted pursuant to FDCA Section 505(b) and described in 21 C.F.R §310.50, and amendments and supplements thereto.

" *Person* " means an individual, a partnership, a corporation, a limited liability company, an association, a joint stock company, a trust, a joint venture, an unincorporated organization and a Governmental Entity.

" *Phase 3 Clinical Trial* " means a human Phase 3 clinical trial of the Product Candidate, sponsored by Buyer or an Affiliate or licensee or development partner thereof, which trial is designed to: (a) establish that the Product Candidate is safe and efficacious for its intended use; (b) define warnings, precautions and adverse reactions that are associated with the Product Candidate in the dosage range to be prescribed; (c) support regulatory approval of such Product Candidate; and (d) be generally consistent with 21 CFR § 312.21(c).

" *Product Candidate* " means the "Product" as defined in the BioVascular License Agreement or a product containing the active ingredient Anagrelide.

" *SEC* " means the Securities and Exchange Commission or any other Federal agency at the time administering the Securities Act.

" *Securities Act* " shall mean the Securities Act of 1933, as amended.

" *Software* " means any software, computer instructions, assembly code, routines, configuration files, scripts, compilers, interpreters, virtual machines, development environments, application programming interfaces, database engines, or computer-readable data and all Intellectual Property Rights embodied or contained in any of the foregoing.

" *Strategic Collaboration Agreement* " means a definitive written agreement or agreements between Buyer or an Affiliate of Buyer and a third party or third parties regarding an assignment, transfer, license or grant of any other right to develop, market or commercialize the Product Candidate, under which Buyer or its Affiliate actually receives at least an aggregate of **[***]** Dollars ($ **[***]**) in consideration or services.

" *Tax* " or " *Taxes* " means federal, state, county, local, foreign or other income, gross receipts, *ad valorem* , franchise, profits, sales or use, transfer, registration, excise, utility, environmental, communications, real or personal property, capital stock, license, payroll,

wage or other withholding, employment, social security, severance, stamp, occupation, alternative or add-on minimum, estimated and other taxes of any kind whatsoever imposed by a Governmental Entity (including deficiencies, penalties, additions to tax, and interest attributable thereto) whether disputed or not.

" *Tax Return* " means any return, information report or filing with respect to Taxes, including any schedules attached thereto and including any amendment thereof.

ARTICLE IX- MISCELLANEOUS

9.1 Amendment and Waiver . This Agreement may be amended, and any provision of this Agreement may be waived; provided that (i) with respect to Buyer, only if set forth in a writing executed by Buyer, and (ii) with respect to the Company or Owners, only if set forth in a writing executed by the Representative.

9.2 Notices . All notices, demands and other communications to be given or delivered under or by reason of the provisions of this Agreement will be in writing and will be deemed to have been given (i) when personally delivered, when sent by facsimile (if sent before 5 p.m. local time for the recipient on a business day, otherwise on the next succeeding business day) or one (1) business day following mailing by reputable overnight express courier (charges prepaid), or (ii) three (3) business days following mailing by certified or registered mail, postage prepaid and return receipt requested. Unless another address is specified in writing, notices, demands and communications to the Company, the Owners, and Buyer will be sent to the addresses indicated below:

If to Buyer:

Galena Biopharma, Inc.
4640 SW Macadam, Ste. 270
Portland, OR 97239
Facsimile: (855) 883-7422
Attention: President & CEO

With copies to (which will not constitute notice hereunder):

Fredrikson & Byron, P.A.
4000 U.S. Bank Plaza
200 South Sixth Street
Minneapolis, MN 55402-1425
Facsimile: (612) 492-7077
Attn: Christopher Melsha

If to the Representative, to him/her at:

Aceras Partners LLC
325 East 41st Street, Suite 107
New York, New York 10017
Attention: Matt Wyckoff
Facsimile: (818) 797-2250

With a copy to (which shall not constitute notice hereunder):

Wyrick Robbins Yates & Ponton LLP
4101 Lake Boone Trail, Suite 300
Raleigh, NC 27607
Attention: Thomas A. Allen
Facsimile: (919) 781-4865

9.3 Assignment; Third Party Beneficiaries . This Agreement and all of the provisions hereof will be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns. Neither this Agreement nor any of the rights, interests or obligations under this Agreement may be assigned or delegated by the Company or the Owners without the prior written consent of Buyer (which consent may be not be unreasonably withheld). Buyer may not assign or delegate any or all of its rights, interests or obligations under this Agreement without the prior written consent of the Representative (which consent may be not be unreasonably withheld), except that no such consent shall be required in connection with a Change of Control of Buyer or the assignment of Buyer's rights or interests in the Transaction Documents to any of its lender(s) as collateral security. This Agreement will not confer any rights or remedies upon any person or entity other than the Parties and their respective successors and permitted assigns other than with respect to the Company Indemnified Parties and Buyer Indemnified Parties who are intended third party beneficiaries of the provisions set forth in Article VII.

9.4 Severability . If any term or other provision of this Agreement is invalid, illegal or incapable of being enforced by any applicable Laws or public policy, all other terms and provisions of this Agreement shall nevertheless remain in full force and effect for so long as the economic or legal substance of the transactions contemplated hereby are not affected in any manner materially adverse to any of the Parties. Upon such determination that any term or other provision is invalid, illegal or incapable of being enforced, the Representative and Buyer shall negotiate in good faith to modify this Agreement so as to effect the original intent of the Parties as closely as possible in an acceptable manner in order that the transactions contemplated hereby are consummated as originally contemplated to the greatest extent possible.

9.5 Interpretation . The headings and captions of this Agreement are for convenience of reference only and will not define or limit any of the terms or provisions hereof.

9.6 Entire Agreement . This Agreement (including the documents and agreements referred to herein and that certain letter agreement between the Parties of even date herewith) constitutes the entire agreement among the Parties and supersedes any prior understandings,

agreements, or representations among the Parties, written or oral, that may have related in any way to the subject matter hereof, including that certain Letter of Intent dated December 6, 2013.

9.7 Governing Law; Forum . This Agreement will be governed by and construed in accordance with the laws of the State of Delaware, without regard to the principles of conflicts of law thereof. Any judicial proceeding brought with respect to this Agreement must be brought in any court of competent jurisdiction in the State of Delaware, and, by execution and delivery of this Agreement, each Party (a) accepts, generally and unconditionally, the exclusive jurisdiction of such courts and any related appellate court, and irrevocably agrees to be bound by any judgment rendered thereby in connection with this Agreement, and (b) irrevocably waives any objection it may now or hereafter have as to the venue of any such suit, action or proceeding brought in such a court or that such court is an inconvenient forum.

9.8 WAIVER OF JURY TRIAL. EACH PARTY ACKNOWLEDGES AND AGREES THAT ANY CONTROVERSY WHICH MAY ARISE UNDER THIS AGREEMENT OR THE OTHER TRANSACTION DOCUMENTS IS LIKELY TO INVOLVE COMPLICATED ISSUES AND, THEREFORE, EACH SUCH PARTY IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY LEGAL ACTION ARISING OUT OF OR RELATING TO THIS AGREEMENT, THE OTHER TRANSACTION DOCUMENTS OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY. EACH PARTY TO THIS AGREEMENT CERTIFIES AND ACKNOWLEDGES THAT (A) NO REPRESENTATIVE OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT SEEK TO ENFORCE THE FOREGOING WAIVER IN THE EVENT OF A LEGAL ACTION, (B) SUCH PARTY HAS CONSIDERED THE IMPLICATIONS OF THIS WAIVER, (C) SUCH PARTY MAKES THIS WAIVER VOLUNTARILY, AND (D) SUCH PARTY HAS BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 9.8.

9.9 Expenses . Except as set forth in Section 1.2(b)(ii) hereof, each Party hereto will pay all of its own costs and expenses (including attorneys', accountants' and investment bankers' fees and other out-of-pocket expenses) in connection with the negotiation and execution of this Agreement, the performance of its obligations under this Agreement and the consummation of the transactions contemplated by the Transaction Documents.

9.10 Counterparts . This Agreement may be executed in separate counterparts (including via facsimile or other electronic means), and when executed, separately or together, all of such counterparts will constitute a single original instrument, effective in the same manner as if all Parties hereto had executed one and the same instrument.

9.11 Specific Performance . The Parties agree that irreparable damage may occur in the event that any of the provisions of this Agreement were not performed in accordance with their specific terms or were otherwise breached and that money damages may not be an adequate remedy therefore. It is accordingly agreed that the Parties hereto shall be entitled to seek an injunction or injunctions to prevent breaches of this Agreement by the other Party and to seek to enforce

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specifically the terms and provisions of this Agreement against the other Party, this being in addition to any other remedy to which it is entitled at law or in equity.

** [The remainder of this page has been intentionally left blank] **

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IN WITNESS WHEREOF, the Parties hereto have caused this Unit Purchase Agreement to be duly executed as of the date and year first written above.

BUYER : GALENA BIOPHARMA, INC.

By: /s/ Mark J. Ahn
Name: Mark J. Ahn, Ph.D.
Title: President and Chief Executive Officer

THE COMPANY : MILLS PHARMACEUTICALS, LLC

By: /s/ Peter H. Barber
Name: Peter H. Barber
Title: Manager

OWNERS : /s/ Peter H. Barber
Peter H. Barber

/s/ Daniel DiPierto
Daniel DiPietro

/s/ John Liatos
John Liatos

/s/ Matthew G. Wyckoff
Matthew G. Wyckoff, M.D.

/s/ Paul Glidden
Paul Glidden

REPRESENTATIVE : ACERAS PARTNERS LLC

By: /s/ John Liatos
Name: John Liatos
Title: Partner

Exhibit Index

Exhibit A	Consulting Agreements, dated as of January 12, 2014, by and between Buyer and Daniel DiPietro, and by and between Buyer and Peter Barber.

Schedule Index

Schedule 1.1	Membership Interests of Owners
Schedule 1.2(b)(i)	Indebtedness
Schedule 4.6(d)	Indebtedness Agreements
Schedule 4.6(k)	Banks and Depositories
Schedule 4.9	Unaudited Balance Sheet of the Company dated as of December 31, 2013
Schedule 4.10	Absence of Change
Schedule 4.12	Material Contracts
Schedule 4.13	Title; Sufficiency of Assets

Galena Biopharma, Inc. agrees to furnish supplementally a copy of any omitted schedule to the Securities and Exchange Commission upon request.

REGISTRATION RIGHTS AGREEMENT

THIS REGISTRATION RIGHTS AGREEMENT (this " *Agreement* "), is made and entered into as of January 12, 2014, by and among the members of Mills Pharmaceuticals, LLC, a Delaware limited liability company (the " *Company* "), as identified on the signature pages attached to this Agreement (each such party, an " *Owner* " and collectively, the " *Owners* "), and Galena Biopharma, Inc., a Delaware corporation (" *Buyer* "). The Owners and Buyer may be referred to individually as a " *Party* " and collectively as the " *Parties* . Capitalized terms used but not defined in this Agreement shall have the meanings provided in that certain Unit Purchase Agreement (the " *Purchase Agreement* ") by and among the Parties hereto and the Company and dated as of the date hereof.

WHEREAS, the Parties have entered into the Purchase Agreement, pursuant to which Buyer is acquiring from the Owners all of the issued and outstanding membership interests of the Company (the " *Units* ");

WHEREAS, in partial consideration for the Units acquired by Buyer under the Purchase Agreement, Buyer has agreed to issue shares of its Common Stock upon achievement of the First Milestone and upon achievement of the Second Milestone (collectively, the " *Shares* "); and

WHEREAS, Buyer has agreed to provide certain registration rights to the Owners with respect to any Shares issued under the Purchase Agreement.

NOW, THEREFORE, in consideration of the mutual representations, warranties, covenants and agreements contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Buyer and the Owners agree as follows:

1. Definitions . As used in this Agreement, the following terms shall have the respective meanings set forth in this Section 1:

" *Commission* " means the United States Securities and Exchange Commission.

" *Exchange Act* " means the Securities Exchange Act of 1934, as amended.

" *Excluded Form* " means a Form S-4 or Form S-8, pursuant to the Securities Act or any similar or successor form then in effect.

" *Majority in Interest* " means Owners holding a majority of the Registrable Securities.

" *Register, registered and registration* " means a registration effected by preparing and filing a registration statement on a form approved by the Commission other than an Excluded Form in compliance with the Securities Act and the declaration of effectiveness ordering the effectiveness of such registration statement.

" *Registrable Securities* " means the Shares and all shares of Common Stock issued or issuable in respect of the Shares by virtue of any stock split, stock dividend, recapitalization or similar event, excluding shares which have been (a) registered under the Securities Act pursuant to an effective registration statement filed thereunder and disposed of in accordance

with the registration statement covering them or (b) publicly sold pursuant to Rule 144 promulgated under the Securities Act.

" *Registration Expenses* " shall have the meaning set forth in Section 5.

" *Securities Act* " means the Securities Act of 1933, as amended.

" *Staff* " means the staff of the Commission's Division of Corporation Finance.

" *Violation* " shall have the meaning set forth in Section 6(a).

2. Registration .

(a) Subject to the terms, conditions and limitations set forth herein, Buyer shall use commercially reasonable efforts to file with the Commission within 90 days following the date of this Agreement (the " *Initial Filing Date* "), and thereafter use its commercially reasonable efforts to cause to be declared effective no later than the earlier of (i) 180 days following the date of this Agreement and (ii) the date on which the First Milestone is achieved (such applicable date, the " *Initial Effective Date* ") a registration statement (the " *Initial Registration Statement* ") on an appropriate form under the Securities Act relating to the offer and sale of the maximum amount of Registrable Securities by the Owners thereof from time to time in accordance with the methods of distribution set forth in the Initial Registration Statement and Rule 415 under the Securities Act (hereinafter, the " *Initial Resale Registration* "). For purposes of this Section 2(a), to the extent that the Initial Filing Date or the Initial Effective Date falls on a weekend or other date that the Commission is closed, the Initial Filing Date or Effective Date shall be extended to the next day the Commission is open for business.

(b) If any Registrable Securities are not covered by, or are not permitted by the Commission to be covered by, the Initial Registration Statement or if there is not otherwise then an effective registration statement under the Securities Act covering the resale of the Shares by the Owners, then subject to the terms, conditions and limitations set forth herein, Buyer shall use commercially reasonable efforts to file with the Commission within 21 days following the achievement of each of the First Milestone and Second Milestone (provided that Shares are issued to the Owners in connection with such Milestone Payments), respectively (the " *Additional Filing Date* "), and thereafter use its commercially reasonable efforts to cause to be declared effective a registration statement (an " *Additional Registration Statement* ," and together with the Initial Registration Statement, a " *Registration Statement* ") no later than the earlier of (i) 60 days following the achievement of such applicable milestone and (ii) 3 business days after the Staff tells Buyer the Staff is not, or is done, reviewing the Additional Registration Statement (such applicable date, the " *Additional Effective Date* "), on an appropriate form under the Securities Act relating to the offer and sale from time to time by the Owners of the Registrable Securities issued in connection with such milestone achievement in accordance with the methods of distribution set forth in the Additional Registration Statement and Rule 415 under the Securities Act (hereinafter, the " *Additional Resale Registration* " and together with the Initial Resale Registration, a " *Resale*

Registration "). For purposes of this Section 2(b), to the extent that the Additional Filing Date or the Additional Effective Date falls on a weekend or other date that the Commission is closed, the Initial Filing Date or Additional Effective Date shall be extended to the next day the Commission is open for business.

(c) If (i) Buyer fails to file a Registration Statement with the Commission on or before the Initial Filing Date or Additional Filing Date, as applicable, (ii) an Additional Registration Statement is not declared effective by the Commission by the applicable Additional Effective Date, (iii) the Owners cannot sell their Registrable Securities under a Registration Statement because the Commission has issued a stop order or taken similar action with respect to such Registration Statement, or (iv) an event described in Section 3(g) hereof occurs and remains uncured for more than five business days (each, an " *Event* "), then on the date such Event occurs (an " *Event Date* ") and on each monthly anniversary of each such Event Date (if the applicable Event shall not have been cured by such date) until the applicable Event is cured, Buyer shall pay to each Owner an amount in cash, as liquidated damages and not as a penalty, equal to 1.0% of the aggregate value of the Registrable Securities (based on the Average Closing Price of the Shares when issued) required to be covered by the applicable Registration Statement (the " *Subject Shares* "). Notwithstanding anything to the contrary contained herein, (A) no liquidated damages shall be payable by Buyer in connection with any Event to the extent the applicable Subject Shares may be resold pursuant to Rule 144 during the Event period, and (B) the maximum payment to an Owner associated with all Events with respect to a Registration Statement in the aggregate shall not exceed 6% of the aggregate value of the Subject Shares as determined in accordance with the Purchase Agreement.

3. Registration Procedures

If and whenever Buyer is required by the provisions hereof to effect the registration of any Registrable Securities under the Securities Act as provided herein, Buyer shall, as expeditiously as possible:

(a) prepare and file with the Commission a registration statement with respect to such Registrable Securities and use commercially reasonable efforts to cause such registration statement to become effective within the time described in Section 2 hereof and remain effective until the earlier of (i) the sale of all Registrable Securities covered thereby and (ii) the date upon which the Owners may sell the Registrable Securities pursuant to Rule 144 promulgated under the Securities Act (the " *Registration Period* ");

(b) register the resale of the Registrable Securities on Commission Form S-3 (" *Form S-3* ") or, if Buyer is not eligible to register the resale of the Registrable Securities on Form S-3, then on such other form of registration statement as is available to effect registration of the resale of the Registrable Securities;

(c) ensure that any registration statement filed with respect to the Registrable Securities (including any amendments or supplements thereto and prospectuses contained therein) shall not contain any untrue statement of a material fact or omit to state a material

fact required to be stated therein, or necessary to make the statements therein, in light of the circumstances in which they were made, not misleading, provided that the Owners acknowledge and agree that Buyer will rely on each Owner with respect to information relating to such Owner that has been provided by such Owner to Buyer;

(d) prepare and file with the Commission such amendments (including post-effective amendments) and supplements to any registration statement referred to in Section 3(a) hereof and the prospectus used in connection therewith as may be necessary to keep such registration statement effective for the period specified by Section 3(a) hereof and to comply with the provisions of the Securities Act with respect to the sale of all Registrable Securities covered by such registration statement during such period in accordance with the intended methods of disposition by the Holders in such registration statement;

(e) submit to the Commission, within one (1) business day after Buyer learns that no review of a Registration Statement will be made by Staff or that the Staff has no further comments on any such previously filed Registration Statement, as the case may be, a request for acceleration of effectiveness of the Registration Statement to a time and date not later than the second business day following the submission of such request;

(f) upon request from any Owner, furnish (including in an electronic form or in written form if requested by an Owner) to such Owner (i) promptly after the same is prepared and filed with the Commission, at least one copy of each Registration Statement and any amendment(s) thereto, including all financial statements and schedules, all documents incorporated therein by reference, all exhibits and each preliminary prospectus, and (ii) upon effectiveness of any such registration statement, at least one copy of the prospectus included in such registration statement and all amendments and supplements thereto (or such other number of copies as such Owner may reasonably request), and (iii) such other documents as such Owner may reasonably request, each as reasonably required by such Owner in order to facilitate the public sale or other disposition of the Registrable Securities covered by such registration statement ;

(g) as promptly as practicable after becoming aware of such event at any time when a prospectus relating to the Registrable Securities is required to be delivered under the Securities Act, (i) notify the Owners of Buyer's becoming aware that the prospectus included in the related Registration Statement, as then in effect, includes an untrue statement of a material fact or omits to state any material fact required to be stated therein or necessary to make the statements therein not misleading in light of the circumstances then existing, (ii) prepare a supplement or amendment to such registration statement and corresponding prospectus as required to correct such untrue statement or omission, and (iii) prepare and furnish to each Owner a reasonable number of copies (including in an electronic form or in written form if requested by an Owner) of a prospectus supplemented or amended so that, as thereafter delivered to the purchasers of such Registrable Securities, such prospectus shall not include an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading in the light of the circumstances then existing;

(h) notify each Owner, at any time when a prospectus relating thereto is required to be delivered under the Securities Act: (i) when the Registration Statement or any post-effective amendment and supplement thereto has become effective; (ii) of the issuance by the Commission of any stop order or the initiation of proceedings for that purpose (in which event Buyer shall make every effort to obtain the withdrawal of any order suspending effectiveness of the Registration Statement at the earliest possible time or prevent the entry thereof); and (iii) of the receipt by Buyer of any notification with respect to the suspension of the qualification of the Registrable Securities for sale in any jurisdiction or the initiation of any proceeding for such purpose;

(i) otherwise use its best efforts to comply with all applicable rules and regulations of the Commission;

(j) use commercially reasonable efforts to prevent the issuance of any stop order or any other suspension of effectiveness or any Registration Statement and, if such an order or suspension is issued, to obtain the withdrawal of such order or suspension at the earliest possible moment and to notify the Owners (and, in the event of an underwritten offering, the managing underwriters) of the issuance of such order and the resolution thereof or its receipt of actual notice of the initiation or threat of any proceeding for such purpose;

(k) use its best efforts to c ause all such Registrable Securities registered hereunder to be listed on the Nasdaq Capital Market, or such other stock exchange or over-the-counter electronic market system on which the Common Stock is then principally listed or eligible for trading or quotation; and

(l) promptly after any registration statement is ordered effective by the Commission, notify Buyer's transfer agent that a registration statement covering the Registrable Securities has been declared effective by the Commission and instruct Buyer's transfer agent to remove the restrictive legend on the stock certificates evidencing any Registrable Securities that have been sold pursuant to a Registration Statement and provide, with the cooperation of the Owners, any required legal opinions at Buyer's sole expense.

4. Furnish Information. It shall be a condition precedent to the obligation of Buyer to take any action pursuant to Sections 2 and 3 with respect to the Registrable Securities that the Owners shall furnish to Buyer such information regarding the Owners, the Registrable Securities, and the intended method of disposition of such securities as shall be reasonably required by Buyer to effect the registration of the Registrable Securities.

5. Registration Expenses . Buyer shall bear and pay all expenses incurred in connection with any registration, filing or qualification of Registrable Securities with respect to registrations pursuant to this Agreement, including (without limitation) all registration, filing, and qualification fees, printer and accounting fees relating or apportionable thereto (the " ***Registration Expenses*** "), but excluding underwriting discounts and commissions relating to Registrable Securities and excluding any professional fees or costs of accounting, financial or legal advisors to the Owners other than the reasonable fees not to exceed an aggregate of $5,000 of a single legal advisor of the

Owners to review the Registration Statement(s), any Commission correspondence, and related amendments, supplements or other Commission or Nasdaq filings.

6. Indemnification . In the event that any Registrable Securities are included in a registration statement under Section 2:

(a) To the extent permitted by law, Buyer will indemnify and hold harmless each Owner, any underwriter (as defined in the Securities Act) for the Owners and each person, if any, who controls any Owner or such underwriter within the meaning of the Securities Act or the Exchange Act, against any losses, claims, damages, liabilities or expenses (joint or several) which arise out of any failure by Buyer to perform its obligations under this Agreement or to fulfill any covenant or undertaking included in any Registration Statement to which any of them may become subject under the Securities Act, the Exchange Act or any other federal or state law, insofar as such losses, claims, damages, liabilities or expenses (or actions in respect thereof) arise out of or are based upon any of the following statements, omissions or violations (each a " *Violation* "): (i) any untrue statement or alleged untrue statement of a material fact contained in such Registration Statement, including any preliminary prospectus or final prospectus contained therein or any exhibits, amendments or supplements thereto and all documents filed as a part thereof and information deemed to be a part thereof; (ii) the omission or alleged omission to state therein a material fact required to be stated therein, or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading; or (iii) any violation or alleged violation by Buyer of the Securities Act, the Exchange Act, any other federal or state law or any rule or regulation promulgated under the Securities Act or the Exchange Act in connection with the offering covered by such Registration Statement, and Buyer will pay to the Owner, underwriter or controlling person, as incurred, any legal or other expenses reasonably incurred by them in connection with investigating or defending any such loss, claim, damage, liability, or action; provided , however , that the indemnity agreement contained in this Section 6 (a) shall not apply to amounts paid in settlement of any such loss, claim, damage, liability or expense (or action in respect thereto) if such settlement is effected without the consent of Buyer, which consent shall not be unreasonably withheld or delayed and that Buyer shall not be liable in any such case for any such loss, claim, damage, liability or action to the extent that it (A) arises out of or is based upon a Violation which occurs in reliance upon and in conformity with written information furnished expressly for use in connection with such registration by the Owners, underwriter or controlling person or (B) is directly caused by an Owner's, underwriter's or controlling person's failure to deliver a copy of the registration statement or prospectus, or any amendments or supplements thereto, after Buyer has furnished such Owner, underwriter or controlling person with a sufficient number of copies of the same.

(b) To the extent permitted by law, each Owner will indemnify and hold harmless, severally and not jointly, Buyer, each of its directors, each of its officers, each person, if any, who controls Buyer within the meaning of the Securities Act, any underwriter, any other holder selling securities in such Registration Statement and any controlling person of any such underwriter or other holder, against any losses, claims, damages, or liabilities (joint or

several) to which any of the foregoing persons may become subject, under the Securities Act, the Exchange Act or other federal or state law, insofar as such losses, claims, damages liabilities or expenses (or actions in respect thereto) arise out of or are based upon any Violation by an Owner , in each case to the extent (and only to the extent) that such Violation occurs in reliance upon and in conformity with written information furnished by such Owner expressly for use in connection with such registration; and such Owner will pay, as incurred, any legal or other expenses reasonably incurred by any person intended to be indemnified pursuant to this Section 6(b), in connection with investigating or defending any such loss, claim, damage, liability, or expense (or action in respect thereto); provided , however , that the indemnity agreement contained in this Section 6(b) shall not apply to amounts paid in settlement of any such loss, claim, damage, liability or expense (or action in respect thereto) if such settlement is effected without the consent of such Owner, which consent shall not be unreasonably withheld or delayed; provided , further, that, in no event shall such Owner be liable for any indemnification obligation under this Section 6(b) in excess of the aggregate amount of net proceeds received by such Owner from the sale of its Registrable Securities pursuant to the applicable Registration Statement.

(c) Promptly after receipt by an indemnified party under this Section 6 of notice of the commencement of any action (including any governmental action), such indemnified party shall, if a claim in respect thereof is to be made against any indemnifying party under this Section 6, deliver to the indemnifying party a written notice of the commencement thereof and the indemnifying party shall have the right to participate in, and, to the extent the indemnifying party so desires, jointly with any other indemnifying party similarly notified, to assume the defense thereof with counsel selected by the indemnifying party and approved by the indemnified party (whose approval shall not be unreasonably withheld or delayed); provided , however , that an indemnified party (together with all other indemnified parties which may be represented without conflict by one counsel) shall have the right to retain one separate counsel, with the fees and expenses to be paid by the indemnifying party, if representation of such indemnified party by the counsel retained by the indemnifying party would be inappropriate due to actual or potential differing interests between such indemnified party and any other party represented by such counsel in such proceeding. The failure to deliver written notice to the indemnifying party within a reasonable time of the commencement of any such action will not relieve it of any liability that it may have to any indemnified party otherwise than under this Section 6, expect to the extent that the indemnifying party has been materially prejudiced.

(d) If the indemnification provided for in this Section 6 is held by a court of competent jurisdiction to be unavailable to an indemnified party with respect to any loss, liability, claim, damage or expense (or action in respect thereto) referred to therein, then the indemnifying party, in lieu of indemnifying such indemnified party hereunder, shall contribute to the amount paid or payable by such indemnified party as a result of such loss, liability, claim, damage or expense (or action in respect thereto) in such proportion as is appropriate to reflect the relative fault of the indemnifying party on the one hand and of the indemnified party on the other in connection with the Violation(s) that resulted in such loss, liability, claim, damage or expense (or action in respect thereto) as well as any other relevant

equitable considerations. The relative fault of the indemnifying party and of the indemnified party shall be determined by a court of law by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the alleged omission to state a material fact relates to information supplied by the indemnifying party or by the indemnified party and the parties' relative intent, knowledge, access to information, and opportunity to correct or prevent such statement or omission.

(e) The indemnity and contribution provisions contained in this Section 6 shall remain operative and in full force regardless of (i) the termination of this Agreement and (ii) the sale of Registrable Securities pursuant to any registration statement. No indemnifying party, in the defense of any such claim or litigation, shall, except with the consent of each indemnified party, consent to entry of any judgment or enter into any settlement that does not include as an unconditional term thereof the giving by the claimant or plaintiff to such indemnified party of a release from all liability in respect to such claim or litigation.

7. Rule 144 Reporting . With a view to making available to the Owners the benefits of Rule 144 and any other rule or regulation of the Commission that may at any time permit the Owners to sell securities of Buyer to the public without registration or pursuant to a registration statement, Buyer agrees to:

(a) make and keep public information available, as those terms are understood and defined in Rule 144 under the Securities Act;

(b) file with the Commission in a timely manner all reports and other documents required of Buyer under the Securities Act and the Exchange Act; and

(c) furnish to each Owner, so long as such Owner owns any Registrable Securities, forthwith upon request (i) a written statement by Buyer as to its compliance with the reporting requirements the Exchange Act, (ii) a copy of the most recent annual or quarterly report of Buyer and such other reports and documents so filed by Buyer with the Commission, (iii) a legal opinion with respect to resale under Rule 144, if required by the Buyer or its transfer agent, and (iv) such other information as may be reasonably requested in availing the Owner of any rule or regulation of the Commission which permits the selling of any such securities without registration or pursuant to such form; provided , however , that Buyer shall have no obligation to furnish any report or other document filed with the Commission via the Commission's EDGAR system.

