BIO-PATH HOLDINGS INC
Form 10-K
March 16, 2015

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-K**

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

**For the fiscal year ended December 31, 2014**

OR

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

**Commission file number 000-53404**

BIO-PATH HOLDINGS, INC.

**(Exact name of registrant as specified in its charter)**

| | |
|---|---|
| Delaware<br>(State or other jurisdiction of incorporation or organization) | 87-0652870<br>(I.R.S. Employer Identification No.) |

4710 Bellaire Boulevard, Suite 210, Bellaire, Texas 77401

(Address of principal executive offices)

Registrant's telephone number, including area code: (832) 742-1357

Securities registered pursuant to Section 12(b) of the Act: Common Stock, par value $0.001 per share

Securities registered pursuant to Section 12(g) of the 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 x

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

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 x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, 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 such shorter period that the registrant was required to submit and post such files). Yes x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of 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. ¨

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.

| | |
|---|---|
| Large accelerated filer ¨ | Accelerated filer x |
| 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 Act). Yes ¨ No x

As of February 27, 2015, there were 89,762,872 of the registrant's common stock issued and outstanding. The aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $248.9 million as of June 30, 2014, the last business day of the registrant's most recently completed second fiscal quarter, based on the last sales price of the registrant’s common stock as reported on the Nasdaq Capital Market on such date. For purposes of the preceding sentence only, all directors, executive officers and beneficial owners of 10% or more of the shares of the registrant’s common stock are assumed to be affiliates.

DOCUMENTS INCORPORATED BY REFERENCE: NONE

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Unless the context requires otherwise, references in this Annual Report on Form 10-K to "we," "our," "us," "the Company" and "Bio-Path" refer to Bio-Path Holdings, Inc. and its subsidiary. Bio-Path Holdings, Inc.'s wholly-owned subsidiary, Bio-Path, Inc., is sometimes referred to herein as "Bio-Path Subsidiary."

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements can be identified by words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," "project," "goal," "strategy," "future," "likely," "may," "should," "will" and va words and similar references to future periods, although not all forward-looking statements contain these identifying words. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based 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 risks, uncertainties, and changes in circumstances, including those discussed in "Item 1A. Risk Factors" of this Annual Report on Form 10-K. As a result, our actual results may differ materially from those expressed or forecasted in the forward-looking statements, and you should not rely on such forward-looking statements. Please refer to "Item 1A. Risk Factors" of this Annual Report on Form 10-K for a discussion of risks and factors that could cause our actual results and financial condition to differ materially from those expressed or forecasted in this Annual Report on Form 10-K.

Any forward-looking statement made by us in this Annual Report on Form 10-K is based only on information currently available to us and speaks only as of the date on which it is made. We undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future developments or otherwise. However, you should carefully review the risk factors set forth in other reports or documents we file from time to time with the U.S. Securities and Exchange Commission ("SEC").

PART I

ITEM 1. DESCRIPTION OF BUSINESS

**Overview**

The Company is a clinical stage biotechnology company with its lead cancer drug candidate, Liposomal Grb-2 ("L-Grb-2" or "BP1001"), currently in clinical trials. The Company was founded with technology from The University of Texas, MD Anderson Cancer Center ("MD Anderson") and is dedicated to developing novel cancer drugs under an exclusive license arrangement. The Company has drug delivery platform technology with composition of matter intellectual property for systemic delivery of antisense. Bio-Path also plans to investigate developing liposome tumor targeting technology, which has the potential to be developed to augment the Company's current delivery technology to improve further the effectiveness of its antisense. In addition to its existing technology under license, the Company expects to maintain a close working relationship with key members of the MD Anderson staff, which has the potential to provide Bio-Path with additional drug candidates in the future. Bio-Path also expects to broaden its technology to include cancer drugs other than antisense, including drug candidates licensed from institutions other than MD Anderson.

Bio-Path believes that its core technology, if successful, will enable it to be at the center of emerging genetic and molecular target-based therapeutics that require systemic delivery of DNA and RNA-like material. The Company's two liposomal antisense drug candidates are targeted to treat acute myeloid leukemia ("AML"), myelodysplastic syndrome ("MDS"), chronic myelogenous leukemia ("CML"), acute lymphoblastic leukemia ("ALL") and follicular lymphoma, and if successful, could potentially be used in treating many other indications of cancer.

Plan of Operation

***Vision***

A world where life-threatening or debilitating diseases become manageable chronic disorders through use of non-toxic drug treatments that preserve the patient's quality of life.

*Mission*

Develop neutral lipid delivery technology for antisense therapeutics to produce safe, effective drugs to control diseases like cancer, diabetes, rheumatoid arthritis, cardiovascular and neuromuscular disorders.

*Strategy*

Our strategy consists of five principle steps:

(1) Complete the Phase I clinical trial of our lead liposomal antisense drug candidate to provide scientific data that will demonstrate the effectiveness of the neutral lipid delivery technology in delivering an antisense drug substance through the human body to a diseased cell, enabling the drug substance to be delivered across the cell's membrane into the interior of the cell where it can block the cell's production of the target disease protein. Utilize proprietary new assays developed by the Company to measure down-regulation of the drug substance target protein and pharmacokinetics as the principle way of demonstrating effectiveness of the delivery technology.

(2) Capitalize on the results of Liposomal Grb-2 in the Phase I trial to build value in the Company quickly, through Phase II development plans of AML, MDS and CML that offer the potential for rapid clinical approval and development plans for additional treatments for other types of cancer that build on Liposomal Grb-2's established safety profile.

(3) After demonstrating proof of principle of the delivery technology in human patients, expand the number of patented drugs in our pipeline by applying the composition of matter delivery technology template to new protein targets that meet scientific, preclinical and commercial criteria. These efforts may include collaboration and will likely include developing drug candidates for diseases other than cancer.

(4) Initiate a wide-ranging, proactive licensing program after proof of principle of the delivery technology that will include a wide range of licensing arrangements including co-development of a specific liposomal antisense drug candidate, sub-licensing the delivery template for outside development of one or more liposomal antisense drug candidates or an out-license of a partially developed drug for final development and marketing.

(5) Enter into a licensing business development transaction in the near term as a means to develop the cash flow to fund burn rate and minimize future dilution.

Our plan of operation over the next three years is focused on achievement of certain milestones with the intent to demonstrate clinical proof-of-concept of our drug delivery technology and our drug candidates. Furthermore, subject to adequate capital, we will attempt to validate our business model by in-licensing additional protein targets for development as liposomal antisense products to broaden our drug product pipeline.

Our Phase I trial proved that L-Grb2 can be safely delivered systemically to patients at high doses. We also believe that the opportunity to develop, in conjunction with MD Anderson, our lead cancer drug Liposomal Grb-2 to treat triple negative breast cancer ("TNBC") and inflammatory breast cancer ("IBC"), two cancers characterized by formation of aggressive tumors and relatively high mortality rates, is promising. We also now have raised sufficient capital to capitalize on the results seen to date in our lead drug candidate Liposomal Grb-2 by aggressively pursuing Phase II clinical trials and developing Liposomal Grb-2 treatments for other cancer types.

Accordingly, our near term plan is to achieve five key milestones:

(1) initiate and complete Phase II clinical trials on our lead drug candidate BP1001 in AML in combination with low dose Ara-C in both refractory patients and new patients that are ineligible for intensive induction therapy with AML, as well as additional combination studies for treatments of CML and MDS;

(2) complete pre-clinical development of BP1001 for TNBC and IBC and, as appropriate, initiate a Phase I clinical trial on BP1001 for TNBC and IBC;

(3) initiate a Phase I clinical trial on our second drug candidate BP1002 in follicular lymphoma;

(4) begin developing additional drug candidates for development and a program to out-license (non-exclusively) or co-develop our delivery technology with a pharmaceutical partner for development of a specific liposomal antisense drug candidate to generate cash flow to cover burn rate and avoid shareholder dilution, as well as to speed development applications of our technology; and

(5) finalize building out a core organization that can develop and conduct the Phase I and Phase II clinical programs and conduct evaluation of several new drug candidates.

Basic Technical Information

Ribonucleic acid ("RNA") is a biologically significant type of molecule consisting of a chain of nucleotide units. Each nucleotide consists of a nitrogenous base, a ribose sugar, and a phosphate. Although similar in some ways to DNA, RNA differs from DNA in a few important structural details. RNA is transcribed from DNA by enzymes called RNA polymerases and is generally further processed by other enzymes. RNA is central to protein synthesis. DNA carries the genetic information of a cell and consists of thousands of genes. Each gene serves as a recipe on how to build a protein molecule. Proteins perform important tasks for the cell functions or serve as building blocks. The flow of information from the genes determines the protein composition and thereby the functions of the cell.

The DNA is situated in the nucleus of the cell, organized into chromosomes. Every cell must contain the genetic information and the DNA is therefore duplicated before a cell divides (replication). When proteins are needed, the corresponding genes are transcribed into RNA (transcription). The RNA is first processed so that non-coding parts are removed (processing) and is then transported out of the nucleus (transport). Outside the nucleus, the proteins are built based upon the code in the RNA (translation).

Our basic drug development concept is to block the expression of proteins that cause disease. RNA is essential in the process of creating proteins. We intend to develop drugs and drug delivery systems that are intended to work by delivering short strands of DNA material that are inserted into a cell to block the production of proteins associated with disease.

The historical perspective of cancer treatments has been the use of drugs that affect the entire body. Advances in the past decade have shifted to treating the tumor tissue itself. One of the main strategies in these developments has been targeted therapy, involving drugs that are targeted to block the expression of specific disease causing proteins while having little or no effect on other healthy tissue. Nucleic acid drug products, specifically antisense, are a promising field of targeted therapy. Development of antisense, however, has been limited by the lack of a suitable method to deliver these drugs to the diseased cells with high uptake into the cell and without causing toxicity. Bio-Path's currently licensed neutral-lipid based liposome technology is designed to accomplish this. Studies conducted at MD Anderson have shown a 10-fold to 30-fold increase in tumor cell uptake with this technology compared to other delivery methods.

BP1001

***Indications for Acute Myeloid Leukemia (AML), Chronic Myelogenous Leukemia (CML), Myelodysplastic Syndrome (MDS) and Acute Lymphoblastic Leukemia (ALL)***

BP1001 is our lead liposome delivered antisense drug candidate, which has been clinically tested in patients having AML, CML, MDS and ALL.

The Investigational New Drug ("IND") for BP1001 was submitted to the U.S. Food and Drug Administration ("FDA") in February 2008 and included all in vitro testing, animal studies and manufacturing and chemistry control studies completed. The FDA requested some changes be made to the application submission. We resubmitted information to the FDA in response to such request. On March 12, 2010, we issued a press release announcing that the FDA had allowed an IND for our lead cancer drug candidate liposomal BP1001 to proceed into clinical trials. The IND review process was performed by the FDA's Division of Oncology Products and involved a comprehensive review of data submitted by us covering pre-clinical studies, safety, chemistry, manufacturing, and controls, and the protocol for the Phase I clinical trial. The primary objective of the Phase I clinical trial, as in any Phase I clinical trial, is the safety of the drug for treatment of human patients. Additional key objectives of the trial are to demonstrate the effectiveness of our drug delivery technology similar to that experienced in pre-clinical treatment of animals and to assess whether the drug candidate test article produces a favorable impact on the cancerous condition of the patient at the dose levels of the study.

The Phase I clinical trial was a dose-escalating study to determine the safety and tolerance of escalating doses of L-Grb-2. The study determined an optimal biologically active dose for further development. The pharmacokinetics of L-Grb-2 in patients from the study are being evaluated. In addition, patient blood samples from the trial were tested using a new assay developed by us to measure down-regulation of the target protein, the critical scientific data that demonstrated the delivery technology does in fact successfully deliver the antisense drug substance to the cell and across the cell membrane into the interior of the cell where expression of the target protein is blocked. The clinical trial was conducted at MD Anderson.

The original IND granted by the FDA in March of 2010 allowed us to proceed with a Phase I clinical trial having five cohorts culminating in a maximum dose of 50 mg/m $^2$. However, in November of 2012, we announced that since there had been no evidence of significant toxicity from treatment of patients with L-Grb-2, we requested the FDA to allow higher dosing in patients. The Principal Investigator (as defined below) for the clinical trial, in consultation with our board of directors (the "Board"), advised us that with the absence of any real toxicity barriers, we should continue to evaluate higher doses of Liposomal Grb-2. The absence of significant toxicity provided a significant opportunity for us to test higher doses in patients in order to find a dose that provides maximum potential benefit and duration of anti-leukemia effect. These actions were approved and a revised protocol was submitted allowing higher dosing. We announced in October of 2014 that we completed Cohort 6, successfully treating three patients at a dose 90 mg/m$^2$. There has been no evidence of significant toxicity from treatment of patients with L-Grb-2 in our Phase I clinical trial.

An important outcome for the Phase I clinical trial is the ability to assess for the first time the performance of our delivery technology platform in human patients. We have developed two new assays to be able to provide scientific proof of concept of the delivery technology. The first involves a novel detection method for the drug substance in blood samples that will be used to assess the pharmacokinetics of the drug. The second involves a method to measure down-regulation of the target protein in a patient blood sample that was achieved. The latter measurement will provide critical proof that the neutral liposome delivery technology delivered the drug substance to the cell and was able to transport it across the cell membrane into the interior to block cellular production of the Grb-2 protein.

In this regard, in August of 2013 we announced that our liposomal delivery technology achieved a major milestone in the development of antisense therapeutics based on a scientific assay confirming that treating patients with its drug candidate BP1001 inhibits the Grb-2 disease-causing target protein in patients with blood cancers. Inhibition of the disease-causing protein has the effect of down regulating the disease. This will allow for Liposomal Grb-2 to be used potentially in combination with current frontline treatments. This discovery also points to the potential use of a liposomal antisense treatment as a standalone treatment to transform and manage a disease, which has a disease causing protein, as a chronic disorder. This accomplishment is potentially a significant breakthrough for antisense therapeutics, whose development, to date, as a class of therapeutics has been severely limited by a lack of a systemic delivery mechanism that can safely distribute the drug throughout the body and get the antisense drug substance across the cell membrane into the interior of the cell. Further, we expect that scientific proof of principal for our delivery technology may lead to licensing and business development opportunities, furthering our business model.

The Principal Investigator for the Phase I clinical trial, Jorge Cortes, M.D. (the "Principal Investigator"), is a leading expert in the treatment of CML, AML, MDS and ALL. Because the results of the first trial produced unexpected and clinically interesting results in some patients, the Principal Investigator prepared an abstract of the results of the first cohort that was accepted for presentation at the American Society of Hematology ("ASH") annual meeting in December of 2011. Results that demonstrated potential anti-leukemia benefits in treated patients were included in the presentation. Subsequently, in fall of 2013 the Principal Investigator prepared an abstract of updated information on the results of the clinical trial through Cohort 5, which was accepted for presentation at the ASH annual meeting in December of 2013. Highlights (which have been updated to include patients from Cohort 6) of the presentation prepared by the Principal Investigator for the meeting included:

*Data from the Phase I Clinical Trial*

- Among 20 evaluable patients, 15 demonstrated anti-leukemia activity with reduction in peripheral or bone marrow blasts from baseline.
- Five patients demonstrated transient improvement and/or stable disease, three of whom received a total of five cycles each.
- Two patients, in addition to achieving market blast percentage declines, also experienced transient improvements in leukemia cutis lesions.

*Disease Stabilization in MDS and AML*

- Two patients with MDS, a 53-year-old male and a 72-year-old female, both achieved disease stabilization and continued therapy for five cycles before disease progression.
- A 54-year-old HIV positive male with AML achieved stable disease and marked reduction in peripheral blasts, continuing therapy for five cycles before disease progression.