8. Permitted Transferees . Except to the extent the Purchase Agreement permits an Owner to transfer its right to receive Shares, the rights of the Owners with respect to Registrable Securities as set out herein shall not be transferable to any other Person, and any attempted transfer by and Owner in contravention of the terms of this Agreement shall cause all rights of such Owner therein to be forfeited.

9. Termination of Registration Rights . Buyer's obligation to file or obtain and maintain the effectiveness of any Registration Statement shall terminate as to any Registrable Securities to the extent such Registrable Securities held by a given Owner may immediately be sold under Rule

144 (or any successor rule thereto) of the Securities Act, but shall continue with respect to all other Registrable Securities that may not be immediately sold under Rule 144. Further, this Agreement shall automatically terminate upon the effective time of a merger, consolidation, tender offer or other similar business combination transaction pursuant to which all of the outstanding shares of Buyer Common Stock are purchased or otherwise acquired by a third party pursuant to such merger, consolidation, tender offer or other business combination transaction.

10. Miscellaneous

(a) This Agreement is intended for the benefit of the parties hereto and their respective permitted successors and assigns, and is not for the benefit of, nor may any provision hereof be enforced by any other Person. Buyer may not assign its rights or obligations hereunder without the prior written consent of a Majority in Interest. Owner may assign its rights and obligations in the manner permitted hereunder.

(b) All notices, requests and other communications under this Agreement shall be in writing, and shall be sufficiently given if delivered to the addressees in person or by recognized overnight courier, mailed by certified or registered mail, return receipt requested, or by facsimile or e-mail delivery followed by a copy sent by recognized overnight delivery, as follows:

If to Buyer: Galena Biopharma, Inc.
4640 SW Macadam, Ste. 270
Portland, OR 97239
Facsimile: (855) 883-7422
Attn: President & CEO
Email: mahn@galenabiopharma.com

With a copy to: Fredrikson & Byron, P.A.
200 South Sixth Street
Suite 4000
Minneapolis, Minnesota 55402
Attn: Christopher J. Melsha, Esq.

If to the Owners: To the address set forth with each Owner's name on the signature pages attached hereto.

With a copy to: Wyrick Robbins Yates & Ponton LLP
4101 Lake Boone Trail, Suite 300
Raleigh, North Carolina 27607
Attn: Thomas A. Allen, Esq

The parties may designate such other addresses in writing hereafter in the same manner as notice is to be given under this Section 10(b).

(c) This Agreement shall be governed by, and construed in accordance with the laws of the State of Delaware, without regard to the conflicts of law rules of such state.

(d) THE PARTIES HERETO WAIVE ALL RIGHT TO TRIAL BY JURY IN ANY ACTION, SUIT OR PROCEEDING BROUGHT TO ENFORCE OR DEFEND ANY RIGHTS OR REMEDIES UNDER THIS AGREEMENT.

(e) This Agreement may be executed in one or more counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument.

(f) If any provision of this Agreement is held by a court of competent jurisdiction or other authority to be invalid or unenforceable, such invalidity or unenforceability shall not affect the validity or enforceability of the remainder of this Agreement, and the parties shall negotiate in good faith to modify this Agreement and to preserve each party's anticipated benefits under this Agreement.

(g) The headings in this Agreement are for convenience of reference only and shall not limit or otherwise affect the meaning hereof.

(h) This Agreement may not be amended or modified, and no provision hereof may be waived, without the written consent of Buyer and a Majority in Interest.

(i) The failure of any party hereto to exercise any right or remedy under this Agreement or otherwise, or delay by any party hereto in exercising such right or remedy, shall not operate as a waiver thereof.

(j) Each party agrees to execute such other documents, instruments, agreements and consents, and take such other actions as may be reasonable requested by the other parties hereto to effectuate the purposes of this Agreement.

(k) This Agreement contains the entire understanding of the parties with respect to the subject matter hereof and thereof and supersede all prior agreements and understandings, oral or written, with respect to such matters.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK;
SIGNATURE PAGE TO FOLLOW]

IN WITNESS WHEREOF, the undersigned has executed this Registration Rights Agreement as of the date first written above.

Buyer :

GALENA BIOPHARMA, INC.

By: /s/ Mark J. Ahn
Name: Mark J. Ahn, Ph.D.
Title:

Owners :

/s/ Peter Barber
Name: Peter H. Barber
Address:

/s/ Daniel DiPietro
Name: Daniel DiPietro
Address:

/s/ John Liatos
Name: John Liatos
Address:

/s/ Matthew G. Wyckoff
Name: Matthew G. Wyckoff, M.D.
Address:

/s/ Paul Glidden
Name: Paul Glidden
Address:

EMPLOYMENT AGREEMENT

This Employment Agreement (this " Agreement ") is made and entered into as of November, 7, 2013 (the " Effective Date ") by and between Galena Biopharma, Inc., a Delaware corporation (the " Company ", or " Employer "), and Brian L. Hamilton, M.D., Ph.D. an individual and resident of the State of (Massachusetts).

WHEREAS, Employer and Employee desire to enter into an employment agreement under which Employee shall serve on a full-time basis as the Company's Executive Vice President and Chief Medical Officer on the terms set forth in this Agreement, with the term of this Agreement to commence on the Effective Date.

NOW, THEREFORE, upon the above premises, and in consideration of the mutual covenants and agreements hereinafter contained, the parties hereto agree as follows.

1. Engagement . Effective as of the Effective Date, Employer shall employ Employee, and Employee shall serve, as the Company's Executive Vice President and Chief Medical Officer. Employee understands that his duties as Executive Vice President and Chief Medical Officer may change from time to time during the Term (as herewith defined) in the discretion of Employer's Board of Directors (hereinafter the " Board "), but such duties shall be consistent with the duties customarily assigned to the Executive Vice President and Chief Medical Officer of a company substantially comparable as of the Effective Date to Employer. As a condition to the Employee's employment by the Employer, Employee and Employer shall execute the Employee Confidentiality, Non-Competition, and Proprietary Information Agreement, attached hereto as Exhibit 1 and made a part hereof (the " Confidentiality Agreement ").

2. Duties . Employee shall perform faithfully, diligently and to the best of his ability all duties assigned to him by the Board. Employee shall perform the services contemplated under this Agreement in accordance with the policies established by and under the direction of the Board. Employee shall have such corporate power and authority as shall reasonably be required to enable him to discharge his duties under this Agreement. Employee's services hereunder shall be rendered at Employee's home office in 35 Gatehouse Drive Waltham, MA 02451, except for travel to the Company's offices and elsewhere when and as required in the performance of Employee's duties hereunder.

3. Time and Efforts . Employee shall devote all of his business time, efforts, attention and energies to Employer's business and the discharge of his duties hereunder. Notwithstanding the foregoing, except as otherwise agreed to in writing, Employee shall have the right to perform such incidental services as are necessary in connection with (a) his private, passive investments, (b) charitable or community activities, (c) participation in trade or professional organizations and (d) service on the board of directors (or comparable body) of not more than one third-party entity or organization that does not compete with the Company Business (as defined in the Confidentiality Agreement), so long as the foregoing do not interfere

materially with Employee's performance of his duties hereunder as determined in good faith by the Board or the President and Chief Executive Officer of the Company

4. Term . Employee's employment shall commence on the Effective Date and shall terminate on November, 7, 2016 (the " Term "), unless sooner terminated in accordance with Section 6. Notwithstanding any other provision of this Agreement, following the expiration of the Term, Employee's employment shall continue on the terms and provisions hereof on an "at will" basis; as such, Employee's employment may be terminated by Employer for any reason at any time upon written notice to Employee, or by Employee for any reason at any time upon not less than 30 days' prior written notice to Employer, subject to Section 6.2(b) of this Agreement.

5. Compensation . As the total consideration for Employee's services rendered under this Agreement, Employer shall pay or provide Employee the following compensation and benefits:

5.1 Salary . Employee shall initially be entitled to receive an annual base salary of $385,000 (hereinafter the " Base Salary "), payable in accordance with the usual payroll practices of Employer as established from time to time.

5.2 Bonus. Employee shall receive a one-time sign on bonus of $50,000.

5.3 Discretionary Bonus . Employee shall be eligible to receive during each calendar year, commencing in 2014, an annual target performance bonus of 30% of base salary, the determination of the amount of any annual performance bonus earned by Employee to be made by the Board upon the recommendation of the Compensation Committee of the Board and in its sole discretion.

5.4 Stock Option . As soon as practicable on or after the Effective Date, the Company shall grant Employee under the Company's Amended and Restated 2007 Incentive Plan (the " Plan ") a stock option (" Option ") to purchase 300,000 shares of the Company's common stock. The Option shall vest in equal quarterly installments over three years beginning on the first quarterly anniversary of the Effective Date, provided, in each case, that Employee remains in the continuous employ of Employer through such quarterly anniversary date. The Option shall (a) be exercisable at an exercise price per share equal to the closing market price of the Company common stock on the date of the grant, (b) have a term of ten years, and (c) be on such other terms as shall be determined by the Board (or the Compensation Committee of the Board) and set forth in a customary form of stock option agreement under the Plan evidencing the Option.

5.5 Expense Reimbursement . Employer shall reimburse Employee for reasonable business expenses incurred by Employee in connection with the performance of Employee's duties in accordance with Employer's usual practices and policies in effect from time to time Any reimbursements hereunder shall be paid to Employee in accordance with the Company's expense reimbursement policies and procedures from time to time in effect.

5.6 Vacation . Employee shall be entitled to 20 days of paid "time off' (vacation days plus sick time/personal time) for each full calendar year in accordance with the Company's policies from time to time in effect, in addition to holidays observed by the Company (for partial calendar years, the Employee's paid time off' will be pro-rated). Paid time off may be taken at such times and intervals as the Employee shall determine, subject to the business needs of the Company, and otherwise shall be subject to the policies of the Company, as in effect from time to time. The number of paid "time off' days will accrue per pay period and will stop accruing once 20 days have been reached.

5.7 Employee Benefits . The Company shall provide Employee and his dependents, if any, with coverage under any and all medical, dental and vision plans and other benefit programs available generally to the Company's senior executives and their dependents, to the extent Employee and his dependents satisfy the applicable eligibility requirements, and the Company shall pay, directly or indirectly, the premiums associated with any such medical plans to the same extent the Company pays such premiums for other senior executives of the Company. Employee shall be eligible to participate in any medical insurance and other employee benefits made available generally by Employer to all senior executives under Employer's plans and employment policies in effect during the Term. Employee acknowledges and agrees that, any such plans or policies now or hereafter in effect may be modified or terminated by Employer at any time in its discretion.

5.8 Payroll Taxes . Employer shall have the right to deduct from the compensation and benefits due to Employee hereunder any and all sums required for social security and withholding taxes and for any other federal, state, or local tax or charge which may be in effect or hereafter enacted or required as a charge on the compensation or benefits of Employee.

6. Termination . This Agreement and Employee's employment may be terminated as set forth in the Section 6.

6.1 Termination by Employer for Cause; Termination by Employee . Employer may terminate Employee's employment hereunder for "Cause" upon notice to Employee, and Employee may terminate his employment hereunder, for any reason or no reason, upon notice to Employer. " Cause " for the purpose of this Agreement shall mean any of the following:

(a) Employee's breach of any material term of this Agreement, including its Exhibits; provided that the first occasion of any particular breach shall not constitute Cause unless Employee shall have previously received written notice from Employer stating the nature of such breach and affording Employee at least ten (10) days to correct such breach;

(b) Employee s conviction of, or plea of guilty or nolo contendere to, any felony or other crime of moral turpitude;

(c) Employee's act of fraud or dishonesty injurious to Employer or its reputation;

(d) Employee s continual failure or refusal to perform his material duties as required under this Agreement after written notice from Employer stating the nature of such failure or refusal and affording Employee at least ten (10) days to correct the same;

(e) Employee's act or omission that, in the reasonable determination of Employer's Board (or a Committee of the Board), indicates alcohol or drug abuse by Employee; or

(f) Employee's act or personal conduct that, in the judgment of the Board (or a Committee of the Board), gives rise to a material risk of liability of Employee or Employer under federal or applicable state law for discrimination, or sexual or other forms of harassment, or other similar liabilities to subordinate employees.

Upon termination of Employee's employment by Employer for Cause or by Employee for any reason, all compensation and benefits to Employee hereunder shall cease except that Employee shall be entitled to payment, not later than three days after the date of termination, of (i) any accrued but unpaid salary and unused paid time off (only as accrued during the then-current year of employment, and (ii) reimbursement of business expenses accrued but unpaid as of the date of termination. In addition, Employer's indemnification obligations shall remain in effect in accordance with the terms thereof.

6.2 Termination by Employer without Cause . Employer may also terminate Employee's employment without Cause; provided, however, that Employer shall remain obligated to continue paying in accordance with Section 5.1 Employee's Base Salary at the time of termination for a period of six months following the termination. Upon any termination pursuant to this Section 6.2, Employee shall, not later than three days after the date of termination, be entitled to payment of any unused vacation time (only as accrued as of the date of such termination as provided in this Agreement and in accordance with applicable law) and reimbursement of business expenses accrued but unpaid as of the date of termination. If, in the event of a change of control of Employer during the Term, the compensation, benefits, title or duties of Employee under this Agreement are reduced **.** Employee shall be considered terminated by Employer without Cause, with all of the benefits and payments due Employee as set forth in this Section 6.2.

7. Equitable Remedies; Injunctive Relief . Employee hereby acknowledges and agrees that monetary damages are inadequate to fully compensate Employer for the damages that would result from a breach or threatened breach of any of the provisions of the Confidentiality Agreement and, accordingly, that Employer shall be entitled to equitable remedies, including, without limitation, specific performance, temporary restraining orders, and preliminary injunctions and permanent injunctions, to enforce the Confidentiality Agreement without the necessity of proving actual damages in connection therewith. The provision shall not, however,

diminish Employer's right to claim and recover damages or enforce any other of its legal or equitable rights or defenses.

8. Indemnification . Employer and Employee acknowledge that, as the **Executive Vice President and** Chief Medical Officer, Employee shall be a corporate officer of Employer and, as such, Employee shall be entitled to indemnification to the full extent mandated by Employer to its officers under the Employer's Amended and Restated Certificate of Incorporation and Amended and Restated By-laws as in effect as of the date of this Agreement.

9. Severable Provisions . The provisions of this Agreement are severable and if any one or more provisions is determined to be illegal or otherwise unenforceable, in whole or in part, the remaining provisions, and any partially unenforceable provisions to the extent enforceable, shall nevertheless be binding and enforceable.

10. Successors and Assigns . This Agreement shall inure to the benefit of and shall be binding upon and enforceable by the parties and their respective successors, assigns, heirs and representatives; provided, however, that neither party may assign this Agreement without the prior written consent of the other party; and, provided further, that this Agreement may be assigned by the Company to a successor (whether direct or indirect, by purchase, merger, consolidation or otherwise) to all or substantially all of the business or assets of Employer, and Employee shall cause any such successor to assume expressly and agree to perform this Agreement in the same manner and to the same extent that Employer would have been required to perform it.

11. Entire Agreement . This Agreement, including the Confidentiality Agreement, contains the entire agreement of the parties relating to the subject matter hereof, and the parties hereto have made no agreements, representations or warranties relating to the subject matter of this Agreement that are not set forth otherwise therein or herein. Except as expressly provided herein, this Agreement (including the Confidentiality Agreement) supersedes any and all prior or contemporaneous agreements, written or oral, between Employee and Employer relating to the subject matter hereof.

12. Amendment . No modification of this Agreement shall be valid unless made in writing, approved by the Board (or a committee of the Board) and signed by the parties hereto and unless such writing is made by an executive officer of Employer (other than Employee). The parties hereto agree that in no event shall an oral modification of this Agreement be enforceable or valid.

13. Governing Law: Arbitration . This Agreement is and shall be governed and construed in accordance with the laws of the State of Delaware without giving effect to the choice-of-law rules of Delaware. Except to the extent a remedy is sought as described in Section 7, above, any dispute arising out of, or relating to, this Agreement or the breach thereof, or regarding the interpretation thereof, shall be exclusively decided by binding arbitration conducted in Portland, Oregon in accordance with the rules of the American Arbitration

Association (the " AAA ") then in effect before a single arbitrator appointed in accordance with such rules. Judgment upon any award rendered therein may be entered and enforcement obtained thereon in any court having jurisdiction. Each of the parties agrees that service of process in such arbitration proceedings shall be satisfactorily made upon it if sent by registered mail addressed to it at the address referred to in Section 14, below. The costs of such arbitration shall be borne proportionate to the finding of fault as determined by the arbitrator. Judgment on the arbitration award may be entered by any court of competent jurisdiction.

14. Notice . All notices and other communications under this Agreement shall be in writing and mailed, electronically mailed, telecopied (in case of notice to Employer only) or delivered by hand or by a nationally recognized courier service guaranteeing overnight delivery to a party at the following:

If to Employer:

Galena Biopharma, Inc.
Attention: Chief Executive Officer
4640 Macadam Avenue, Suite 270
Lake Oswego, Oregon 97239
Phone: 503-961-4466

If to Employee:

Through the Company e-mail rdunlap@galenabiopharma.com, or if Employee shall not longer be employed:

_____
_____
_____

15. Survival . Sections 7 through 16 shall survive the expiration or termination of this Agreement.

16. Counterparts . This Agreement may be executed in counterparts, each of which shall be deemed to be an original and all of which together shall be deemed to be one and the same agreement.

17. Attorney's Fees . In any action or proceeding to construe or enforce any provision of this Agreement the prevailing party shall be entitled to recover its or his reasonable attorneys' fees and other costs of suit in addition to any other recoveries.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties have executed this Agreement as of the day and year first above written.

EMPLOYER

Galena Biopharma, Inc.

By: /s/ Mark J. Ahn
Mark J. Ahn, Ph.D.
President and Chief Executive Officer

EMPLOYEE

By: /s/ Brian L. Hamilton
Brian L. Hamilton, M.D., Ph.D.

Exhibit 1
Galena Biopharma, Inc.

EMPLOYEE CONFIDENTIALITY, NON-COMPETITION, AND PROPRIETARY INFORMATION AGREEMENT

AGREEMENT, effective as of 11, 7, 2013, between Galena Biopharma, Inc., a Delaware corporation (the "Company"), and Brian L. Hamilton, M.D., Ph.D. the "Employee").

1. Employee will make full and prompt disclosure to the Company of all inventions, improvements, modifications, discoveries, methods, technologies, biological materials, and developments, and all other materials, items, techniques, and ideas related directly or indirectly to the business of the Company, whether patentable or not, made or conceived by Employee or under Employee's direction during Employee's employment with the Company, whether or not made or conceived during normal working hours, or on the premises of the Company (all of which are collectively termed "Intellectual Property" hereinafter).

2. Employee agrees that all Intellectual Property, as defined above, shall be the sole property of the Company and its assigns, and the Company and its assigns shall be the sole owner of all patents and other rights in connection therewith. Employee hereby assigns to the Company any rights Employee may have or acquire in all Intellectual Property and all related patents, copyrights, trademarks, trade names, and other industrial and intellectual property rights and applications therefore, in the United States and elsewhere. Employee further agrees that with regard to all future developments of Intellectual Property, Employee will assist the Company in every way that may be reasonably required by the Company (and at the Company's expense) to obtain and, from time to time, enforce patents on Intellectual Property in any and all countries that the Company may require, and to that end, Employee will execute all documents reasonably necessary for use in applying for and obtaining such patents thereon and enforcing the same, as the Company may desire, together with any assignment thereof to the Company or persons designated by the Company, and Employee hereby appoints the Company as Employee's attorney to execute and deliver any such documents or assignments requested by the Company (but only for the purpose of executing and filing any such document). Employee's obligation to assist the Company in obtaining and enforcing patents for Intellectual Property in any and all countries shall continue beyond the termination of Employee's employment with the Company, but the Company shall compensate Employee at a reasonable, standard hourly rate following such termination for time directly spent by Employee at the Company's request for such assistance.

3. Employee hereby represents that Employee has no continuing obligation to assign to any former employer or any other person, corporation, institution, or firm any Intellectual Property as described above. Employee represents that Employee's performance of all the terms of the Agreement and as an employee of the Company does not and will not breach any agreement to keep in confidence proprietary information acquired by Employee, in confidence or in trust, prior to Employee's employment by the Company. Employee has not entered into, and Employee agrees not to enter into, any agreement (either written or oral), which would put Employee in conflict with the Agreement.

- .

4. Employee agrees to assign to the Company any and all copyrights and reproduction rights to any material prepared by Employee in connection with the Agreement and/or developed by Employee during Employee's employment with the Company that are related directly or indirectly to the business of the Company.

5. Employee understands and agrees that a condition of Employee's employment and continued employment with the Company is that Employee has not brought and will not bring to the Company or use in the performance of Employee's duties at the Company any materials or documents rightfully belonging to a former employer which are not generally available to the public.

6. Employee recognizes that the services to be performed by Employee hereunder are special, unique, and extraordinary and that, by reason of Employee's employment with the Company, Employee may acquire Confidential Information (as hereinafter defined) concerning the operation of the Company, the use or disclosure of which would cause the Company substantial loss and damage which could not be readily calculated and for which no remedy at law would be adequate. Accordingly, Employee agrees that Employee will not (directly or indirectly) at any time, whether during or for a period of seven (7) years after Employee's employment with the Company:

(i) knowingly use for personal benefit or for any other reason not authorized by the Company any Confidential Information that Employee may acquire or has acquired by reason of Employee's employment with the Company. or;

(ii) disclose any such Confidential Information to any person or entity except (A) in the performance of Employee obligations to the Company hereunder, (B) as required by a court of competent jurisdiction, (C) in connection with the enforcement of Employee rights under the Agreement, or (D) with the prior consent of the Board of Directors of the Company.

As used herein, "Confidential Information" includes proprietary and confidential information with respect to the facilities and methods of the Company, reagents, chemical compounds, cell lines or subcellular constituents, organisms, or other biological materials, trade secrets, and other Intellectual Property, systems, patent applications, procedures, manuals, confidential reports, financial information, business plans, prospects, or opportunities, personnel information, or lists of customers and suppliers which are generally known only to the Company provided, however, that Confidential Information shall not include any information that is known or becomes generally known or available publicly other than as a result of disclosure by Employee which is not permitted as described in clause (ii) above, or the Company discloses same to others without obtaining an agreement of confidentiality.

Employee confirms that all Confidential Information is the exclusive property of the Company. All business records, papers, documents and electronic materials kept or made by Employee relating to the business of the Company which comprise Confidential Information shall be and remain the property of the Company during the Employee's employment and at all

times thereafter. Upon the termination, for any reason, of Employee's employment with the Company, or upon the request of the Company at any time, Employee shall deliver to the Company, and shall retain no copies of any written or electronic materials, records and documents made by Employee or coming into Employee's possession concerning the business or affairs of the Company and which comprise Confidential Information.

7. During the term of Employee's employment with the Company and for one (1) year thereafter (the "Restricted Period"), the Employee shall not directly or indirectly, for Employee's own account or for the account of others, as an officer, director, stockholder (other than as the holder of less than 1% of the outstanding stock of any publicly traded company), owner, partner, employee, promoter, consultant, manager or otherwise participate in the promotion, financing, ownership, operation, or management of, or assist in or carry on through proprietorship, a corporation, partnership, or other form of business entity which is in competition with the Company in the field of the development of pharmaceutical vaccine products or vaccine product candidates for the treatment of HER2-positive breast cancer (the "Company Business") within the United States or any other country in which the Company is conducting or is actively seeking or planning to conduct the Company Business as of the date of such termination. Notwithstanding the foregoing, except as otherwise agreed to in writing, Employee shall have the right to perform such incidental services as are necessary in connection with (a) his private passive investments, (b) his charitable or community activities,(c) his participation in trade or professional organizations, and (d) his service on the board of directors (or comparable body) of one third-party corporate entity that does not compete with the Company Business.

During the Restricted Period, the Employee shall not, whether for Employee's own account or for the account of any other person (excluding the Company):

(i) solicit or contact in an effort to do business with any person who was or is a customer of the Company during the Restricted Period, or any affiliate of any such person, if such solicitation or contact is for the purpose of competition in the field of cancer vaccines for HER2 positive breast cancer with the Company; or

(ii) solicit or induce any of the Company's employees to leave their employment with the Company or accept employment with anyone else, or hire any such employees or persons who were employed by the Company during the Restricted Period.

Nothing herein shall prohibit or preclude the Employee from performing any other types of services that are not precluded by the Section 7 for any other person.

The Employee shall give prompt notice to the Company of the Employee's acceptance of employment or other fees for services relationship in the field of cancer vaccines for HER2 positive breast cancer during the Restricted Period, which notice shall include the name of, the business of, and the position that Employee shall hold with such other entity.

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8. In the event that Employee's employment is transferred by the Company to a subsidiary, affiliated company, or acquiring company (as the case may be), Employee's employment by such company will, for the purpose of the Confidentiality, Non-Competition, and Proprietary Information Agreement, be considered as continued employment with the Company, unless Employee executes an agreement, substantially similar in substance to the Agreement, and until the effective date of said agreement in any such company for which Employee becomes employed. It is further agreed that changes in Employee's position or title or location unless expressly agreed to in writing will operate to terminate the Confidentiality, Non-Competition, and Proprietary Information Agreement without Cause.

9. Upon termination of Employee's employment for any reason, unless such employment is transferred to a subsidiary, affiliated or acquiring company of the Company, Employee agrees to leave with, or return to, the Company all records, drawings, notebooks, and other documents pertaining to the Company's Confidential Information, whether prepared by Employee or others, as well as any equipment, tools or other devices owned by the Company, that are then in Employee's possession, however such items were obtained, and Employee agrees not to reproduce or otherwise retain any document or data relating thereto.

10. Employee obligations under the Agreement shall survive the termination of Employee's employment with the Company for the respective periods specifically set forth herein regardless of the manner of. and reason for, such termination, and shall be binding upon Employee's heirs, executors, and administrators.

11. Employee understands and agrees that no license to any of the Company's trademarks, patents, copyrights or other proprietary rights is either granted or implied by Employee's access to and utilization of the Confidential Information or Intellectual Property.

12. No delay or omission by the Company in exercising any right under the Agreement will operate as a waiver of that or any other right. A waiver or consent given by the Company on any one occasion is effective only in that instance and will not be construed as a bar to or waiver of any right on any other occasion.

13. Employee agrees that in addition to any other rights and remedies available to the Company for any breach or threatened breach by Employee of Employee's obligations hereunder, the Company shall be entitled to enforcement of Employee's obligations hereunder by whatever means are at the Company's disposal, including court injunction.

14. The Company may assign the Agreement to any other corporation or entity which acquires (whether by purchase, merger, consolidation or otherwise) all or substantially all of the business and/or assets of the Company. In the case of a change of control of the Company in which the compensation. title, duties are reduced, or requires the Employee to relocate more than 50 miles from his then current residence, the Employee is considered Terminated without Cause, with all of the benefits and payments due Employee under Section 6.2 of the Employee Agreement. Employee shall have no rights of assignment.

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15. If any provision of the Agreement shall be declared invalid, illegal, or unenforceable, then such provision shall be enforceable to the extent that a court deems it reasonable to enforce such provision. If such provision shall be unreasonable to enforce to any extent, such provision shall be severed and all remaining provisions shall continue in full force and effect.

16. The Agreement shall be effective as of the date first written above.

17. The Agreement shall be governed in all respects by the laws of the State of Delaware, without regard to principles of conflicts of law.

[Signature Page Follows]

IN WITNESS WHEREOF , Employee has executed the Agreement as of the date set forth above:

By: _____

Name of Employee: ____

ACCEPTED AND AGREED TO:

Galena Biopharma, Inc.

By: _____
Mark J. Ahn, Ph.D.
President and Chief Executive Officer

- .

TEXT MARKED BY [* * *| HAS BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

LICENSE AND DEVELOPMENT AGREEMENT

This License and Development Agreement (as it may be amended as provided herein, this " Agreement ") is entered into as of January 13, 2014 (the " Effective Date ") by and among Galena Biopharma, Inc., a corporation organized under the laws of the State of Delaware, U.S.A. (" Galena "), and Apthera, Inc., a Delaware corporation and wholly owned subsidiary of Galena (" Apthera " and, together with Galena, " Licensor "), each having its principal place of business at 4640 S.W. Macadam Avenue, Suite 270, Portland, Oregon, U.S.A. 97239, on the one hand, and Dr. Reddy's Laboratories Limited, a company organized under the laws of India, having its principal place of business at Door No. 8-2-337, Road No. 3, Banjara Hills, Hyderbad 50034, Andra Pradesh, India (" Licensee "), on the other hand. Licensor and Licensee are sometimes referred to herein individually as a " Party " and collectively as the " Parties. "

RECITALS

WHEREAS, Licensor develops and commercializes innovative targeted oncology treatments to address major unmet medical needs and advance cancer care;

WHEREAS, Licensee an integrated pharmaceutical company with expert knowledge with regard to the development, manufacturing and marketing of active pharmaceutical ingredients and finished products in India and elsewhere;

WHEREAS, the Licensee has existing commercialization capabilities in the Territory;

WHEREAS, Licensor and Licensee wish to partner in the development and commercialization of the Licensed Product in the Licensee Indications in the Territory in accordance with the terms and conditions hereof;

NOW, THEREFORE, in consideration of the mutual promises contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound, the Parties hereto agree as follows:

1. DEFINITIONS.

1.1 Definitions . As used in this Agreement, the following capitalized terms have the meanings indicated:

"Adjuvant" shall mean **[***]** and/or other appropriate pharmacological agent which enhances the immune response of Licensed Product.