*Experience in CML-Blast Phase*

- Patient with myeloid blast crisis of CML.
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- Prior therapies consist of: imatinib, dastinib, nilotinib, DCC-2036, Cytarabine + Fludarabine + Dasatinib + Gemtuzumab, PHA-739358, Clofarabine + Dasatinib.
- Upon start of BP1001, patient showed a significant reduction in blasts from 81 percent to 5 percent but due to leptomeningeal disease progression discontinued therapy before full cycle.

*Inhibition of Target Grb-2 Protein*

- Grb-2 levels were compared to baseline prior to treatment.
- On day 15, BP1001 decreased Grb-2 in seven of eleven samples tested (average reduction 53 percent).
- End of treatment day 15, BP1001 decreased Grb-2 levels in ten out of twelve patients (average reduction 50 percent).

Being a platform technology, a successful demonstration of the delivery technology in this study allows us to begin expanding our drug candidates by simply applying the delivery technology template to multiple new drug product targets. In this manner, we can quickly build an attractive drug product pipeline with multiple drug product candidates for treating cancer as well as treating other important diseases including diabetes, cardiovascular conditions and neuromuscular disorders. Currently, we are researching potential targets for which we can apply our liposomal antisense drug delivery technology and have already identified two new candidates.

The Phase I clinical trial is typically ended when a maximum tolerated dose (“MTD”) is encountered. However, due to the lack of toxicity of the drug, a MTD was not observed. As a result, an optimal biological dose was determined and we completed Cohort 6 of our Phase I clinical trial. It is noted, however, that the lack of toxicity is a major advantage for the drug candidate BP1001 since it allows higher levels of drug to be administered to the patient, increasing the potential therapeutic benefit.

On February 9, 2015, we announced that we began enrollment into the safety segment of our Phase II clinical trial on BP1001 in patients with AML. The safety segment of our combination therapy Phase II clinical trial in AML consists of two dosing cohorts (60 mg/$m^2$ and 90mg/$m^2$) to test the safety profile of treating AML patients first with BP1001 and low dose Ara-C. Patients ineligible for intensive induction therapy are currently treated only with low dose Ara-C. This trial will determine if adding BP1001 will yield better response rates in this AML patient population. Following the safety portion, the trial will then be opened in multiple centers to test 40-60 patients with the combination. An interim analysis will be performed after approximately 20 patients have been treated with the combination therapy.

In addition, plans and evaluation of manufacturing scale-up of the drug substance batch size continued. Scale-up of manufacturing batch size produced divergence from desired drug substance product parameters, with some product in the fourth quarter of 2013 not being acceptable for use. The most recent manufacturing scale-up drug substance batch appears to have corrected this with excellent product performance testing and the most recent batches have met criteria for use in the clinical trial. Scale-up of manufacturing output of drug substance product and final drug product is critical to meeting the anticipated potential for high volume requirements of our drug products for patients in multiple diseases. The larger size drug substance and final product batch sizes will also substantially drive down manufacturing cost per drug unit. Further to this, plans are in place and testing is ongoing to increase the amount of drug substance per manufactured vial, which increase even further effective capacity of our drug manufacturing. We are also currently working to add a second manufacturer for each of the key areas of drug substance, lipids and final drug product. Our recent success in raising capital should also improve drug supply by providing the financial resources that will enable us to commit to multiple drug batches beyond those required to satisfy near-term requirements.

***Indications for Triple Negative Breast Cancer (TNBC) and Inflammatory Breast Cancer (IBC)***

On July 22, 2013, we announced that we were initiating preclinical testing of BP1001 into two additional indications: TNBC and IBC. TNBC tumors do not express estrogen receptors, progesterone receptors, and low Human Epidermal growth factor Receptor 2 (“HER2”). These negative results mean that the growth of the cancer is not supported by the hormones estrogen and progesterone, or by the presence of too many HER2 receptors. Therefore, TNBC does not respond to hormonal therapy or therapies that target HER2 receptors. In addition, TNBC tumors are very aggressive. Approximately 15 to 20 percent of breast cancers are triple-negative. IBC is a rare and very aggressive disease in which cancer cells block lymph vessels in the skin of the breast. This type of breast cancer is called “inflammatory” because the breast often looks swollen and red, or “inflamed.” IBC accounts for two to five percent of all breast cancers. IBC tumors are very aggressive and are frequently hormone receptor negative, which means hormone therapies may not be effective. Five year survival rate for IBC is approximately 40% versus approximately 87% for all breast cancers combined, making IBC a priority area for development of new treatments.

Our plan is to develop BP1001 as a targeted therapy against TNBC and IBC. Treatment goals are two-pronged: the first being to develop BP1001 as a tumor reduction agent in combination with other approved drugs in pre-operative settings, and the second is to develop BP1001 as a drug to treat and control or eliminate cancer metastasis in TNBC and IBC patients. Both of these treatment goals address high need situations for patients. Following successful completion of the preclinical studies, we expect to start a Phase I clinical trial in TNBC and IBC in late 2015. We believe that the observations that we learned from the original Phase I trial will allow us to progress relatively quickly in such Phase I trial in TNBC and IBC, as the toxicity profile of BP1001 is currently well established.

BP1002

BP-100-1.02 (“Bcl-2” or “BP1002”) is our second liposome delivered antisense drug candidate. The scientific name for BP1002 is Liposomal Bcl-2, a liposome delivered antisense cancer drug. BP1002 is ready for clinic and is intended to target the lymphoma and certain solid tumor markets. Clinical targets for BP1002 include lymphoma, breast cancer, colon cancer, prostate cancer and leukemia. Liposomal Bcl-2 has the potential to treat 40%-60% of solid tumors.

Bcl-2 is a protein that is involved in regulating apoptosis or programmed cell death. Apoptosis is a physiologic mechanism of cell turnover by which cells actively commit suicide in response to aberrant external signals. Over-expression of Bcl-2 prevents the induction of apoptosis in response to cellular insults such as treatment with chemotherapeutic agents. Bcl-2 is over-expressed in more than 90% of follicular B-cell non-Hodgkins lymphoma due to a chromosomal rearrangement and is the key factor in the initiation of this malignancy. Bcl-2 is also overexpressed in a wide variety of solid tumors (it is estimated to be over-expressed in 40% of cancers). For example, Bcl-2 over-expression has been associated with the progression of prostate cancer from hormone dependence to hormone independence and may contribute to the relative drug resistant phenotype typically observed in hormone independent prostate cancer.

On December 22, 2014, we announced that we initiated development of BP1002 as a treatment for follicular lymphoma. We expect to file a new IND to begin clinical testing of BP1002 in patients with follicular lymphoma in the first half of 2015.

**Other Liposomal Antisense Products**

As noted previously, we intend to apply our drug delivery technology template to new disease-causing protein targets as a means to develop new, liposomal antisense drug candidates. A new product identification template was recently approved that defines a process of scientific, pre-clinical, commercial and intellectual property evaluation of potential new drug candidates for inclusion into our drug product development pipeline. A significant amount of capital will be allocated for in-licensing promising protein targets that can be developed as new liposomal antisense drug candidates.

Definitions

The following definitions are intended to assist you in understanding certain matters discussed in this “Item 1. Description of Business”:

***Antisense*** is a medication containing part of the non-coding strand of messenger RNA (mRNA), a key molecule involved in the translation of DNA into protein. Antisense drugs hybridize with and inactivate mRNA. This stops a particular gene from producing the protein for which it holds the recipe. Antisense drugs have been developed or are "in the pipeline" to treat eye disease in AIDS, lung cancer, diabetes and diseases such as arthritis and asthma with a major inflammatory component.

***Acute Myeloid Leukemia (AML)*** is a cancer of the myeloid line of white blood cells, characterized by the rapid proliferation of abnormal cells which accumulate in the bone marrow and interfere with the production of normal blood cells. AML is the most common acute leukemia affecting adults, and its incidence increases with age. Although AML is a relatively rare disease, accounting for approximately 1.2% of cancer deaths in the United States, its incidence is expected to increase as the population ages. The symptoms of AML are caused by replacement of normal bone marrow with leukemic cells, resulting in a drop in red blood cells, platelets, and normal white blood cells. These symptoms include fatigue, shortness of breath, easy bruising and bleeding, and increased risk of infection. Although several risk factors for AML have been identified, the specific cause of AML remains unclear. As an acute leukemia, AML progresses rapidly and is typically fatal within weeks or months if left untreated. Acute myeloid leukemia is a potentially curable disease, but only a minority of patients are cured with current therapy.

***Chronic Myelogenous Leukemia (CML)*** is a form of leukemia characterized by the increased and unregulated growth of predominantly myeloid cells in the bone marrow and the accumulation of these cells in the blood. CML is a clonal bone marrow stem cell disorder in which proliferation of mature granulocytes (neutrophils, eosinophils, and basophils) and their precursors is the main finding. It is a type of myeloproliferative disease associated with a characteristic chromosomal translocation called the Philadelphia chromosome.

***Liposomal Delivery Technology*** is used for drug delivery due to their unique properties. A liposome encapsulates a region on aqueous solution inside a hydrophobic membrane; dissolved hydrophilic solutes cannot readily pass through the lipids. Hydrophobic chemicals can be dissolved into the membrane, thereby incorporating the materials, and in this way liposome can carry both hydrophobic molecules and hydrophilic molecules. To deliver the molecules to sites of action, the lipid bilayer can fuse with other bilayers such as the cell membrane, thus delivering the liposome contents. By making liposomes in a solution of DNA or drugs (which would normally be unable to diffuse through the membrane) they can be (indiscriminately) delivered past the lipid bilayer.

***Myelodysplastic Syndromes (MDS)*** are a diverse collection of hematological conditions united by ineffective production (or dysplasia) of myeloid blood cells and risk of transformation to acute myelogenous leukemia. Anemia requiring chronic blood transfusion is frequently present. Myelodysplastic syndromes are bone marrow stem cell disorders resulting in disorderly and ineffective hematopoiesis (blood production) manifested by irreversible quantitative and qualitative defects in hematopoietic (blood-forming) cells. In a majority of cases, the course of disease is chronic with gradually worsening cytopenias due to progressive bone marrow failure.

***Nucleic Acid Drug Products*** are nucleic acid base sequences that play a crucial role in the expression of gene. The gene is responsible for the synthesis of proteins and these proteins, which are synthesized, are responsible for the biological process including diseases. If the nucleic acid sequence is altered, it could be possible to block or transfer the message for protein synthesis, thereby preventing the particular protein, which is responsible for the disease. These nucleic acids act as drugs by different mechanisms, they may bind with the synthesized proteins, and they can hybridize to a messenger RNA leading to translation arrest or may induce degradation to target RNA. In this way the nucleic acids can act as drugs for inhibiting gene expression or protein synthesis.

**Research and Development**

Our research and development is currently conducted through agreements we have with MD Anderson. We have added a new research and development relationship for pre-clinical testing and anticipate that new research and development relationships will be added in the future for clinical trials that require multiple sites for patient testing. Research and development expenses incurred for the years ended December 31, 2014, 2013 and 2012 were approximately $1.63 million, $1.52 million and $1.13 million, respectively. Research and development - related party expenses incurred for the years ended December 31, 2014, 2013 and 2012 were approximately $0.2 million, $0.1 million and $0.5 million, respectively.

Projected Financing Needs

We currently have projects defined including a multicenter Phase II trial in AML for BP1001, potential multicenter center Phase II trials in CML and MDS, a Phase I trial in TNBC and IBC, a Phase I trial in BP1002 in follicular lymphoma, and administrative, license and business development costs over the next three years. These projects and support costs could require up to $22 million through December 2018. We had approximately $14 million cash on hand at December 31, 2014, so an additional $8 million would be required to be raised over the next three years.

The scientific evidence that our liposomal delivery technology achieved a major milestone in the development of antisense therapeutics based on a scientific assay confirming that treating patients with its drug candidate BP1001 inhibits the Grb-2 disease-causing target protein in patients with blood cancers could potentially be very significant in helping to meet future funding needs. We envision that we might be able to enter into licensing/development agreements with potential pharmaceutical company partners seeking systemic antisense drug treatments, which could potentially provide funding from the partner for us to develop their liposomal antisense drug candidate, with residual milestone payments and potential back-end royalty payments if the drug candidate became an FDA approved drug. There are many potential licensing/development structures, which would vary in terms of favorability.

We have generated approximately seven full years of financial information and have demonstrated that we have been able to expand our business through an increased investment in our technology and trials. We cannot guarantee that plans as described in this Annual Report on Form 10-K will be successful or that we can continue to receive additional capital investment. Our business is subject to risks inherent in growing an enterprise, including, but not limited to, limited capital resources and possible rejection of our new products and/or clinical development methods. If financing is not available on satisfactory terms or at all, we may be unable to continue expanding our operations. Equity financing will result in a dilution to existing shareholders. For a detailed discussion of risks associated with our business, please see “Item 1A. Risk Factors.”

Background Information about MD Anderson

We anticipate that our initial drug development efforts will be pursuant to our exclusive license agreement with MD Anderson. MD Anderson's stated vision is "Making Cancer History" (www.mdanderson.org). Achieving that goal begins with integrated programs in cancer treatment, clinical trials, educational programs and cancer prevention. MD Anderson is one of the largest and most widely recognized cancer centers in the world: U.S. News & World Report's America's "Best Hospitals" survey has ranked MD Anderson as one of the top two best hospitals in the nation since the survey began in 1990. MD Anderson will treat more than 100,000 patients this year, of which approximately 11,000 will participate in therapeutic clinical research exploring novel treatments, which is the largest such program in the nation. MD Anderson employs more than 15,000 people including more than 1,000 medical doctors and Ph.D. clinicians and researchers, and is routinely conducting more than 700 clinical trials at any one time.

Each year, researchers at MD Anderson and around the globe publish numerous discoveries that have the potential to become or enable new cancer drugs. The pharmaceutical and biotechnology industries have more than four hundred cancer drugs in various stages of clinical trials. Yet the number of actual new drugs that are approved to treat this dreaded disease is quite small and its growth rate is flat or decreasing. A successful new drug in this market is significant and substantially impacts those companies who have attained it: Genentech's Avastin, Novartis' Gleevec, OSI's Tarceva and Millennium's Velcade are examples of such drugs.

Over the past several years MD Anderson has augmented its clinical and research prominence through the establishment of the Pharmaceutical Development Center ("PDC"). The PDC was formed for the sole purpose of helping researchers at MD Anderson prepare their newly discovered compounds for clinical trials. It has a full-time staff of professionals and the capability to complete all of the studies required to characterize a compound for the filing of an IND with the FDA, which is required to initiate clinical trials. These studies include pharmacokinetics, tissue distribution, metabolism studies and toxicology studies.

We anticipate being able to use the PDC as a possible source for some of the pre-clinical work needed in the future, potentially at a lower cost than what it would cost to use a for-profit contract research organization. There is no formal arrangement between us and PDC and there can be no certainty that we will have access to PDC or that even if we do have access, that our costs will be reduced over alternative service providers.

Relationship with MD Anderson

We were founded to focus on bringing the capital and expertise needed to translate drug candidates developed at MD Anderson (and potentially other research institutions) into real treatment therapies for cancer patients. To carry out this mission, we negotiated or plan to negotiate several agreements with MD Anderson that will:

- allow us to develop MD Anderson's neutral lipid delivery technology;
- give us access, if needed, to MD Anderson's PDC for drug development;
- provide us with rapid communication of new drug candidate disclosures in the Technology Transfer Office;
- standardize clinical trial programs sponsored by us; and
- standardize sponsored research under a master agreement addressing intellectual property sharing.

Our executive officers are experienced in working with MD Anderson and its personnel. We believe that if we obtain adequate financing, we will be positioned to translate current and future MD Anderson technology into treatments for cancer patients. This, in turn, is expected to provide a steady flow of cancer drug candidates to commercialize or to out-license to pharmaceutical partners.