" Affiliate " shall mean any corporation or other entity which directly or indirectly controls, is controlled by or is under common control with a Party, for so long as such control exists. For the purposes of this definition and Section 16.2, " control " shall mean: (i) in the case of any corporate entity, direct or indirect ownership of fifty percent (50%) or more of the stock or shares having the right to vote for the election of directors thereof; or (ii) in the case of any non-corporate entity, direct or indirect ownership of fifty percent (50%) or more of the equity or income interest therein with the power to direct the management and policies of such non-corporate entities.

" Agreement " shall have the meaning set forth in the Preamble.

" Bundle " shall mean the Licensed Product sold together with another pharmaceutical compound or compounds for a single price except the Adjuvant.

" CIS " shall mean the Commonwealth of Independent States.

" Claims " shall have the meaning set forth in Section 14.1.

" Clinical Trial " shall have the meaning set forth in subsection 6.1.1.

" Clinical Trial Agreement " shall mean a clinical trial agreement mutually satisfactory to the Parties relating to Licensee's conduct of the Clinical Trial with the general conditions of the Clinical Trial and the protocol herein attached as ANNEX 2, ANNEX 3 & ANNEX 4.

" Competing Product " shall mean a product irrespective of mode of administration in patients, that is marketed and sold by a Third Party whose patient population as defined in the products approved label is the same as in the Licensed Indications in the Territory.

" Confidential Information " shall have the meaning set forth in Section 11.1.

" Contemporaneous Agreements " shall mean the Clinical Trial Agreement, Supply Agreement, Quality Agreement, Pharmacovigilance Agreement.

" Contract Interest Rate " with respect to a payment, shall mean prevailing LIBOR rate .

" Control " shall mean, with respect to any Information or intellectual property, that the applicable Party owns or has a sublicense to such Information or intellectual property and has the ability to grant to the other Party access to and a sublicense or sublicense (as applicable) under such Information or intellectual property as set forth herein without violating the terms of any agreement with any Third Party as of the time such Party would first be required hereunder to grant such access and sublicense or sublicense, or requiring any payment (whether or not then due and payable) under any agreement with any Third Party as of the time such Party would first be required hereunder to grant such access and sublicense or license.

" Effective Date " shall have the meaning set forth in the Preamble.

" Federal Court " shall have the meaning set forth in Section 16.11.

" First Commercial Sale " shall mean the first Sale of the Licensed Product following Regulatory Approval in the Territory.

" First Licensee Indication " shall mean use of the Licensed Product in breast cancer patients and for which Licensor or its licensee has received Regulatory Approval in the U.S. or in the E.U., including as such Regulatory Approval may be amended from time to time.

" Force Majeure " shall have the meaning set forth in Section 16.8.

" GAAP " shall mean U.S. generally accepted accounting principles.

" Governmental Authority " shall mean any government administrative agency, commission or other governmental authority, body or instrumentality, or any federal, state, local, domestic or foreign governmental regulatory body.

" IFRS " shall mean international financial reporting standards to the extent consistent with GAAP.

" Improvement " shall mean any change to the Licensed Product, including with respect to formulation, dosage, or other advance or modification made by Licensor to the Licensed Product.

" Indemnified Party " and " Indemnifying Party " shall have the respective meanings set forth in Section 14.2.

" Information " shall mean all tangible and intangible techniques, information, technology, practices, trade secrets, inventions, methods, knowledge, know-how, conclusions, skill, experience, test data and results (including pharmacological, toxicological and clinical test data and results), analytical and quality control data, results or descriptions, software and algorithms, sales, marketing and distribution arrangements, plans and strategies, and similar information.

" Law " shall mean, individually and collectively, any and all laws, ordinances, rules, directives, administrative circulars, orders and regulations of any kind whatsoever of any Governmental Authority within the applicable jurisdiction.

" Licensed Know-How " shall mean Information in Licensor's possession or Control as of the Effective Date or thereafter during the Term that is reasonably necessary for Licensee to (i) obtain Regulatory Approval and to commercialize the Licensed Product in the Licensee Indications in the Territory, and/or (ii) to conduct the Clinical Trial, all as contemplated in this Agreement.

" Licensed Product " means Licensor's proprietary E75 peptide (nelipepimut-S) (NeuVax™) for use in the Licensee Indications.

" Licensed Technology " shall mean the Licensed Know-How, the Licensed Trademarks, if any, and the Registration Dossier, collectively.

" Licensed Trademarks " shall mean trademark rights (including NeuVax™), if any, Controlled by Licensor in the Territory on or after the Effective Date and corresponding to any trademarks adopted by Licensor for use with a Licensed Product in a Licensee Indication outside the Territory (not including any corporate or house marks, and not including any such marks to the extent such marks would conflict with any right of any Third Party inside the Territory).

" Licensee " shall have the meaning set forth in the Preamble.

" Licensee Indemnitees " and " Licensor Indemnitees " shall have the respective meanings set forth in Section 14.1.

" Licensee Indications " shall mean the First Licensee Indication and the Second Licensee Indication, collectively. References to a " Licensee Indication " shall mean either of the Licensee Indications.

" Licensee Trademark " means such trademark created or developed and owned by the Licensee for use in respect of the Licensed Product as contemplated in Section 4.3.

" Losses " shall have the meaning set forth in Section 14.1.

"Materials " shall mean the Licensed Product and the Adjuvant.

" Net Sales " shall mean the gross amount invoiced in arm's-length Sales in the Territory by Licensee, its Affiliates and sublicensees to Third Parties, less the following deductions from such gross amounts which are actually incurred, allowed, accrued or specifically allocated to such Licensed Product, all as determined in accordance with GAAP:

(i) credits, price adjustments or allowances for damaged products, returns or rejections of Product;

(ii) normal and customary trade, cash and quantity discounts, allowances and credits (other than price discounts granted at the time of invoicing which have already been included in the gross amount invoiced);

(iii) chargeback payments, repayments and rebates (or the equivalent thereof) granted to or imposed by group purchasing organizations, managed health care organizations or federal, state/provincial, local and other governments, including any or all of their regulatory authorities, agencies, review boards or tribunals, or trade customers;

(iv) any invoiced freight, postage, shipping, insurance and other transportation charges;

(v) sales, value-added (to the extent not refundable in accordance with applicable law), and excise taxes, tariffs and duties, and other taxes directly related to the sale (but not including taxes assessed against the income derived from such sale);

(vi) stocking allowances; and

(vii) any other payment which reduces gross revenue and is permitted to be deducted in calculating net sales in accordance with GAAP.

" Party " and " Parties " shall have the meanings set forth in the Preamble.

" Positive Interim PRESENT Data " shall mean interim data within the meaning of the special protocol assessment for the PRESENT Trial, except such interim data as would prohibit in any manner the continuance of the PRESENT Trial.

" PRESENT Trial " shall mean the Licensor's ongoing human clinical trial of the Licensed Product, that, if the defined end-points are met, is intended to establish safety and efficacy in breast cancer patients for purposes of filing for Regulatory Approval with the United States Food and Drug Administration (or its successor) as required under 21 C.F.R. §312.21(c).

" Prior Agreement " shall have the meaning set forth in Section 11.4.

" Quarterly Period " shall mean each three-month period ending March 31, June 30, September 30 and December 31 of each year during the Term and any partial period ending on the last day of the Term.

" Reasonably Diligent Efforts " shall mean, with respect to Licensee, the application of a level of human and financial resources, efforts and urgency to commercialize the Licensed Product consistent with Licensee's practices in the Territory in pursuing the commercialization of its other high-value pharmaceutical products in light of the Licensed Product's characteristic features, target indication, competitiveness and sales volume, but in no event less than the level commonly applied by other pharmaceutical companies to their own high-value pharmaceutical products of a similar nature; and with respect to Licensor shall mean, the application of a level of human and financial resources, efforts and urgency to develop, compile the Registration Dossier, file for and seek the Regulatory Approval consistent with Licensor's protection in the U.S. or in the E.U., as the case may be, in pursuing the development and commercialization of its other high-value pharmaceutical products in light of the Licensed Product's characteristic features, target indication, competitiveness and sales volume, but in no event less than the level commonly applied by other pharmaceutical companies to their own high-value pharmaceutical products of a similar nature.

" Registration Dossier " shall mean the dossier of technical data and information compiled by or on behalf of Licensee with respect to the Licensed Product on the basis of which the Licensed Product may be registered in the Territory, including updates to such data and information and evidence of marketing approval, if any, of the Licensed Product in the U.S. or the E.U.

" Regulatory Approval " shall mean the approval from Governmental Authorities necessary for the marketing and sale of the Licensed Product in either or both of the Licensee Indications or for conduct of Clinical Trial, as the case may be.

" Regulatory Filing " shall mean any filing with any Governmental Authority with respect to the development, marketing, commercialization or reimbursement of the Licensed Product.

" Sale ," " Sell " or " Sold " means the sale, transfer or other disposition for value of the Licensed Product.

" Second Licensee Indication " shall mean use of Licensed Product in gastric cancer patients and for which Licensor or its licensees have received Regulatory Approval in the U.S. or in the E.U., including as such Regulatory Approval as may be amended from time to time.

" Sell-off Period " shall have the meaning set forth in subsection 15.3.3.

" State Court " shall have the meaning set forth in Section 16.11.

" Taxes " shall mean any tax, excise or duty, other than taxes upon income.

" Term " shall mean the period beginning on the Effective Date and ending upon the expiration or termination of this Agreement pursuant to Article 15.

" Territory " shall mean India.

" Third Party " shall mean any entity other than a Party or an Affiliate of a Party.

" VAT " shall mean any value added tax.

" Underlying License Agreements " shall mean (i) the Patent and Technology License Agreement, dated September 11, 2006, by and among the Board of Regents of the University of Texas System, the University of Texas M.D. Anderson Cancer Center, the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., and Apthera (formerly Advanced Peptide Therapeutics, Inc.), as amended by Amendments Nos. 1-5 thereto, dated December 21, 2007, September 3, 2008, July 8, 2009, February 11, 2010, and January 10, 2011, respectively, and (ii) the Exclusive License Agreement, dated as of July 11, 2011, by and among The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., Galena (formerly RXi Pharmaceuticals Corporation) and Apthera.

2. CONDITION PRECEDENCE

2.1 This Agreement and its validity is subject to the execution of all Contemporaneous Agreements related hereto.

3. COLLABORATION SCOPE

3.1 Conduct of the Collaboration . The Parties shall cooperate to commercialize the Licensed Product in the Licensee Indications in the Territory in accordance with the terms and conditions of this Agreement.

3.2 Ex-Territory Activities . No rights are granted hereunder to Licensee with respect to any jurisdiction outside the Territory, except as provided in Section 7.1.3 and 7.1.4. Except as expressly provided in this Agreement, Licensor shall have the sole right to research, develop, use, manufacture, have manufactured and commercialize the Licensed Product inside and outside the Territory.

4. GRANT OF LICENSE

4.1 Exclusive Rights . Subject to the terms and conditions hereof, Licensor hereby grants Licensee: (i) the exclusive (except as to Licensor) right and license during the Term to the Licensed Know-How solely to utilize and practice under the Licensed Know-How as part of and in connection with conduct of the Clinical Trial; and (ii) the exclusive right (including as to Licensor) and license during the Term to the Licensed Technology to apply for and pursue on behalf of Licensor and in Licensee's name Regulatory Approval in the Territory and thereafter to market, Sell, promote and distribute the Licensed Product in the Licensee Indications in the Territory. Licensor shall disclose the Licensed Know-How to Licensee as reasonably required for these purposes upon reasonable notice from Licensee and during Licensor's normal business hours, and shall designate one or more technical liaisons for communications with Licensee's technical personnel. Such license shall include the right to sublicense only as set forth in Section 4.2.

4.2 Licensee Sublicensing . Licensee shall have the right to sublicense the rights granted it hereunder only with Licensor's prior written consent, which Licensor may withhold or condition in its sole discretion. Any permitted sublicensee shall be required to enter into a written agreement obligating it to maintain the confidentiality of the Confidential Information of Licensor, and Licensee shall be responsible for any disclosure of the Confidential Information of Licensor by such sublicensee in violation of the provisions of Section 11. In addition, such written agreement shall require such sublicensee to comply with the obligations and prohibitions of this Agreement relevant to the rights sublicensed, and Licensee shall be responsible for a breach by such sublicensee of any such obligations or prohibitions. No sublicense shall operate to excuse Licensee's compliance with its obligations hereunder.

4.3 Trademarks .

4.3.1 Grant to Licensee . Licensor hereby grants Licensee the exclusive right and license under the Licensed Trademarks for the Licensed Indications during the Term, subject to the terms and conditions hereof, solely to apply for and pursue Regulatory Approval and thereafter to market, sell, promote and distribute the Licensed Product in the Licensee Indications in the Territory. Such license shall include the right to sublicense only as set forth in Section 4.2. Should there be

no Licensed Trademark in the Territory, or should the Licensee desire that a Licensee Trademark be used for a Licensee Indication in the Territory, Licensee, upon notifying the Licensor, may use such Licensee Trademark. For avoidance of doubt, and ample clarity, any Licensee Trademark shall be owned by Licensee and Licensee shall register the same with the trademark registry in the Territory and country of manufacture. Similarly, Licensor warrants that the Licensed Trademark shall be registered by the Licensor, with the trademark registry or such other similar registry as may be prescribed under law, both in the Territory and the country of manufacture.

4.4 Trademark Quality Standards . Licensee shall (i) maintain such reasonable quality standards for the Licensed Trademarks, if any, in the Territory as Licensor maintains for such Licensed Trademarks outside the Territory, and shall comply with Licensor's reasonable specifications and usage standards supplied to it in writing (and as may be updated by written notice from time to time); (ii) not use any Licensed Trademark in a manner that suggests any connection with any product other than the Licensed Product or any service; and (iii) not use or display the Licensed Trademarks in any manner that might dilute, tarnish, disparage or reflect adversely on Licensor or such marks. From time to time, upon request by Licensor, Licensee shall provide copies of the usage of the Licensed Trademarks used in the marketing or promotion of the Licensed Product in the Licensee Indications in the Territory in order to review such usage. Licensee agrees that it shall not seek to register or obtain ownership rights in any Licensed Trademark (or confusingly similar trademark) or any trademark used by Licensor in connection with the Licensed Product outside the Territory in any indication.

4.5 Retained Rights and Limitations . No rights are granted to Licensee hereunder to Licensed Technology outside the Licensee Indications or outside the Territory. No rights are granted to Licensee hereunder to import the Licensed Product from any Third Party other than from Licensor or its designee. No rights to either Party's patents, trademarks or other proprietary rights are granted pursuant to this Agreement, except as expressly set forth herein, and all other rights are reserved.

5. DEVELOPMENT AND REGULATORY APPROVAL

5.1 Development . Licensor confirms that, as of the Effective Date, Licensor is conducting the PRESENT Trial of the Licensed Product for the First Licensee Indication and that Licensor 's current estimated timelines for Regulatory Approval, if any, of the Licensed Product for the First Licensee Indication are attached hereto as ANNEX 1. Licensor shall use Reasonably Diligent Efforts to complete the development of the Licensed Product in the First Licensee Indication in accordance with the timelines set forth in ANNEX 1 (as they may be amended from time to time as necessary or appropriate based on the progress of the PRESENT trial) and procure the Regulatory Approval for the Licensed Product in the U.S, the European Union (E.U.) or other territory. Licensor shall, as soon as practicable but in no event later than fifteen (15) days, notify Licensee of any material changes or updates to the development plan or regulatory strategy for the Licensed Product in the U.S, E.U. or other territory.

5.2 Sharing of Regulatory Filings by Licensor. In order to enable Licensee to plan, allocate its resources and fulfill its obligations under the Agreement, Licensor shall furnish to

Licensee as soon as practicable: (i) provide within 30 (thirty) days a copy of each Regulatory Filing made for seeking Regulatory Approval in the U.S. and/or the E.U. in respect of the Licensed Product (including any regulatory filing relating to manufacturing made by Licensor) for Licensee Indications upon Licensee's written request together with all accompanying documents including the Registration Dossier, (ii) copies of any communication received from the Governmental Authority and response submitted to such Governmental Authority, together with all accompanying documents, with respect to such Regulatory Filing; (iii) copies of any other Regulatory Filing made by the Licensor in respect of the Licensed Product in the Licensee Indications; and (iv) copies of any communications received by the Licensor from any Governmental Authority in respect of the Licensed Product in the Licensee Indications. Where a Regulatory Filing is not in English, Licensor shall also provide an English translation thereof to the Licensee.

5.3 Sharing of Information of the PRESENT Trial . Licensor shall as soon as practicable, but in any event not exceeding thirty (30) days, inform the Licensee in writing, together with supporting documents, of any changes in CMC data of the Licensed Product, investigative brochure, interim or final results of the PRESENT Trial, and any additional safety studies required by the Governmental Authority and the results of any such studies.

5.4 Responsibility for Regulatory Filings to Commercialize the Licensed Product . Following notice from Licensor to Licensee of the Regulatory Approval of the Licensed Product in the First Licensee Indication in the U.S. or the E.U., Licensee shall use its Reasonably Diligent Efforts, at Licensee's sole cost and expense and in Licensee's name, to procure Regulatory Approval for the Licensed Product in the First Licensee Indication in the Territory. Licensor shall make its regulatory expert available to Licensee, if required, for the inperson interactions with Governmental Authorities in the Territory at Licensors cost.

5.5 Sharing of Regulatory Filings by Licensee . Licensee shall furnish to Licensor a draft copy of any Regulatory Filing in the Territory (including any regulatory filing relating to manufacturing made by Licensee in accordance with Section 8.2) as soon as practicable prior to filing it with a Governmental Authority. Licensee will consider in good faith any comments made by Licensor with respect to such Regulatory Filing. Where a Regulatory Filing is not in English, Licensee shall also provide an English tranlation. Upon the request of either Party, the other Party shall provide a right of reference to any requested Regulatory Filings or Regulatory Approval for the Licensed Product in the Territory, and Licensor shall provide the same such right of reference to Licensee with respect to such Regulatory Filings and Regulatory Approvals outside the Territory, in each case as reasonably necessary for the requesting Party's commercialization of the Licensed Product as permitted hereunder (or, with respect to Licensor, the manufacture of the Licensed Product). Neither Party shall have an obligation to provide information relating to any product other than the Licensed Product and Adjuvant.

5.6 No Transfer of Regulatory Filing . Licensee shall not transfer title in, fail to maintain or otherwise attempt in any manner to dispose of any Regulatory Filing or Regulatory Approval or

other governmental sublicenses, approvals or certificates for the Licensed Product in the Territory without the prior written approval of Licensor.

5.7 Certain Covenants .

5.7.1 Promptly following Regulatory Approval of the Licensed Product in a Licensee Indication in the Territory, Licensor and Licensee will develop and agree upon safety data exchange procedures governing the coordination of collection, investigation, reporting, and exchange of information concerning adverse events with respect to the Licensed Product in such Licensee Indication sufficient to permit each Party, its Affiliates and permitted sublicensees to comply with applicable Law.

5.7.2 Throughout the Term, Licensor shall provide to Licensee with any updates to the Registration Dossier as soon as is practicable after such updates become available to Licensor.

5.7.3 Following Regulatory Approval of the Licensed Product in a Licensee Indication in the Territory, Licensee shall, as soon as reasonably possible and in its discretion and at its cost and expense, submit applications to the relevant Regulatory Authorities and use Reasonably Diligent Efforts to obtain pricing approval, if necessary, for such Licensed Product in the Territory.

5.8 Adverse Event Reporting . Licensee shall be responsible in accordance with applicable Law for reporting to the relevant Governmental Authorities and Licensor, all adverse events with respect to the Licensed Product in the Territory, including in connection with the Clinical Trial, to the extent required by and in accordance with applicable Law. Licensor (or its designee) shall be responsible in accordance with applicable Law for reporting to the relevant Governmental Authorities and Licensee all adverse events with respect to the Licensed Product outside the Territory, including in connection with any clinical trial of the Licensed Product in the Licensee Indications.

5.9 Communications .

5.9.1 Licensee Responsibility . Licensee shall have at all times, whether before or after Regulatory Approval, exclusive responsibility for all correspondence and for any official communication (except as Licensor may be required by Law or a Governmental Authority to communicate) regarding the Licensed Product in the Licensee Indication with applicable Governmental Authorities in the Territory. Without prejudice to the time periods relevant to Regulatory Filings pursuant to Section 5.5, Licensee will supply to Licensor a copy of: (i) all such correspondence and communications to any such Governmental Authority as soon as practicable prior to provision of such correspondence or communication to such Governmental Authority; and (ii) all such correspondence and communications from any such Governmental Authority after receipt of any such correspondence. Materials provided pursuant to Section 5.5 need not be re-provided pursuant to this subsection 5.9.1 unless changed. Where correspondence or communications are not in English, Licensee shall also provide an English language translation.

Licensee shall consider in good faith any comments or suggestions made by Licensor with respect to any such communication.

5.9.2 Licensor Responsibility . Licensor shall have exclusive responsibility for all correspondence and for any official communication (except as Licensee may be required by Law or a Governmental Authority to communicate or as expressly provided in subsection 5.7.1) regarding the Licensed Product outside the Territory in all indications, including the Licensee Indications. With respect to correspondence and communication with Governmental Authorities relating to Licensed Product outside the Territory, Licensor shall provide Licensee all copies of all written correspondences to and from Governmental Authorities with respect to the Licensed Product as soon as practicable; provided, however, that any correspondence from or to Governmental Authorities in relation to an adverse event shall be communicated to Licensee in accordance with the reporting guidelines of the applicable Governmental Authority.

5.9.3 Licensor Cooperation – Manufacturing Information . Upon Licensee's request, Licensor will make and provide copies of any direct communications by Licensor either to or from the Governmental Authorities having jurisdiction outside the Territory regarding the manufacture of any Licensed Product by Licensor or its designee, for supply to Licensee; provided, however, that Licensor's obligation to provide Licensee with manufacturing and process information is limited to the circumstance where the information is reasonably required for Licensee to carry out its obligations under Section 5.1, or access to such information is required by Law or a Governmental Authority having jurisdiction in the Territory; but Licensee shall only be entitled to use such information to the extent required by such Law or Governmental Authority or to the extent reasonably required to carry out its responsibilities hereunder.

5.10 Recalls . The Parties shall exchange their internal standard operating procedures as to product recalls reasonably promptly after obtaining Regulatory Approval in the Territory. Notwithstanding the foregoing, Licensor shall during the Term, inform Licensee in writing any instances of recall of the Licensed Product outside the Territory, together with such information as may be reasonably requested by Licensee.

5.11 Cooperation Generally . The Parties shall cooperate generally with respect to obtaining Regulatory Approval and commercialization of the Licensed Product in the Licensee Indications in the Territory. Licensor shall support Licensee during such regulatory procedure whether for obtaining Regulatory Approval or any other procedure, and shall undertake Reasonably Diligent Efforts to cooperate and assist with Licensee in addressing any queries raised by the Governmental Authority by providing Licensee as soon as practicable all additional data or information under Licensor's Control as Licensee may reasonably request to enable Licensee to submit the same to Governmental Authority within any period stipulated by such Governmental Authority.

5.12 Joint Steering Committee . Within thirty (30) calendar days following the Effective Date, the Parties shall establish a joint steering committee (the " Joint Steering Committee " or " JSC ") for the purpose of facilitating the sharing of knowledge, information and best practices regarding

the development, registration, and management of the Licensed Product in the U.S, and/or European Union by the Licensor (or its designee); and to collaborate and co-ordinate the registration, supply, promotion, marketing, distribution, execution and management of the Licensed Product in the Territory.

5.12.1 The JSC shall comprise of minimum three (3) members designated by each Party consisting of representatives of the medical, regulatory and business departments of each Party. The JSC shall meet quarterly or more or less frequently as it may deem fit, with meetings to be held by teleconference, video conference or, if deemed fit, in-person.

5.12.2 The JSC shall perform the following functions, some or all of which may be addressed directly at each meeting of the JSC:

(i) During the development stage of the Licensed Product, provide updates, information on the development and the regulatory phase, including, but not limited to, conduct of the PRESENT Trial, changes in the investigative brochure, CMC data, other clinical studies, results of the trials and studies compiling of the Registration Dossier, Regulatory Approval, and communications with Governmental Authority outside the Territory.

(ii) During the development stage of the Licensed Product, coordinate, discuss, and develop a strategy for seeking patent protection for the Licensed Product in the Territory.

(iii) During the commercialization of the Licensed Product outside the Territory, the Parties shall provide updates on the Regulatory Approval, if any, of the Licensed Product, instances of any recalls or adverse events of the Licensed Product and manufacturing information.

(iv) During the Regulatory Filing for securing the Regulatory Approval and after the receipt of Regulatory Approval by Licensee in the Territory, the Parties shall provide updates on the Regulatory Filings, marketing strategy, recalls and adverse events and other aspects pertaining to the collaboration.

6. DEVELOPMENT AND COMMERCIALIZATION

6.1 Development .

6.1.2 As soon as is practicable following the Effective Date, Licensee shall, **[***]**, use Reasonable Diligent Efforts to initiate a epidemiology study and Phase 2 clinical study in the Second Licensee Indication in accordance with ANNEX 2, ANNEX 3, and ANNEX 4 in the Territory pursuant to the Clinical Trial Agreement (the " Clinical Trial "). For clarity, the Clinical Trial shall be conducted solely pursuant to the Clinical Trial Agreement, and Licensee shall not conduct any clinical trials of the Licensed Product outside the Territory. Licensor agrees to share all the data, study results and information, Licensed Product and Adjuvant without any further charge or cost, as may be required, by the Licensee to enable the Licensee to conduct the Clinical Trial under the

Clinical Trial Agreement. Notwithstanding anything stated herein, post the analysis of interim data of the PRESENT Trial, or final data review of the PRESENT Trial by US Governmental Authority, the Parties shall review and make a decision on the feasibility of initiating or continuing with the Clinical Trial. In absence of Positive Interim Data, the Licensee have the option to discontinue the trial.

6.1.3 Licensor hereby grants Licensee the exclusive right (except as to Licensor) and license during the Term, subject to the terms and conditions hereof, to utilize and practice the Licensed Know-How in the Territory solely for purposes of the Clinical Study. Licensor shall disclose the Licensed Know-How to Licensee for these purposes upon reasonable notice from Licensee and during Licensor's normal business hours, and shall designate one or more technical liaisons for communications with Licensee's technical personnel. Such exclusivity and license extends only to the conduct of the Clinical Trial. Such license shall not include any right to sublicense. For avoidance of doubt, Licensee may sub-contract any or all parts of the Clinical Study to one or more sub-contractors; provided that Licensee shall be responsible hereunder for any such subcontractor with the provisions of this Agreement.

6.1.4 Licensor may, but shall not be obliged to, seek Regulatory Approval of the Licensed Product in the Second Licensee Indication, or any other indication in its discretion, outside the Territory. For avoidance of doubt, Licensee shall have a right to apply for the Regulatory Approval of the Licensed Product in the Second Licensee Indication in the Territory. In the event Licensee proceeds with the application for the Regulatory Approval of the Licensed Product in the Second Licensee Indication in the Territory, Licensor shall provide to Licensee all documents, information, data, test or study results, reports including the Registration Dossier, if any, under Licensor's Control, as reasonably required to enable Licensee to file for the Regulatory Approval. The Parties shall keep each other reasonably apprised on a current basis of the progress of the Clinical Trial and of any clinical trials of the Licensed Product in the Licensee Indications outside the Territory.

6.2 Operational Control in Licensee Indications . Following Regulatory Approval of the Licensed Product in a Licensee Indication in the Territory, Licensee shall have operational right and responsibility, in its discretion and at its cost and expense, for commercialization of the Licensed Product in the Licensee Indications in the Territory, including the commercial strategy, and shall use its Reasonably Diligent Efforts to commercialize the Licensed Product in the Licensee Indications in the Territory. Similarly, following the grant of Regulatory Approval for the Licensed Product in a Licensee Indication in the Territory, Licensor shall supply the Licensed Product in required quantities in a timely manner in accordance with terms and conditions as may be agreed between the Parties under a separate supply agreement. Licensee shall promote and commercialize the Licensed Product with a view to optimizing Sales of the Licensed Product in the Territory using only professional and well-trained employees of Licensee, and shall not utilize a contract sales organization in connection with the Licensed Product without Licensor's prior written approval. Licensee shall develop an annual marketing plan for the Licensed Product, which plan shall include recommended pricing, reimbursement and positioning of the Licensed Product in the Territory, sales

and distribution strategies and promotional programs. Licensee shall afford Licensor a reasonable opportunity to review and comment on Licensee's annual marketing plans, and Licensee shall duly consider any changes or additions to such plans that Licensor may suggest. At the request of either Party, the Parties also shall meet not less frequently than annually to discuss Licensee's marketing plan in the Territory. As a part of Licensor's cooperation with Licensee, Licensor shall provide relevant data and information for creation of promotional materials for the Licensee Indications in the Territory and use its Reasonably Diligent Efforts to make available, at Licensee's sole cost and expense, key opinion leaders for conduct of continuing medical education programs by Licensee in the Territory and the marketing and promotional materials used for the Licensee Indications in other territories. Licensee shall be solely responsible for its costs incurred in connection with its commercialization of the Licensed Product in the Territory.

6.3 Commercialization Outside the Territory . Except as provided in subsection 7.1.3 and 7.1.4, Licensee shall have no rights with respect to the commercialization of the Licensed Product outside the Territory in any indication, including the Licensee Indications.

6.4 Compliance with Laws, Regulations and Guidelines . Each Party agrees to comply with Law with respect to the development and commercialization of the Licensed Product in the Licensee Indications in the Territory.

6.5 Cooperation Generally . The Parties shall cooperate generally with respect to the commercialization of the Licensed Product in the Licensee Indications in the Territory.

7. IMPROVEMENTS; ADDITIONAL TERRITORY

7.1 Notice of Improvements .

7.1.1 Promptly after the development by or on behalf of Licensor or, where applicable, any assignment or transfer to Licensor, of any Improvement, Licensor shall provide written notice to Licensee (" Improvement Notice "). The Improvement Notice shall include a description of the Improvement and a summary of the subject matter claimed in any Improvement patents.

7.1.2 If Licensee wishes to include any Improvement as a Licensed Product under this Agreement, Licensee shall provide within ninety (90) days of the Improvement Notice written notice to Licensor specifying that the Licensee wishes to include the Improvement as a Licensed Product. Immediately upon Licensee's notice to Licensor, each Improvement identified by Licensee in its notice hereunder will be a Licensed Product under this Agreement. No rights are granted to Licensee hereunder to make any Improvement, and Licensee shall not undertake to make any Improvement or obtain any Improvement other than from Licensor or its designee.

7.1.3 In the event during the Term of this Agreement, Licensor receives inquiries from any Third Party for an exclusive license to market, sell and distribute a Licensed Product in any of jurisdictions of **[***]** , **[***]** , or **[***]** for any of the Licensee Indications, Licensor shall in

good faith provide **[***]**. **[***]**, the Parties will proceed with the license and supply arrangement for the Licensed Product for any of jurisdictions of **[***]**, **[***]**, or **[***]** then Licensor shall give due consideration to Licensee's co-ownership of any intellectual property developed in the Clinical Trial and provide an equivalent economic benefit in respect of the business arrangements between the Licensor and the Licensee in such jurisdictions. **[***]**.

7.1.4 In the event during the Term of this Agreement, Licensor receives inquiries for an exclusive license to market, sell and distribute a Licensed Product in **[***]** for any of the Licensee Indications, Licensor shall in good faith provide Licensee with an opportunity to discuss and negotiate with Licensor for the same to arrive at mutually acceptable commercial terms. In the event that the Parties agree to proceed with the license and supply arrangement for the Licensed Product **[***]** then Licensor shall give due consideration to Licensee's co-ownership of any intellectual property developed in the Clinical Trial and provide an equivalent economic benefit in respect of the business arrangements between the Licensor and the Licensee in such jurisdiction.

8. MANUFACTURE AND SUPPLY

8.1 Timely Supply: Following the grant of the Regulatory Approval the Licensed Product in a Licensee Indication in the Territory, Licensor shall supply the Licensed Product in required quantities in a timely manner in accordance with terms and conditions as may be agreed between the Parties under a separate supply agreement.

8.2 Manufacturing Rights and Price . No rights are granted to Licensee hereunder to manufacture the Licensed Product or to obtain the Licensed Product other than from Licensor or its designee. Licensee shall not manufacture the Licensed Product or obtain the Licensed Product other than from Licensor or its designee and as expressly provided in one or more supply agreements to be entered into between the Parties. Each such supply agreement shall provide for a purchase price to Licensee for the Licensed Product equal to the Cost of Licensed Product, plus any applicable sales Taxes or VAT or similar levies on Licensor's sales to Licensee of the Licensed Product.

8.2.1 "Cost of Licensed Product" shall during the Term hereof not be more than **[***]** ($ **[***]**) US Dollars per dose of the Licensed Product on EX WORKS incoterms 2010.

8.2.2 Adjuvant Supply **[***]**. **[***]**.

8.2.3 **[***]**.

9. PAYMENT

9.1 Royalty Payments . (i) It is agreed that Licensor shall supply **[***]** as the Adjuvant along with the Licensed Product and in such case the Licensee shall pay the Licensor a royalty of **[***]** percent (**[***]** %) on all Net Sales of the Licensed Product during the Term. (ii) In the event that the Adjuvant to be approved as a part of the label is any other Adjuvant which is available in the Territory, matches Licensee's quality standards, and is procured by Licensee directly, then Licensee shall pay Licensor a royalty of **[***]** percent (**[***]** %) on all Net Sales during the Term, except that the royalty shall be in a reduced to an amount equal to **[***]** percent (**[***]** %) of Net Sales of the Licensed Product during any Quarterly Period or portion thereof in which a Competing Product is being marketed and sold in the Territory. In this regard, Licensee shall notify Licensor promptly if it becomes aware of any Competing Product being marketed or sold in the Territory.

The payment made pursuant to claim 9.1 shall be inclusive of any taxes applicable and Licensor needs to pay any tax if applicable.

9.2 **[***]** .

9.3 Not Included . The payments to be made pursuant to Section 9.1 do not include any amounts payable pursuant to Section 9.8 or pursuant to any section of the any supply agreement contemplated by Section 8.2, each of which are separately due and payable without reference to amounts payable pursuant to Section 9.1.

9.4 Appropriate Measure of Value . Each of the Parties acknowledges that the value provided by the other hereunder is comprised of many related items, including intellectual property of various types, access to development and commercial expertise, clinical data, including Regulatory Filings both inside and outside the Territory, and other financial and non-financial consideration.

9.5 The Parties also hereby agree to renegotiate the Cost of Licensed Product on the fifth (5) anniversary of the Effective Date if the Licensors actual cost of goods sold for the Licensed Product increases or decreases by **[***]** (**[***]** %) percent or more as determined in accordance with GAAP (the "Cost of Licensed Product Adjustment"). Upon the Licensors written notice, the Parties shall have three (3) month to execute an amendment detailing the Cost of Licensed Product Adjustment. In the event the Parties do not reach an agreement within the three (3) month period the Cost of Licensed Product shall be Licensor's actual cost of goods sold as determined in accordance with GAAP. In addition to the foregoing elements, the royalty payments set forth in Section 9.1 have been premised on the basis that cost of goods sold being **[***]** ($ **[***]**) U.S. dollars per dose of the Licensed Product remain unchanged throughout the Term hereof while the cost of goods of **[***]** is **[***]** ($ **[***]**) U.S. dollars per dose. Accordingly, in the event that cost of goods sold for the Licensed Product increases then the Parties agree to decrease the royalty payments reasonably.

9.6 Calculation of Net Sales Revenue . In calculating Net Sales:

9.6.1 Free Products . Any disposal of the Licensed Product at no charge for, or use of the Licensed Product along with Adjuvant without charge in, clinical or preclinical trials, given as free samples, or distributed at no charge to patients unable to purchase the same shall not be included in Net Sales.

9.6.2 Bundled Products . Licensor acknowledged that, under current applicable Law, the Licensed Product (except Adjuvant) is not able to be sold in a Bundle in the Territory. In the event, however, that the Licensed Product (except Adjuvant) is sold in a Bundle in accordance with applicable Law, then for the purposes of calculating the Net Sales under this Agreement, such Licensed Product shall be deemed to be sold for an amount equal to (X÷Y) × Z, where: X is the average sales price during the applicable reporting period generally achieved for such Licensed Product in the Territory; Y is the sum of the average sales price during the applicable reporting period generally achieved in the Territory, when sold alone, by each pharmaceutical product included in the Bundle; and Z equals the price at which the Bundle was actually sold. In the event that the Licensed Product or one or more of the other pharmaceutical products in the Bundle are not sold separately, the Parties shall confer in good faith to determine an equitable fair market price to apply to such bundled Licensed Product.

9.7 Reports . Beginning with the first Quarterly Period in which the First Commercial Sale occurs, and thereafter for each Quarterly Period until the expiration or termination of Licensee's obligation to pay royalties hereunder, royalty payments for each Quarterly Period shall be calculated and delivered by Licensee to Licensor under this Agreement within forty five (45) days after the end of each such Quarterly Period. Each royalty payment shall be accompanied by a report of Sales and Net Sales stating: (a) the quantity Sold, Sales and Net Sales (on a Licensed Product-by-Licensed Product basis) by or on behalf of Licensee, its Affiliates or sublicensees during the applicable Quarterly Period (detailed with gross invoice amounts and deductions to determine Net Sales); (b) a calculation of the royalty payment due from Licensee hereunder for such Quarterly Period; and (c) such additional information as reasonably requested by Licensor from time to time to enable it to comply with its obligations to its licensors.

9.8 No Wrongful Reductions . Licensee shall not attempt to reduce compensation rightly due to Licensor hereunder by shifting compensation otherwise payable to Licensee from a Third Party with respect to a Licensed Product to another product or service for which no royalties are payable by it hereunder.

9.9 Milestone Payments . In addition to the other payments provided for or referenced herein, Licensee shall pay Licensor one-time only the following non-refundable amounts: (i) **[***] ($ [***])** U.S. dollars upon the execution and delivery of this Agreement and Contemporaneous Agreements by the Parties; (ii) **[***] ($ [***])** U.S. dollars upon confirmation in writing by Licensee of the Positive Interim PRESENT Data; (iii) **[***] ($ [***])** U.S. dollars upon achievement of cumulative aggregate Net Sales during the Term of **[***] ($ [***])** U.S. dollars; and (iv) **[***] ($ [***])** U.S. dollars upon achievement of cumulative aggregate Net Sales during the Term of **[***] ($ [***])** U.S. dollars, over and above the Net Sales referred to in clause (iii). Payment of the

amounts referred to in the foregoing clauses (iii) and (iv) shall not be payable, in the event that, at the time either such amount otherwise would have become payable hereunder, a Competing Product is then being marketed and sold in the Territory. Licensee shall pay Licensor the foregoing milestone payments in accordance with Section 9.8 within thirty (30) days after the event giving rise to such payment.

The payment made pursuant to claim 9.9 shall be inclusive of any taxes applicable and Licensor needs to pay any tax if applicable.

9.10 Payment Method . All payments made hereunder by Licensee to Licensor shall be made in U.S. Dollars, except as set forth in Section 9.11. Licensee shall pay all sums due hereunder by wire-transfer or electronic funds transfer in immediately available funds. Licensor shall promptly notify Licensee of Licensor's account information to facilitate such payments. Regardless of the amounts of any royalty or other payments due under this Agreement or any other agreement between the Parties or their Affiliates, all amounts payable under this Agreement shall be paid in full (subject to Sections 9.12 and Section 9.13).

9.11 Audits . (i) Licensee shall keep complete and accurate records pertaining to Sales of the Licensed Product in the Territory in sufficient detail to permit Licensor to confirm the accuracy of all payments due hereunder, and such records shall be open (in such form as may be available or reasonably requested by an independent certified public accountant appointed in accordance with this Section 9.11 (Audits)) to inspection for five (5) years following the end of the Quarterly Period to which they pertain. Licensor shall have the right, at its own expense, to have an independent, certified public accountant or other representative selected by it review the records of Licensee upon reasonable notice. Within fifteen (15) days following such notice, Licensee shall make such records available electronically to such accountant and Licensor by computer remote access. The report of such accountant shall be made available to both Parties simultaneously, promptly upon its completion. Licensor's audit rights with respect to any Quarterly Period shall expire five (5) years after the end of such Quarterly Period and the books and records for any particular Quarterly Period shall only be subject to one (1) audit. Should the inspection lead to the discovery of a discrepancy to Licensor's detriment, then Licensee shall pay to Licensor the amount of the discrepancy plus interest accrued at the Contract Interest Rate, from the day the relevant payment was due. Should the inspection lead to the discovery of a discrepancy to Licensee's detriment, then Licensor shall pay to Licensee the amount of the discrepancy without interest thereon. Licensor shall pay the full cost of the inspection, except that Licensee shall pay or reimburse Licensor for the cost of such inspection if the inspection leads to the discovery of a discrepancy to Licensor's detriment. (ii) Licensor shall keep complete and accurate records pertaining to the Cost of Adjuvant and Licensed Product in sufficient detail to permit Licensee to confirm the accuracy of thereof and all payments due therefor, and such records shall be open (in such form as may be available or reasonably requested by an independent certified public accountant appointed in accordance with this Section 9.11 (Audits)) to inspection for five (5) years following the end of the Quarterly Period to which they pertain. Licensee shall have the right, at its own expense, to have an independent, certified public accountant or other representative selected by it review the records of Licensor upon

reasonable notice. All the rights of the Licensor in respect of the audit stated hereinbefore shall mutatis mutandis apply to Licensee in respect of the audit for Cost of Adjuvant and Licenced Product.

9.12 Blocked Currency . If Licensee is prohibited by a Governmental Authority from making any payment due under this Agreement then, within the prescribed period for making the payment Licensee shall promptly request and use its Reasonably Diligent Efforts to obtain permission from the Governmental Authority to make the payment, and shall make the payment, within ten (10) days after receiving such permission. In cases of eventualities under this clause 9.12, the Parties agree that no interest on the delayed payment shall apply.

9.13 Taxes . All Taxes levied on account of a payment made by Licensee to Licensor pursuant to this Agreement will be subject to the withholding and remittance provisions of Section 9.14.

9.14 Withholding . In the event that Law requires Licensee to pay or withhold Taxes with respect to any payment to be made by Licensee pursuant to this Agreement, Licensee shall notify Licensor in writing of such payment or withholding requirements and provide such assistance to Licensor, including the provision of such documentation as may be required by a tax authority, as may be reasonably necessary in Licensor's efforts to claim an exemption from or reduction of such Taxes. Licensee will, in accordance with Law, withhold Taxes from the amount due, remit such Taxes to the appropriate tax authority, and furnish Licensor with proof of payment of such Taxes as and when such proof is issued by the Governmental Authority . If Taxes are paid to a tax authority, Licensee shall provide such assistance to Licensor as is reasonably required to obtain a refund of Taxes withheld, or obtain a credit with respect to Taxes paid. For the sake of clarity, the payments made by the Licensee to the Licensor pursuant to clause 9.1 and 9.9 shall be inclusive of all the applicable taxes and such taxes shall not be payable by the Licensee.

9.15 Late Payment . Save for payments under Section 9.11, any payments or portions thereof due hereunder which are not paid when due shall bear interest at the Contract Interest Rate, compounded daily, calculated on the number of days such payment is delinquent. This Section 9.15 shall in no way limit any other remedies available to either Party.

9.16 Third Party Royalties . Except as expressly set forth in Sections 9.14, neither Party shall have the right to make any deduction from amounts otherwise payable pursuant to this Agreement on account of any royalty or other amount payable to any Third Party.

10. INTELLECTUAL PROPERTY

10.1 Ownership . Except to the extent expressly specified to the contrary in this Agreement: (i) each Party shall retain and own all right, title, and interest in and to all patent rights, trade secrets, proprietary rights and other intellectual property rights conceived or created solely by such Party; (ii) the Parties shall jointly own all right, title, and interest in and to all patent rights, trade secrets, proprietary rights and other intellectual property rights conceived or created as part

of or in connection with the Clinical Trial (the "Clinical Trial Intellectual Property") and, subject to the provisions of this Agreement (including those sublicenses granted pursuant to Article 3) and; (iii) inventorship and authorship of any invention or work of authorship conceived or created by either Party, or pursuant to the Clinical Trial, shall follow the rules of the U.S. Patent and Trademark Office and the Laws of the United States (without reference to any conflict of law principles) and; (iv) Licensor herby grants Licensee an exclusive license to the Clinical Trial Intellectual Property in the Territory for the Licensed Indications, and; (v) Licensee herby grants Licensor an exclusive license to the Clinical Trial Intellectual Property without duty to account or obtain the consent of Licensee (such consent deemed given hereunder) in order to exploit, sublicense or assign such intellectual property rights outside the Territory except Russia, China and Germany. For Russia, CIS, China and Germany, the Licensor shall seek from Licensee in order to exploit sublicence or assign such intellectual property rights, written consent which the Licensee shall not unreasonably withhold from Licensor.

10.2 Enforcement . Each Party shall promptly notify the other Party in writing if it reasonably believes that any of the Licensed Know-How or Licensed Trademarks is misappropriated by a Third Party in the Territory. Licensor, at its expense, shall be entitled to enforce the Licensed Know-How and Licensed Trademarks exclusively against infringement by a Third Party and to retain recoveries from such enforcement. If Licensor does not file suit against a substantial infringer within six (6) months of knowledge thereof, then Licensee may, at its sole discretion and expense, enforce any Licensed Know-How and Licensed Trademarks on behalf of itself and Licensor, with Licensee retaining all recoveries from such enforcement. In any suit or dispute involving an infringer, the Parties agree to cooperate fully with each other. At the request and expense of the Party bringing suit, the other Party will permit access during regular business hours, to all relevant personnel, records, papers, information, samples, specimens, and the like in its possession.

11. CONFIDENTIALITY AND PUBLICATIONS

11.1 Confidentiality; Exceptions . Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Parties agree that, during the Term and for five (5) years thereafter, the receiving Party shall keep confidential and shall not publish or otherwise disclose or use for any purpose other than as provided for in this Agreement any confidential and proprietary information and materials furnished to it by the other Party pursuant to this Agreement (collectively, " Confidential Information "). Neither Party shall have right to and shall not utilize any Confidential Information of the other Party for activities inside or outside the Territory. For clarity, Confidential Information of a Party shall include, without limitation, all information and materials disclosed by such Party or its designee that (i) is marked as "Confidential," "Proprietary" or with similar designation at the time of disclosure or (ii) by its nature can reasonably be expected to be considered Confidential Information by the recipient. Information disclosed orally shall not be required to be identified as such to be considered Confidential Information. Notwithstanding the foregoing, Confidential Information shall not include any information to the extent that it can be established by written documentation by the receiving Party that such information:

11.1.4 Was already known to the receiving Party, other than under an obligation of confidentiality (except to the extent such obligation has expired or an exception is applicable under the relevant agreement pursuant to which such obligation was established), at the time of disclosure;

11.1.5 Was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

11.1.6 Became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

11.1.7 Was independently developed by the receiving Party (without reference to or use of Confidential Information of the other Party) as demonstrated by documented evidence prepared contemporaneously with such independent development; or

11.1.8 Was disclosed to the receiving Party, other than under an obligation of confidentiality (except to the extent such obligation has expired or an exception is applicable under the relevant agreement pursuant to which such obligation was established), by a Third Party who had no obligation to the disclosing Party not to disclose such information to others.

11.2 Authorized Disclosure . Except as expressly provided otherwise in this Agreement, each Party may use and disclose Confidential Information of the other Party solely as follows: (i) under appropriate confidentiality provisions substantially equivalent to those in this Agreement: (a) in connection with the performance of its obligations or as reasonably necessary or useful in the exercise of its rights under this Agreement; (b) to the extent such disclosure is to a Governmental Authority as reasonably necessary in filing or prosecuting patent, copyright and trademark applications in accordance with this Agreement, prosecuting or defending litigation in accordance with this Agreement, complying with applicable governmental regulations with respect to performance under this Agreement, filing Regulatory Filings, obtaining Regulatory Approval or fulfilling post-approval regulatory obligations for a Licensed Product, or otherwise required by Law, including the rules of any securities exchange or automated quotation system; (c) to advisors (including lawyers and accountants) on a need-to-know basis, in each case under appropriate confidentiality agreements or professional standards of confidentiality substantially similar to those of this Agreement; and (d) to the extent otherwise mutually agreed to by the Parties.

11.3 Terms and Conditions Confidential . Neither Party shall disclose the terms and conditions of this Agreement except as may be required by Law. Notwithstanding the foregoing, with respect to complying with the disclosure requirements of any Governmental Authority in connection with any required filing of this Agreement, the Parties shall consult with one another concerning which terms of this Agreement shall be requested to be redacted in any public disclosure of the Agreement, and in any event each Party shall seek reasonable confidential treatment for any public disclosure by any such Governmental Authority. Notwithstanding the foregoing, the Parties also shall agree upon and release a mutual press release to announce the execution of this Agreement;

thereafter, Licensee and Licensor may each disclose to Third Parties the information contained in such press release without the need for further approval by the other. Each Party shall additionally have the right to issue additional press releases in regards to this Agreement and the Licensed Product with the prior written agreement of the other Party or as required to comply with any Law or by the rules of any securities exchange or automated quotation system.

11.4 Prior Agreement . This Agreement supersedes the Confidential Disclosure Agreement between the Parties dated October 16, 2012, as it may be amended and supplemented, including any written requests thereunder (the " Prior Agreement "), with respect to information disclosed thereunder relating to the Licensed Product and the research and development related thereto. All confidential information exchanged between the Parties under the Prior Agreement shall be deemed Confidential Information of the disclosing Party and shall be subject to the terms of this Agreement.

11.5 Attorney-Client Privilege . Neither Party is waiving, nor shall be deemed to have waived or diminished, any of its attorney work product protections, attorney-client privileges or similar protections and privileges as a result of disclosing information pursuant to this Agreement, or any of its Confidential Information (including Confidential Information related to pending or threatened litigation) to the receiving Party, regardless of whether the disclosing Party has asserted, or is or may be entitled to assert, such privileges and protections. The Parties: (i) share a common legal and commercial interest in such disclosure that is subject to such privileges and protections; (ii) are or may become joint defendants in proceedings to which the information covered by such protections and privileges relates; (iii) intend that such privileges and protections remain intact should either Party become subject to any actual or threatened proceeding to which the disclosing Party's Confidential Information covered by such protections and privileges relates; and (iv) intend that after the Effective Date both the receiving Party and the disclosing Party shall have the right to assert such protections and privileges.

12. REPRESENTATIONS, WARRANTIES AND COVENANTS

12.1 Mutual Representations and Warranties . Each of the Parties hereby represents and warrants to the other Party as of the Effective Date that:

12.1.1 It is duly organized and validly existing under the Law of its jurisdiction of incorporation or organization and it has full corporate or company power and authority and has taken all corporate or company action necessary to enter into and perform this Agreement;

12.1.2 This Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms; the execution, delivery and performance of the Agreement by such Party does not conflict with any agreement, instrument or understanding, oral or written, by which it is bound, nor to its knowledge, violate any Law; and the person executing this Agreement on such Party's behalf has been duly authorized to do so by all requisite corporate or company action;

12.1.3 All regulatory approvals, sublicenses, exemptions, registrations, clearances and the like necessary for the research, development, Clinical Trial, manufacture, sale or marketing of pharmaceutical products, for the performance by it of its respective obligations under this Agreement has been or shall be obtained and maintained throughout the term of this Agreement; and

12.1.4 It has not been debarred or the subject of debarment proceedings by any Governmental Authority.

12.2 Licensor's Representations and Warranties . Licensor represents and warrants to Licensee as of the Effective Date that:

12.2.4 It has not knowingly used in connection with the research, development, manufacture or commercialization to take place pursuant to this Agreement any employee, consultant or investigator that has been debarred or the subject of debarment proceedings by any Governmental Authority.

12.2.5 It has the necessary right, (whether as a owner, joint owner, beneficial owner or under any other legally recognized right) of the Licensed Technology, the Licensed Trademark and the Licensed Product and as such has an unconditional and unfettered right to grant license of the same under Section 4 hereof to Licensee for the term and under the terms hereof;

12.2.6 Neither the Licensed Technology, the Licensed Trademark or the Licensed Product infringes upon any Third Party right;

12.2.7 It shall (whether as a owner, joint owner, beneficial owner or under any other legally recognized right) file and pursue for a trademark in a timely manner in respect of the Licensed Trademark and the Licensed Product in the Territory;

12.2.8 There is no settled, pending or to its knowledge threatened litigation or re-examination, post-grant or *inter partes* review, interference, derivation, opposition, claim or invalidity or other claim or proceeding (including the form of an offer to obtain a license) challenging Licensor's ownership of, or right to utilize, practice or sublicense, the Licensed Technology, the Licensed Trademark or the Licensed Product, or alleging any adverse right, title or interest with respect thereto; and

12.2.9 It has not brought or threatened any claim against any Third Party alleging infringement of any Licensed Technology, the Licensed Trademark or the Licensed Product, nor, to its knowledge, is any Third Party infringing or, to its knowledge, preparing or threatening to infringe the Licensed Technology, the Licensed Trademark or the Licensed Product.

12.3 Disclaimer of Warranties . Except as set forth in this article 12, the parties expressly disclaim any and all representations and warranties, express, implied, statutory or otherwise, with respect to the collaboration, the licensed sublicensor trademarks, the licensed sublicensor know-

how, this agreement, the license product, or any other subject matter relating to this agreement, including any warranty of merchantability, fitness for a particular purpose, validity or noninfringement of intellectual property rights.

12.4 Certain Mutual Covenants . Each of the Parties hereby covenants to the other Party as follows:

12.4.1 It shall not knowingly use in connection with the research, development, manufacture or commercialization to take place pursuant to this Agreement any employee, consultant or investigator that has been debarred or the subject of debarment proceedings by any Governmental Authority;

12.4.2 It shall carry out its activities hereunder in compliance with Law (including relevant Laws relating to economic sanctions and bribery);

12.4.1 It shall not misappropriate any trade secret of a Third Party in connection with the performance of its activities hereunder; and

12.4.2 It shall not grant any right to any Third Party that conflicts with the rights granted to the other Party hereunder.

12.5 Certain Covenants of Licensee . Licensee covenants to Licensor that during the Term of this Agreement Licensee and its Affiliates shall not undertake to develop, market, sell or distribute any product other than the Licensed Product that is targeted for one or more indications that include either of the Licensee Indications in the Territory.

13. LIMITATIONS OF LIABILITY

13.1 Limitations of Liability . In no event shall either party be liable to the other party for any indirect, special, incidental, exemplary or consequential damages of any kind arising out of or in connection with this agreement, however caused and on any theory of liability (whether in contract, tort (including negligence), strict liability or otherwise), even if such party was advised or otherwise aware of the likelihood of such damages. The limitations set forth in this Section 13.1 shall not apply with respect to (i) either Party's indemnification obligations under Article 14, (ii) breach of Section 11.1 or Section 11.2 (Confidentiality) , or (iii) gross negligence or intentional misconduct of a Party.

13.2 Insurance . During the Term and for two (2) years thereafter each Party shall obtain and maintain comprehensive general liability insurance covering its obligations and activities hereunder, including product liability insurance, with reputable and financially secure insurance carriers in a form and at levels as customary for a company of its size in the pharmaceutical industry in the Territory (or reasonable self-insurance sufficient to provide materially the same level and type of protection). Each Party shall provide the other Party with written evidence of such insurance within thirty (30) days following the Effective Date. Additionally, each Party shall provide the

other Party with written notice of at least fifteen (15) days prior to the cancellation, non-renewal or material change in such insurance.

14. INDEMNIFICATION

14.1 Indemnity .

(A) Subject to the remainder of this Article 14, Licensee shall defend, indemnify, and hold harmless Licensor, its Affiliates, and their respective directors, officers, employees and agents (collectively, " Licensor Indemnitees "), at Licensee's cost and expense, from and against any and all liabilities, losses, costs, damages, fees or expenses (including reasonable legal expenses and attorneys' fees incurred by any Licensor Indemnitees until such time as Licensee has acknowledged and assumed its indemnification obligation hereunder with respect to a claim) (collectively, " Losses ") arising out of any claim, action, lawsuit, or other proceeding (other than a shareholder derivative suit or like action) (collectively, " Claims ") brought against any Licensor Indemnitee, by a Third Party to the extent such Losses result from (i) the negligence or willful misconduct of Licensee, its Affiliates or agents in performing under this Agreement or (ii) a breach by Licensee of this Agreement, including any failure of Licensee's representations or warranties in Section 12.1 to be true, but excluding such Losses to the extent they are attributable to clause (y) or (z) of subsection 14.1(B), below.

(B) Subject to the remainder of this Article 14, Licensor shall defend, indemnify, and hold harmless Licensee, its Affiliates, and their respective directors, officers, employees and agents (collectively, " Licensee Indemnitees "), at Licensor's cost and expense, from and against any and all Losses (including reasonable legal expenses and attorneys' fees incurred by any Licensee Indemnitees) suffered or incurred by Licensee Indemnitee (including those arising out of any Claim brought against any Licensee Indemnitee, by a Third Party) to the extent such Losses result from (x) any product liability claims including adverse events or any manufacturing defects in respect of the Licensed Product (y) the negligence or willful misconduct of Licensor, its Affiliates or agents in performing under this Agreement or (z) a breach by Licensor of this Agreement, including any failure of Licensor's representations or warranties in Section 12 to be true, but excluding such Losses to the extent they are attributable to clause (i) or (ii) of subsection 14.1(A), above.