License Agreement

We currently maintain an exclusive license agreement with MD Anderson (the “License Agreement”). The License Agreement relates to the delivery technology platform for antisense nucleic acids including two single nucleic acid (antisense) drug products. The License Agreement requires, among other things, that we reimburse MD Anderson for ongoing patent expense. Accrued license payments totaling approximately $100,000 for accrued maintenance fees and past patent expenses are included in Current Liabilities as of December 31, 2014. Past patent expenses represent patent expenses incurred by MD Anderson prior to executing the License Agreement with Bio-Path that are being amortized in quarterly payments. As of December 31, 2014, we estimate that remaining reimbursable past patent expenses total approximately $75,000 for the license. We will be required to pay these patent expenses at the rate of approximately $25,000 per quarter when invoiced by MD Anderson. In addition, accrued related party expense of approximately $67,050 was included in current liabilities as of December 31, 2014, representing accrued hospital expense for MD Anderson services treating patients in our clinical trial of BP1001. This expense is unrelated to the License Agreement.

We intend to use our relationship with MD Anderson to develop drug compounds covered by the License Agreement through Phase IIa clinical trials, the point at which we will have demonstrated proof-of-concept of the efficacy and safety for our product candidates in cancer patients. At such time, we may seek a development and marketing partner in the pharmaceutical or biotechnology industry. In certain cases, we may choose to complete development and market the products ourselves. Our basic guide to a decision of whether or not to obtain a license for a potential drug candidate is as follows:

***Likelihood of efficacy*:** Are the *in vitro* pre-clinical studies on mechanism of action and the *in vivo* animal models robust enough to provide a compelling case that the "molecule/compound/technology" has a high probability of working in humans?

***Does it fit with the Company's expertise*:** Do we possess the technical and clinical assets to significantly reduce the scientific and clinical risk to a point where a pharmaceutical company partner would likely want to license this candidate within 36-48 months from the date of our acquiring a license?

***Affordability and potential for partnering*:** Can the clinical trial endpoints be designed in a manner that is unambiguous, persuasive, and can be professionally conducted in a manner consistent with that expected by the pharmaceutical industry at a cost of less than $5-7 million dollars without "cutting corners"?

***Intellectual property and competitive sustainability*:** Is the intellectual property and competitive analysis sufficient to meet criteria established by major pharmaceutical companies assuming successful early clinical human results?

Out-Licenses and Other Sources of Revenue

Subject to demonstrating proof of concept for our delivery technology and obtaining adequate capital, we intend to develop a steady series of drug candidates through Phase II clinical trials and then to engage in a series of out-licensing transactions to pharmaceutical and biotechnology companies. Such companies would then conduct later-stage clinical development, regulatory approval, and eventual marketing of the drug. We expect that such out-license transactions would include upfront license fees, milestone/success payments, and royalties. We intend to maximize the quality and frequency of these transactions, while minimizing the time and cost to achieve meaningful candidates for out-licensing. Our near-term strategy for these licensing transactions is to develop sufficient revenue to cover our burn rate and provide development capital for clinical testing of drug candidates through Phase II for out-licensing, and for some candidates, potentially through full development and commercialization. Longer term out-licensing transactions will be viewed in terms of creating maximum stockholder value to add to the economic value of drug candidates fully developed and marketed by us, as noted below.

In addition to out-licensing revenue and value creation, we may fully develop one or more of our own drug candidates. For example, there are certain cancers that are primarily treated only in a comprehensive cancer center, of which there are approximately 40 in the US and perhaps 200 throughout the world. As a result, marketing and distribution can become a realistic possibility for select products. These candidates may be eligible for orphan drug designation by the FDA, which provides additional incentives in terms of market exclusivities and non-dilutive grant funding for clinical trials.

Finally, there are technologies for which we anticipate acquiring licenses whose application goes well beyond cancer treatment. The ability to provide the delivery of antisense and small molecules and their efficient uptake into cells is a very important technological asset that is expected to be commercialized in other areas of medicine.

Business Strategy

In order to capitalize on the growing need for new drug candidates by the pharmaceutical industry, and recognizing the value of clinical data, we have developed our business strategy based on the following concepts:

- Develop in-licensed compounds to proof-of-concept in patients through Phase IIa.

- Manage trials as if they were being conducted by a major pharmaceutical company: seamless transition; quality systems; documentation; disciplined program management recognized by diligence teams of major pharmaceutical companies; trials conducted, monitored and data collected consistent with applicable FDA regulations to maximize

our credibility and value in order to minimize time to gain registration by partner.

- Leverage outside testing firms for pre-clinical capabilities and MD Anderson for clinical development capabilities. Outside testing firms perform pre-clinical studies as well as clinical pharmacokinetics and pharmacodynamics while MD Anderson's world-renowned clinics will be used for clinical trials, particularly for early clinical trials. This should allow us to develop our drug candidates with experienced professional staff at a reduced cost compared to using external contract research organizations to run clinical trials. This should also allow us to operate in an essentially virtual fashion, thereby avoiding the expense of setting up and operating laboratory facilities, and without losing control over timing or quality or IP contamination.

- Use our scientific advisors and the Board to supplement our management team to critically monitor existing programs and evaluate new technologies and/or compounds discovered or developed at MD Anderson or elsewhere for in-licensing.

- Hire a small team of employees or consultants: business development, regulatory management, and project management.

- Outsource manufacturing and regulatory capabilities. We will not need to invest our resources in building functions that do not add substantial value or differentiation. Instead, we will leverage an executive team with expertise in the selection and management of high quality contract manufacturing and regulatory firms. Future manufacturing capabilities may be developed at a later date as a means to control the technology and ensure adequate supplies of our future internally developed drug products and for out-licensed drug products.

Manufacturing

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. Accordingly, we have no ability to internally manufacture the drug candidates that we need to conduct our clinical trials. For the foreseeable future, we expect to continue to rely on third-party manufacturers and other third parties to produce, package and store sufficient quantities of our drug candidates and any future drug candidates for use in our clinical trials. We have entered into agreements with our third-party manufacturer for the manufacture of our drug requirements, including agreements for the manufacture of L-Grb-2 for use in our Phase II clinical trial, a development agreement for Bcl-2 and an agreement for the manufacture of Bcl-2 for use in our planned Phase I clinical trial. To date, we have made steady progress with our current third-party manufacturers, overcoming challenges associated with scaling up manufacturing to develop their capabilities to supply us with our necessary quantities of drug supplies for our clinical trials. However, we may face various risks and uncertainties in connection with our reliance on third-party manufacturers, as discussed in “Item 1A. Risk Factors” of this Annual Report on Form 10-K under the heading “Risks Related to Manufacturing Our Drug Candidates.” If the FDA or other regulatory agencies approve any of our drug candidates for commercial sale, we expect that we would continue to rely, at least initially, on third-party manufacturers to produce commercial quantities of such approved drug candidates. However, we may in the future elect to manufacture certain of our drug candidates in our own manufacturing facilities. If we do so, we will require substantial additional funds and need to recruit qualified personnel in order to build or lease and operate any manufacturing facilities.

Sales and Marketing

We currently do not have any commercial products, and we do not currently have an organization for the sales and marketing of pharmaceutical products. In order to successfully commercialize any drug candidates that may be approved in the future by the FDA or comparable foreign regulatory authorities, we must build our sales and marketing capabilities or make arrangements with third parties to perform these services. For certain drug candidates in selected indications where we believe that an approved product could be commercialized by a specialty sales force that calls on a limited but focused group of physicians, we may commercialize these products ourselves. However, in therapeutic indications that require a large sales force selling to a large and diverse prescribing population, we may enter into arrangements with other companies for commercialization. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable.

Intellectual Property

Patents, trademarks, trade secrets, technology, know-how, and other proprietary rights are important to our business. Our success depends in large part on our ability to obtain and maintain patent protection both in the United States and in other countries for our drug candidates and on our ability to operate without infringing the proprietary

rights of third parties. Our ability to protect our drug candidates from unauthorized or infringing use by third parties depends in substantial part on our ability to obtain and maintain valid and enforceable patents.

We rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. In order to protect our proprietary technology and processes, we also rely in part on confidentiality and intellectual property assignment agreements with our corporate partners, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information nor result in the effective assignment to us of intellectual property, and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information or other breaches of the agreements. In addition, others may independently discover our trade secrets and proprietary information, and in such case we could not assert any trade secret rights against such party.

As previously noted, we have entered into the License Agreement with MD Anderson, which relates to the delivery technology platform for antisense nucleic acids, including two single nucleic acid (antisense) drug products. In addition, we may enter into out-license and in-license agreements in the future. Our success will depend in part on the ability of our licensors to obtain, maintain and enforce patent protection for their intellectual property, in particular, those patents to which we have secured exclusive rights.

Employees

We currently employ eight full-time employees.  We also have contractual relationships with additional professionals who perform certain medical officer, regulatory and drug development duties. We believe relations with such professionals and employees are good.

Scientific Advisors

Our scientific advisors consist of the following scientists and drug development professionals:

*Ana M. Tari, Ph.D., M.S.* Dr. Tari serves as our Director of Preclinical Operations and Research. Dr. Tari is the lead researcher who has developed our lead cancer drug, BP1001. Dr. Tari is also an Associate Professor at the University of Florida at Gainesville. Previously, Dr. Tari was an Associate Professor at MD Anderson.

*Bradley G. Somer, M.D.* Dr. Somer is employed by ACORN CRO, a full service, oncology-focused clinical research organization ("CRO"). Under our agreement with ACORN CRO, Dr. Somer serves as our Medical Advisor and medical liaison for the conduct of our Phase I clinical study of liposomal BP1001 in refractory or relapsed acute myeloid leukemia, chronic myelogenous leukemia, acute lymphoblastic leukemia and myelodysplastic syndrome.

We anticipate that we may engage additional scientists and clinicians at a time and as appropriate as determined by the Board.

Competition

We are engaged in segments of the pharmaceutical and biotechnology industry that are highly competitive and characterized by rapid and significant technological change. Many large pharmaceutical and biotechnology companies, academic and research institutions, governmental agencies and other public and private research organizations are pursuing the development of novel drugs that target AML, CML, ALL, MDS, breast cancer and other cancer generally. We face, and expect to continue to face, intense and increasing competition as new products enter the market and advanced technologies become available. Our competitors may discover, develop or commercialize products or other novel technologies that are more effective, safer or less costly than our drug candidates. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our drug candidates.

Many of our competitors have:

- significantly greater capital, technical and human resources than we have and may be better equipped to discover, develop, manufacture and commercialize drug candidates;

- more experience in drug discovery, development and commercialization, obtaining regulatory approvals and manufacturing and marketing pharmaceutical products;

- drug candidates that have been approved or are in late-stage clinical development; and/or

- collaboration arrangements in our target markets with leading companies and research institutions.

Mergers and acquisitions in the pharmaceutical and biotechnology industry may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patent registration for clinical trials, and acquiring technologies complementary to, or necessary for, our drug candidates and programs.

Competitive products and technological developments may render our drug candidates noncompetitive or obsolete before we can recover the expenses of developing and commercializing our drug candidates. Furthermore, the development of new treatment methods and/or the widespread adoption or increased utilization of any vaccine for the diseases we are targeting could render our drug candidates noncompetitive, obsolete or uneconomical. If we successfully develop and obtain approval for any of our drug candidates, we will face competition based on the safety and effectiveness of our drug candidates, the timing of their entry into the market in relation to competitive products in development, the availability and cost of supply, marketing and sales capabilities, reimbursement coverage, price, patent position and other factors. If we successfully develop drug candidates but those drug candidates do not achieve and maintain market acceptance, our business will not be successful.

Government Regulation

***Overview***

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, record keeping, packaging, promotion, storage, advertising, distribution, marketing and export and import of products such as those we are developing. The nature and extent to which such regulations will apply to us will vary depending on the nature of any drug candidates we develop. We anticipate that all of our drug candidates will require regulatory approval by governmental agencies prior to commercialization. This process and subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations will require the expenditure of substantial time and financial resources.

***United States Drug Development Process***

In the United States, drugs are subject to rigorous regulation by the FDA under the Federal Food, Drug and Cosmetic Act (the "FDCA"), and implementing regulations, as well as other federal and state statutes. Failure by us or our collaborators to comply with the applicable United States requirements at any time during the drug candidate development process, approval process or after approval, may subject us to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution. Any agency or judicial enforcement action could have a material adverse effect on us.

The process required by the FDA before a new drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies according to FDA's Good Laboratory Practice regulations;

- submission of an IND, which must become effective before human clinical trials may begin and which must include approval by an institutional review board at each clinical site before the trials are initiated;

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performance of adequate and well-controlled human clinical trials according to FDA's Good Clinical Practice ("GCP") regulations to establish the safety and efficacy of the proposed drug for its intended use;

- submission to, and acceptance by, the FDA of an new drug application (an "NDA");

- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current Good Manufacturing Practice ("cGMP") regulations to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and

- FDA review and approval of the NDA.

*Pre-Approval Studies*

Once a drug candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of drug candidate chemistry, toxicity and formulation, as well as animal studies. Prior to beginning human clinical trials, an IND sponsor must submit an IND to the FDA, which includes submitting the results of the preclinical tests, together with manufacturing information and analytical data. Some preclinical or nonclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the trial. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Even after the 30-day time period, the FDA may impose a clinical hold on ongoing clinical trials. If the FDA imposes a clinical hold, clinical trials cannot commence or recommence without FDA authorization and then only under terms authorized by the FDA. The IND application process may be extremely costly and substantially delay the development of our drug candidates for certain indications. Moreover, positive results of preclinical tests will not necessarily indicate positive results in subsequent clinical trials in humans. The FDA may require additional animal testing after an initial IND application is approved and prior to Phase III trials.

Clinical trials involve the administration of the IND to volunteers or patients under the supervision of one or more qualified investigators in accordance with FDA's GCP regulations. Clinical trials must be conducted under protocols detailing the objectives of the trial and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND. Further, an institutional review board at each institution participating in the clinical trial must review and approve each protocol before any clinical trial commences at that institution. All research subjects must provide informed consent, and informed consent information must be submitted to the institutional review board for approval prior to initiation of the trial. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if adverse events or other certain types of other changes occur.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- *Phase I:* The drug candidate is initially introduced into human subjects or patients with the disease and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some drug candidates for severe or life-threatening diseases, the initial human testing is often conducted in patients.

- *Phase II:* Involves studies in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the drug candidate for specific targeted diseases and to determine dosage tolerance and optimal dosage.

- *Phase III:* Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population, typically at geographically dispersed clinical study sites. These studies are intended to establish the overall risk-benefit ratio of the drug candidate and provide, if appropriate, an adequate basis for product labeling.

Phase I, Phase II and Phase III testing may not be completed successfully within any specified period, if at all. The FDA or an institutional review board or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug candidate and finalize a process for manufacturing the product in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other requirements, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

Our business model relies on developing drug candidates through Phase IIa and either entering into out-license agreements with pharmaceutical licensee partners who will be responsible for post-Phase II clinical testing and working with the FDA on necessary regulatory submissions resulting in approval of new drug applications for commercialization, or internally developing a drug candidate through commercialization.

*Approval Process*

After successful completion of the required clinical trials, an NDA is generally submitted, which is required before marketing of the product may begin in the United States. The NDA must include the results of drug development,

preclinical studies and clinical studies, together with other detailed information, including information on the chemistry, manufacture and composition of the drug. The FDA has 60 days from its receipt of the NDA to review the application to ensure that it is sufficiently complete for substantive review before accepting it for filing and may request additional information rather than accept an NDA for filing. If additional information is requested, the NDA must be resubmitted. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The submission of an NDA is also subject to the payment of user fees, which may be waived under certain limited circumstances.

The FDA reviews an NDA that has been accepted for filing to determine, among other things, whether a product is safe and effective for its intended use. The approval process for an NDA is lengthy and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data and information. Even if such data and information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. The FDA may also refer applications for drug candidates which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee. Before approving an NDA, the FDA will also inspect the facility or facilities where the product is manufactured to determine whether its manufacturing is cGMP-compliant to assure and preserve the product’s identity, strength, quality, purity and stability.

There are various programs that are intended to expedite the development and review of drug candidates, and/or provide for approval on the basis of surrogate endpoints, including Fast Track, breakthrough therapy, priority review and accelerated approval. Even if a drug candidate qualifies for one or more of these programs, the FDA may later decide that the drug candidate no longer meets the conditions for qualification or that the time period for FDA review or approval will not be shortened. Generally, drug candidates that may be eligible for these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs or those that offer meaningful benefits over existing treatments.

Fast Track is a process designed to facilitate the development, and expedite the review of drug candidates to treat serious diseases and fill an unmet medical need. Breakthrough therapy requires preliminary clinical evidence that demonstrates the drug candidate may have substantial improvement on at least one clinically significant endpoint over available therapy. A breakthrough therapy designation conveys all of the Fast Track program features, as well as more intensive FDA guidance on an efficient drug development program. Priority review is designed to give drug candidates that offer major advances in treatment or provide a treatment where no adequate therapy exists an initial review within six months as compared to a standard review time of 10 months. Although Fast Track, breakthrough therapy and priority review do not affect the standards for approval, the FDA will attempt to facilitate early and frequent meetings with a sponsor of a Fast Track designated drug candidate and expedite review of the application for a drug candidate designated for priority review. Accelerated approval provides an earlier approval of drugs to treat serious diseases and that fill an unmet medical need based on a surrogate endpoint, which is a laboratory measurement or physical sign used as an indirect or substitute measurement representing a clinically meaningful outcome. As a condition of approval, the FDA may require that a sponsor of a product receiving accelerated approval perform post-marketing clinical trials.

If the FDA evaluations of the application and the manufacturing facilities are favorable, the FDA may issue an approval letter or an “approvable” letter. An approvable letter will usually contain a number of conditions that must be met in order to secure final approval of the NDA and authorization of commercial marketing of the drug for certain indications. An approval letter authorizes commercial marketing of the drug with specific prescribing information for a specific indication. As a condition of NDA approval, the FDA may require post-approval testing, including Phase IV trials, and surveillance to monitor the drug’s safety or efficacy and may impose other conditions, including labeling or distribution restrictions which can materially impact the potential market and profitability of the drug. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems occur after the product reaches the market. The FDA may also refuse to approve the NDA or issue a “not approvable” letter outlining the deficiencies in the submission and often requiring additional testing or information.

To date, we have not submitted a marketing application for any drug candidate to the FDA or any foreign regulatory agency, and none of our drug candidates have been approved for commercialization in any country. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA. The time required to complete clinical trials and for the FDA’s review processes is uncertain and typically takes many years. Our analysis of data obtained from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unanticipated delays or increased costs due to government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials, and FDA

regulatory review.

*Timing to Approval*

We estimate that it generally takes 10 to 15 years or possibly longer to discover, develop and bring to market a new pharmaceutical product in the United States as outlined below:

| **Phase:** | **Objective:** | **Estimated Duration:** |
|---|---|---|
| Discovery | Lead identification and target validation. | 2 to 4 years |
| Preclinical | Initial toxicology for preliminary identification of risks for humans; gather early pharmacokinetic data. | 1 to 2 years |
| Phase I | Test for safety, dosage tolerance, absorption, metabolism, distribution and excretion. | 1 to 2 years |
| Phase II | Identify possible adverse effects and safety risks; preliminarily evaluate the efficacy of the drug candidate for specific targeted diseases; determine dosage tolerance and optimal dosage. | 2 to 4 years |
| Phase III | Further evaluate dosage, clinical efficacy and safety in an expanded patient population, typically at geographically dispersed clinical study sites; establish the overall risk-benefit ratio of the drug candidate and provide, if appropriate, an adequate basis for product labeling. | 2 to 4 years |

| | | |
|---|---|---|
| FDA approval | Approval by the FDA to sell and market the drug for the approved indication. | 6 months to 2 years |

A drug candidate may fail at any point during this process. Animal and other non-clinical studies typically are conducted during each phase of human clinical trials.

Our business model is primarily focused on the pre-clinical to Phase IIa interval. This greatly reduces the time frame for us from in-license of a new, pre-clinical stage drug candidate to be developed to out-licensing to a pharmaceutical partner.

*Post-Approval Studies*

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products that have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

Any drug products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things:

- record-keeping requirements;
- reporting of adverse experiences with the drug;
- providing the FDA with updated safety and efficacy information;
- drug sampling and distribution requirements;
- notifying the FDA and gaining its approval of specified manufacturing or labeling changes;
- complying with certain electronic records and signature requirements; and

· complying with FDA promotion and advertising requirements.

Drug manufacturers and their subcontractors are required to register their establishments with the FDA and some state agencies, and are subject to periodic unannounced inspections by the FDA and some state agencies for compliance with cGMPs and other laws.

We rely, and expect to continue to rely, on third parties for the production of clinical quantities of our drug candidates. Future FDA and state inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our drug candidates. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

*Foreign Regulations*

Whether or not we obtain FDA approval for a drug candidate, we must obtain the requisite approvals from regulatory authorities in non-U.S. countries prior to the commencement of clinical trials or marketing of our products in those countries. Certain countries outside of the United States have a process that requires the submission of a clinical trial application (“CTA”), much like an IND, prior to the commencement of human clinical trials. In Europe, for example, a CTA must be submitted to the competent national health authority and to independent ethics committees in each country in which a company intends to conduct clinical trials. Once the CTA is approved in accordance with a country’s requirements, clinical trial development may proceed in that country.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country, but typically takes several years and requires significant resources. In all cases, the clinical trials must be conducted in accordance with GCPs and other applicable regulatory requirements.

To obtain regulatory approval of an investigational drug under European Union ("E.U.") regulatory systems, we must submit a marketing authorization application. This application is similar to the NDA in the United States, with the exception of, among other things, country-specific document requirements. Drugs can be authorized in the E.U. by using (i) the centralized authorization procedure, (ii) the mutual recognition procedure, (iii) the decentralized procedure or (iv) national authorization procedures.

The European Medicines Agency ("EMA") implemented the centralized procedure for the approval of human drugs to facilitate marketing authorizations that are valid throughout the E.U. This procedure results in a single marketing authorization granted by the European Commission that is valid across the E.U., as well as in Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for certain human drugs including those that are: (i) derived from biotechnology processes, such as genetic engineering, or (ii) contain a new active substance indicated for the treatment of certain diseases.

*Reimbursement*

Sales of pharmaceutical products depend in significant part on the availability of third-party reimbursement, which is time consuming and expensive. Reimbursement may not be available or sufficient to allow us to sell our future products, if any, on a competitive and profitable basis.

The passage of the Medicare Prescription Drug and Modernization Act of 2003 (the "MMA") imposed requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries, which may affect the marketing of our future products, if any. The MMA also introduced a reimbursement methodology, part of which went into effect in 2004, and a prescription drug plan, which went into effect on January 1, 2006. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the E.U. provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect

controls on the profitability of the company placing the medicinal product on the market.

There have been and we expect that there will continue to be frequent federal and state proposals to impose governmental pricing controls or cost containment measures for prescription drugs. While we cannot predict whether such legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our business, financial condition and profitability. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, contains provisions that may reduce the profitability of drugs, including, for example, increased rebates for drugs sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Even if favorable coverage and reimbursement status is attained for one or more of our drug candidates for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

*Other Regulations*

Pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, under certain conditions a sponsor may be granted marketing exclusivity for a period of five years following FDA approval. During this period, third parties would not be permitted to obtain FDA approval for a similar or identical drug through an Abbreviated NDA, which is the application form typically used by manufacturers seeking approval of a generic drug. The Hatch-Waxman Act also permits a patent extension term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent extension cannot extend the remaining term of a patent beyond a total of 14 years. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA, plus time of active FDA review between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and it must be applied for prior to expiration of the patent and within 60 days of the approval of the NDA.

Liposomal Grb-2 previously received orphan drug designations for the treatment of CML in the United States. Orphan designation is available to drugs intended to treat, diagnose or prevent a rare disease or condition that affects fewer than 200,000 people in the United States at the time of application for orphan designation. Orphan drug designation must be requested before submitting an application for marketing authorization. Orphan designation qualifies the sponsor of the product for a tax credit and marketing incentives. The first sponsor to receive FDA marketing approval for a drug with an orphan designation is entitled to a seven-year exclusive marketing period in the United States for that product for that indication and, typically, a waiver of the prescription drug user fee for its marketing application. However, a drug that the FDA considers to be clinically superior to, or different from, the approved orphan drug, even though for the same indication, may also obtain approval in the United States during the seven-year exclusive marketing period. Orphan drug exclusive marketing rights may also be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug. There is no guarantee that any of our other drug candidates will receive orphan drug designation or that, even if such drug candidate is granted such status, the drug candidate's clinical development and regulatory approval process will not be delayed or will be successful.

Pharmaceutical companies are also subject to various federal and state laws pertaining to health care "fraud and abuse," including anti-kickback laws and false claims laws. Anti-kickback laws make it illegal for any entity or person to solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented, for payment to third party payors, including Medicare and Medicaid, claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services.

**Company History and Available Information**

We were originally incorporated in May 2000 as a Utah corporation under the name Ogden Golf Co. Corporation, but terminated our retail golf store operations in December 2006. In February of 2008, we completed a reverse merger with Bio-Path, Inc., a Utah corporation. The name of Ogden Golf Co. Corporation was changed to Bio-Path Holdings, Inc. and the directors and officers of Bio-Path, Inc. became the directors and officers of Bio-Path Holdings, Inc. On March 10, 2014, our common stock ceased trading on the OTCQX and commenced trading on the NASDAQ Capital Market under the ticker symbol "BPTH." Effective December 31, 2014, we changed our state of incorporation from Utah to Delaware through a statutory conversion pursuant to the Utah Revised Business Corporation Act and the Delaware General Corporation Law. Our principal executive offices are located at 4710 Bellaire Boulevard, Suite 210, Bellaire, Texas 77401, and our telephone number is (832) 742-1357.

Our Internet address is *www.biopathholdings.com*. We are not including the information contained in our website as part of, or incorporating it by reference into, this Annual Report on Form 10-K. We make available free of charge through our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to these reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such materials with the SEC. We also make available on our

website our Corporate Governance Guidelines; the charters for our Audit Committee, Nominating/Corporate Governance Committee and Compensation Committee; our Employee Code of Business Conduct and Ethics, which applies to all of our employees, including our executive officers; and our Code of Business Conduct and Ethics for Members of the Board. All such information is also available in print and free of charge to any of our stockholders who request it. In addition, we intend to disclose on our website any amendments to, or waivers from, our codes of business conduct and ethics that are required to be publicly disclosed pursuant to rules of the SEC.

ITEM 1A. RISK FACTORS

Risks Relating to Our Business

***We are a clinical stage biotechnology company with no revenue. We have incurred significant operating losses since our inception, and we expect to incur losses for the foreseeable future and may never achieve profitability.***

We have incurred significant operating losses since our inception. As of December 31, 2014, we had accumulated net losses of approximately $19.9 million. To date, we have not generated any revenue from the sale of our drug candidates and we do not expect to generate any revenue for the foreseeable future. We expect to continue to incur significant operating losses and we anticipate that our losses may increase substantially as we expand our drug development programs and commercialization efforts.

To achieve profitability, we must successfully develop and obtain regulatory approval for one or more of our drug candidates and effectively commercialize any drug candidates we develop. Even if we succeed in developing and commercializing one or more of our drug candidates, we may not be able to generate sufficient revenue and we may never be able to achieve or sustain profitability.

***We will continue to require substantial additional capital for the foreseeable future. If we are unable to raise additional capital when needed, we may be forced to delay, reduce or eliminate our drug development programs and commercialization efforts.***

We expect to continue to incur significant operating expenses in connection with our ongoing activities, including conducting clinical trials, manufacturing and seeking regulatory approval of our drug candidates, Liposomal Grb-2 and Bcl-2. In addition, if we obtain regulatory approval of one or more of our drug candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution.

We believe that we have sufficient capital to fund our projected operating requirements through at least the first quarter of 2016. However, our future capital requirements may change and will depend on numerous factors, including:

- the rate of progress, results and costs of completion of ongoing clinical trials of our drug candidates;

- the rate of progress, results and costs of completion of the ongoing preclinical trials of Liposomal Grb-2 for indications TNBC and IBC;

- the size, scope, rate of progress, results and costs of completion of any potential future clinical trials and preclinical trials of our drug candidates that we may initiate;

- the costs to obtain adequate supply of the compounds necessary for our drug candidates;

- the costs of obtaining regulatory approval of our drug candidates;

- the scope, prioritization and number of drug development programs we pursue;

- the costs for preparing, filing, prosecuting, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;

- the extent to which we acquire or in-license other products and technologies and the costs to develop those products and technologies;

- the costs of future commercializing activities, including product sales, marketing, manufacturing and distribution, of any of our drug candidates or other products for which marketing approval has been obtained;

- our ability to establish strategic collaborations and licensing or other arrangements on terms favorable to us; and

- competing technological and market developments.

There can be no assurance that we will be able to raise additional capital when needed or on terms that are favorable to us, if at all. If adequate funds are not available on a timely basis, we may be forced to:

- delay, reduce the scope of or eliminate one or more of our drug development programs;
- relinquish, license or otherwise dispose of rights to technologies, drug candidates or products that we would otherwise seek to develop or commercialize ourselves at an earlier stage or on terms that are less favorable than might otherwise be available; or
- liquidate and dissolve our company.

If our operating plans change, we may require additional capital sooner than planned. Such additional financing may not be available when needed or on terms favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current and future operating plan.

***The pharmaceutical and biotechnology industry is highly competitive. If we are unable to compete effectively, our drug candidates may be rendered noncompetitive or obsolete.***

We are engaged in segments of the pharmaceutical and biotechnology industry that are highly competitive and characterized by rapid and significant technological change. Many large pharmaceutical and biotechnology companies, academic and research institutions, governmental agencies and other public and private research organizations are pursuing the development of novel drugs that target AML, CML, ALL, MDS, breast cancer and other cancer generally. We face, and expect to continue to face, intense and increasing competition as new products enter the market and advanced technologies become available. Our competitors may discover, develop or commercialize products or other novel technologies that are more effective, safer or less costly than our drug candidates. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our drug candidates.

Many of our competitors have:

- significantly greater capital, technical and human resources than we have and may be better equipped to discover, develop, manufacture and commercialize drug candidates;

- more experience in drug discovery, development and commercialization, obtaining regulatory approvals and manufacturing and marketing pharmaceutical products;

- drug candidates that have been approved or are in late-stage clinical development; and/or

- collaboration arrangements in our target markets with leading companies and research institutions.

Mergers and acquisitions in the pharmaceutical and biotechnology industry may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patent registration for clinical trials, and acquiring technologies complementary to, or necessary for, our drug candidates and programs.

Competitive products and technological developments may render our drug candidates noncompetitive or obsolete before we can recover the expenses of developing and commercializing our drug candidates. Furthermore, the development of new treatment methods and/or the widespread adoption or increased utilization of any vaccine for the diseases we are targeting could render our drug candidates noncompetitive, obsolete or uneconomical. If we successfully develop and obtain approval for any of our drug candidates, we will face competition based on the safety and effectiveness of our drug candidates, the timing of their entry into the market in relation to competitive products in development, the availability and cost of supply, marketing and sales capabilities, reimbursement coverage, price, patent position and other factors. If we successfully develop drug candidates but those drug candidates do not achieve and maintain market acceptance, our business will not be successful.