(C) For clarity, the indemnification obligations of this Article 14 shall not apply to obligations under the Clinical Trial Agreement or any supply obligations under any Supply Agreement to be entered into in connection herewith; any indemnification obligations related to the Clinical Trial Agreement or supply obligations shall be provided for in the Clinical Trial Agreement or the supply agreements to be entered into pursuant to Section 5.7.2 or Section 8.1, respectively.

14.2 Claim for Indemnification . Whenever any Claim or Loss shall arise for which a Licensee Indemnitee or an Licensor Indemnitee (the " Indemnified Party ") may seek indemnification under this Article 14, the Indemnified Party shall promptly notify the other Party (the " Indemnifying Party ") of the Claim or Loss and, when known, the facts constituting the basis for the Claim;

provided, however, that the failure by an Indemnified Party to give such notice or to otherwise meet its obligations under this Section 14.2 shall not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that the Indemnifying Party is actually prejudiced as a result of such failure. The Indemnifying Party shall have exclusive control of the defense and settlement of all Claims for which it is responsible for indemnification and shall promptly assume defense thereof at its own expense. The Indemnified Party shall not settle or compromise any Claim by a Third Party for which it is entitled to indemnification without the prior written consent of the Indemnifying Party, unless the Indemnifying Party is in breach of its obligation to defend hereunder. In no event shall the Indemnifying Party settle any Claim without the prior written consent of the other Party if such settlement does not include a complete release from liability on such Claim or if such settlement would involve undertaking an obligation other than the payment of money, would bind or impair the other Party, or includes any admission of wrongdoing or that any intellectual property or proprietary right of the other Party is invalid or unenforceable. The Indemnified Party shall reasonably cooperate with the Indemnifying Party at the Indemnifying Party's expense and shall make available to the Indemnifying Party reasonably requested information under the control of the Indemnified Party, which information shall be subject to Article 11.

15. TERM AND TERMINATION

15.1 Term . This Agreement shall come into effect as of the Effective Date and shall remain in effect for an initial term ending upon the tenth annual anniversary of the first Regulatory Approval in the Territory, unless renewed as provided below, or until terminated in accordance with this Article 15. The initial term of the Agreement shall be extended automatically for an additional three (3) years, unless either Party notifies the other Party at least ninety (90) days prior to the expiration of the initial term of its intention that the initial term shall not be so renewed.

15.2 Termination . This Agreement may be terminated as follows:

15.2.1 Termination by Licensor . Licensor shall have the right to terminate this Agreement, in whole or in part per Licensee Indications, immediately by giving written notice to Licensee if:

(a) Subject to Section 9, Licensee fails to pay any amount due under this Agreement on the due date for payment and remains in default not less than twenty five (25) days after Licensor's written notice to make such payment, including the payment of interest in accordance with Section 9.15.

(a) Licensee materially breaches this Agreement (excluding a failure to pay any amounts due under this Agreement referred to in subsection 15.2.1(a), above), including without limitation, if, Licensee fails to use Reasonably Diligent Efforts to initiate epidemiological study and Clinical Trial as provided in subsection 6.1.1 or to obtain Regulatory Approval and to commercialize the Licensed Product in the Territory as provide in Sections 6.4 and 6.2, and, if such

breach is curable, fails to cure such breach within forty five (45) days of Licensor's written notice of such breach;

(b) Licensee: (i) becomes insolvent or admits its inability to pay its debts generally as they become due; (ii) becomes subject, voluntarily or involuntarily, to any proceeding under any domestic or foreign bankruptcy or insolvency law, which is not fully stayed within thirty (30) days or is not dismissed or vacated within sixty (60) days after filing; (iii) is dissolved or liquidated or takes any corporate action for such purpose; (iv) makes a general assignment for the benefit of creditors; (v) has a receiver, trustee, custodian or similar agent appointed by order of any court of competent jurisdiction to take charge of or sell any material portion of its property or business; or

(c) if Licensee, its Affiliate or any sublicensee brings or joins in any challenge to the validity or enforceability of any Licensed Know-How or Licensed Trademark in any Territory unless such an act by Licensee is curable within 30 days of Licensors written notice.

(d) if Regulatory Approval in the Territory is denied after exhaustion of all appeals and/or measures available to Licensee. Licensee shall promptly notify Licensor of any preliminary or final denial of Regulatory Approval in the Territory.

15.2.2 Termination by Licensee . Licensee shall have the right to terminate this Agreement, in whole or in part per Licensee Indications, immediately by giving written notice to Licensor if:

(a) Licensor materially breaches this Agreement, including without limitation, if Licensor fails to use Reasonably Diligent Efforts, to obtain or cause its licensee to obtain, Regulatory Approval in the U.S. or in the E.U or any other territory as provided in Section 5.1, and, if such breach is curable, fails to cure such breach within forty-five (45) days of Licensee's written notice of such breach;

(b) Licensor: (i) becomes insolvent or admits its inability to pay its debts generally as they become due; (ii) becomes subject, voluntarily or involuntarily, to any proceeding under any domestic or foreign bankruptcy or insolvency law, which is not fully stayed within thirty (30) days or is not dismissed or vacated within sixty (60) days after filing; (iii) is dissolved or liquidated or takes any corporate action for such purpose; (iv) makes a general assignment for the benefit of creditors; or (v) has a receiver, trustee, custodian or similar agent appointed by order of any court of competent jurisdiction to take charge of or sell any material portion of its property or business;

(c) if Regulatory Approval to the Licensed Product in the U.S. or the E.U. is denied after exhaustion of all appeals and/or measures available to Licensor. Licensor shall promptly notify Licensee of any preliminary or final denial of Regulatory Approval in the U.S. or the E.U.;

15.3 Effect of Termination .

15.3.1 General . Any termination or expiration of this Agreement shall be without prejudice to any other right or remedy to which a Party may be entitled.

15.3.2 In the event this Agreement is terminated under subsections 15.2.2 (a) and 15.2.2 (b) and due to (1) the non receipt of Regulatory Approval by the Licensee in the Territory and such non receipt of Regulatory Approval can be attributed to a material breach by the Licensor or (2) the Licensor is unamble to supply Licensed product or Adjuvant then, Licensee shall be entitled to and Licensor shall refund to Licensee all milestone payments actually paid to Licensor by Licensee under Section 9.9.

15.3.3 Sell-Off Period . On expiration or termination of this Agreement for any reason, Licensee shall have the right to dispose of all stocks of the Licensed Product in its possession at the date of termination for a period of one hundred eighty (180) days after the date of termination (the " Sell-off Period "), in each case, in accordance with the terms and conditions of this Agreement. The royalty payments under the provisions of Section 9.1 shall be made to Licensor within thirty (30) days after (a) expiration or termination, with respect to Earned Royalties accrued prior to the expiration of the effective date of termination, and (b) the expiration of the Sell-off Period, with respect to royalty payments accrued during the Sell-off Period.

15.4 Surviving Provisions . In addition and without prejudice to the provisions of Section 14.3, in the event of any expiration or termination of this Agreement the following provisions shall survive: Articles 11, 13, 14, 15 and 16; and Sections 9.1 (with respect to Net Sales prior to such expiration or termination); 9.9 (with respect to reimbursement events reached prior to such expiration or termination); 9.9 through 9.16 inclusive (with respect to Net Sales made prior to such expiration or termination); 10.1; 10.2 (with respect to periods prior to termination); and 12.3.

16. MISCELLANEOUS

16.1 Affiliates . Licensee shall have the right to exercise its rights and perform its obligations hereunder through its Affiliates (including by licensing rights hereunder where such rights are held in the name of any such Affiliate), provided, that Licensee shall be responsible for such Affiliates' performance hereunder.

16.2 Assignment . Neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred (except by operation of Law) by either Party without the prior written consent of the other. Either Party may assign this Agreement, and its rights and obligations hereunder without prior written consent to any Affiliate or, with prior notice, in connection with the transfer or sale of all or substantially all of the business of such Party to which this Agreement relates. Any assignment not in accordance with this Agreement shall be void. Subject to the foregoing, the rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties. Notwithstanding anything stated herein, this Agreement with full force and effect and in its true spirit, shall survive the Change

of Control of either Party or sale of all or substantially all of the business of a Party. For the purpose of this clause, " **Change of Control** " shall occur with regard to a Party if another person who controls such Party ceases to do so, or if a new person acquires control of such person: (i) in the case of any corporate entity , direct or indirect ownership of fifty percent (50%) or more of the stock or shares having the right to vote for the election of directors thereof or (ii) in the case of any non-corporate entity, direct or indirect ownership of fifty percent (50%) or more of the equity or income interest therein with the power to direct the management and policies of suh non-corporate entities.

16.3 Choice of Law . This Agreement shall be governed by, and enforced and construed in accordance with, the laws of the State of Delaware without regard to its conflicts of law provisions.

16.4 Change in Law . In the event any Law, judgment, ruling or order of any administrative, quasi-judicial or judicial body in the Territory after the date hereof: (i) requires Licensee to sell the Licensed Product in the Territory at a reduced price then the selling price contemplated by the Licensee as notified to Licensor or in a particular manner not contemplated by this Agreement; (ii) directs either Licensor or Licensee to grant a license or sub-license to a third party for the Licensed Product in the Territory not contemplated by this Agreement; or (iii) makes it unlawful for Licensee to sell the Licensed Product, then the Parties shall re-negotiate in good faith an amendment to this Agreement to address such event, which amendment shall conform as closely as possible to the original terms and provision of this Agreement and the intent of the Parties at the Effective Date hereof provided that any such amendment shall not put a Party in a materially adverse position than contemplated herein.

16.5 Construction . The definitions of the terms herein shall apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. The words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation". The word "will" shall be construed to have the same meaning and effect as the word "shall". The Parties each acknowledge that they have had the advice of counsel with respect to this Agreement, that this Agreement has been jointly drafted, and that no rule of strict construction shall be applied in the interpretation hereof. Unless the context requires otherwise, (i) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (ii) any reference to any Laws herein shall be construed as referring to such Laws as from time to time enacted, repealed or amended, (iii) any reference herein to any person shall be construed to include the person's permitted successors and assigns, (iv) the words "herein," "hereof" and "hereunder," and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, and (v) all references herein to Articles, Sections, Schedules or Exhibits, unless otherwise specifically provided, shall be construed to refer to Articles, Sections, Schedules or Exhibits of this Agreement. This Agreement has been executed in English, and the English version of this Agreement shall control.

16.6 Counterparts . This Agreement may be executed in counterparts with the same effect as if both Parties had signed the same document. All such counterparts shall be deemed an original, shall be construed together and shall constitute one and the same instrument. Signature pages of this Agreement may be exchanged by facsimile or other electronic means without affecting the validity thereof.

16.7 Entire Agreement . This Agreement constitutes the entire agreement between the Parties as to the subject matter of this Agreement, and supersedes and merges all prior negotiations, representations, agreements and understandings regarding the same.

16.8 Force Majeure . Neither Party shall be liable for delay or failure in the performance of any of its obligations hereunder if such delay or failure is due to causes beyond its reasonable control, including acts of God, fires, floods, earthquakes, labor strikes, acts of war, terrorism or civil unrest; provided, however, that the affected Party promptly notifies the other Party in writing (and continues to provide monthly status updates to the other Party for the duration of the effect) and further provided that the affected Party shall use its commercially reasonable efforts to avoid or remove such causes of non-performance and to mitigate the effect of such occurrence, and shall continue performance with reasonable dispatch whenever such causes are removed.

16.9 Further Assurances . Each Party agrees to do and perform all such further acts and things and shall execute and deliver such other agreements, certificates, instruments and documents necessary or that the other Party may reasonably request in order to carry out the intent and accomplish the purposes of this Agreement and to evidence, perfect or otherwise confirm its rights hereunder.

16.10 Headings . Headings and captions are for convenience only and are not to be used in the interpretation of this Agreement.

16.11 Jurisdiction and Venue . Each Party hereby irrevocably submits to the exclusive jurisdiction of the courts of the State of Delaware (" State Court ") and the courts of the United States of America located in the State of Delaware (" Federal Court "), for the purposes of any suit, action or other proceeding arising out of or relating to this Agreement or out of any transaction contemplated hereby. Each Party agrees that service of any process, summons, notice or document by personal delivery, by registered mail, or by a recognized international express delivery service to such Party's respective address set forth in Section 16.13 (as such address may be changed by notice delivered pursuant to such section) shall be effective service of process for any action, suit or proceeding in the applicable Federal Court or State Court with respect to any matters to which it has submitted to jurisdiction in this Section 16.11. Each Party irrevocably and unconditionally waives any objection to the laying of venue of any action, suit or proceeding arising out of this Agreement or the transactions contemplated hereby in the applicable Federal Court or State Court, and hereby and thereby further irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum. Any action brought arising out of or relating to this Agreement or out of any transaction contemplated hereby shall be conducted in English. Notwithstanding the foregoing,

either Party shall have the right to seek exigent, injunctive or temporary relief in any court of competent jurisdiction. Each Party irrevocably waives any and all right to trial by jury in any legal proceeding arising out of or relating to this Agreement or the transactions contemplated hereby. Except as may be expressly set forth to the contrary herein (including in Section 13.1 hereof), nothing in this Agreement shall serve to limit any remedy to which a Party might otherwise be entitled, at law or in equity.

16.12 No Set-Off . Unless the Parties otherwise agree in writing, no Party shall have the right to deduct from amounts otherwise payable hereunder any amounts payable to such Party (or its Affiliates) from the other Party (or its Affiliates).

16.13 Notices . Any notice required or permitted to be given by this Agreement shall be in writing, in English, and shall be delivered by hand or overnight courier with tracking capabilities or mailed postage prepaid by registered or certified mail addressed as set forth below unless changed by notice so given:

If to Licensor:

Galena Biopharma, Inc.
4640 S.W. Macadam Ave.
Suite 270
Portland, Oregon, U.S.A. 97239
Attention: Mark W. Schwartz, Ph.D.

If to Licensee:

Dr. Reddy's Laboratories Limited
Hyderabad, 500034, India
8-2-337 Road No.3 Banjara Hills
Hyderabad, 500034, India
Attention: Alok Sonig

Any such notice shall be deemed given on the date delivered. A Party may add, delete (so long as at least one person is remaining), or change the person or address to which notices should be sent at any time upon written notice delivered to the other Party in accordance with this Section 16.13

16.14 Re-importation . Licensee shall use Reasonably Diligent Efforts to prevent the Licensed Product provided to or made for or on behalf of Licensee for use or sale inside the Territory from being distributed or sold outside the Territory. Licensee shall notify Licensor promptly if it becomes aware of the exportation of a Licensed Product from the Territory.

16.15 Relationship of the Parties . Each Party is an independent contractor under this Agreement. Nothing contained herein is intended or is to be construed so as to constitute Licensee and Licensor as partners, agents or joint venturers. Neither Party shall have any express or implied

right or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any contract, agreement or undertaking with any Third Party.

16.16 Severability . If any one or more of the provisions of this Agreement is held to be invalid or unenforceable, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall negotiate in good faith to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

16.17 Third Party Beneficiaries . Except as expressly provided with respect to Licensor Indemnitees or Licensee Indemnities in Article 14, there are no third party beneficiaries intended hereunder, and no Third Party shall have any right or obligation hereunder.

16.18 Waivers and Modifications .

16.18.1 The failure of any Party to insist on the performance of any obligation hereunder shall not be deemed to be a waiver of such obligation. Waiver of any breach of any provision hereof shall not be deemed to be a waiver of any other breach of such provision or any other provision on such occasion or any other occasion. No waiver, modification, release or amendment of any right or obligation under or provision of this Agreement shall be valid or effective unless in writing and signed by the Parties hereto.

16.18.2 The Parties shall modify or amend this Agreement from time to time upon notice from Licensor that such modification or amendment is necessary or appropriate to conform any provisions hereof to any corresponding provision of the Underlying License Agreements, provided, that no such modification or amendment shall adversely affect in any material respect Licensee's rights or obligations under this Agreement, as determined in good faith by Licensee.

****

(Signature page follows)

IN WITNESS WHEREOF, the Parties have executed this License Agreement as of the Effective Date.

GALENA BIOPHARMA, INC.

By: /s/ Mark J. Ahn
Mark J. Ahn, Ph.D.
President and Chief Executive Officer

DR. REDDY'S LABORATORIES LIMITED

By: /s/ Alok Sonig
Alok Sonig
SVP and India Business Head

[Signature Page of License and Development Agreement]

ANNEX 1

Currently estimated Interim data readout for PRESENT trial -- **[***]**.

Currently estimated end of trial readout **[***]** and filing for Regulatory Approval in the U.S. or in the E.U. **[***]**.

ANNEX – 2

Protocol - NeuVax in High Risk Gastric Cancer

Title	Phase 2 Study Schema of NeuVax™ to Prevent or Delay Recurrence in Resected HER2 Expressing Gastric Cancer (HER2 1+,2+, or 3+) Patients
Objectives	Primary Objective: • Disease-free survival (DFS) in subjects with resected R0/R1 gastric cancer at 24 months. Secondary Objectives: • 36 month DFS and Overall Survival (OS)
IND	IND will be filed in the US by Galena and all trial sites will be in India
Treatment	NeuVax (nelipepimut_S) with [***] vs. non-treated (observation) controls
Background	Cancers of the GE junction or stomach represent >20% of the malignancies diagnosed in Korea, Japan, Russia and Chile, and result in 800,000 annual worldwide deaths, with 100,000 new cases annually in India. Despite the fact that approximately 50% of these tumors are diagnosed while still "resectable", there remains a high rate (40%) of disease recurrence within 24 months. Because of the preponderance of HER2 expression in gastric cancer, Herceptin (trastuzumab) has been shown to increase overall survival (when used with chemotherapy) in HER2 IHC 3+ or overexpressing metastatic gastric/GE junction adenocarcinoma. NeuVax is a cancer vaccine targeting the immunodominant peptide in the extracellular domain of HER2. When used as an adjuvant therapy following resection and standard of care chemoradiation in early stage node positive breast cancer patients, NeuVax increased disease free survival by more than 35% at 24 months. The use of this HER2 targeted vaccine in early stage gastric cancer to prevent recurrence is the primary objective of this study.
Study Design/Type	A multicenter, two-arm trial where eligible patients post-resection and standard of care treatment who are no evidence of disease (NED) are enrolled, and then assigned to receive the NeuVax vaccine injection series or be in the control observation group based on the HLA status. Patient cohort assignment would be on the basis of HLA type, with only HLA A2-3 positive patients going onto active treatment.
Study Centers	The study will be conducted in approximately XX-XX sites.
Study Patients	**[***]**

Statistics *(NOTE: To be finalized)*	Assuming a baseline recurrence rate of 40% in two years and a benefit of the vaccine to reduce the rate to half, i.e., 20% in two years, then approximately 40 pts per arm or a trial of 80 pts is required to show a statistical difference.
Duration of Study	The primary analysis is at 24 months, with the secondary analysis at 36 months. The study enrollment should take a period of 12 months; therefore the entire study should be complete after 48 months.
Inclusion Criteria	**[***]**
Exclusion Criteria	**[***]**
Methodology:	• CT scan will assess patients for disease status prior to enrollment. • Subjects who are HLA A2 or A3 positive will be assigned to treatment with NeuVax and **[***]**. Patients will be enrolled until 40 patients are assigned to the treatment arm. • Subjects who are HLA A2 or A3 negative will be assigned to the observational control arm. Patients will be enrolled until 40 patients are assigned to the treatment arm which shall be no less than 40 patients in the control arm. • Patients will receive standard of care in addition to NeuVax. • All patients will have disease status evaluated by standard of care, with confirmation by PET/CT scan at 24 months or sooner as indicated. • Any follow-up for any symptoms of disease that might lead to a diagnosis of relapse should be done during the trial as medically appropriate.
NeuVax Administration	• NeuVax will be administered combined with **[***]** as an intradermal injection in the same thigh. • Treatment with NeuVax will be initiated between 4-12 weeks after the last SoC treatment. • The primary vaccination series (PVS) will consist of one injection per month for 6 months; and the booster series will consist of one injection every 6 months, initiating after the last of the 6 PVS injections. • Subjects will receive a total of 9 injections over 24 months; and 11 injections over 36 months.
Name of Company:	Galena Biopharma, Inc. 4640 SW Macadam St., Suite 270 Portland, OR 97239

ANNEX – 3

Financial Terms, Budget, and Time

Galena will use Reasonably Diligent Efforts to Provide	1) Study Materials 2) **[***]** 3) **[***]** 4) Filing of Investigational New Drug Application in the USA
Dr. Reddy's will use Reasonably Diligent Efforts to Provide	1) **[***]** 2) Hiring and managing all CRO's required for the conduct of the Clinical Trial 3) Identifying and setting up of all Study Centers in India for conduct of the Clinical Trial 4) Enrollment, treatment and follow up on all patients enrolled in the Clinical Trial 5) Collection, curation and analysis of all data 6) Drafting and submitting all respective Regulatory Filings regarding this Clinical Trial to the appropriate Governmental Authority in the Territory.
Anticipated Start Date	Within three (3) months of availability of regulatory approval for initiating phase-2 gastric cancer trial
Anticipated End Date	Within 48 months of Anticipated Start date of clinical trial.

ANNEX 4

Protocol for Epidemiological Study

Title	An Observational study to estimate the expression of HER2 (1+,2+, or 3+) with HLA A2-3 typing positivity in 50 consecutive Gastric Cancer patients.
Objectives	To estimate the expression of HER2 (1+,2+, or 3+) with HLA A2-3 type positive in Gastric Cancer patients
Background	Gastric cancer remains a major health issue and a leading cause of cancer death worldwide, although the prevalence and mortality of the disease have gradually decreased. The investigators have very few options for patients with advanced disease. Cancers of the GE junction or stomach represent >20% of the malignancies diagnosed in Korea, Japan, Russia and Chile, and result in 800,000 annual worldwide deaths. Despite the fact that approximately 50% of these tumors are diagnosed while still “resectable”, there remains a high rate (40%) of disease recurrence within 24months. Because of the preponderance of HER2 expression in gastric cancer, Herceptin (trastuzumab) has been shown to increase overall survival (when used with chemotherapy) in HER2 IHC 3+ or overexpressing metastatic gastric/GE junction adenocarcinoma. NeuVax (HER2/[***] NeuVax is a first-in-class peptide-based,active, specific immunotherapy for the treatment and prevention of cancer. NeuVax has been tested as an immunotherapy to prevent recurrence in Phase 1/2 clinical trials in node-negative (NN) and node-positive (NP) breast cancer patients as well as in early-stage prostate cancer patients at high risk for disease recurrence. NeuVax binds to HLA-A2 and HLA-A3 molecules on tumor and antigen presenting cells (APC) and elicits a proliferative CD8+ (cytotoxic)T-cell immune response against HER2-expressing cancer cells while demonstrating minimal clinical toxicity to normal tissues and organs. A POC study is being planned to be conducted to assess the effectiveness of Neuvax to prevent recurrence and increase disease free survival in Gastric Cancer patients HER2 (1+,2+, or 3+) with HLA A2-3 positive . The current observational study is being planned to estimate the incidence of the above patient population in Indian setting. Hence, the investigators plan to test HER2 (1+,2+, or 3+) in 50 patients with IHC and correlate with the HLA A2-3 positive in the same population of Gastric Cancer patients.
Study Design/Type	Prospective, observational study
Study Center	The study will be conducted in gastric cancer patients attending
Sample size	A Total of 50 patients will be enrolled in the study
Study Patients	Patients with gastric or GE junction adenocarcinoma.
Duration of Study	06 months duration

Inclusion Criteria	• 50 consecutive patients with gastric cancer who have a pathology tissue specimen. • Willing to allow serum sample for HLA testing.
Primary Outcome Measures:	• Incidence of Her2 testing(IHC) in Gastric cancer [Time Frame: 6 month] [Designated as safety issue: No] • Incidence of HLA A2 A3 in the HER -2 +ve gastric cancer patient.
Study Design &Methodology:	• Initially Existing Tissue section blocks of gastric cancer patients will be included in this study. • IHC will be employed for detection of HER-2 from tissue samples of gastric cancer patients. • HLA Sero-typing will be performed from the gastric cancer patients, who have provided the tissue samples for HER-2 • detection • Both the tests will be performed by a central Lab based in Mumbai.
Overview of Data collection & statistics	• The principal investigator will maintain and supervise data collection and maintaining records. The patient will be de- o Identified. • Being an Observational study the Results will be analyzed as o %age of total population with the descriptive statistics.

TEXT MARKED BY [* * *] HAS BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

EXCLUSIVE LICENSE AGREEMENT

THIS **EXCUSIVE LICENSE AGREEMENT** (the " Agreement ") is entered into as of December 20, 2013 (the " Effective Date ") by and between **Mills Pharmaceuticals, LLC** ., a Delaware limited liability company having an address at 557 Seventh Street, Brooklyn, NY 11215 (" MPI "), and **BioVascular, Inc.** , a Delaware corporation having an address at P.O. Box #2343, Rancho Santa Fe, California 92067 (" BVI "). BVI and MPI may be referred to herein individually as a " Party " or collectively, as the " Parties ."

RECITALS

WHEREAS , BVI has developed and owns or controls certain intellectual property rights with respect to a controlled release formulation of anagrelide, among other things, and owns or controls certain know-how, technology, documentation, data, and other materials relating thereto; and

WHEREAS , MPI wishes to license such rights in order to develop and commercialize Products.

NOW, THEREFORE , in consideration of the foregoing and the covenants and promises contained in this Agreement, the Parties agree as follows:

1. DEFINITIONS **.** The following capitalized terms shall have the subsequent meanings when used in this Agreement. All other capitalized terms used herein are defined elsewhere in this Agreement.

1.1 " API " means active pharmaceutical ingredient.

1.2 " Affiliate " means, with respect to either Party, any person, corporation or other business entity which, directly or indirectly through one or more intermediaries, actually controls, is actually controlled by, or is under common control with such party. As used in this Section 1.2, "control" means to possess, directly or indirectly, the power to affirmatively direct the management and policies of such person, corporation or other business entity, whether through ownership of at least fifty percent (50%) of the voting securities or by contract relating to voting rights or corporate governance.

1.3 " Applicable Law " means all applicable laws, rules, regulations and guidelines that may apply to the development, marketing, manufacturing or sale of Products or the performance of either party's obligations, or the exercise of either party's rights, under this Agreement, including but not limited to all laws, regulations and guidelines governing the import, export, development,

marketing, distribution and sale of the Product in the Territory and, to the extent relevant, all GCP, GLP or GMP standards or guidelines promulgated by any Regulatory Authorities or the ICH.

1.4 " BVI Know-How " means all Know-How owned, licensed, or controlled by BVI or its Affiliates as of the Effective Date or during the term of the Agreement necessary or useful for the discovery, research, Development, manufacture, or Commercialization of any Product.

1.5 " BVI Patents " means (a) those Patents set forth on Schedule 1.5 attached hereto (the " Initial BVI Patents "); (b) any other Patents owned, licensed, or controlled by BVI or any Affiliate thereof, or subject to an obligation of assignment to BVI or any Affiliate thereof, Covering or relating to any portion of the Technology; (c) any additions, divisionals, continuations, continuations-in-part, conversion, supplemental examinations, extensions, term restorations, registrations, re-instatements, amendments, reissuances, corrections, substitutions, re-examinations, registrations, revalidations, supplementary protection certificates, renewals, and foreign counterparts of the Initial BVI Patents or the Patents described in (b) above, and any other Patents owned, controlled, or licensed by BVI claiming priority to any of the foregoing or any of the Patents referenced in clause (a) or (b) above; and (d) all patents issuing from any of the Patents mentioned in clause (a), (b), or (c) above and any foreign counterparts of any such Patents, and which shall include, in any case, patents surviving post grant review and inter partes review.

1.6 " BVI Technology " means the BVI Know-How and the BVI Patents.

1.7 " BLA " means a Biologics License Application under the United States' Public Health Services Act and Federal Food, Drug and Cosmetics Act, each as amended, and the regulations promulgated thereunder, or a comparable filing seeking Regulatory Approval in any country.

1.8 " Business Day " means any day other than Saturday, Sunday, or a day that is a federal legal holiday in the U.S.

1.9 " Calendar Day " means each of those seven (7) days in the week.

1.10 " Calendar Year " means (a) for the first Calendar Year, the period commencing on the Effective Date and ending on December 31 of the same year, (b) for the Calendar Year in which this Agreement expires or is terminated, the period beginning on January 1 of such Calendar Year and ending on the effective date of such expiration or termination, and (c) for all other years, each successive twelve (12) consecutive month period beginning on January 1 and ending December 31.

1.11 " Cardiovascular Field " means the direct prevention, treatment, diagnosis of myocardial infarction, strokes and peripheral arterial disease in humans or other animals. For sake of clarity the Cardiovascular Field will not include the prevention, treatment or diagnosis of conditions that may ultimately lead to a decrease in the risk of thrombotic events, such as Myeloproliferative Disorders and other hematological indications.

1.12 " Commence " or " Commencement, " when used to describe any human clinical trial of a Product, means the first dosing of the first patient or subject for such trial with a Product or placebo.

1.13 " Commercialization " means all activities that are undertaken after Regulatory Approval of a Product in a particular jurisdiction and that relate to the commercial marketing, sale, and/or distribution of such Product, including but not limited advertising and/or promotional activities.