***Our plan to use collaboration arrangements to leverage our capabilities may not be successful***.

As part of our business strategy, we may enter into collaborative arrangements for the development and commercialization of our drug candidates. For our collaboration efforts to be successful, we must identify partners whose competencies complement ours. We must also successfully enter into collaboration agreements with them on terms attractive to us and integrate and coordinate their resources and capabilities with our own. We may be unsuccessful in entering into collaboration agreements with acceptable partners or negotiating favorable terms in these agreements. In addition, we may face a disadvantage in seeking to enter into or negotiating collaborations with potential partners because other potential collaborators may have greater management and financial resources than we do.

If we do enter into collaborative arrangements, the success of these collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Furthermore, we may face risks and uncertainties in connection with collaborative arrangements, including:

- inability to integrate the resources or capabilities of collaborators;
- collaborators may prove difficult to work with or less skilled than we originally expected;
- disputes arising with respect to the ownership of rights to technology developed with collaborators;
- disagreements with collaborators could delay or terminate the research, development or commercialization of products or result in litigation or arbitration;
- difficulty enforcing our arrangements if one of our collaborators fails to perform;
- termination of our collaboration arrangements by collaborators, which could make it difficult for us to attract new collaborators or adversely affect the perception of us in the business or financial communities;
- collaborators may have considerable discretion in electing whether to pursue the development of any additional drug candidates and may pursue technologies or products either on their own or in collaboration with our competitors that are similar to or competitive with our technologies; and
- collaborators may change the focus of their development and commercialization efforts.

If we are unsuccessful in our collaborative efforts, our ability to develop and market drug candidates could be severely limited.

***If we are unable to attract and retain key management, scientific personnel and advisors, we may not successfully develop our drug candidates or achieve our other business objectives.***

Our success depends on the availability and contributions of members of our senior management team, scientific team and other key personnel. The loss of services of any of these individuals could delay, reduce or prevent our drug development and other business objectives. Furthermore, recruiting and retaining qualified scientific personnel to perform drug development work will be critical to our success. We face intense competition for qualified individuals from numerous pharmaceutical and biotechnology companies, universities, governmental entities and other research institutions. We may be unable to attract and retain these individuals, and our failure to do so could materially adversely affect our business and financial condition.

***Our employees, agents, consultants, and commercial partners may engage in misconduct or other improper activities, including non-compliance with applicable regulatory standards and requirements.***

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants, advisors and commercial partners. Misconduct by these persons could include intentional failures to comply with the regulations of the FDA and non-U.S. regulators, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and cause serious harm to our business, financial condition and reputation. We currently have codes of business conduct and ethics applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and our codes of business conduct and ethics and the other precautions we take to detect and prevent improper activities may not be effective in controlling unknown or unmanaged risks or losses, or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, which could materially adversely affect our business and financial condition. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations.

***If we acquire or license technologies, resources or drug candidates, we will incur a variety of costs and may never realize benefits from the transaction.***

If appropriate opportunities become available, we may license or acquire technologies, resources, drugs or drug candidates. We may never realize the anticipated benefits of such a transaction. In particular, due to the risks inherent in drug development, we may not successfully develop or obtain marketing approval for the drug candidates we acquire. Future licenses or acquisitions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, the creation of contingent liabilities, material impairment expenses related to goodwill, and impairment or amortization expenses related to other intangible assets, which could harm our business and financial condition.

***Our business has a substantial risk of product liability claims. If we are unable to obtain or maintain appropriate levels of insurance, a product liability claim could adversely affect our business.***

Our business exposes us to significant potential product liability risks that are inherent in the development, manufacturing and sales and marketing of human therapeutic products. Although we do not currently commercialize any products, claims could be made against us based on the use of our drug candidates in clinical trials. Product liability claims could delay or prevent completion of our clinical development programs**.** We currently have product liability insurance, but we may not be able to maintain such insurance on acceptable terms. However, even if we maintain or obtain other product liability insurance, our insurance may not provide adequate coverage against potential liabilities. As a result, we may be unable to obtain or maintain insurance coverage at a reasonable cost to protect against losses that could harm our business and financial condition. If any claims are brought against us, and we are not successful in defending ourselves, those claims could result in damage awards against us, which could materially adversely affect our business and financial condition. Whether or not we are successful in defending against such claims, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims.

***We are increasingly dependent on information technology systems to operate our business and a cyber-attack or other breach of our systems, or those of third parties on whom we may rely, could subject us to liability or interrupt the operation of our business.***

We are increasingly dependent on information technology systems to operate our business. A breakdown, invasion, corruption, destruction or interruption of critical information technology systems by employees, others with authorized access to our systems or unauthorized persons could negatively impact operations. In the ordinary course of business, we collect, store and transmit confidential information and it is critical that we do so in a secure manner to maintain the confidentiality and integrity of such information. Additionally, we outsource certain elements of our information technology systems to third parties. As a result of this outsourcing, our third party vendors may or could have access to our confidential information making such systems vulnerable. Data breaches of our information

technology systems, or those of our third party vendors, may pose a risk that sensitive data may be exposed to unauthorized persons or to the public. For example, the loss of clinical trial data from completed or ongoing clinical trials or preclinical studies could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. While we believe that we have taken appropriate security measures to protect our data and information technology systems, and have been informed by our third party vendors that they have as well, there can be no assurance that our efforts will prevent breakdowns or breaches in our systems, or those of our third party vendors, that could materially adversely affect our business and financial condition.

Risks Relating to the Development of Our Drug Candidates

***We must complete extensive clinical trials to demonstrate the safety and efficacy of our drug candidates. If we are unable to demonstrate the safety and efficacy of our drug candidates, we will not be successful.***

To date, none of our drug candidates have been approved for sale in the United States or any foreign country. The success of our business depends primarily on our ability to develop and commercialize our drug candidates successfully. Our drug candidates must satisfy rigorous standards of safety and efficacy before they can be approved for sale. To satisfy these standards, we must engage in expensive and lengthy testing of our drug candidates.

On February 9, 2015, we announced that we began enrollment into the safety segment of our Phase II clinical trial of BP1001 in patients with AML. The safety segment of our combination therapy Phase II clinical trial in AML consists of two dosing cohorts (60 mg/m$^2$ and 90 mg/m$^2$) to test the safety profile of treating AML patients first with BP1001 and Ara-C. Patients ineligible for intensive induction therapy are currently treated only with low dose Ara-C. The trial will determine if adding BP1001 will yield better response rates in this AML patient population. Following the safety portion, the trial will then be opened in multiple centers to test 40-60 patients with the combination. An interim analysis will be performed after approximately 20 patients have been treated with the combination therapy. In addition, (i) we are currently conducting preclinical studies on BP1001 for TNBC and IBC and (ii) we plan to initiate two other Phase II clinical trials for BP1001 in CML and MDS, among other things. We may not be able to obtain authority from the FDA or other equivalent foreign regulatory agencies to move on to further efficacy segments of the Phase II or Phase III clinical trials or commence and complete any other clinical trials for any of our drug candidates. Positive results in preclinical studies of a drug candidate may not be predictive of similar results in human clinical trials, and promising results from early clinical trials of a drug candidate may not be replicated in later clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in early-stage development. Accordingly, the results from the preclinical trials or clinical trials for our drug candidates may not be predictive of the results we may obtain in later stage trials. The failure of clinical trials to demonstrate safety and efficacy of one or more of our drug candidates will have a material adverse effect on our business and financial condition.

***Delays in the commencement of clinical trials of our drug candidates could result in increased costs to us and delay our ability to generate revenues.***

Our drug candidates will require continued extensive clinical trials prior to the submission of a regulatory application for commercial sales. Because of the nature of clinical trials, we do not know whether future planned clinical trials will begin on time, if at all. Delays in the commencement of clinical trials could significantly increase our drug development costs and delay any commercialization of our drug candidates. In addition, many of the factors that may cause, or lead to, a delay in the commencement of clinical trials may also ultimately lead to denial of regulatory approval of a drug candidate.

The commencement of clinical trials can be delayed for a variety of reasons, including delays in:

- demonstrating sufficient safety and efficacy in past clinical trials to obtain regulatory approval to commence a further clinical trial;
- convincing the FDA that we have selected valid endpoints for use in proposed clinical trials;
- reaching agreements on acceptable terms with prospective contract manufacturers for manufacturing sufficient quantities of our drug candidate; and

- obtaining institutional review board approval to conduct a clinical trial at a prospective site.

In addition, the commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the availability of effective treatments for the relevant disease and the eligibility criteria for the clinical trial.

***Delays in the completion of, or the termination of, clinical trials of our drug candidates could result in increased costs to us, and could delay or prevent us from generating revenues.***

Once a clinical trial has begun, it may be delayed, suspended or terminated by us or the FDA or other regulatory authorities due to a number of factors, including:

- regulators or institutional review boards may not authorize us to commence or conduct a clinical trial at a prospective trial site;
- our preclinical tests or clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical testing or clinical trials or we may abandon projects that we expect may not be promising;
- we might have to suspend or terminate our clinical trials if the participating patients are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
- the cost of our clinical trials may be greater than we currently anticipate and we may lack adequate funding to continue the clinical trial;

- the timing of our clinical trials may be longer than we currently anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner (including delays or inability to manufacture or obtain sufficient quantities of materials for use in clinical trials);
- inadequacy of or changes in our manufacturing process or compound formulation;
- slower than expected rates of patient recruitment and enrollment or lower than expected patient retention rates;
- the effects of our drug candidates may not be the desired effects or may include undesirable side effects or our drug candidates may have other unexpected characteristics;
- changes in applicable regulatory policies and regulations;
- delays in identifying and reaching agreement on acceptable terms with prospective clinical trial sites;
- uncertainty regarding proper dosing;
- failure of our clinical research organizations to comply with all regulatory and contractual requirements or otherwise fail to perform their services in a timely or acceptable manner;
- scheduling conflicts with participating clinicians and clinical institutions;
- failure to construct appropriate clinical trial protocols;
- insufficient data to support regulatory approval;
- inability or unwillingness of medical investigators to follow our clinical protocols; and
- the timing of discussions and meetings with the FDA or other regulatory authorities regarding the scope or design of our clinical trials.

Many of these factors that may lead to a delay, suspension or termination of clinical trials of our drug candidates may also ultimately lead to denial of regulatory approval of our drug candidates. If we experience delays in the completion of, or termination of, clinical trials of any product candidates in the future, our business, financial condition and the commercial prospects for our drug candidates could be materially adversely affected, and our ability to generate product revenues will be delayed.

***If we are unable to obtain United States and/or foreign regulatory approval, we will be unable to commercialize our drug candidates.***

Our drug candidates are subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, record keeping, labeling, marketing and distribution of drugs. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process are required in the United States and in many foreign jurisdictions prior to the commercial sale of our drug candidates. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. It is possible that none of the drug candidates we are developing will obtain marketing approval. In connection with the clinical trials for our drug candidates, we face risks that:

- the drug candidate may not prove to be efficacious;
- the drug candidate may not prove to be safe;
- the drug candidate may not be readily co-administered or combined with other drugs or drug candidates;
- the results may not confirm the positive results from earlier preclinical studies or clinical trials;
- the results may not meet the level of statistical significance required by the FDA or other regulatory agencies; and
- the FDA or other regulatory agencies may require us to carry out additional studies.

We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA. The time required to complete clinical trials and for the FDA and other countries' regulatory review processes is uncertain and typically takes many years. Our analysis of data obtained from preclinical and clinical trials is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unanticipated delays or increased costs due to government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials, and FDA regulatory review.

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Any regulatory approval to market a product may be subject to limitations on the indicated uses for which we may market the product and affect reimbursement by third-party payors. These limitations may limit the size of the market for the product. We may also become 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 FDA approval described above as well as risks attributable to the satisfaction of foreign regulations. Approval by the FDA does not ensure approval by regulatory authorities outside the United States. Foreign jurisdictions may have different approval procedures than those required by the FDA and may impose additional testing requirements for our drug candidates.

***In addition to regulations in the United States, we may be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products, if approved.***

Whether or not we obtain FDA approval for a drug candidate, we must obtain the requisite approvals from regulatory authorities in non-U.S. countries prior to the commencement of clinical trials or marketing of our products in those countries. Certain countries outside of the United States have a process that requires the submission of a clinical trial application, much like an IND, prior to the commencement of human clinical trials. In Europe, for example, a CTA must be submitted to the competent national health authority and to independent ethics committees in each country in which a company intends to conduct clinical trials. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed in that country.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials must be conducted in accordance with GCP and other applicable regulatory requirements.

To obtain regulatory approval of an investigational drug under E.U. regulatory systems, we must submit a marketing authorization application. This application is similar to the NDA in the United States, with the exception of, among other things, country-specific document requirements. Drugs can be authorized in the E.U. by using (i) the centralized authorization procedure, (ii) the mutual recognition procedure, (iii) the decentralized procedure or (iv) national authorization procedures.

The EMA implemented the centralized procedure for the approval of human drugs to facilitate marketing authorizations that are valid throughout the E.U. This procedure results in a single marketing authorization granted by the European Commission that is valid across the E.U., as well as in Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for certain human drugs including those that are: (i) derived from biotechnology processes, such as genetic engineering, or (ii) contain a new active substance indicated for the treatment of certain diseases.

***Changes in existing laws and regulations affecting the healthcare industry could increase our costs and otherwise adversely affect our business.***

Our research and development activities, preclinical studies and clinical trials, and the manufacturing, marketing and labeling of any products we may develop, are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries. Changes in existing federal, state and foreign laws and agency regulations may be established that could prevent or delay regulatory approval of our drug candidates or materially increase our costs, including:

- changes in the FDA and foreign regulatory processes for new therapeutics that may delay or prevent the approval of any of our drug candidates;

- new laws, regulations, or judicial decisions related to healthcare availability or the payment for healthcare products and services, including prescription drugs, that would make it more difficult for us to market and sell products once they are approved by the FDA or foreign regulatory agencies;

- changes in FDA and foreign regulations that may require additional safety monitoring prior to or after the introduction of new products to market, which could materially increase our costs of doing business; and

- changes in FDA and foreign current cGMPs that would make it more difficult for us to manufacture our drug candidates in accordance with cGMPs.

Delays in obtaining or preventing our obtaining regulatory approval of our drug candidates could materially adversely affect our ability to commercialize any of our drug candidates and our ability to receive product revenues or to receive milestone payments or royalties from any product rights we might license to others.

***We rely on third parties to conduct clinical trials for our drug candidates, and their failure to timely and properly perform their obligations may result in costs and delays that prevent us from obtaining regulatory approval or successfully commercializing our drug candidates.***

We rely on independent contractors, including CROs, in certain areas that are particularly relevant to our research and drug development plans, such as for data management for the conduct of clinical trials. The competition for these relationships is intense, and we may not be able to maintain our relationships with them on acceptable terms. Independent contractors generally may terminate their engagements at any time, subject to notice. As a result, we can control their activities only within certain limits, and they will devote only a certain amount of their time conducting research on and trials of our drug candidates and assisting in developing them. If they do not successfully carry out their duties under their agreements with us, fail to inform us if these trials fail to comply with clinical trial protocols or fail to meet expected deadlines, our clinical trials may need to be extended, delayed or terminated. We may not be able to enter into replacement arrangements without undue delays or excessive expenditures. If there are delays in testing or regulatory approvals as a result of the failure to perform by our independent contractors or other outside parties, our drug candidate development costs will increase and we may not be able to attain regulatory approval for or successfully commercialize our drug candidates.

In addition, we have no control over the financial health of our independent contractors. Several of our independent contractors are in possession of valuable and sensitive information relating to the safety and efficacy of our drug candidates, and several others provide services to a significant percentage of the patients enrolled in our clinical trials in which such independent contractors participate. Should one or more of these independent contractors become insolvent, or otherwise are not able to continue to provide services to us, the clinical trial in which such contractor participates could become significantly delayed and we may be materially adversely affected as a result of the delays and additional expenses associated with such event.

***We may not be able to obtain or maintain orphan drug exclusivity for our product candidates.***

Liposomal Grb-2 has received orphan drug designations for the treatment of CML in the United States. Orphan designation is available to drugs intended to treat, diagnose or prevent a rare disease or condition that affects fewer than 200,000 people in the United States at the time of application for orphan designation. Orphan drug designation must be requested before submitting an application for marketing authorization. Orphan designation qualifies the sponsor of the product for a tax credit and marketing incentives. The first sponsor to receive FDA marketing approval for a drug with an orphan designation is entitled to a seven-year exclusive marketing period in the United States for that product for that indication and, typically, a waiver of the prescription drug user fee for its marketing application.

However, a drug that the FDA considers to be clinically superior to, or different from, the approved orphan drug, even though for the same indication, may also obtain approval in the United States during the seven-year exclusive marketing period. Orphan drug exclusive marketing rights may also be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug. There is no guarantee that any of our other drug candidates will receive orphan drug designation or that, even if such drug candidate is granted such status, the drug candidate's clinical development and regulatory approval process will not be delayed or will be successful.

**Risks Related to Manufacturing Our Drug Candidates**

***We rely on third parties for manufacturing of our clinical drug supplies; our dependence on these manufacturers may impair the development of our drug candidates.***

We have no ability to internally manufacture the drug candidates that we need to conduct our clinical trials. For the foreseeable future, we expect to continue to rely on third-party manufacturers and other third parties to produce, package and store sufficient quantities of our drug candidates and any future drug candidates for use in our clinical trials. We have entered into agreements with our third-party manufacturer for the manufacture of our drug requirements, including an agreement for the manufacture of L-Grb-2 for use in our Phase II clinical trial, a development agreement for Bcl-2 and an agreement for the manufacture of Bcl-2 for use in our planned Phase I clinical trial. To date, we have made steady progress with our current third-party manufacturers, overcoming challenges associated with scaling up manufacturing to develop their capabilities to supply us with our necessary quantities of drug supplies for our clinical trials. However, we may face various risks and uncertainties in connection with our reliance on third-party manufacturers, including:

- reliance on third-party manufactures for regulatory compliance and quality assurance;

- the possibility of breach of the manufacturing agreement by the third-party manufacturer because of factors beyond our control;

- the possibility of termination or nonrenewal of our manufacturing agreement by the third-party manufacturer at a time that is costly or inconvenient for us;

- the potential that third-party manufacturers will develop know-how owned by such third-party manufacturer in connection with the production of our drug candidates that is necessary for the manufacture of our drug candidates; and

- reliance on third-party manufacturers to assist us in preventing inadvertent disclosure or theft of our proprietary knowledge.

Our drug candidates are complicated and expensive to manufacture. If our third-party manufacturers fail to deliver our drug candidates for clinical use on a timely basis, with sufficient quality, and at commercially reasonable prices, we may be required to delay or suspend clinical trials or otherwise discontinue development of our drug candidates. While we may be able to identify replacement third-party manufacturers or develop our own manufacturing capabilities for these drug candidates, this process would likely cause a delay in the availability of our drug candidates and an increase in costs. In addition, third-party manufacturers may have a limited number of facilities in which our drug candidates can be manufactured, and any interruption of the operation of those facilities due to events such as equipment malfunction or failure or damage to the facility by natural disasters could result in the cancellation of shipments, loss of product in the manufacturing process or a shortfall in available drug candidates.

We may in the future elect to manufacture certain of our drug candidates in our own manufacturing facilities. If we do so, we will require substantial additional funds and need to recruit qualified personnel in order to build or lease and operate any manufacturing facilities.

***There are underlying risks associated with the manufacture of our drug candidates, which have never been manufactured in large scale. Furthermore, we anticipate continued reliance on third-party manufacturers if we are successful in obtaining marketing approval from the FDA or other regulatory agencies for any of our drug candidates.***

To date, our drug candidates have been manufactured in relatively small quantities for preclinical testing and clinical trials by third-party manufacturers, and have never been manufactured in large scale. Additionally, as in the development of any new compound, there are underlying risks associated with their manufacture. These risks include, but are not limited to, cost, process scale-up, process reproducibility, construction of a suitable process plant, timely availability of raw materials, as well as regulatory issues associated with the manufacture of an active pharmaceutical agent. Any of these risks may prevent us from successfully developing our drug candidates. Our failure, or the failure

of our third-party manufacturers to achieve and maintain these high manufacturing standards, including the incidence of manufacturing errors and reliable product packaging for diverse environmental conditions, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could materially adversely affect our business and financial condition.

If the FDA or other regulatory agencies approve any of our drug candidates for commercial sale, we expect that we would continue to rely, at least initially, on third-party manufacturers to produce commercial quantities of such approved drug candidates. These manufacturers may not be able to successfully increase the manufacturing capacity for any of our approved drug candidates in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA or other regulatory authorities must review and approve. If our third-party manufacturers are unable to successfully increase the manufacturing capacity for a drug candidate, or we are unable to establish our own manufacturing capabilities, the commercial launch of any approved products may be delayed or there may be a shortage in supply.

***Identification of previously unknown problems with respect to a drug candidate, manufacturer or facility may result in restrictions on the drug candidate, manufacturer or facility.***

The FDA stringently applies regulatory standards for the manufacturing of our drug candidates. Identification of previously unknown problems with respect to a drug candidate, manufacturer or facility may result in restrictions on the drug candidate, manufacturer or facility, including warning letters, suspensions of regulatory approvals, operating restrictions, delays in obtaining new product approvals, withdrawal of the product from the market, product recalls, fines, injunctions and criminal prosecution. Any of the foregoing could have a material adverse effect on our business and financial condition.

***We may experience delays in the development of our drug candidates if the third-party manufacturers of our drug candidates cannot meet FDA requirements relating to current Good Manufacturing Practices.***

Our third-party manufacturers are required to produce our drug candidates under FDA cGMPs in order to meet acceptable standards for our preclinical testing and clinical trials. If such standards change, the ability of third-party manufacturers to produce our drug candidates on the schedule we require for our preclinical tests and clinical trials may be affected. In addition, third-party manufacturers may not perform their obligations under their agreements with us or may discontinue their business before the time required by us to gain approval for or commercialize our drug candidates. Any difficulties or delays in the manufacturing and supply of our drug candidates could increase our costs or cause us to lose revenue or postpone or cancel clinical trials.

The FDA also requires that we demonstrate structural and functional comparability between the same drug candidate produced by different third-party manufacturers. Because we may use multiple sources to manufacture our drug candidates, we may need to conduct comparability studies to assess whether manufacturing changes have affected the safety, identity, purity or potency of any drug candidate compared to the drug candidate produced by another manufacturer. If we are unable to demonstrate comparability, the FDA could require us to conduct additional clinical trials, which would be expensive and significantly delay commercialization of our drug candidates.

**Risks Related to Commercialization**

***If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our drug candidates, we may not generate product revenue***.

We have no commercial products, and we do not currently have an organization for the sales and marketing of pharmaceutical products. In order to successfully commercialize any drug candidates that may be approved in the future by the FDA or comparable foreign regulatory authorities, we must build our sales and marketing capabilities or make arrangements with third parties to perform these services. For certain drug candidates in selected indications where we believe that an approved product could be commercialized by a specialty sales force that calls on a limited but focused group of physicians, we may commercialize these products ourselves. However, in therapeutic indications that require a large sales force selling to a large and diverse prescribing population, we may enter into arrangements with other companies for commercialization. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable.

***If our future drugs do not achieve market acceptance, we may be unable to generate significant revenue, if any.***

Even if our drug candidates obtain regulatory approval, they may not gain market acceptance among physicians, health care payors, patients and the medical community. Factors that we believe could materially affect market acceptance of our drug candidates include:

- the timing of market introduction of competitive drugs;
- the demonstrated clinical safety and efficacy of our drug candidates compared to other drugs and other drug candidates;
- the suitability of our drug candidates to be co-administered or combined with other drugs or drug candidates;
- the durability of our drug candidates in their ability to prevent the emergence of drug-resistant viral mutants;
- the convenience and ease of administration of our drug candidates;
- the existence, prevalence and severity of adverse side effects;
- other potential advantages of alternative treatment methods;
- the effectiveness of marketing and distribution support;
- the cost-effectiveness of our drug candidates; and
- the availability of reimbursement from managed care plans, the government and other third-party payors.

If our approved drug candidates fail to achieve market acceptance, we would not be able to generate significant revenue. In addition, even if our approved drug candidates achieve market acceptance, we may not be able to maintain that market acceptance over time if:

- new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete;

- unforeseen complications arise with respect to the use of our products; or

- sufficient third-party insurance coverage or reimbursement does not remain available.

***If third-party payors do not adequately reimburse patients for any of our drug candidates that are approved for marketing, they might not be purchased or used, and our revenues and profits will not develop or increase.***

Our revenues and profits will depend significantly upon the availability of adequate reimbursement for the use of any approved drug candidates from governmental and other third-party payors, both in the United States and in foreign markets. Reimbursement by a third party may depend upon a number of factors, including the third-party payor's determination that use of an approved drug candidate is:

- a covered benefit under its health plan;

- safe, effective and medically necessary;

- appropriate for the specific patient;

- cost effective; and

- neither experimental nor investigational.

The regulations that govern marketing approvals, pricing and reimbursement for new therapeutic and diagnostic products vary widely from country to country. Some countries require approval of the sale price of a drug candidate before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a drug candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the approved drug and negatively impact the revenues we are able to generate from the sale of the approved drug in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more drug candidates, even if our drug candidates obtain regulatory approval.

Obtaining reimbursement approval for an approved drug from each third-party and government payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of any approved drug candidates to each payor. We may not be able to provide data sufficient to gain acceptance with respect to reimbursement. There also exists substantial uncertainty concerning third-party reimbursement for the use of any approved drug incorporating new technology, and even if determined eligible, coverage may be more limited than the purposes for which the drug is approved by the FDA. Moreover, eligibility for coverage does not imply that any approved drug will be reimbursed in all cases or at a rate that allows us to make a profit or even cover our costs. Interim payments for new products, if applicable, may also be insufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the approved drugs and the clinical setting in which it is used, may be based on payments allowed for lower-cost products or combinations of products that are already reimbursed, may be incorporated into existing payments for other products or services, and may reflect budgetary constraints and/or imperfections in Medicare or Medicaid data used to calculate these rates. Net prices for products may be reduced by mandatory discounts or rebates required by government health care programs or by any future relaxation of laws that restrict imports of certain medical products from countries where they may be sold at lower prices than in the United States.

In the United States, at both the federal and state levels, the government regularly proposes legislation to reform health care and its cost, and such proposals have received increasing political attention. In 2010, Congress passed legislation to reform the U.S. health care system by expanding health insurance coverage, reducing health care costs and making other changes. While health care reform may increase the number of patients who have insurance coverage for the use of any approved drug, it may also include changes that adversely affect reimbursement for approved drugs. In addition, there has been, and we expect that there will continue to be, federal and state proposals to constrain expenditures for medical products and services, which may affect payments for any of our drug candidates that obtain approval. The Centers for Medicare and Medicaid Services frequently change product descriptors, coverage policies, product and service codes, payment methodologies and reimbursement values. Third-party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates and may have sufficient market power to demand significant price reductions. As a result of actions by these third-party payors, the health care industry is experiencing a trend toward containing or reducing costs through various means, including lowering reimbursement rates, limiting therapeutic class coverage and negotiating reduced payment schedules with service providers for drug products.

Our inability to promptly obtain coverage and profitable reimbursement rates from government-funded and private payors for any of our drug candidates that obtain approval could have a material adverse effect on our business and financial condition.

**Risks Related to Intellectual Property**

***If our patent position does not adequately protect our drug candidates, others could compete against us more directly, which would harm our business.***

We have an exclusive license with MD Anderson to several issued patents and other certain technology rights. Our success depends in large part on our ability to obtain and maintain patent protection both in the United States and in other countries for our drug candidates. Our ability to protect our drug candidates from unauthorized or infringing use by third parties depends in substantial part on our ability to obtain and maintain valid and enforceable patents. Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and the scope of claims made under these patents, our ability to maintain, obtain and enforce patents is uncertain and involves complex legal and factual questions. Accordingly, rights under any issued patents may not provide us with sufficient protection for our drug candidates or provide sufficient protection to afford us a commercial advantage against competitive products or processes. We cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to us.

Even if patents have issued or will issue, we cannot guarantee that the claims of these patents are or will be valid or enforceable or will provide us with any significant protection against competitive products or otherwise be commercially valuable to us. Patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the United States Patent and Trademark Office (the “USPTO”) for the entire time prior to issuance as a United States patent. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Consequently, we cannot be certain that we or our licensors were the first to invent, or the first to file patent applications on, our drug candidates. The costs of these proceedings could be substantial and it is possible that our efforts would be unsuccessful, resulting in a loss of our United States patent position. Furthermore, we may not have identified all United States and foreign patents or published applications that affect our business either by blocking our ability to commercialize our drugs or by covering similar technologies that affect our drug market.

The claims of the issued patents that are licensed to us, and the claims of any patents which may issue in the future and be owned by or licensed to us, may not confer on us significant commercial protection against competing products. Additionally, our patents may be challenged by third parties, resulting in the patent being deemed invalid, unenforceable or narrowed in scope, or the third party may circumvent any such issued patents. Our patents might not contain claims that are sufficiently broad to prevent others from utilizing our technologies. Consequently, our competitors may independently develop competing products that do not infringe our patents or other intellectual

property. To the extent a competitor can develop similar products using a different molecule, our patents may not prevent others from directly competing with us.

The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as in the United States and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. If we encounter such difficulties in protecting or are otherwise precluded from effectively protecting our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed.

Because of the extensive time required for development, testing and regulatory review of a drug candidate, it is possible that, before any of our drug candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization of our drug candidates, thereby reducing any advantages of the patent. To the extent our drug candidates based on that technology are not commercialized significantly ahead of the date of any applicable patent, or to the extent we have no other patent protection on such drug candidates, those drug candidates would not be protected by patents, and we would then rely solely on other forms of exclusivity, such as regulatory exclusivity provided by the FDCA or trade secret protection.

The Leahy-Smith America Invents Act (the “America Invents Act”) was signed into law in September 2011, and many of the substantive changes became effective in March 2013. The America Invents Act reforms United States patent law in part by changing the standard for patent approval from a “first to invent” standard to a “first to file” standard and developing a post-grant review system. This legislation changes United States patent law in a way that may weaken our ability to obtain patent protection in the United States for those applications filed after March 2013.

***We license patent rights from MD Anderson. If MD Anderson or any third-party owners of intellectual property we may license in the future do not properly maintain or enforce the patents underlying such licenses, our competitive position and business prospects will be harmed.***

We are party to an exclusive license with MD Anderson that give us rights to intellectual property that is necessary or useful for our business. We may enter into additional licenses for third-party intellectual property in the future. Our success will depend in part on the ability of our licensors to obtain, maintain and enforce patent protection for their intellectual property, in particular, those patents to which we have secured exclusive rights. If applicable, our licensors may not successfully prosecute the patent applications to which we are licensed. Even if patents issue in respect of any such patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we would. In addition, our licensors may terminate their agreements with us in the event we breach the applicable license agreement and fail to cure the breach within a specified period of time. Without protection for the intellectual property we license, other companies might be able to offer substantially identical products for sale, which could materially adversely affect our competitive business position, business prospects and financial condition.