1.14 " Commercially Reasonable Efforts " means the carrying out of obligations or tasks in a manner consistent with the efforts a similarly situated bio-pharmaceutical company with sufficient resources devotes to research, development and/or marketing of a pharmaceutical product or products of similar market potential, profit potential or strategic value resulting from its own research efforts or for its own benefit, taking into account technical, regulatory and intellectual property factors, target product profiles, product labeling, costs, economic return, the regulatory environment and competitive market conditions in the therapeutic or market niche, all based on conditions then prevailing.

1.15 " Confidential Information " means all information and know-how and any tangible embodiments thereof provided by or on behalf of one Party to the other Party either in connection with the discussions and negotiations pertaining to this Agreement or in the course of performing under this Agreement, which may include data, knowledge, practices, processes, ideas, research plans, formulation or manufacturing processes and techniques, scientific, manufacturing, marketing and business plans, and financial and personnel matters relating to the disclosing Party or to its present or future products, sales, suppliers, customers, employees, investors or business; provided, that, information or know-how of a Party will not be deemed Confidential Information of such Party for purposes of this Agreement if such information or know-how: (a) was already known to the receiving Party, other than under an obligation of confidentiality or non-use, at the time of disclosure to such receiving Party, as can be shown by written records; (b) was generally available or known to parties reasonably skilled in the field to which such information or know-how pertains, or was otherwise part of the public domain, at the time of its disclosure to such receiving Party; (c) became generally available or known to parties reasonably skilled in the field to which such information or know-how pertains, or otherwise became part of the public domain, after its disclosure to such receiving Party through no fault of the receiving Party; (d) was disclosed to such receiving Party, other than under an obligation of confidentiality or non-use, by a Third Party who had no obligation to the disclosing Party not to disclose such information or know-how to others, as can be shown by written records; or (e) was independently discovered or developed by such receiving Party, as can be shown by its written records, without the use or benefit of, or reliance on, Confidential Information belonging to the disclosing Party. Notwithstanding anything to the contrary herein information regarding the BVI Technology shall be deemed Confidential Information of both Parties.

1.16 " Controlled " means, with respect to any intellectual property or right therein, or any Regulatory Filing or Regulatory Approval, the possession by a Party of the ability to grant a license or sublicense, or make an assignment or transfer thereof, as provided for herein without violating the terms of any arrangement or agreements between such Party and any Third Party.

1.17 " Cover " means that the use, manufacture, sale, offer for sale, development, commercialization or importation of the subject matter in question by an unlicensed entity would infringe a Valid Claim of a Patent.

1.18 " Develop " or " Development " means, with respect to a Product, engaging in preclinical, clinical, and other research or development activities, which may include but is not limited to research, pre-clinical, clinical and regulatory activities directed towards obtaining the initial Regulatory Approval of a Product in a particular jurisdiction.

1.19 " DMF " means a drug master file, as provided for in 21 CFR § 314.420 or similar submission to or file maintained with the FDA or other Governmental Authority or Regulatory Authority that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs.

1.20 " EMA " means the European Medicines Agency or any successor agency thereof.

1.21 " FDA " means the United States Food and Drug Administration, or any successor federal agency thereto.

1.22 " Field " means the prevention, treatment, diagnosis, detection, monitoring, predisposition testing of all diseases, states or conditions in humans or other animals.

1.23 " First Commercial Sale " means, with respect to a particular jurisdiction, the first sale in such jurisdiction of a Product to a Third Party by MPI, any Affiliate thereof, or any Sublicensee in such jurisdiction following Regulatory Approval and Pricing Approval of such Product in such jurisdiction.

1.24 " GCP " means all applicable Good Clinical Practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials, including, as applicable, (a) CFR Title 21, Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards), and 312 (Investigational New Drug Application), as may be amended from time to time, (b) as set forth in European Commission Directive 2001/20/EC relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, and brought into law by European Commission Directive 2005/28/EC laying down the principles and detailed guidelines for good clinical practice for investigational medicinal products, (c) as set forth in the ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) and any other guidelines for good clinical practice for trials on medicinal products in the Territory, and (d) the equivalent Applicable Laws in any relevant country, each as may be amended and applicable from time to time and in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.

1.25 " GLP " means all applicable Good Laboratory Practice standards, including, as applicable, (a) as set forth in the then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in Title 21, Part 58 of the CFR, (b) as set forth in European Commission Directive 2004/10/EC relating to the application of the principles of good laboratory practices, as may be amended from time to time as well as any Rules Governing Medicinal Products in the European Community Vol. III, ISBN 92.825 9619-2 (ex—OECD principles of GLP), and

(c) the Applicable Laws in any relevant country, each as may be amended and applicable from time to time.

1.26 " GMP " means all applicable Good Manufacturing Practices including, as applicable, (a) the principles detailed in the U.S. Current Good Manufacturing Practices, Title 21, Parts 210, 211, 601 and 610 of the CFR, (b) the applicable part of quality assurance to ensure that products are consistently produced and controlled in accordance with the quality standards appropriate for their intended use, as defined in European Commission Directive 2003/94/EC laying down the principals and guidelines of good manufacturing practice, (c) the principles detailed in the ICH Q7A guidelines, (d) the Rules Governing Medicinal Products in the European Community, Volume IV Good Manufacturing Practice for Medicinal Products, and (e) the equivalent Applicable Laws in any relevant country, each as may be amended and applicable from time to time.

1.27 " Governmental Authority " means any court, agency, department or other instrumentality of any foreign, federal, state, county, city or other political subdivision (including any supra-national agency such as in the European Union).

1.28 " ICH " means the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

1.29 " IND " means an Investigational New Drug Application filed with the FDA or the equivalent application or filing filed with any Regulatory Authority outside of the United States (including any supra-national agency such as in the European Union) necessary to commence human clinical trials in such jurisdiction, and including all regulations at 21 CFR § 312 et. seq., and equivalent foreign regulations.

1.30 " Know-How " means all technical, scientific and other know-how and information, trade secrets, knowledge, technology, inventions, means, methods, processes, practices, formulas, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results and other material, and other drug discovery and development technology, pre-clinical and clinical trial results, manufacturing procedures, test procedures and purification and isolation techniques, (whether or not confidential, proprietary, patented or patentable) in written, electronic or any other form now known or hereafter developed, and all improvements, whether to the foregoing or otherwise, and other discoveries, developments inventions and other intellectual property (whether or not confidential, proprietary, patented or patentable), provided that Know-How shall not include Patents

1.31 " NDA " means a new drug application (as defined in Title 21 of the United States Code of Federal Regulations, as amended from time to time) submitted to the FDA seeking regulatory approval to market and sell the Product for human therapeutic use in the United States (including a new drug application submitted under Section 505(b)(2) of the Act).

1.32 " Net Sales " means gross amounts invoiced or otherwise received for MPI's, its Affiliates', and Sublicensees' sales of Products, less the sum of the following, to the extent related to the sale of such Products: (1) discounts in amounts reasonable or customary in the trade, including

but not limited to trade, cash, consumer, and quantity discounts, and credits, price adjustments or allowances for damaged Products, returns, defects, recalls or rejections of Products or retroactive price reductions; (2) reasonable rebates, credits, and chargeback payments granted to federal, state/provincial, local and other governments or managed health care organizations, including their agencies, purchasers, and/or reimbursers, under programs available under or required by Applicable Law, or reasonably entered into to sustain and/or increase market share for Products; (3) sales, value added, use, excise, and similar taxes; (4) amounts allowed or credited on returns for defective, damaged, expired, or otherwise unuseable or unsaleable Products; (5) freight, shipping, handling, and insurance charges; and (6) import or export duties, tariffs, or similar charges incurred with respect to the import or export of Products into or out of any country. Such amounts shall be determined from the books and records of MPI, its Affiliates, and Sublicensees maintained in accordance with such reasonable accounting principles as may be consistently applied by MPI, its Affiliates, and Sublicensees.

Products and Services are considered " sold " when billed out or invoiced or, in the event such Products are not billed out or invoiced, when the consideration for sale of the Products is received. Notwithstanding the foregoing, Net Sales shall not include, and shall be deemed zero with respect to, (i) Products used by MPI, its Affiliates, or Sublicensees for their internal use, (ii) the distribution of reasonable quantities of promotional samples of Products, (iii) Products provided for clinical trials or research, development, or evaluation purposes, or (iv) Products provided by or on behalf of MPI, an Affiliate or a Sublicensee to MPI, an Affiliate or a Sublicensee for purposes of resale, provided such resale is subject to a payments due BVI under Section 3.2(a) or Section 3.2(b) (as applicable) of this Agreement.

Notwithstanding anything to the contrary, in the event that any Product includes APIs, drug delivery devices, or other technologies for which rights are not included in the licenses or sublicenses granted under this Agreement (" Other Technologies ") but, with respect to the Other Technologies, may each or collectively form the basis for a product separate from a Product (a " Combination Product "), the Net Sales of such Combination Product in a particular country, for the purposes of determining royalty payments due to BVI hereunder, shall be determined by multiplying the Net Sales of the Combination Product in such country by the fraction A/(A+B), where A is the weighted average sale price of the Product without the Other Technologies (the " Basic Product ") when sold separately in finished form in such country, and B is the weighted average sale price(s) of product(s) including the Other Technologies (such products, " Other Products ") sold separately in finished form in such country (if there is more than one Other Product, B shall equal the sum of all such Other Products' weighted average sale prices in such country).

In the event that, with respect to any Combination Product sold in a particular country, the weighted average sale price of the Basic Product in such country can be determined but the weighted average sale price(s) of the Other Product(s) in such country cannot be determined, Net Sales for purposes of determining royalty payments for such Combination Product in such country shall be calculated by multiplying the Net Sales of the Combination Product in such country by the fraction A/C where A is the weighted average sale price of the Basic Product when sold separately in finished form in such country and C is the weighted average sale price of the Combination Product in such country.

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In the event that, with respect to any Combination Product sold in a particular country, the weighted average sale price(s) of the Other Product(s) in such country can be determined but the weighted average sale price of the Basic Product cannot be determined, Net Sales for purposes of determining royalty payments shall be calculated by multiplying the Net Sales of the Combination Product by the formula one (1) minus (B/C) (which may also be written as 1- (B/C)), where B is the weighted average sale price(s) of the Other Product(s) when sold separately in finished form in such country and C is the weighted average sale price of the Combination Product in such country (if there is more than one Other Product, B shall equal the sum of all such Other Products' weighted average sale prices in such country).

In the event that, with respect to any Combination Product sold in a particular country, the weighted average sale price(s) in such country of neither the Basic Product nor the Other Product(s) in the Combination Product can be determined, the Net Sales of the Combination Product shall, for the purposes of determining royalty payments with respect to such Combination Product, be commercially reasonable and determined by good faith negotiation between MPI and BVI consistent with the ratios and related principles referenced above and based on the relative value of the Technology and the Other Technologies included in such Combination Product.

The weighted average sale price for a Basic Product, Other Product(s), or Combination Product in a particular country shall be calculated once for each Calendar Year and such price shall be used during all applicable royalty reporting periods for such Calendar Year. When determining the weighted average sale price of a Basic Product, Other Product(s), or Combination Product in a particular country, the weighted average sale price shall be calculated by dividing the sales dollars by the units of Basic Product, Combination Product, or Other Product sold in such country during the twelve (12) months (or the number of months sold in a partial Calendar Year) of that Calendar Year for the respective Basic Product, Other Product(s), or Combination Product. For each Calendar Year, a reasonably forecasted weighted average sale price will be used for the Basic Product, Other Product(s), or Combination Product, which forecasted weighted average sale price will be, for each Calendar Year other than the initial Calendar Year (or portion thereof) during which the Combination Product is sold, no less than the weighted average sale price for the Basic Product, Other Product(s), or Combination Product in a particular country calculated for the preceding Calendar Year. Any over or under payment due to a difference between forecasted and actual weighted average sale prices will be paid or credited in the payment due with respect to the following Calendar Year.

Notwithstanding anything to the contrary, in the case of discounts on " bundles " of separate products or services which include Products (such "bundles" including but not limited to (i) contingent arrangements involving drugs that share the same NDC (whether the same or different package sizes), drugs with different NDCs, or drugs and other products or services, (ii) circumstances in which a discount is conditioned on the achievement of some other performance requirement for the Product or other product or service (e.g. achievement of market share or placement on a formulary tier), or (iii) otherwise where the resulting price concessions or discounts are greater than those which would have been available had the bundled products or services been purchased separately or outside the bundled arrangement), MPI may calculate Net Sales and royalties due hereunder by applying a discount to the price of a Product equal to the average percentage discount of all products or services of MPI, its Affiliate(s), or Sublicensee(s) in a particular "bundle", calculated as follows:

Average percentage discount on a particular "bundle"	=	[1 - (X/Y)] x 100

where X equals the total discounted price of a particular "bundle" of products or services , and Y equals the sum of the undiscounted bona fide list prices of each unit of every product or service in such "bundle". MPI shall provide BVI documentation reasonably supporting such average discount with respect to each "bundle." If a Product in a "bundle" is not sold separately, and no bona fide list price exists for such Product, MPI and BVI shall, for purposes of calculating Net Sales and royalties due hereunder, negotiate in good faith a reasonable imputed list price for such Product and Net Sales with respect thereto shall be based on such imputed list price.

1.33 " Paragraph IV Certification " means a certification pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417), as amended, which shall include but not be limited to any such certification pursuant to 21 U.S.C. §355(b)(2)(A)(iv) or 21 U.S.C. §355(j)(2)(A)(vii)(IV), or any reasonably similar or equivalent certification or notice in the United States or any jurisdiction outside the United States, included in (or made with respect to or in connection with) a regulatory filing concerning a Product or Competing Product and challenging the validity, infringement, or enforceability of any BVI Patent(s).

1.34 " Patent(s) " means any granted or issued patents and pending patent applications, together with all additions, divisionals, continuations, continuations-in-part, substitutions, reissues, re-examinations, supplemental examinations, patents reviewed under post grant review or inter partes review, extensions, registrations, patent term extensions, revalidations, supplementary protection certificates, and renewals of any of the foregoing, and all foreign applications and patents corresponding to or claiming priority from any of the foregoing.

1.35 " Phase 2 Trial " means a human clinical trial of a Product, the principal purpose of which is to make a preliminary determination that such Product is safe and active in a patient population for its intended use and to obtain sufficient information about such Product's efficacy to permit the design of further clinical trials, and generally consistent with 21 CFR § 312.21(b).

1.36 " Phase 3 Trial " means a human clinical trial of a Product, which trial is designed to: (a) establish that a Product is safe and efficacious for its intended use; (b) define warnings, precautions and adverse reactions that are associated with the Product in the dosage range to be prescribed; (c) support Regulatory Approval of such Product; and (d) be generally consistent with 21 CFR § 312.21(c).

1.37 " Pricing Approval " means any pricing and reimbursement approvals which must be obtained by MPI from Regulatory Authorities prior to it being reimbursed for sales of Products.

1.38 " Product " means a product that is Covered by one or more BVI Patents in any country in which such product or any part thereof is made, used, or sold.

1.39 " Regulatory Approval " means any and all approvals (including supplements, amendments, and pre- and post-approvals), licenses, registrations, clearances, or authorizations of

any national, supra-national (e.g., the European Commission or the Council of the European Union), regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity, that are necessary for the manufacture, distribution, use or, in MPI's reasonable judgment, sale of a Product for human therapeutic use in a particular jurisdiction.

1.40 " Regulatory Authority " means any Governmental Authority with responsibility for granting any licenses or approvals necessary for the marketing and sale of pharmaceutical or biological products in a particular jurisdiction, including the FDA with respect to the United States, and where applicable any ethics committee or any equivalent review board.

1.41 " Regulatory Filing " means, with respect to the United States, an NDA, BLA, or IND, any foreign counterparts or equivalents of any of the foregoing, any DMFs, and any other filings or submissions required by or provided to Regulatory Authorities relating to the manufacture, Development or Commercialization of any Product, including any supporting documentation, data, correspondence, meeting minutes, amendments, supplements, registrations, licenses, regulatory drug lists, advertising and promotion documents, adverse event files, complaint files, and manufacturing, shipping, or storage records with respect to any of the foregoing.

1.42 " Sublicensee " means a Third Party granted a sublicense to any of the rights granted to MPI and its Affiliates under this Agreement.

1.43 " Sublicensing Royalty Revenue " means sales-based royalties actually received by MPI or its Affiliate from a U.S. Sublicensee as consideration for the grant of rights under BVI Technology to such U.S. Sublicensee pursuant to a U.S. Sublicense.

1.44 " Technology " means the controlled release formulation of anagrelide more fully described in Schedule 1.44 hereto.

1.45 " Term " has the meaning assigned to it in Section 8.1.

1.46 " Territory " means the world.

1.47 " Third Party " means any entity other than (a) BVI, (b) MPI, or (c) any Affiliate of either Party.

1.48 " TRIPS " means the Agreement on Trade Related Aspects of Intellectual Property Rights administered by the World Trade Organization.

1.49 " United States " or " U.S. " shall mean the United States of America and its territories and protectorates.

1.50 " U.S. Sublicense " means a sublicense granted to a third party under the BVI Technology that includes rights to Commercialize the Product in the United States (whether alone or with other territories).

1.51 " U.S. Sublicenses " means a Sublicensee under a U.S. Sublicense.

1.52 " Valid Claim " means a claim of any pending patent application or any issued, unexpired United States or granted foreign patent that has not been dedicated to the public, disclaimed, abandoned or held invalid or unenforceable by a court or other body of competent jurisdiction from which no further appeal can be taken, and that has not been explicitly disclaimed, or admitted in writing to be invalid or unenforceable or of a scope not Covering a particular product or service through reissue, disclaimer or otherwise, provided that if a particular claim has not issued within five (5) years of its initial filing, it shall not be considered a Valid Claim for purposes of this Agreement unless and until such claim is included in an issued Patent, notwithstanding the foregoing definition.

2. LICENSES; SUBLICENSING.

2.1 **License to MPI.** BVI hereby grants to MPI and its Affiliates an exclusive license, with the right to sublicense as set forth in Section 2.2, under the BVI Technology to make, have made, use, sell, offer for sale, import, and export Products in the Field in the Territory.

2.2 **Sublicensing.** MPI and its Affiliates shall have the right to sublicense their rights under this Agreement (including but not limited to such rights granted under Section 2.1) to one or more Third Parties (and such Third Parties' rights may include the right to further sublicense the rights granted hereunder). MPI shall, subject to any obligations of confidentiality to any Sublicensee, provide BVI a written copy of each such sublicense (and each amendment thereto, if any) promptly following its execution. Each such sublicense shall (i) be consistent with this Agreement and (ii) contain terms and conditions reasonably sufficient to enable MPI to comply with the terms of this Agreement.

2.3 **Section 365(n).** All licenses granted under this Agreement are deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of right to "intellectual property" as defined in Section 101 of such Code. The Parties agree that MPI may fully exercise all of its rights and elections under the U.S. Bankruptcy Code and any foreign equivalent thereto in any country having jurisdiction over a Party or its assets. The Parties further agree that, in the event MPI elects to retain its rights as a licensee under such Code, MPI shall be entitled to complete access to any technology or intellectual property licensed to it hereunder and all embodiments of such technology and intellectual property. Such embodiments of the technology and intellectual property shall be delivered to MPI not later than:

(a) the commencement of bankruptcy proceedings against BVI, upon written request, unless BVI elects to perform its obligations under this Agreement, or

(b) if not delivered above under this Section 2.4, upon the rejection of this Agreement by or on behalf of BVI, upon MPI's written request.

3. FINANCIAL TERMS

3.1 **Up-front Payment.** Subject to payments to be made to Comerica Bank pursuant to Section 3.8, upon the later of (i) BVI performing all of its obligations under Section 4.1 as requested to date by MPI to MPI's reasonable satisfaction and BVI having delivered all of the

items in Schedule 3.1 or (ii) 30 days from the Effective Date, MPI will pay BVI a license fee equal to **[***]** Dollars ($ **[***]**).

3.2 **Royalties.**

(b) Subject to payments to be made to Comerica Bank pursuant to Section 3.8, MPI shall pay to BVI royalties on Net Sales at the rates set forth in the following tiers:

Cumulative Net Sales' in a Calendar Year (" Annual Net Sales ")	**Rate**
Portion of Annual Net Sales under $ **[***]**	**[***]** %
Portion of Annual Net Sales equal to or greater than $ **[***]** or less than $ **[***]**	**[***]** %
Portion of Annual Net Sales equal to or greater than $ **[***]**	**[***]** %

1. In calculating the Annual Net Sales for the purposes of determining the applicable royalty rate Annual Net Sales shall include the cumulative Net Sales of MPI, its Affiliates and all Sublicensees (including U.S. Sublicensees) in a Calendar Year. For the avoidance of doubt, the Net Sales of U.S. Sublicensees shall not be included in the calculation of royalties due under Section 3.2(a).

(c) Notwithstanding the foregoing, in the event of a U.S. Sublicense, MPI shall, with respect to the territories covered by such U.S. Sublicense and subject to payments to be made to Comerica Bank pursuant to Section 3.8, pay to BVI the higher (as determined at the end of each Calendar Year with respect to Net Sales occurring or Sublicensing Royalty Revenue received during such Calendar Year) of (i) the applicable royalty payable under Section 3.2(a) or (ii) the percentage of Sublicensing Royalty Revenue at the rates set forth below.

Time of Entering into the U.S. Sublicense	**Percentage of Sublicensing Royalty Revenue**
Prior to the Commencement of Phase 3 Trials	**[***]** %
Following the Commencement of Phase 3 Trials	**[***]** %

3.3 **Third Party Royalties.** If (a) a Product is Covered by a claim of any patent(s) or patent application(s) owned, licensed, or controlled by a Third Party in any country of the Territory, and MPI, an Affiliate thereof, or any Sublicensee licenses such patent(s) or patent application(s) or (b) MPI, an Affiliate thereof, or any Sublicensee reasonably determines that it is necessary or advisable to obtain a license to any patent(s) or patent application(s) owned, licensed, or controlled by a Third Party in order to minimize, mitigate, or avoid the risk of infringement-related litigation with respect to the manufacture, use, Commercialization or Development of a Product in any country of the Territory, then MPI shall notify BVI of the same and shall be entitled to deduct **[***]** percent (**[***]** %) of the earned royalties paid to any such Third Party for any such rights with respect to a sale of such Product in a particular country (such consideration, " Third Party Royalties ") from the payments due BVI under Section 3.2(a) of this Agreement, provided that such amounts payable shall not be reduced, with respect to Net Sales of any Product, below **[***]** percent (**[***]** %) of the amounts otherwise due BVI under Section 3.2(a) with respect to such Product.

3.4 **Compulsory Licenses.** Should a compulsory license be granted, or be the subject of a possible grant, to a Third Party under the Applicable Laws of any country in the Territory under the BVI Patents, the Party receiving notice thereof or otherwise becoming aware thereof shall promptly notify the other Party thereof, including any material information concerning such compulsory license, and the total amount payable under this Section 3 with respect to sales of Products in such country will be adjusted to match any lower amount such Third Party may be allowed to pay with respect to the sales of such Products with such lower amount subject to further adjustments pursuant to Sections 3.3 above.

3.5 **Milestone Payments.** Subject to payments to be made to Comerica Bank pursuant to Section 3.8, MPI shall pay BVI the following amounts, which shall be non-refundable and non-creditable, within thirty (30) Calendar Days of the initial achievement of the indicated milestone (the " Milestone Payments ") with respect to Products outside of the Cardiovascular Field:

Milestone	Payment
Commencement of Phase 2 Clinical Trial under an IND submitted by MPI or its Sublicensee	$ **[***]**
Commencement of Phase 3 Clinical Trial under an IND submitted by MPI or its Sublicensee	$ **[***]**
Acceptance by FDA of an NDA submitted by MPI or its Sublicensee	$ **[***]**
Approval by FDA of an NDA submitted by MPI or its Sublicensee	$ **[***]**
Upon the First Commercial Sale in two of the following five countries: France, Germany, Spain, Italy and the United Kingdom.	$ **[***]**

In addition, additional onetime Milestone Payments shall be payable by MPI to BVI within thirty (30) Calendar Days of the initial achievement of the milestone indicated above with respect to a Product in the Cardiovascular Field. The Milestone Payments for the Cardiovascular Field shall be in the same amounts as indicated above, except that the first Milestone Payment for the commencement of Phase 2 Clinical Trial in the Cardiovascular Field shall be **[***]** Dollars ($ **[***]**).

MPI shall provide BVI written notice of the achievement of each milestone described above within thirty (30) Calendar Days of such achievement. Notwithstanding anything to the contrary, each Milestone Payment is payable not more than twice under this Agreement (not more than once for Products outside of the Cardiovascular Field and not more than once for Products within the Cardiovascular Field, with respect to the initial accomplishment thereof in the respective segment of the Field), regardless of the number of Products (or indications therefor) or the number of times such milestone may be achieved within the respective segment of the Field.

3.6 **Royalty Term.** Subject to any earlier termination of this Agreement, amounts due under Section 3.2 shall only be payable on a country-by-country and Product-by-Product basis for sales occurring, as applicable, with respect to a particular Product in a particular country prior to the first date on which there are no Valid Claims of any BVI Patent Covering such Product in such country, (such period for a particular Product in a particular country, the " Royalty Term " for such Product in such country).

3.7 **Payments and Payment Reports.** Except as otherwise provided in this Section 3, all royalties and payments due under this Section 3 shall be paid within sixty (60) Calendar Days of the end of the Calendar Year during which the applicable Net Sales occur or Sublicensing Royalty Revenue is received. Each royalty payment shall be accompanied by a statement (i) stating (as applicable) the aggregate Net Sales, by country, of each Product sold during the relevant Calendar Year by MPI, its Affiliates and Sublicensees, and the Sublicensing Royalty Revenue received by MPI and its Affiliates during the relevant Calendar Year, and (ii) detailing the calculation of royalties and amounts due for such Calendar Year. Notwithstanding anything to the contrary herein, to the extent MPI is unable to make a payment or provide a report when due as a result of a Sublicensee failing to (i) provide MPI with the information needed for MPI to prepare the reports required under this Section 3.7 or (ii) pay royalties due to MPI for Net Sales accruing during the applicable Calendar Year, MPI shall have up to an additional sixty (60) Calendar Days after the end of the Calendar Year to report to BVI Sublicensee Net Sales for such Calendar Year and to provide the royalty payment due thereon.

3.8 **Payment Method.** All payments due under this Agreement to BVI shall be made by bank wire transfer in immediately available funds to an account designated by BVI in writing, provided, however, that the portion of the payments due to BVI under Sections 3.1, 3.2 and 3.5 of this Agreement that are identified in Schedule 3.8 hereto (the " Comerica Payments ") shall be paid to Comerica Bank pursuant to the Consent and Assignment Agreement between Comerica Bank, BVI and MPI dated as of December 16, 2013, and the amount to be paid directly to BVI pursuant to such Sections shall be reduced by the applicable Comerica Payments. Any such payment made to Comerica Bank shall be deemed to be a payment of such amount to BVI hereunder and shall satisfy in full MPI's obligations to BVI with respect to such payments. All payments hereunder shall be made in the legal currency of the United States.

3.9 **Taxes.** In the event any tax or similar amount is paid or required to be withheld by MPI or any Affiliate thereof for the benefit of BVI on account of any royalties or other payments payable to BVI under this Agreement, the corresponding amounts payable to BVI shall be reduced by the amount of taxes or similar amounts deducted and withheld, and MPI shall pay the amounts of such taxes or similar amounts to the proper Governmental Authority in a timely manner and promptly transmit to BVI an official tax certificate or other evidence of such tax or other obligations together with proof of payment from the relevant Governmental Authority of all amounts deducted and withheld sufficient to enable BVI to claim such payment of taxes or similar amounts. Any such withholding taxes or similar amounts required under applicable law to be paid or withheld shall be an expense of, and borne solely by, BVI. MPI will provide BVI with, at BVI's expense, reasonable assistance to enable BVI to recover such taxes or amounts otherwise withheld as permitted by law.

3.10 **Sublicenses.** For avoidance of doubt, the Parties agree that in the event that MPI grants licenses or sublicenses to Third Parties any right under BVI Technology to sell Products, MPI shall include in such licenses or sublicenses an obligation for such Sublicensee to account for and report its sales of Products on a basis reasonably sufficient to enable MPI to pay BVI the royalties due under this Agreement and satisfy MPI's reporting obligations hereunder.

3.11 **Foreign Exchange.** With respect to Net Sales invoiced in a currency other than United States dollars, such Net Sales will be converted into the United States dollar equivalent using the average conversion rate existing in the United States (as reported in The Wall Street Journal, New York edition) during the applicable Calendar Year. If The Wall Street Journal ceases to be published, then the rate of exchange to be used shall be that reported in such other business publication of national circulation in the United States on which the Parties reasonably agree.

3.12 **Blocked Currency.** In each country where the local currency is blocked and cannot be removed from the country, payments under this Agreement arising from activities in that country for which MPI or an Affiliate thereof does not receive payment in United States' currency, freely useable outside of such country, shall, notwithstanding anything to the contrary, be paid to BVI in the country in local currency by deposit in a local bank designated by MPI, unless the Parties otherwise mutually agree in writing.

3.13 **Interest.** If MPI fails to make any payment when due to BVI under this Agreement, then interest shall accrue on the balance due on a daily basis at a rate equal to LIBOR (as published in The Wall Street Journal, New York edition) plus one percent (1%), or at the maximum rate permitted by applicable law, whichever is the lower, until MPI meets the full financial obligation due.

3.14 **Records; Audits.** MPI shall keep or cause to be kept such records as are reasonably required to determine, in a manner, with respect to any financial records, consistent with generally accepted accounting principles in the United States, the amounts due under this Agreement; such records must be kept for a minimum of three (3) years following the Calendar Year to which such records pertain. At the request (and expense) of BVI, MPI shall permit BVI to engage an independent certified public accounting firm reasonably acceptable to MPI, at reasonable times not more than once a year and upon reasonable notice, to examine only those records as may be necessary to determine, with respect to any Calendar Year ending not more than three (3) years prior to BVI's request, the correctness or completeness of any royalty report or payment made under this Agreement. BVI shall promptly provide a copy of the results of any such audit or examination to MPI. BVI shall bear the full cost of the performance of any such audit or examination, unless such audit or examination discloses an underpayment exceeding ten

percent (10%) of the amount actually due hereunder with respect to any particular Calendar Year, in which case MPI shall bear the reasonable, documented cost of the performance of such audit or examination. MPI shall promptly pay to BVI the amount of any underpayment of royalties revealed by such an examination and review. Any overpayment by MPI of royalties or any other amount paid to BVI revealed by an examination and review shall, in MPI's sole discretion, (i) be fully-

creditable against future payments under this Agreement or (ii) refunded to MPI within thirty (30) Calendar Days of its request.

4. TECHNOLOGY/REGULATORY TRANSFER; CLINICAL SUPPLY; JOINT STEERING COMMITTEE; DILIGENCE; RELATED MATTERS

4.1 **Technology/Regulatory Transfer.** Upon execution of this Agreement, (i) BVI shall transfer to MPI, at no additional cost, all BVI Know-How, which shall include but not be limited to all formulation, development, manufacturing, analytical testing, device testing, stability, pre-clinical, and clinical data, trade secrets, and other regulatory data related to any Compound, Product, or pump or other device for the delivery or administration thereof in its possession and (ii) BVI hereby assigns all right, title, and interest in all Regulatory Filings identified in Schedule 4.1 hereto (the " Transferred Regulatory Filings "), to MPI free and clear of all liens, claims, and encumbrances. BVI shall, at BVI' s cost, take any and all actions requested by MPI to effect the foregoing as promptly as practicable following the execution of this Agreement, which shall include but not be limited to (i) preparing and filing whatever filings, requests or applications are required or deemed advisable to be filed with any Regulatory Authority, if any, in connection with the preceding assignment (including but not limited to, if applicable with respect to the FDA, a "transfer of ownership letter") and (ii) taking all reasonable actions necessary to enable MPI to undertake the manufacture, Development and Commercialization of Products under this Agreement. Such actions shall include providing MPI with:

i. copies of all Regulatory Filings;

ii. any communications with Governmental Authorities or Regulatory Authorities, and the minutes of any meetings with Governmental Authorities or Regulatory Authorities, relating to any Product;

iii. DMFs and any trial, drug, device, or other master files relating to any Product;

iv. copies of all data files, analyses, listings and tables of results, and copies of all case report forms from all clinical trials relating to any Product;

v. copies of all adverse event reports relating to any Product;

vi. storage of and access permission to any retained samples of materials used in clinical trials relating to any Product;

vii. access to all contractors, including but not limited to clinical research organizations, involved in the preclinical studies and clinical trials relating to any Product (or the manufacture or supply of any Product or any pump or other devices for the

delivery or administration of Product (any device for such delivery or administration, a " Delivery Device ")) and any contracts therewith;

viii. the data, files and results of any chemistry, manufacturing, or control-related activities regarding any Product; and

ix. all other information that MPI may reasonably request that may be useful to MPI for the manufacturing of Products or conducting preclinical studies and clinical trials and other Development activities with respect to any Products, or manufacture or Commercialization of any Products.

To the extent BVI Know-How (including, without limitation, any of the items described above) comes into the possession of BVI anytime following the Effective Date, it shall promptly transfer such BVI Know-How to MPI.

4.2 **Clinical Supply.** Upon the request of MPI, BVI shall deliver to, or make available for pick-up by or on behalf of, MPI, as elected by MPI, all Product, placebo, and Delivery Devices in the possession, or under the control of, BVI or its Affiliates that was manufactured for use in human clinical trials (such Product, placebo, and Delivery Devices, the " Clinical Trial Material "), at no cost to MPI. The amount and type of such Clinical Trial Material is detailed on Schedule 4.2 attached hereto, provided that, notwithstanding the foregoing, MPI shall be responsible for the reasonable, direct, documented cost of shipping such Clinical Trial Material to MPI or MPI's desired destination therefor. BVI represents and warrants that the specifications for such Clinical Trial Material, which are in compliance with Applicable Law and GMP, are set forth on Schedule 4.2 hereto.

4.3 **Regulatory Filings.** MPI (or its Affiliates or Sublicensees) will own and be responsible for all Regulatory Filings and Regulatory Approvals in the Territory.

4.4 **Contract Assignment.** To the extent requested by MPI, BVI shall assign to MPI the contracts identified on Schedule 4.4 or that may be identified in the future hereof and execute all documents and instruments reasonably requested by MPI in connection with such assignment.

4.5 **Diligence.** MPI shall, during the Term, use Commercially Reasonable Efforts to pursue the Development and Commercialization of a Product. The Parties agree that the efforts of MPI's Affiliates, Sublicensees, and contractors or consultants of MPI, its Affiliates, or Sublicensees shall constitute the efforts of MPI for purposes of satisfying MPI's obligations under this Section 4.5. Without limiting the generality of the foregoing, MPI shall, on or before the four (4) year anniversary of the Effective Date (a) achieve the Commencement of Phase 2 Clinical Trial for a Product in the Cardiovascular Field under an IND submitted by MPI or its Sublicensee, or (b) pay BVI **[***]** Dollars ($ **[***]**) which shall be credited towards the Commencement of Phase 2 Clinical Trial Milestone for a Cardiovascular Field. If MPI fails to do so on or before the four (4) year anniversary of the Effective Date, BVI shall have the right to terminate all rights and licenses granted to MPI under this Agreement with respect to the Cardiovascular Field, provided that (i) BVI provides notice of termination to MPI at least 90 days prior to the fourth (4 th) anniversary of the Effective

Date and (ii) MPI does not cure such failure prior to the fourth (4th) anniversary of the Effective Date. Following such

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termination, (x) BVI will reimburse MPI for 50% of all future expenses incurred by MPI or its Sublicensees in connection with the prosecution and maintenance of the Patent Rights and (y) MPI will deduct from payments due to BVI under Section 3.5, 50% of the costs and expenses incurred by MPI and its Sublicensees as of the date of such termination in connection with the prosecution and maintenance of the Patent Rights.

4.6 **Joint Steering Committee.**

(a) **Establishment.** Promptly after execution of this Agreement, the Parties shall establish a joint steering committee to oversee, review and coordinate the activities of the Parties under this Agreement and to facilitate communications between the Parties regarding Development of Products under this Agreement (the " **Joint Steering Committee** "). Each Party shall name two (2) representatives to the Joint Steering Committee, and either Party may replace any of its representatives to the Joint Steering Committee upon written notice to the other Parties. The representatives will receive no compensation for their service on the Joint Steering Committee.

(b) **Meetings.** The Joint Steering Committee shall meet at least once every six (6) months during the term of the Agreement. Such meetings may be in person or by telephonic or video conference. The Joint Steering Committee shall appoint at each meeting a member who shall keep accurate minutes of its deliberations, which record all discussions. The minutes shall be forwarded to the members of the Joint Steering Committee by the minute taker within ten (10) business days after each meeting for comment and approval. The members of the Joint Steering Committee shall be required to submit such comments or approval within two (2) weeks after receipt of the draft minutes, with failure to respond be deemed as approval. All records of the Joint Steering Committee shall at all times be available to all Parties.

(c) **Functions.** The Joint Steering Committee shall (i) discuss activities conducted under this Agreement with respect to Development of Products under this Agreement, (ii) coordinate the technology transfer for Product; (iii) make recommendations to MPI relating to the pre-clinical and clinical Development strategy; (iv) discuss the ongoing pre-clinical and clinical development of the Product; and (v) assisting the Licensee to prepare pre-clinical and clinical development budgets. The Joint Steering Committee is solely a forum for discussion and shall have no decision making authority, provided, however, that MPI will reasonably consider advice provided to it by the Joint Steering Committee.

4.7 **Development Plan and Progress Reports.** No later than April 1 of each Calendar Year until the third Calendar Year after the Calendar Year of the First Commercial Sale, MPI shall prepare and provide to BVI and the Joint Steering Committee an annual written plan and strategy describing in reasonable detail MPI's proposed activities to fulfill its obligations under Section 4.5 of this Agreement during such Calendar Year (each, a " **Development Plan** "). The Development Plan shall at a minimum contain with respect to the relevant Calendar Year: (a) MPI's proposed budget dedicated to the development of Products, (b) MPI' s plans for research, development and commercialization activities for the Products, and (c) MPI's planned activities regarding sublicensing. This Section 4.7 will not be deemed to create any obligation beyond MPI' s obligations to use Commercially Reasonable Efforts to pursue the Development and Commercialization of a Product under Section 4.5. Each

Development Plan provided by MPI (other than the first Development Plan), shall also include a progress report with respect to the preceding Calendar Year, which shall detail the progress achieved by MPI with respect to the development of Products during the preceding year in furtherance of the Development Plan.

5. PATENT PROSECUTION AND MAINTENANCE.

5.1 **Prosecution and Maintenance by MPI.** MPI shall assume and have primary responsibility for, and use Commercially Reasonable Efforts to pursue, the filing, prosecution, and maintenance of the BVI Patents, at MPI's sole cost and expense. BVI shall take all actions reasonably requested by MPI, at MPI's sole cost and expense (other than costs related to Paul Glidden's time, which shall be compensated as set forth in a separate consulting agreement between Paul Glidden and MPI), in connection with the transition to MPI of such filing, prosecution, and maintenance, including without limitation, facilitating communication with BVI's patent counsel.

5.2 **Abandonment by MPI; Prosecution and Maintenance by BVI.** If MPI provides BVI with written notification that it will no longer support or pursue the filing, prosecution, or maintenance of a specified BVI Patent in a particular country, then (A) MPI's responsibility for such filing, prosecution, or maintenance of such BVI Patent in such country, and the fees and costs related thereto, will terminate on the earlier of (x) the date sixty (60) Calendar Days after BVI' s receipt of such written notice from MPI or (y) BVI's assumption of the filing, prosecution and maintenance of such BVI Patent in such country, (B) BVI shall have the right, upon written notice to MPI given during such sixty (60) Calendar Day period, to assume control of, and responsibility for, the filing, prosecution, or maintenance of such BVI Patent in such country, at BVI's expense, and (C) such BVI Patent shall on the going-forward basis be excluded from the license grant to MPI under Section 2.1.

5.3 **Patent Term Extensions.** MPI shall promptly notify BVI of the issuance of each Regulatory Approval and, where reasonably and legally possible and reasonably useful or materially valuable in the Commercialization of Products, use Commercially Reasonable Efforts to apply (or cause its Affiliates or Sublicensee(s) to apply) for a patent term extension, adjustment or restoration, supplementary protection certificate, or other form of market exclusivity conferred by Applicable Laws (collectively, " Patent Term Extensions ") in the relevant country(ies) of the Territory. BVI shall, if and as requested by MPI, (i) use Commercially Reasonable Efforts to, assist MPI, its Affiliates, and Sublicensees in obtaining all available Patent Term Extensions and (ii) take all actions necessary to obtain all Patent Term Extensions. The Parties shall cooperate with each other in obtaining Patent Term Extensions wherever and whenever applicable.

6. PATENT INFRINGEMENT.

6.1 **Notice.** If either Party becomes aware of any actual, potential, or alleged infringement of any of the rights to BVI Patents granted to MPI under this Agreement with respect to Products, such Party shall give to the other Party prompt and reasonably detailed written notice of such actual, potential, or alleged infringement. Notwithstanding the foregoing,

each Party shall notify the other Party within two (2) Business Days of its receipt of, or receipt of notice of, any Paragraph IV Certification.

6.2 **Infringement of BVI Patents.** With respect to any actual, potential, or alleged infringement of the rights to BVI Patents in the Field, which shall include, to the extent permitted under Applicable Law, any infringement or other claims resulting from, or legal actions or proceedings enabled or permitted by, any Paragraph IV Certification, MPI shall have the first and primary right, but not the obligation, to, at its expense, initiate, prosecute, and control any action or legal proceedings, and/or enter into a settlement, including any declaratory judgment action, with respect thereto. In any such litigation brought by MPI, MPI shall have the right to use and sue in BVI's name and join BVI as a party to such litigation, and BVI shall cooperate reasonably with respect thereto, as requested by MPI, at MPI's cost. If, within one hundred eighty (180) Calendar Days of the notice in Section 6.1 (or, in the case of a Paragraph IV Certification, thirty-five (35) Calendar Days from the date of MPI's receipt of the Paragraph IV Certification or notice thereof from BVI), MPI shall, (i) have been unsuccessful in persuading the actual, potential, or alleged infringer to desist, (ii) shall not have brought and shall not be diligently prosecuting an infringement or other action with respect to such actual, potential, or alleged infringement or Paragraph IV Certification, or (iii) has not entered into settlement discussions with respect to such actual, potential, or alleged infringement or Paragraph IV Certification, or if MPI notifies BVI that it has decided not to undertake any of the foregoing against any such alleged, potential, or actual infringer or Third Party making such Paragraph IV Certification, then BVI shall have the right, at its expense, to bring suit to enforce such BVI Patents against such actual, alleged, or potential infringer, or take action with respect to such Paragraph IV Certification, at its own expense, unless MPI has provided BVI with a reasonable strategic rationale for not taking action to terminate such actual, potential, or alleged infringement or with respect to such Paragraph IV Certification. Notwithstanding the foregoing, BVI shall not, and shall not permit any Affiliate thereof or Third Party to, proceed against an alleged infringer of the BVI Patents in the Territory in the Field (1) unless significant damages are reasonably expected to be recovered from the infringer in such proceeding and (2) without first consulting with MPI regarding the strategy for such proceeding and considering in good faith MPI's comments regarding such proceeding.

6.3 **Infringement of Third Party Rights.** In the event that a claim of infringement of a Third Party's Patents is made or brought against either Party with respect to the manufacture, use, sale, or importation of the Product, the Party receiving such claim shall promptly inform the other Party in writing, and the Parties shall consult with each other in order to develop a strategy for addressing the alleged infringement. Each Party shall reasonably cooperate with the other Party, as reasonable requested thereby, in any investigations undertaken to determine any potential infringement. As between the Parties, MPI (and/or its Affiliates and Sublicensees) shall have the first and primary right, but not the obligation, at its own expense (subject to Section 6.6) to defend, control the defense of, and/or settle any such claim against MPI, its Affiliates, or Sublicensees, using counsel of its own choice.

6.4 **Litigation Control.** The Party pursuing or controlling any action or defense under Section 6.2 or 6.3 (the " Controlling Party ") shall be free to enter into a settlement, consent judgment,

or other voluntary disposition of any such action or defense, provided, however, that (i) the Controlling Party shall consult with the other Party (the " Secondary Party ") prior to

entering into any settlement or voluntary disposition thereof, (ii) any settlement, consent judgment or other voluntary disposition of such actions which (1) subjects the Secondary Party to any non-indemnified liability or obligation or (2) admits fault or wrongdoing on the part of Secondary Party must, in each case, be approved in advance and in writing by the Secondary Party, (iii) any settlement, consent judgment or other voluntary disposition of such actions which materially limits the scope, validity, or enforceability of, or otherwise may adversely affect, any BVI Patents shall not be entered into, consented to, approved, or agreed upon without the other Party's prior written approval, and (iv) any settlement, consent judgment or other voluntary disposition of such actions that would reasonably be expected to materially adversely affect the BVI Patents, MPI Patents or ability of MPI to manufacture, Develop or Commercialize Products shall not be entered into, consented to, approved, or agreed upon without MPI's prior written consent. With respect to clause (ii) or (iii) above in this Section 6.4, the Secondary Party shall provide the Controlling Party notice of its approval or denial of such approval within fifteen (15) Business Days of any request for such approval by the Controlling Party, provided that (X) in the event Secondary Party wishes to deny such approval, such notice shall include a written description summarizing the Secondary Party's reasonable objections to the proposed settlement, consent judgment, or other voluntary disposition and (Y) Secondary Party shall be deemed to have approved such proposed settlement, consent judgment, or other voluntary disposition in the event it fails to provide such notice within such fifteen (15) Business Day period. Any recovery or damages received by the Controlling Party with respect to the infringement of the rights to BVI Patents granted under this Agreement, or in settlement of any matter subject to Section 6.2 or 6.3, shall be used first to reimburse the Parties for unreimbursed reasonable, documented expenses incurred in connection with such action or settlement, and the remainder shall be split ninety percent (90%) to Controlling Party and ten percent (10%) to Secondary Party Notwithstanding the foregoing, the Secondary Party, at its expense, shall have the right to be represented by counsel of its choice in any proceeding governed by this Section 6.4.

6.5 **Reimbursement.** Each Party shall invoice the other Party for any reasonable, documented costs incurred that are to be borne by the other Party pursuant to this Section 6. Each Party shall pay the other Party such amounts within thirty (30) Calendar Days of the date of any such invoice.

7. CONFIDENTIALITY

7.1 **Confidentiality Obligations** . The Parties agree that, for the Term and for five (5) years thereafter, each Party will keep completely confidential and will not publish, submit for publication or otherwise disclose, and will not use for any purpose except for the purposes contemplated by this Agreement, any Confidential Information of the other Party.

7.2 **Authorized Disclosure** . Each Party may disclose Confidential Information of the other Party to the extent that such disclosure is:

(a) made in response to a valid order of a court of competent jurisdiction; provided, however, that in each case such disclosing Party will, to the extent reasonably practicable, (i) first have given written notice to the other Party and given such other Party a reasonable opportunity to take appropriate action and (ii) cooperate with such other Party as necessary to obtain an appropriate protective order or other protective remedy or treatment; provided, further, that in

each case, the Confidential Information disclosed in response to such court or governmental order will be limited to that information which is legally required to be disclosed in response to such court or governmental order, as determined in good faith by counsel to the Party that is obligated to disclose Confidential Information pursuant to such order;

(b) otherwise required to be disclosed by any applicable law, rule, or regulation (including, without limitation, the U.S. federal securities laws and the rules and regulations promulgated thereunder) or the requirements of any stock exchange to which a Party is subject; provided, however, that the Party that is so required will provide such other Party with written notice of such disclosure reasonably in advance thereof to the extent reasonably practicable and reasonable measures will be taken to assure confidential treatment of such information, including such measures as may be reasonably requested by the disclosing Party with respect to such Confidential Information;

(c) made by such Party, in connection with the performance of this Agreement, to such Party's Affiliates, licensees or sublicensees, directors, officers, employees, consultants, representatives or agents, or to other Third Parties, in each case on a need to know basis and solely to use such information for business purposes relevant to and permitted by this Agreement, and provided that each individual and entity to whom such Confidential Information is disclosed is bound in writing to non-use and non-disclosure obligations no less than substantially as restrictive as those set forth in this Agreement and (ii) the Party making such disclosure shall be liable for such Third Parties' compliance with such obligations; or

(d) made by such Party to existing or potential acquirers, existing or potential collaborators, licensees, licensors, sublicensees, investment bankers, accountants, attorneys, existing or potential investors, merger candidates, partners, venture capital firms or other financial institutions or investors for use of such information for business purposes relevant to this Agreement or for due diligence in connection with the financing, licensing or acquisition of such Party (or such Party's acquisition of, or merger with, a Third Party), and provided that (i) each individual and entity to whom such Confidential Information is disclosed is bound in writing to non-use and non-disclosure obligations (or in the case of attorneys or accountants, an equivalent professional duty of confidentiality) at least as restrictive as those set forth in this Agreement and the Party making such disclosure shall be liable for such Third Parties' compliance with such obligations.

7.3 **Publicity** . Press releases or other similar public communication by either Party not required by any applicable law, rule, or regulation or the requirements of any stock exchange to which a Party is subject and disclosing the existence or terms of this Agreement, or concerning either Party's performance or exercise of its rights under this Agreement, will require the advance written approval of the other Party, provided that BVI will not unreasonably withhold, condition, or delay any such approval sought by MPI. The foregoing notwithstanding, communications required by any applicable law, rule, or regulation or the requirements of any stock exchange to which a Party is subject, and disclosures of information for which consent has previously been obtained, will not require advance approval, but will be provided to the other Party as soon as practicable after the release or communication thereof, provided that, with respect to any such communications required by any applicable law, rule, or regulation or the requirements of any stock exchange to which a Party is subject, the Party required to make such

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disclosure shall, to the extent reasonable practicable and such disclosure does not include information for which consent has previously been obtained, provide the other Party a reasonable opportunity to review and comment on such communications.

8. TERM AND TERMINATION

8.1 **Term** . This Agreement shall become effective on the Effective Date and shall continue, on a country-by-country and Product-by-Product basis, until the earlier of (i) the expiration of the Royalty Term for a particular Product in a particular country or (ii) the effective date of termination pursuant to Section 8.2 or 8.3 (the period from the Effective Date until such expiration or termination, the " Term "). Upon expiration of this Agreement pursuant to clause (i) above with respect to a particular Product and country, MPI and its Affiliates shall have, and are hereby granted, the perpetual, unrestricted, irrevocable, fully-paid, royalty-free, exclusive right, with rights of sublicense, to make, have made, use, sell, offer for sale, and import such Product in such country in the Field.

8.2 **Termination for Material Breach** . If either Party materially breaches this Agreement at any time, the non-breaching Party shall have the right to terminate this Agreement by written notice to the breaching Party, if such material breach is not cured within ninety (90) Calendar Days (forty-five (45) Calendar Days with respect to undisputed payment defaults) of such written notice or if such breach cannot be reasonably cured within 90 days, but the breaching Party has commenced reasonable actions to cure such breach, then such longer period as may be required to cure such breach provided that the breaching Party continues to diligently cure such breach, and (b) the non-breaching Party provides notice confirming such termination within thirty (30) Calendar Days following the expiration of such ninety (90) or forty-five (45) Calendar Day period, as applicable, without cure of such material breach. The foregoing notwithstanding, if such material breach is cured or remedied or shown to be non-existent or not material within the aforesaid ninety (90) or forty-five (45) Calendar Day period, as applicable, the non-breaching party's notice(s) hereunder shall be automatically withdrawn and of no effect.

8.3 **Termination for Convenience by MPI** . This Agreement may be terminated by MPI, in its sole discretion, upon sixty (60) Calendar Days' written notice to BVI.

8.4 **Effects of Termination** .

(a) Upon any termination of this Agreement other than the expiration of this Agreement or a termination of this Agreement by MPI pursuant to Section 8.2, MPI shall cease all Development and Commercialization of the Products, provided that MPI shall have the right, subject to MPI' s payment of royalties as required under Section 3.2, of selling, within twelve (12) months of the date this Agreement is terminated (the " Termination Date "), any finished Products or Products in inventory or the process of manufacture as of the Termination Date.

(b) Notwithstanding any provision herein to the contrary, in the event (A) MPI or an Affiliate thereof has entered into any sublicense agreement granting any Third Party rights to Develop and/or Commercialize Products as permitted by this Agreement, (B) this Agreement is

terminated, and (C) such sublicense is in effect as of such termination, such sublicense granted hereunder and such Sublicensee's rights under such sublicense will survive

such termination, with BVI as the Sublicensee's direct licensor, provided that such Sublicensee delivers to BVI within ninety (90) Calendar Days after termination of this Agreement a license agreement, executed by such Sublicensee and proposed thereby for execution by BVI, that is consistent with the terms and conditions set forth in this Agreement with respect to the BVI Technology, as reasonably modified to be no greater in scope than the scope of the sublicense granted to Sublicensee with respect to territory, duration/term of sublicense grant, Products, fields of use, etc. (e.g. if the Sublicensee's sublicense, as in effect immediately prior to such termination, included rights and obligations only with respect to a particular Product, country, and/or indication, the New License Agreement shall only include rights and obligations with respect to such a particular Product, country, and/or indication) (such a license agreement, a " New License Agreement "), provided, further, that (a) such New License Agreement shall not be required to impose any obligations on such Sublicensee in excess of those obligations of MPI under this Agreement corresponding to such Sublicensee's rights to BVI Technology, and BVI shall not be entitled to impose any additional obligations on such Sublicensee as a condition to BVI' s execution of a New License Agreement therewith; and (b) BVI shall not have any obligations to such Sublicensee in excess of those obligations corresponding to, and consistent with, those of BVI set forth in this Agreement with respect to the applicable rights of such Sublicensee to BVI Technology. BVI shall promptly (but in any event, within two Business Days) execute any New License Agreement, provided that all of the conditions thereto for the benefit of BVI in subclauses (a) — (b) above have been materially satisfied, and BVI shall not require, as a condition to its exercise of any New License Agreement, that any Sublicensee assume any obligations or liabilities in connection with the rights to BVI Technology that are greater than the corresponding obligations and liabilities of MPI under this Agreement.

(c) Upon termination of this Agreement by MPI pursuant to Section 8.3 or BVI pursuant to Section 8.2 where there are no Sublicensees on the Effective Date of such termination, the following shall apply:

(i) at BVI' s written request, MPI shall promptly provide to BVI all documents, materials, instruments, records and data (m) generated or developed solely by MPI solely in connection with the Development of the Product during the term of this Agreement, (n) in MPI' s possession and Control and (o) necessary to make, use, develop, sell or seek regulatory approval to market, solely the Products (provided that MPI shall be allowed to retain one copy) (collectively, " MPI Know-How "), including the following generated or developed solely by MPI and solely in connection with the Development of the Product: (w) all preclinical data, human clinical experience database and any other data or information in its possession and Control that is necessary to make, use, develop, sell or seek regulatory approval to market solely the Product; (x) all Regulatory Approvals and related filings in its possession and Control related solely to the Products; (y) copies of all material Know-How in its possession and Control necessary to make, use, develop, sell or seek regulatory approval to market solely the Products; and (z) copies of all correspondence in its possession and Control with the FDA or equivalent foreign Regulatory Authorities relating solely to the Products;

(ii) MPI shall provide BVI with a report summarizing its Development activities and the results up to termination;

(iii) MPI shall be deemed without any further action to have granted to BVI a non-exclusive, worldwide, royalty-bearing license (including the right to grant sublicenses), under the (m) MPI Know-How and (n) Patents Controlled by MPI on the effective date of termination solely covering inventions (x) conceived and reduced to practice by MPI solely in connection with the Development of the Product and (y) necessary to make, use and sell Product, for use by BVI as reasonably necessary to develop, have developed, make, have made, use, have used, offer for sale, sell, have sold, import and have imported the Products. If MPI terminates this Agreement for its convenience, then MPI will not grant such rights to any third party for Products in the Cardiovascular Field or treating myeloproliferative disorders (the " BVI Field "). In the event this Agreement is terminated for MPI's breach of this agreement, MPI will negotiate terms and conditions of an exclusive license agreement in the BVI Field with BVI in good faith.

Section 2.2 shall apply mutatis mutandis to any sublicense of the rights granted by MPI under this Section 8.4(c)(iii) as they apply to MPI and, solely for such purpose, each reference in each such Section (and any related defmitions) to (A) MPI shall be deemed to be a reference to BVI, (B) BVI shall be deemed to be a reference to MPI and (C) a Sublicensee shall be deemed to be a reference to a licensee or sublicensee of BVI. BVI shall pay MPI a royalty equal to 3% of Net Sales. For purposes of this Section 8.4(c)(iii), the definition of " Net Sales, " and Sections 3.6 through 7.14 shall apply mutatis mutandis to the calculation, payment, recording, and auditing of BVI's obligations to pay royalties under this Section 8.4(c)(iii) as they apply to MPI and, solely for such purpose, each reference in each such Section (and any related definitions) to (M) MPI shall be deemed to be a reference to BVI, (N) BVI shall be deemed to be a reference to MPI and (0) a Sublicensee shall be deemed to be a reference to a licensee or sublicensee of BVI. In the event BVI breaches any provision of this Section 8.4(c)(iii), MPI shall have the right to terminate the license and all of the rights granted to BVI under this Section 8.4(c)(iii) upon thirty (30) days written notice, unless such breach is cured within such thirty (30) day period. Upon such termination MPI shall cease all use, and destroy all copies, of MPI Know-How.

8.5 **Remedies** . Any rights or remedies set forth in this Section 8 are not exclusive, and shall not limit any other legal or equitable remedies that are available to the Parties

8.6 **Survival** . Termination or expiration of this Agreement for any reason will be without prejudice to any rights that will have accrued to the benefit of any Party prior to such termination or expiration, and any termination or expiration of this Agreement shall not relieve either Party of any obligation which has accrued prior to the effective date of such termination or expiration, which obligations shall remain in full force and effect. The following provisions shall survive any expiration or termination of this Agreement: Sections 1, 7, 8.4, 8.6, 10, 11 and 12, together with any Sections referenced in such surviving provisions or necessary to give them effect.