Because our research and development of drug candidates incorporates compounds and other information that is the intellectual property of third parties, we depend on continued access to such intellectual property to conduct and complete our preclinical and clinical research and commercialize the drug candidates that result from this research. Our license with MD Anderson imposes, and we expect that future licenses would impose, numerous obligations on us. For example, under our existing and future license agreements, we may be required to pay (i) annual maintenance fees until a drug candidate is sold for the first time, (ii) running royalties on net sales of drug candidates, (iii) minimum annual royalties after a drug candidate is sold for the first time, and (iv) one-time payments upon the achievement of specified milestones. We may also be required to reimburse patent costs incurred by the licensor, or we may be obligated to pay additional royalties, at specified rates, based on net sales of our drug candidates that incorporate the licensed intellectual property rights. We may also be obligated under some of these agreements to pay a percentage of any future sublicensing revenues that we may receive. Future license agreements may also include payment obligations such as milestone payments or minimum expenditures for research and development. In addition to our payment obligations under our license with MD Anderson, we are required to comply with reporting, insurance and indemnification requirements under the License Agreement. We expect that any future licenses would contain similar requirements.

If we fail to comply with these obligations or otherwise breach our license agreement with MD Anderson, the licensor may have the right to terminate the license in whole, terminate the exclusive nature of the license or bring a claim against us for damages. Any such termination or claim could prevent or impede our ability to market any approved drug candidate that is covered by the licensed intellectual property. Even if we contest any such termination or claim and are ultimately successful, our financial results and stock price could suffer. In addition, upon any termination of the License Agreement with MD Anderson, we may be required to grant to the licensor a license to any related intellectual property that we developed. For example, the licensors have the right to terminate our license of the intellectual property covered by its licenses to us under certain circumstances, including our failure to make payments to the licensor when due and our uncured breach of any other terms of the licenses. If access to such intellectual property is terminated, or becomes more expensive as a result of renegotiation of our existing license agreement with

MD Anderson, our ability to continue development of our drug candidates or the successful commercialization of our drug candidates could be severely compromised and our business could be adversely affected.

***If we infringe or are alleged to infringe intellectual property rights of third parties, our business could be harmed.***

Our research, development and commercialization activities, including any drug candidates resulting from these activities, may infringe or be claimed to infringe patents or other proprietary rights owned by third parties and to which we do not hold licenses or other rights. There may be applications that have been filed but not published that, if issued, could be asserted against us. If a patent infringement suit were brought against us, we could be forced to stop or delay research, development or manufacturing of drug candidate that is the subject of the suit. Further, if we are found to have infringed a third- party patent, we could be obligated to pay royalties and/or other payments to the third party related to our drug candidates, which may be substantial, or we could be enjoined from selling our drug candidates that obtain approval.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference proceedings declared by the USPTO and opposition proceedings in the European Patent Office, regarding intellectual property rights with respect to our drug candidates and technology. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our business and financial condition.

***Litigation regarding patents, intellectual property and other proprietary rights may be expensive and time consuming. If we are involved in such litigation, it could cause delays in bringing drug candidates to market and harm our ability to operate.***

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. Although we are not currently aware of any litigation or other proceedings or third-party claims of intellectual property infringement related to our drug candidates, the pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may obtain patents in the future and allege that the use of our technologies infringes these patent claims or that we are employing their proprietary technology without authorization. Likewise, third parties may challenge or infringe upon our existing or future patents. Under the License Agreement with MD Anderson we are responsible to enforce any patent exclusively licensed thereunder against substantial infringement by third parties. If we fail to enforce a substantial infringement, within a specified number of days, the licensor may bring an action against the infringing party on the licensor's and our behalf and retain all recoveries and/or reduce the license granted under the License Agreement to non-exclusive for the technology infringed. Proceedings involving our patents or patent applications or those of others could result in adverse decisions regarding:

- the patentability of our inventions relating to our drug candidates; and/or
- the enforceability, validity or scope of protection offered by our patents relating to our drug candidates.

Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may:

- incur substantial monetary damages;
- encounter significant delays in bringing our drug candidates to market; and/or
- be precluded from participating in the manufacture, use or sale of our drug candidates or methods of treatment requiring licenses.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

***Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information and may not adequately protect our intellectual property.***

We rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. In order to protect our proprietary technology and processes, we also rely in part on confidentiality and intellectual property assignment agreements with our corporate partners, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information nor result in the effective assignment to us of intellectual property, and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information or other breaches of the agreements. In addition, others may independently discover our trade secrets and proprietary information, and in such case we could not assert any trade secret rights against such party. Enforcing a claim that a party illegally obtained and is using our trade secrets is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. Costly and time-consuming litigation could be necessary to seek to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could materially adversely affect our business and financial condition.

Risks Related to Our Securities

***Raising additional capital may cause dilution to existing stockholders, restrict our operations or require us to relinquish rights. Additionally, sales of a substantial number of shares of our common stock or other securities in the public market could cause our stock price to fall***.

We may seek the additional capital necessary to fund our operations through public or private equity offerings, collaboration agreements, debt financings or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, existing stockholders' ownership interests will be diluted and the terms may include liquidation or other preferences that adversely affect their rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or drug candidates, or grant licenses on terms that are not favorable to us. In addition, sales of a substantial number of shares of our common stock or other securities in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

***The trading price of our common stock has been volatile and is likely to be volatile in the future.***

The trading price of our common stock has been highly volatile. On March 10, 2014, our common stock ceased trading on the OTCQX and commenced trading on the NASDAQ Capital Market, and there is a limited history on which to gauge the volatility of our stock price on the NASDAQ Capital Market. Since January 1, 2013 through February 27, 2015, our stock price has fluctuated from a low of $0.30 to a high of $5.25. The market price for our common stock will be affected by a number of factors, including:

- the denial or delay of regulatory approvals of our drug candidates or receipt of regulatory approval of competing products;
- our ability to accomplish clinical, regulatory and other drug development milestones;
- the ability of our drug candidates, if they receive regulatory approval, to achieve market success;
- the performance of third-party manufacturers and suppliers;

- developments with respect to patents and other intellectual property rights;
- sales of common stock or other securities by us or our stockholders in the future;
- additions or departures of key scientific or management personnel;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our drug candidates;
- trading volume of our common stock;
- investor perceptions about us and our industry;
- public reaction to our press releases, other public announcements and SEC and other filings;
- the failure of analysts to cover us, or changes in analysts' estimates or recommendations;
- the failure by us to meet analysts' projections or guidance;
- general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors; and
- the other factors described elsewhere in this "Item 1A. Risk Factors" or the section titled "Risk Factors" contained in our other public filings.

The stock prices of many companies in the biotechnology industry have experienced wide fluctuations that have often been unrelated to the operating performance of these companies. Following periods of volatility in the market price of a company's securities, securities class action litigation often has been initiated against a company. If any class action litigation is initiated against us, we may incur substantial costs and our management's attention may be diverted from our operations, which could materially adversely affect our business and financial condition.

***Our common stock is thinly traded and in the future, may continue to be thinly traded, and our stockholders may be unable to sell at or near asking prices or at all if they need to sell their shares to raise money or otherwise desire to liquidate such shares.***

To date, we have a low volume of daily trades in our common stock on the NASDAQ Capital Market. Our stockholders may be unable to sell their common stock at or near their asking prices or at all, which may result in substantial losses to our stockholders.

The market for our common stock may be characterized by significant price volatility when compared to seasoned issuers, and we expect that our share price will be more volatile than a seasoned issuer for the foreseeable future. As noted above, our common stock may be sporadically and/or thinly traded. As a consequence of this lack of liquidity, the trading of relatively small quantities of shares by our stockholders may disproportionately influence the price of those shares in either direction.

***Our certificate of incorporation grants our Board the power to designate and issue additional shares of common and/or preferred stock.***

Our authorized capital consists of 200,000,000 shares of common stock and 10,000,000 shares of preferred stock. Our preferred stock may be designated into series pursuant to authority granted by our certificate of incorporation, and on approval from our Board. The Board, without any action by our stockholders, may designate and issue shares in such classes or series as the Board deems appropriate and establish the rights, preferences and privileges of such shares, including dividends, liquidation and voting rights. The rights of holders of other classes or series of stock that may be issued could be superior to the rights of holders of our common shares. The designation and issuance of shares of capital stock having preferential rights could adversely affect other rights appurtenant to shares of our common stock.

***We do not anticipate paying cash dividends, and accordingly stockholders must rely on stock appreciation for any return on their investment in us.***

We anticipate that we will retain our earnings, if any, for future growth and therefore do not anticipate paying cash dividends in the future. As a result, only appreciation of the price of our common stock will provide a return to stockholders.

***Our management is required to devote substantial time and incur additional expense to comply with public company regulations. Our failure to comply with such regulations could subject us to public investigations, fines,***

***enforcement actions and other sanctions by regulatory agencies and authorities and, as a result, our stock price could decline in value.***

As a public reporting company, we are subject to the Sarbanes-Oxley Act of 2002, as well as to the information and reporting requirements of the SEC and other federal securities laws. We are also subject to the rules of the NASDAQ Stock Market. As a result, we incur significant legal, accounting, and other expenses that we would not incur as a private company, including costs associated with our public company reporting requirements and corporate governance requirements. Compliance with these public company obligations places significant additional demands on our limited number of finance and accounting staff and on our financial, accounting and information systems.

In particular, as a public company, our management is required to conduct an annual evaluation of our internal controls over financial reporting and include a report of management on our internal controls in our Annual Reports on Form 10-K. If we are unable to continue to conclude that we have effective internal controls over financial reporting or, if our independent auditors are unable to provide us with an attestation and an unqualified report as to the effectiveness of our internal controls over financial reporting, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the value of our common stock.

***Our common stock may be delisted from the NASDAQ Capital Market which could negatively impact the price of our common stock and our ability to access the capital markets.***

The listing standards of the NASDAQ Capital Market provide that a company, in order to qualify for continued listing, must maintain a minimum stock price of $1.00 and satisfy standards relative to minimum stockholders' equity, minimum market value of publicly held shares and various additional requirements. If we fail to comply with all listing standards applicable to issuers listed on the NASDAQ Capital Market, our common stock may be delisted. If our common stock is delisted, it could reduce the price of our common stock and the levels of liquidity available to our stockholders. In addition, the delisting of our common stock could materially adversely affect our access to the capital markets and any limitation on liquidity or reduction in the price of our common stock could materially adversely affect our ability to raise capital. Delisting from the NASDAQ Capital Market could also result in other negative consequences, including the potential loss of confidence by suppliers, customers and employees, the loss of institutional investor interest and fewer business development opportunities.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We currently lease approximately 3,002 square feet of office space for general and administrative purposes in Bellaire, Texas, which is part of the Houston metropolitan area, under a lease agreement that expires in 2019. We do not own or lease any other real property. We believe that our current facility is adequate for our current needs and that additional space will be available when and as needed.

ITEM 3. LEGAL PROCEEDINGS

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON STOCK AND RELATED SECURITY HOLDER MATTERS

Our common stock is listed on the NASDAQ Capital Market under the symbol "BPTH." Our common stock commenced trading on the NASDAQ Capital Market on March 10, 2014. Our common stock was previously quoted on the OTCQX under the symbol "BPTH." The following table sets forth the high and low sale prices per share for our common stock, as reported on the NASDAQ Capital Market or OTCQX, as applicable, for the periods indicated:

| | High | Low |
|---|---|---|
| Fiscal Year Ended December 31, 2013 | | |
| First Fiscal Quarter | $.60 | $.30 |
| Second Fiscal Quarter | $.60 | $.40 |
| Third Fiscal Quarter | $2.85 | $.42 |
| Fourth Fiscal Quarter | $4.10 | $1.55 |
| Fiscal Year Ended December 31, 2014 | | |
| First Fiscal Quarter | $5.25 | $2.51 |
| Second Fiscal Quarter | $3.62 | $2.26 |
| Third Fiscal Quarter | $3.02 | $1.90 |
| Fourth Fiscal Quarter | $3.02 | $1.95 |

Holders

As of February 27, 2015, there were 89,762,872 shares of our common stock outstanding and approximately 349 stockholders of record.

Dividends

We have not paid any cash dividends since our inception and do not anticipate or contemplate paying dividends in the foreseeable future.

Equity Compensation Plan Information

The following table contains information about our equity compensation plans as of December 31, 2014. There are no equity compensation plans that have not been approved by our stockholders.

| Plan Category | Number of shares of common stock to be issued upon exercise of outstanding options, warrants and rights (1) | Weighted-average exercise price of outstanding options, warrants and rights | Number of shares of common stock remaining available for future issuance under equity compensation plans (2) |
|---|---|---|---|
| Equity compensation plans approved by stockholders | 5,427,778 | $ 1.03 | 2,471,009 |
| Equity compensation plans not approved by stockholders | — | — | — |

(1) All of the shares shown in this column as securities to be issued upon exercise of outstanding options, warrants and rights were subject to outstanding stock option awards as of December 31, 2014.

(2) All of the shares shown in this column as remaining available for issuance as of December 31, 2014 are under our First Amended 2007 Stock Incentive Plan, as amended (the “2007 Stock Incentive Plan”).

**Performance Graph**

*The following performance graph and related information shall not be deemed to be "soliciting material" or to be "filed" with the SEC, nor shall such information be incorporated by reference into any future filing under the Securities Act, except to the extent that we specifically incorporate it by reference into such filing.*

The following performance graph compares the cumulative total return on our common stock during the last five fiscal years with the NASDAQ Composite Index (U.S.) and the NASDAQ Biotechnology Index during the same period. The graph shows the value at the end of each of the last five fiscal years, of $100 invested in our common stock. Pursuant to applicable SEC rules, all values assume reinvestment of the full amount of all dividends, however no dividends have been declared on our common stock to date. The stockholder return shown on the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.

Unregistered Sales of Equity Securities and Use of Proceeds

None.

**Purchases of Equity Securities by the Issuer and Affiliated Purchasers**

None.