9. REPRESENTATIONS AND WARRANTIES

9.1 Representations and Warranties of BVI. BVI represents and warrants to MPI as follows:

(a) BVI is a corporation, duly incorporated, validly existing and in good standing under the laws of its jurisdiction of incorporation, with full corporate power and authority to operate its properties and to carry on its business as presently conducted.

(b) BVI has full power and authority to execute, deliver and perform this Agreement. There are no liens or other encumbrances on the BVI Technology, BVI Transferred Regulatory Filings, or any part of either of the foregoing which would interfere with the rights granted, or assignment of assets, to MPI hereunder. This Agreement constitutes the legally binding and valid obligation of BVI, enforceable in accordance with its terms, except as such enforcement may be limited by applicable bankruptcy, moratorium and other laws affecting creditors' rights generally.

(c) The execution, delivery and performance by BVI of this Agreement and the consummation of the transactions contemplated hereby will not result in any violation of, conflict with, result in a breach of or constitute a default under any contract or agreement to which BVI or any Affiliate thereof is a party.

(d) There is no action, suit, proceeding or investigation pending or, to BVI's and its Affiliates' knowledge, currently threatened orally or in writing against or affecting BVI or any Affiliate thereof that questions the validity of this Agreement, the validity or ownership of any BVI Patent(s), or the right of BVI to enter into this Agreement or consummate the transactions contemplated hereby and, to BVI's and its Affiliates' knowledge, there is no basis for the foregoing.

(e) To the best of BVI's and its Affiliates' knowledge, no consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with, any federal, state or local governmental authority, or any Third Party, on the part of BVI or any Affiliate thereof is required in connection with the execution, delivery and performance of this Agreement.

(f) To the best of BVI's and its Affiliates' knowledge, BVI has disclosed in writing to MPI all Patents Controlled by BVI or its Affiliates as of the Effective Date which Cover any Products, or which are necessary or appropriate to develop, manufacture and commercialize Products in the Field, and all such Patents are set forth on Schedule 1.5 attached hereto.

(g) There are no inventors of BVI Patents other than those listed as inventors on the Initial BVI Patents as they exist as of the Effective Date, and no BVI Patents are subject to any assignment of obligation of assignment, in whole or in part, to any Third Party.

(h) No research or Development of the BVI Technology, manufacture of Products, or research leading to the inventions Covered by the BVI patents was supported

in whole or part by funding or grants by any governmental agency or philanthropic or charitable organization.

(i) The BVI Technology is wholly-owned by BVI, free and clear of all mortgages, pledges, charges, liens, equities, security interests, shop rights, or other encumbrances or similar agreements, or any other obligation, except as disclosed on Schedule 9.1.

(j) No Third Party or Affiliate of BVI has any rights or ownership interest in any BVI Technology, and neither BVI nor any Affiliate thereof obtained rights to any of the BVI Technology by license or any similar contract or agreement with any Third Party or Affiliate of BVI.

(k) Neither BVI nor any Affiliate thereof is aware of any Third Party intellectual property rights (including any Patent(s)) that were (prior to the Effective Date) or would be (following the Effective Date) infringed, misappropriated, or otherwise violated by the, or that are reasonably required for the anticipated, use, manufacture, sale, import, export, Development, or Commercialization of any Products or any Delivery Device(s) previously used, or that would reasonably required, for the delivery or administration of any Product.

(l) BVI is not aware of, and does not own or control (by license or otherwise), any intellectual property rights (including but not limited to any Patent(s)) claiming or concerning (i) any Delivery Device(s) used with respect to any Product prior to the Effective Date, or any portion or component thereof, or (ii) the use or manufacture of any of the foregoing.

(m) No written or oral communication has been received by BVI or any Affiliate thereof, and no investigation, regulatory enforcement action (including seizure, injunction, civil penalty or criminal action) or any related Governmental Authority or Regulatory Authority review is or, in respect of any Product, to the knowledge of the BVI or any Affiliate thereof, was at any time pending or is threatened by any Governmental Authority or Regulatory Authority with respect to (i) any alleged or actual violation by the BVI, any Affiliate thereof, or any contractor of either of the foregoing of any permit, Applicable Law or other requirement of any Governmental Authority or Regulatory Authority relating to the operations conducted by or on behalf of BVI or any Affiliate thereof with respect to any Product or BVI Technology or (ii) any alleged or actual failure to have or maintain in effect all permits required in connection with the operations conducted by or on behalf of BVI or any Affiliate thereof with respect to any Product or BVI Technology. Neither BVI or any Affiliate thereof has received from the FDA, the U.S. Drug Enforcement Administration (" DEA "), or any similar state, local, federal, or foreign Governmental Authority or Regulatory Authority any written notice regarding the approvability or approval of any Products. With respect to any Products, no officer, employee or, to the knowledge- of BVI or any Affiliate thereof, agent of the BVI has made any untrue statement of a material fact or a fraudulent statement to the FDA, DEA or any similar state, local, federal, or foreign Governmental Authority or Regulatory Authority, failed to disclose any material fact required to be disclosed to the FDA, the

DEA or any similar state, local, federal, or foreign Governmental Authority or Regulatory Authority, or committed an act, made a statement or failed to make a statement that, at the time such act, statement or omission was made, could reasonably be expected to provide a basis for the FDA, the DEA or any similar state, local, federal or foreign Governmental Authority or Regulatory Authority to invoke the FDA's policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" set forth in 56 Fed. Reg. 46191 (September 10, 1991) or any similar policy, nor has any director, officer, employee or, to the knowledge of BVI or any Affiliate thereof, agent of BVI or any Affiliate thereof been convicted of any crime or engaged in any conduct for which debarment is mandated by 21 U.S.C. Article 335a(a) (or any similar law, rule, or regulation) or authorized by 21 U.S.C. Article 335a(b) (or any similar law, rule, or regulation inside the United States or in any jurisdiction outside the United States).

(n) To the knowledge of BVI and its Affiliates, BVI and its Affiliates have taken all reasonable actions necessary or appropriate to preserve the confidentiality of all trade secrets, proprietary and other confidential information material to Products and BVI Technology.

(o) Neither BVI nor any Affiliate thereof is aware of any Third Party activities which would constitute misappropriation or infringement of any BVI Technology.

(p) BVI owns all right, title, and interest to the Transferred Regulatory Filings free and clear of all liens, claims, and encumbrances (except as disclosed on Schedule 9.1), the Transferred Regulatory Filings constitute the only Regulatory Filings concerning any Product made or submitted prior to the Effective Date, and there are no Regulatory Approvals or other Regulatory Filings in place or effective in any jurisdiction with respect to any Product.

(q) Except as disclosed on Schedule 9.1, the Transferred Regulatory Filings are and have been filed, updated, and maintained in accordance with Applicable Laws and pharmaceutical industry standards, and neither BVI nor any Affiliate thereof has received nor been the subject of, nor is aware of any information for which one would reasonably expect BVI or any Affiliate thereof to receive or be the subject of, any correspondence or other action on the part of any Regulatory Authority which would or could reasonably be expected to have a material adverse effect on any study with respect to the Product or on the Development or Commercialization of any Product.

(r) All information provided to MPI, its Affiliates, and their employees, officers, directors, agents, and other representatives by or on behalf of BVI or any Affiliate thereof with respect to Products and the BVI Technology has been accurate, and there is no information known to, or in the possession or control of, BVI or any Affiliate thereof related to any Product or the BVI Technology that has not been provided to MPI prior to the Effective Date.

(s) All Clinical Trial Material has been manufactured, handled, shipped, and stored in accordance with Applicable Laws and GMP and strictly conforms to the specifications therefor set forth on Schedule 4.2 attached hereto (the " Specifications ").

(t) All Development of Product performed prior to the Effective Date was performed in accordance with GLP, GCP, and all Applicable Laws, all human clinical studies of Products performed prior to the Effective Date were performed in accordance with the protocols established therefor, and all Product or placebo administered to patients or subjects in any such studies was, and any Delivery Device(s) used in any such studies were, manufactured, handled, shipped, and stored in accordance with GMP, Applicable Laws, and the Specifications.

9.2 Representations and Warranties of MPI . MPI represents and warrants to BVI as follows as of the Effective Date:

(a) MPI is a limited liability company, duly organized, validly existing and in good standing under the laws of its jurisdiction of organization, with full power and authority to operate its properties and to carry on its business as presently conducted.

(b) MPI has full power and authority to execute, deliver and perform this Agreement. This Agreement constitutes the legally binding and valid obligations of MPI, enforceable in accordance with their terms, except as such enforcement may be limited by applicable bankruptcy, moratorium and other laws affecting creditors' rights generally.

(c) The execution, delivery and performance by MPI of this Agreement and the consummation of the transactions contemplated thereby will not result in any violation of, conflict with, result in a breach of or constitute a default under any contract or agreement material to MPI, its business or its assets.

(d) No consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with, any federal, state or local governmental authority on the part of MPI is required in connection with the execution, delivery and performance of this Agreement.

(e) There is no action, suit, proceeding or investigation pending or, to MPI' s knowledge, currently threatened against or affecting MPI or that questions the validity of this Agreement, or the right of MPI to enter into this Agreement or consummate the transactions contemplated hereby and, to MPI's knowledge, there is no reasonable basis for the foregoing.

9.3 **Disclaimer** . EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH IN THIS AGREEMENT, INCLUDING SECTIONS 9.1 AND 9.2, AS APPLICABLE, THE PARTIES MAKE NO REPRESENTATIONS AND GRANT NO WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND THE PARTIES EACH SPECIFICALLY DISCLAIM ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE, OR AS TO THE SUCCESS OR LIKELIHOOD OF

SUCCESS OF THE RESEARCH, DEVELOPMENT OR COMMERCIALIZATION OF THE COMPOUND OR PRODUCT UNDER THIS AGREEMENT.

10. INDEMNITIES; LIMITS ON LIABILITY

10.1 **Indemnification by BVI** . Subject to Section 10.3, BVI hereby agrees to defend, indemnify and hold harmless MPI, its Affiliates, Sublicensees, any contractors of any of the foregoing, and each of their directors, officers, employees, agents, and other representatives (" MPI Indemnitees ") from and against all suits, claims, proceedings or causes of action brought by Third Parties (" Claims "), and all associated damages, liabilities, expenses and/or loss, including reasonable legal expenses and reasonable attorneys' fees (" Losses "), to the extent arising out of BVI' s, its Affiliates', or BVI' s or its Affiliates' officers', directors', employees', contractors', agents', or other representatives' (i) negligence or willful misconduct, (ii) breach of any warranty by BVI under Sections 4.2, 7 or 9.1 of this Agreement, (iii) failure to comply with any Applicable Law, except in each case to the extent resulting from any MPI Indemnitee's: (A) negligence or willful misconduct, (B) breach of this Agreement, or (C) failure to comply with any Applicable Laws.

10.2 **Indemnification by MPI** . Subject to Section 10.3, MPI hereby agrees to indemnify, defend and hold BVI, its Affiliates, and BVI's and its Affiliates' officers, directors, employees, contractors, agents, and other representatives (collectively, " BVI Indemnitees ") harmless from and against any Losses resulting from Claims brought against any BVI Indemnitee(s) resulting from MPI's, its Affiliates', Sublicensees' or any MPI Representative's (i) negligence or willful misconduct, (ii) breach of Section 7 or 9.2 of this Agreement, or (iii) failure to comply with Applicable Laws, except to the extent such Losses result from any BVI Indemnitee's (A) negligence or willful misconduct, (B) breach of this Agreement, or (C) failure to comply with any Applicable Laws.

10.3 **Indemnification Procedures** . Each Party's agreement to indemnify, defend, and hold harmless under Section 10.1 or 10.2, as applicable, is conditioned upon the indemnified party (a) providing written notice to the indemnifying Party of any claim, demand or action arising out of the indemnified matter as soon as reasonably possible, and in any event no later than within thirty (30) Calendar Days after the indemnified Party has actual knowledge of such claim, demand or action, (b) permitting the indemnifying Party to assume control over the investigation of, preparation and defense against, and settlement or voluntary disposition of any such claim, demand or action, (c) assisting the indemnifying Party, at the indemnifying Party's reasonable expense, in the investigation, preparation, defense, and settlement or voluntary disposition of any such claim, demand or action, and (d) not compromising, settling, or entering into any voluntary disposition of any such claim, demand or action without the indemnifying Party's prior written consent, which consent shall not be unreasonably withheld; provided, however, that, if the party entitled to indemnification fails to promptly notify the indemnifying Party pursuant to the foregoing clause (a), the indemnifying Party will only be relieved of its indemnification obligation to the extent materially prejudiced by such failure. In no event may the indemnifying Party compromise, settle, or enter into any voluntary disposition of any claim, demand or action in any manner that admits material fault or wrongdoing on the part of the indemnified party or incurs non-indemnified liability

on the part of the indemnified party without the prior written consent of the indemnified party, and in no event may the indemnifying Party

settle, compromise, or agree to any voluntary disposition of any matter subject to indemnification hereunder in any manner which may adversely affect any portion of the BVI Technology, or MPI's ability to exploit BVI Technology, without MPI's prior written consent.

10.4 **Limitation of Liability** . IN NO EVENT SHALL EITHER PARTY OR ITS AFFILIATES BE LIABLE TO THE OTHER PARTY FOR ANY PUNITIVE, EXEMPLARY OR CONSEQUENTIAL DAMAGES ARISING OUT OF A BREACH OF THIS AGREEMENT, PROVIDED THAT, NOTWITHSTANDING ANYTHING TO THE CONTRARY, THE FOREGOING SHALL NOT BE CONSTRUED TO LIMIT THE INDEMNITY OBLIGATIONS SET FORTH IN SECTIONS 10.1 AND 10.2, BVI'S OR ITS AFFILIATES DIRECT OR INDIRECT VIOLATION OF THE EXCLUSIVE RIGHTS GRANTED TO MPI HEREUNDER OR EITHER PARTY'S LIABILITY FOR A BREACH OF SECTION 7.

10.5 **Insurance** . Each party shall carry and maintain insurance of the types and in amounts which are reasonable and customary in the U.S. pharmaceutical industry for companies of comparable size and activities. Such insurance will insure against all liability, including but not limited to, bodily injury or property damage arising out of the manufacture, sale, distribution, marketing, Development or Commercialization of Products. Such insurance shall include commercial general liability insurance, including product liability insurance, which coverage shall have limits of liability which are commercially reasonable for the U.S. pharmaceutical industry. Notwithstanding the foregoing, (i) BVI shall not be required to obtain product liability insurance and (ii) MPI shall not be required to obtain product liability insurance until such time as it doses a patient with Product in human clinical trials. Such coverage shall be maintained by each party for not less than three (3) Calendar Years following expiration or termination of this Agreement or if such coverage is of the " claims made " type, for five (5) Calendar Years following expiration or termination of this Agreement. Upon written request from a party, the other party shall promptly provide written evidence (e.g., certificates) of such insurance that is reasonably satisfactory to the requesting Party.

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11. DISPUTE RESOLUTION. In the event that a dispute arises between the Parties in the course of this Agreement, the dispute will be referred to the attention of the Chief Executive Officer of BVI and the Chief Executive Officer of MPI or their designees (or, in the case of a Party that does not have a Chief Executive Officer, the highest-ranking executive officer thereof or their designee) (the " Executive Officers "). The Executive Officers will meet as soon as reasonably possible thereafter and in good faith attempt to resolve such dispute. If, within thirty (30) Calendar Days after referral of such dispute to the Executive Officers by either Party, the Executive Officers are unable to resolve such dispute, either Party will have the right to have the dispute resolved by binding arbitration, initiated by either Party on fifteen (15) Business Days notice to the other Party following the expiration of the thirty (30) Calendar Day period referenced above (the " Initiation Notice "), under the Commercial Arbitration Rules of the American Arbitration Association (" AAA ") then pertaining (available at www.adr.org), except where those rules conflict with this provision, in which case this provision controls, applying the laws of the State of New York, without regards to its conflicts of law provisions, before three (3) independent, neutral arbitrators experienced in the pharmaceutical industry and licensing transactions in such industry. The place of arbitration shall be New York, New York. BVI and MPI shall each be entitled to select one (1) such arbitrator, with the two (2) such arbitrators so selected selecting the third (3 rd) such arbitrator. In the event either Party fails to select its arbitrator within fifteen (15) Business Days of the Initiation Notice, the arbitrator selected by the other Party within such fifteen (15) Business Day period shall be entitled to select such arbitrator. The arbitration shall be conducted in English. The decision of the arbitrators will be final and binding on the Parties, and any decision of the arbitrators may be enforced in any court of competent jurisdiction. Each Party shall bear its own expenses and an equal share of the reasonable, documented expenses of the arbitration panel and any fees required by AAA to submit such matter to arbitration, unless the panel determines that any such fees or expenses are to be paid by the non-prevailing Party. Notwithstanding the foregoing, either Party may seek injunctive, equitable, or similar relief from a court of competent jurisdiction in accordance with Section 12.5 as necessary to enforce its rights hereunder without the requirement of arbitration

12. MISCELLANEOUS

12.1 **Force Majeure** . Neither Party shall be held liable or responsible to the other Party, nor be deemed to have defaulted under or breached this Agreement, for failure or delay in fulfilling or performing any term of this Agreement, to the extent, and for so long as, such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, including fire, floods, embargoes, power shortage or failure, acts of war (whether war be declared or not), insurrections, riots, terrorism, civil commotions, strikes, lockouts or other labor disturbances, acts of God or any acts, omissions or delays in acting by any governmental authority or the other Party, provided that, notwithstanding the foregoing, the payment of amounts due under this Agreement may not be delayed due to a force majeure affecting the Party required to make such payment.

12.2 **Assignment** . Neither Party may assign this Agreement, or any of its rights or obligations hereunder without the other Party's prior written consent, provided that (X) neither Party will unreasonably withhold, condition, or delay any such consent sought by the other Party; and (Y) each Party will, notwithstanding anything to the contrary, be entitled, without the other Party's prior written consent, to assign or transfer this Agreement: (i) in connection with the transfer or sale

of all or substantially all of such Party's assets or business (or that portion thereof related to the subject matter of this Agreement), (ii) in the event of such Party's merger, consolidation, reorganization, change of control or similar transaction, or (iii) to an Affiliate of such Party. Any permitted assignee of either Party will, as a condition to such assignment, assume all obligations of its assignor arising under this Agreement following such assignment. Any purported assignment by a Party of this Agreement, or any of such Party's rights or obligations hereunder, in violation of this Section 12.2 will be void.

12.3 **Severability** . If one or more provisions of this Agreement is held to be invalid, illegal or unenforceable, the Parties shall substitute, by mutual consent, valid provisions for such invalid, illegal or unenforceable provisions which valid provisions are, in their economic effect, sufficiently similar to the invalid provisions that it can be reasonably assumed that the Parties would have entered into this Agreement with such provisions. In the event that such provisions cannot be agreed upon, the invalidity, illegality or unenforceability of one or more provisions of the Agreement shall not affect the validity of this Agreement as a whole.

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12.4 **Notices** . Any notice, consent or report required or permitted to be given or made under this Agreement by one Party to the other Party shall be in English and in writing, delivered personally or by U.S. first class mail or express courier providing evidence of receipt, postage prepaid (where applicable), at the following address for a Party (or such other address for a Party as may be specified by like notice):

To MPI:	To BVI:
557 Seventh Street	16506 Los Morros
Brooklyn, NY 11215	PO Box 2343
Attn: Dan DiPietro	Rancho Santa Fe, CA 92067 Attn: John Parrish

All such notices, consents or reports shall be effective upon receipt.

12.5 **Applicable Law; Jurisdiction** . This Agreement shall be governed by and construed in accordance with the laws of the state of New York, without regard to the conflicts of law principles that would provide for application of the law of a jurisdiction other than the state of New York and excluding the United Nations Convention on Contracts for the International Sales of Goods. Subject to Section 14, each Party (a) irrevocably submits to the exclusive jurisdiction in the United States District Court for the Southern District of New York located in New York, New York and any State courts sitting in New York, New York (collectively, the " Courts "), for purposes of any action, suit or other proceeding arising out of this Agreement, and (b) agrees not to raise any objection at any time to the laying or maintaining of the venue of any such action, suit or proceeding in any of the Courts, irrevocably waives any claim that such action, suit or other proceeding has been brought in an inconvenient forum and further irrevocably waives the right to object, with respect to such action, suit or other proceeding, that such Courts do not have any jurisdiction over such Party.

12.6 **Entire Agreement** . This Agreement (including the Schedules or Exhibits attached hereto) contains the entire agreement by the Parties with respect to the subject matter hereof and supersedes any prior or contemporaneous express or implied agreements, understandings and representations, either oral or written, which may have related to the subject matter hereof in any way.

12.7 **Interpretation** . The captions to the several Sections of this Agreement are not a part of this Agreement, but are included for convenience of reference and shall not affect its meaning or interpretation. In this Agreement: (a) the word " including " shall be deemed to be followed by the phrase " without limitation ", " including but not limited to ", or like expression; (b) the singular shall include the plural and vice versa; and (c) masculine, feminine and neuter pronouns and expressions shall be interchangeable. The Parties expressly agree that any ambiguity in this Agreement shall not be construed against the Party who drafted this Agreement or the relevant provision hereof.

12.8 **Independent Contractors** . It is expressly agreed that MPI and BVI shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency or other fiduciary relationship. Neither MPI nor BVI shall

have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party to do so.

12.9 **Waiver; Amendment** . Except as otherwise expressly provided in this Agreement, any term of this Agreement may be waived only by a written instrument executed by a duly authorized representative of the Party waiving compliance. The delay or failure of any Party at any time to require performance of any provision of this Agreement shall in no manner affect such Party's rights at a later time to enforce the same. This Agreement may be amended, and any term of this Agreement may be modified, only by a written instrument executed by a duly authorized representative of each Party.

12.10 **Binding Effect** . This Agreement shall be binding upon and inure to the benefit of the Parties and their respective legal representatives, successors and permitted assigns.

12.11 **Counterparts** . This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Facsimile and other electronically scanned signatures shall have the same effect as their originals.

12.12 **United States Dollars** . References in this Agreement to "Dollars", "dollars", or "$" shall mean the legal tender of the United States of America.

12.13 **No Strict Construction** . This Agreement has been prepared jointly and shall not be strictly construed against either Party.

12.14 **Responsibility for Affiliates** . The Parties recognize that each Party may perform some or all of its obligations, or exercise its rights, under this Agreement through such Party's Affiliates, provided, however, that each Party shall remain responsible for the payment and performance by its Affiliates and shall cause its Affiliates to comply with the provisions of this Agreement. Any breach of any provision of this Agreement by any Affiliate of a Party shall be deemed a breach hereof by such Party, with such Party being liable hereunder with respect to such breach as if such Party itself had breached this Agreement.

[SIGNATURE PAGE TO FOLLOW.]

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IN WITNESS WHEREOF , the Parties have executed this Agreement by their proper officers as of the date and year first above written.

BIOVASCULAR, INC.

BY: /s/ John H. Parrish

NAME: John H. Parrish

TITLE: President/CEO

MILLS PHARMACEUTICALS, LLC

BY: /s/ Peter Barber

NAME: Peter Barber

TITLE: Manager

SCHEDULE 1.5

BVI Patents

1. US patent 6,585,995 B1
2. US Patent Application 20130022671
3. Issued UK Patent GB 2462022B
4. Issued UK Patent GB 2460915B
5. PCT/US2009/003632 (Publication No. WO 2010/005480) and related regional and national applications

SCHEDULE 3.1

Post Closing Deliverables

1. Executed payoff letter with Pharmaceuticals International, Inc. ("Pii") that is satisfactory to MPI and includes an agreement to release all data, information and material currently held by Pii without further compensation to Pii by MPI.

2. Executed Consent and Assignment Agreement between Comerica Bank, BVI and MPI.

3. Amended and Executed Forbearance Agreement with Comerica Bank.

4. Written confirmation from Anapharm Inc. or it successor that it will release all data and methods currently under its control without further compensation by MPI.

5. Authorization letter directing former service providers to disclose confidential information, reports and data generated on BVI's behalf to MPI.

SCHEDULE 3.8

Amounts to be paid to Comerica Bank

1. $ **[***]** of the $ **[***]** due pursuant to Section 3.1 shall be paid to Comerica Bank
2. **[***]** % of all royalty payments due pursuant to Section 3.2 shall be paid to Comerica Bank
3. The following amounts due pursuant to Section 3.5 with respect to Products outside of the Cardiovascular Field:
    a. $ **[***]** of the $ **[***]** due pursuant to Section 3.5 upon commencement of Phase 2 Clinical Trial under an IND submitted by MPI or its Sublicensee shall be paid to Comerica Bank
    b. $ **[***]** of the $ **[***]** due pursuant to Section 3.5 upon commencement of Phase 3 Clinical Trial under an IND submitted by MPI or its Sublicense shall be paid to Comerica Bank
    c. $ **[***]** of the $ **[***]** due pursuant to Section 3.5 upon acceptance by FDA of an NDA submitted by MPI or its Sublicensee shall be paid to Comerica Bank
    d. $ **[***]** of the $ **[***]** due pursuant to Section 3.5 upon acceptance by FDA of an NDA submitted by MPI or its Sublicensee shall be paid to Comerica Bank
    e. The lesser of (i) $ **[***]** due pursuant to Section 3.5 or (ii) an amount equal to the remaining balance of the Indebtedness (as defined in the Consent and Assignment Agreement between Comerica Bank, BVI and MPI) owed by BVI to Comerica upon the First Commercial Sale in two of the following five countries: France, Germany, Spain, Italy; and the United Kingdom.
4. The following amounts due pursuant to Section 3.5 with respect to Products in the Cardiovascular Field:
    a. $ **[***]** of the $ **[***]** due pursuant to Section 3.5 upon commencement of Phase 2 Clinical Trial under an IND submitted by MPI or its Sublicensee shall be paid to Comerica Bank
    b. $ **[***]** of the $ **[***]** due pursuant to Section 3.5 upon commencement of Phase 3 Clinical Trial under an IND submitted by MPI or its Sublicense shall be paid to Comerica Bank
    c. $ **[***]** of the $ **[***]** due pursuant to Section 3.5 upon acceptance by FDA of an NDA submitted by MPI or its Sublicensee shall be paid to Comerica Bank
    d. $ **[***]** of the $ **[***]** due pursuant to Section 3.5 upon acceptance by FDA of an NDA submitted by MPI or its Sublicensee shall be paid to Comerica Bank
    e. The lesser of (i) $ **[***]** due pursuant to Section 3.5 or (ii) an amount equal to the remaining balance of the Indebtedness (as defined in the Consent and Assignment Agreement between Comerica Bank, BVI and MPI) owed by BVI to Comerica upon the First Commercial Sale in two of the following five countries: France, Germany, Spain, Italy; and the United Kingdom.

SCHEDULE 4.1

Transferred Regulatory Filings

1. US IND filed with the Division of Medical Imaging and Hematology Products of the FDA.
2. US IND filed with the Division of Cardiovascular and Renal Products of the FDA.
3. IMPD filed with BfArM in Germany.

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SCHEDULE 4.2

Clinical Trial Material

1. Clinical trial material manufactured and stored at Pii

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Exhibit 21.1

SUBSIDIARIES OF THE REGISTRANT

Name	Ownership Percentage	Jurisdiction of Incorporation
Apthera, Inc.	100%	Delaware
Mills Pharmaceuticals, LLC	100%	Delaware

- .

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-167025, 333-174076, 333-188847, 333-182505, 333-181589 and 333-188849), Form S-3MEF (No. 333-185526), and Form S-8 (No. 333-151154, 333-153847, 333-175763, 333-174819, 333-183300, 333-182578, and 333-190540) of our report dated March 17, 2014, relating to the consolidated financial statements of Galena Biopharma, Inc., and the effectiveness of internal control over financial reporting of Galena Biopharma, Inc., appearing in this Annual Report (Form 10-K) for the year ended December 31, 2013.

/s/ Moss Adams LLP

Portland, Oregon
March 17, 2014

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-167025, 333-174076, 333-188847, 333-182505, 333-181589 and 333-188849), Form S-3MEF (No. 333-185526), and Form S-8 (No. 333-151154, 333-153847, 333-175763, 333-174819, 333-183300, 333-182578, and 333-190540) of Galena Biopharma, Inc. of our report dated March 12, 2013, relating to the consolidated financial statements, which appear in this Form 10-K.

/s/ BDO USA, LLP

Seattle, Washington
March 17, 2014

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Mark J. Ahn, certify that:

1. I have reviewed this Annual Report on Form 10-K of Galena Biopharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 17, 2014

/s/ Mark Ahn
Mark J. Ahn
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL AND ACCOUNTING OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Ryan M. Dunlap, certify that:

1. I have reviewed this Annual Report on Form 10-K of Galena Biopharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 17, 2014

/s/ Ryan M. Dunlap
Ryan M. Dunlap
Vice President, Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the accompanying Annual Report of Galena Biopharma, Inc., (the "Company") on Form 10-K for the period ended December 31, 2013 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officers of the Company certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to their knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the Company's financial condition and result of operations.

/s/ Mark Ahn
Mark J. Ahn
President and Chief Executive Officer

March 17, 2014

/s/ Ryan M. Dunlap
Ryan M. Dunlap
Vice President, Chief Financial Officer

March 17, 2014