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

*The statement of operations data for the years ended December 31, 2014, 2013 and 2012, and the balance sheet data as of December 31, 2014 and 2013, have been derived from our financial statements included elsewhere in this Annual Report on Form 10-K. The statement of operations data for the years ended December 31, 2011 and 2010, and the balance sheet data as of December 31, 2012, 2011 and 2010 have been derived from our financial statements not included in this Annual Report on Form 10-K. Our historical results are not necessarily indicative of results to be expected for any future period. The data presented below have been derived from financial statements that have been prepared in accordance with accounting principles generally accepted in the United States of America and should be read with our financial statements, including notes, and with "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Annual Report on Form 10-K.*

| Statements of Operations Data | 2014 | 2013 | 2012 | 2011 | 2010 |
|---|---|---|---|---|---|
| Revenues and Other Income: | | | | | |
| Interest income | $22,632 | $4,037 | $779 | $2,907 | $1,302 |
| Other income | — | — | — | — | 244,479 |
| Total revenues and other income | 22,632 | 4,037 | 779 | 2,907 | 245,781 |
| Expenses: | | | | | |
| Research and development | 1,630,439 | 1,518,885 | 1,132,712 | 596,802 | 1,158,438 |
| Research and development – related party | 196,661 | 115,705 | 463,870 | 544,000 | 41,000 |
| General and administrative | 2,715,146 | 1,634,650 | 986,097 | 1,224,813 | 1,126,991 |
| Other expense | 335 | 810 | 637 | 636 | 852 |
| Total expenses | 4,542,581 | 3,270,050 | 2,583,316 | 2,366,251 | 2,327,281 |
| Net loss | $(4,519,949) | $(3,266,013) | $(2,582,537) | $(2,363,344) | $(2,081,500) |
| Net loss per share – basic and diluted | $(0.05) | $(0.05) | $(0.04) | $(0.04) | $(0.04) |
| Basic and diluted weighted average number of common shares outstanding | 89,281,622 | 71,372,672 | 59,317,779 | 53,844,195 | 48,153,321 |
| Balance Sheet Data | | | | | |
| Cash, cash equivalents | $13,858,798 | $3,551,832 | $534,046 | $952,252 | $238,565 |
| Other current assets | 255,161 | 115,481 | 237,575 | 201,439 | 405,872 |
| Total assets | 15,477,978 | 5,078,831 | 2,343,764 | 3,231,105 | 3,108,504 |
| Total liabilities | 561,971 | 294,898 | 329,244 | 316,131 | 246,758 |
| Accumulated deficit | (19,917,245) | (15,397,296) | (12,131,283) | (9,548,746) | (7,185,402) |
| Total stockholders' equity | $14,916,007 | $4,783,933 | $2,014,520 | $2,914,974 | $2,861,746 |

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

*In addition to historical information, this Annual Report on Form 10-K contains forward-looking statements that involve significant risks and uncertainties, which may cause our actual results to differ materially from plans and results discussed in forward-looking statements. We encourage you to review the risks and uncertainties, discussed in "Item 1A. Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements," included elsewhere in this Annual Report on Form 10-K. The risks and uncertainties can cause actual results to differ significantly from those forecasted in forward-looking statements or implied in historical results and trends.*

*The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements and related notes included elsewhere in this Annual Report on Form 10-K.*

Overview

We are a biotechnology company with a lead cancer drug candidate, BP1001, currently in clinical trials. We were founded with technology from MD Anderson and are dedicated to developing novel cancer drugs under an exclusive license arrangement with MD Anderson. We were originally incorporated in May 2000 as a Utah corporation under the name of Ogden Golf Co. Corporation. We terminated our retail golf store operations in December 2006. On February 14, 2008, we acquired Bio-Path, Inc., a Utah corporation, in a reverse merger transaction (the "Merger"). In connection with the Merger, we changed our name to Bio-Path Holdings, Inc., acquired Bio-Path Subsidiary as a wholly-owned subsidiary and appointed the officers and directors of Bio-Path Subsidiary as officers and directors of Bio-Path Holdings, Inc. We also increased our authorized capital stock and adopted a stock incentive plan. The Merger and related matters are further described in a Current Report on Form 8-K filed with the SEC on February 19, 2008. Subsequent to the Merger, we changed our fiscal year end from June 30th to December 31st. On March 10, 2014, our common stock ceased trading on the OTCQX and commenced trading on the NASDAQ Capital Market under the ticker symbol "BPTH." We changed our state of incorporation from Utah to Delaware on December 31, 2014 through a statutory conversion pursuant to the Utah Revised Business Corporation Act and the Delaware General Corporation Law.

We were formed to finance and facilitate the development of novel cancer therapeutics. Our plan is to acquire licenses for drug technologies from MD Anderson and other leading medical research institutions, to fund clinical and other trials for such technologies and to commercialize such technologies. We currently maintain the License Agreement with MD Anderson. The License Agreement specifically provides drug delivery platform technology with composition of matter intellectual property that enables systemic delivery of antisense. We are currently developing only the liposomal antisense delivery technology and products. Our business plan is to act efficiently as an intermediary in the process of translating newly discovered drug technologies into authentic therapeutic drugs candidates. Our strategy is to selectively license potential drug candidates for certain cancers, and, primarily utilizing

the comprehensive drug development capabilities of MD Anderson, to advance these candidates into initial human efficacy trials (Phase IIa), and out-license and/or market each successful potential drug to a pharmaceutical company.

As of December 31, 2014, we had an accumulated deficit of approximately $19.92 million. Our net loss was approximately $4.52 million, $3.27 million, $2.58 million for the years ended December 31, 2014, 2013 and 2012, respectively. We expect to continue to incur significant operating losses and we anticipate that our losses may increase substantially as we expand our drug development programs and commercialization efforts. To achieve profitability, we must successfully develop and obtain regulatory approval for one or more of our drug candidates and effectively commercialize any drug candidates we develop. In addition, if we obtain regulatory approval of one or more of our drug candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. There can be no assurance that we will be able to raise additional capital when needed or on terms that are favorable to us, if at all. Even if we succeed in developing and commercializing one or more of our drug candidates, we may not be able to generate sufficient revenue and we may never be able to achieve or sustain profitability.

Financial Operations Overview

***Revenue***

To date, we have not generated any revenues. Our ability to generate revenues from our drug candidates, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our drug candidates.

***Research and development expenses***

Research and development expenses consist of costs associated with our research activities, including the development of our drug candidates. Our research and development expenses consist of:

- external research and development expenses incurred under arrangements with third parties, such as contract research organizations, clinical sites, manufacturing organizations and consultants;

- license fees, including maintenance fees and patent expense paid to MD Anderson in connection with the License Agreement; and

- costs of materials used during research and development activities.

Costs and expenses that can be clearly identified as research and development are charged to expense as incurred in accordance with generally accepted accounting policies ("GAAP"). Advance payments, including nonrefundable amounts, for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts will be recognized as an expense as the related goods are delivered or the related services are performed. If the goods will not be delivered, or services will not be rendered, then the capitalized advance payment is charged to expense.

We expect research and development expenses associated with the completion of the associated clinical trials to be substantial and to increase over time. The successful development of our drug candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete development of our drug candidates or the period, if any, in which material net cash inflows from our drug candidates may commence. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the rate of progress, results and costs of completion of ongoing clinical trials of our drug candidates;

- the size, scope, rate of progress, results and costs of completion of any potential future clinical trials and preclinical trials of our drug candidates that we may initiate;

- competing technological and market developments;

- the performance of third-party manufacturers and suppliers;

- the ability of our drug candidates, if they receive regulatory approval, to achieve market success;

- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our drug candidates.

A change in the outcome of any of these variables with respect to the development of a drug candidate could mean a significant change in the costs and timing associated with the development of that drug candidate. For example, if the FDA or other regulatory authority were to require us to conduct clinical trials beyond those which we currently anticipate will be required for the completion of clinical development of a drug candidate or if we experience significant delays in enrollment in any clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

***General and administrative expenses***

Our general and administrative expenses consist primarily of salaries and benefits for management and administrative personnel, professional fees for legal, accounting and other services, travel costs and facility-related costs such as rent, utilities and other general office expenses.

Results of Operations

***Comparisons of the Twelve Months Ended December 31, 2014 to the Twelve Months Ended December 31, 2013***

*Research and Development Expenses*. Our research and development expense was approximately $1.63 million for the twelve-month period ended December 31, 2014, an increase of approximately $0.1 million compared to the twelve-month period ended December 31, 2013. The increase in research and development expense was primarily due to approximate increases in manufacturing development and testing expense of $0.2 million and clinical trial expense of $0.1 million, offset to some extent by $0.2 million in lower drug material used in the clinical trial and other decreases in expense. Research and development – related party expense was approximately $0.2 million for the twelve-month period ended December 31, 2014, an increase of $0.1 million compared to the twelve-month period ended December 31, 2013. The increase in research and development – related party expense was primarily due to approximate increases of $0.1 million in clinical trial hospital expense and license patent maintenance fees.

*General and Administrative Expenses*. Our general and administrative expense was approximately $2.72 million for the twelve-month period ended December 31, 2014, an increase of approximately $1.1 million compared to the twelve-month period ended December 31, 2013. The increase in general and administrative expense was primarily due to approximate increases in compensation and healthcare expense of $0.9 million for our new organization put in place in 2014, $0.1 million in expense for legal and auditor services, $0.2 million associated with being a public company, and increases in other expenses totaling $0.2 million, offset to some degree by lower stock expense for personnel involved in administrative activities of $0.3 million.

*Net Loss*. Our net loss was approximately $4.5 million for the twelve-month period ended December 31, 2014, an increase of approximately $1.25 million compared the twelve-month period ended December 31, 2013. The increase in the net loss was primarily due to increased research and development expense of $0.1 million and general and administrative expense of $1.1 million primarily resulting from our new organization established to take advantage of opportunities to accelerate development of our technology. Net loss per share, both basic and diluted, was $0.05 per share for the twelve-month period ended Decembers 31, 2014 and for the twelve-month period ended December 31, 2013.

***Comparisons of the Twelve Months Ended December 31, 2013 to the Twelve Months Ended December 31, 2012***

*Research and Development Expenses*. Our research and development expense was approximately $1.52 million for the twelve-month period ended December 31, 2013, an increase of approximately $0.4 million compared to the twelve-month period ended December 31, 2012. The increase in research and development expense was primarily due to an approximate $0.3 million increase in expense for drug product material used in our clinical trial due to higher drug doses being administered to patients, and an approximate $0.1 million for new preclinical testing programs undertaken in 2013. Research and development – related party expense was approximately $0.1 million for the twelve-month period ended December 31, 2013, a decrease of approximately $0.3 million compared to the twelve-month period ended December 31, 2012. The decrease in research and development – related party expense was primarily due to a decrease in technology impairment expense for the twelve-month period ended December 31, 2013.

*General and Administrative Expenses*. Our general and administrative expense was approximately $1.63 million for the twelve-month period ended December 31, 2013, an increase of approximately $0.6 million compared to the twelve-month period ended December 31, 2012. The increase in general and administrative expense was primarily due to an increase in stock option expense for management, officers and directors totaling approximately $0.7 million, a non-cash expense that is based upon the Black Scholes fair value of the options grants. Excluding stock option expense, general and administrative expense for the twelve-month period ended December 31, 2013 was approximately $13,000 lower than the comparable period ended December 31, 2012.

*Net Loss*. Our net loss was approximately $3.27 million for the twelve-month period ended December 31, 2013, an increase of approximately $0.7 million compared to the twelve-month period ended December 31, 2012. The increase

in the net loss was primarily due to an increase in research and development and general and administrative expenses more than offsetting a decrease in research and development – related party expenses. Net loss per share, both basic and diluted, was $0.05 per share for the twelve-month period ended Decembers 31, 2013, an increase of approximately $.01 compared to the twelve-month period ended December 31, 2012.

Liquidity and Capital Resources

***Overview***

To date, we have not generated any revenues. Since our inception, we have funded our operations primarily through public and private offerings of our capital stock and other securities. We expect to finance our foreseeable cash requirements through cash on hand, cash from operations and public or private equity offerings. Additionally, we may seek collaborations and license arrangements for our drug candidates. We may seek to access the public or private equity markets whenever conditions are favorable. We currently have no lines of credit or other arranged access to debt financing.

We had a cash balance of approximately $13.86 million at December 31, 2014, an increase of approximately $10.31 million compared to December 31, 2013. The increase in the cash balance is primarily due to us selling an aggregate of 5.0 million shares of our common stock and warrants to purchase a total of 2.5 million shares of our common stock to an institutional investor for gross proceeds of approximately $15.0 million. We had a cash balance of approximately $3.55 million at December 31, 2013, an increase of approximately $3.02 million compared to December 31, 2012. We believe that our available cash at December 31, 2014 will be sufficient to fund our liquidity and capital expenditure requirements through the first quarter of 2016.

***Cash Flows***

*Comparisons of the Twelve Months Ended December 31, 2014 to the Twelve Months Ended December 31, 2013*

*Operating Activities*. Net cash used in operating activities was approximately $3.82 million for the twelve-month period ended December 31, 2014, an increase of approximately $1.51 million compared to the twelve-month period ended December 31, 2013. The increase in net cash used in operating activities is primarily due to an increase in cash operating loss of $1.5 million.

*Financing Activities*. Net cash provided by financing activities was approximately $14.25 million for the twelve-month period ended December 31, 2014, an increase of approximately $8.92 million compared to the twelve-month period ended December 31, 2013. The increase in net cash provided by financing activities is primarily due to us selling an aggregate of 5.0 million shares of our common stock and warrants to purchase a total of 2.5 million shares of our common stock to an institutional investor for gross proceeds of approximately $15.0 million.

*Comparisons of the Twelve Months Ended December 31, 2013 to the Twelve Months Ended December 31, 2012*

*Operating Activities*. Net cash used in operating activities was approximately $2.31 million for the twelve-month period ended December 31, 2013, an increase of approximately $0.3 million compared to the twelve-month period ended December 31, 2012. The increase in net cash used in operating activities is primarily due to an increase of $0.4 million in cash operating loss offset to some extent by reductions of $0.1 million in cash required for current assets net of current liabilities.

*Financing Activities*. Net cash provided by financing activities was approximately $5.33 million for the twelve-month period ended December 31, 2013, in an increase of approximately $3.73 million compared to the twelve-month period ended December 31, 2012. The increase in net cash provided by financing activities is primarily due to us selling shares of our common stock to accredited investors in private placements.

*2014 Shelf Registration and Registered Direct Offering*

On November 5, 2013, we filed a shelf registration statement on Form S-3 with the SEC, which was declared effective by the SEC on January 13, 2014. The shelf registration statement was filed to register the offering and sale of up to

$100 million of our common stock, preferred stock, warrants to purchase common stock or preferred stock or any combination thereof, either individually or in units. The foregoing does not constitute an offer to sell or the solicitation of an offer to buy securities, and shall not constitute an offer, solicitation or sale in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of that jurisdiction.

On January 15, 2014, we entered into a securities purchase agreement, as amended, with certain investors, pursuant to which we agreed to sell an aggregate of 5.0 million shares of our common stock and warrants to purchase a total of 2.5 million shares of our common stock to such certain investors for gross proceeds of approximately $15.0 million. The net proceeds to us from the registered direct public offering, after deducting the placement agent's fees and expenses, our estimated offering expenses, and excluding the proceeds to us from the exercise of the warrants issued in the offering, were approximately $13.8 million. The offering closed on January 21, 2014.

Future Capital Requirements

We expect to continue to incur significant operating expenses in connection with our ongoing activities, including conducting clinical trials, manufacturing and seeking regulatory approval of our drug candidates, Liposomal Grb-2 and Bcl-2. Accordingly, we will continue to require substantial additional capital to fund our projected operating requirements. Such additional capital may not be available when needed or on terms favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current and future operating plan. There can be no assurance that we will be able to continue to raise additional capital through the sale of our securities in the future. Our future capital requirements may change and will depend on numerous factors, which are discussed in detail in "Item 1A. Risk Factors" of this Annual Report on Form 10-K.

Off-Balance Sheet Arrangements

As of December 31, 2014, we did not have any material off-balance sheet arrangements.

Contractual Obligations and Commitments

The following table sets forth a summary of our commitments as of December 31, 2014:

| | Payment Due by Period | | | | |
|---|---|---|---|---|---|
| | **Total** | **Less Than 1 Year** | **2-3 Years** | **4-5 Years** | **More than 5 Years** |
| | | | **(in thousands)** | | |
| Operating Lease(1) | $382,000 | $79,000 | $ 165,000 | $138,000 | $ - |
| Technology License Maintenance Agreement | 350,000 | 50,000 | 200,000 | 100,000 | - |
| Total | $732,000 | $129,000 | $ 365,000 | $238,000 | $ - |

(1) In April 2014, we entered into a lease for a larger office space, which we occupied as of August 2014. The remaining lease payments due under this lease as of December 31, 2014 are approximately $382,000.

Critical Accounting Policies

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in conformity with GAAP in the United States. The preparation of such financial statements has required our management to make assumptions, estimates and judgments that affect the amounts reported in the financial statements, including the notes thereto, and related disclosures of commitments and contingencies, if any. We consider our critical accounting policies to be those that require the more significant judgments and estimates in the preparation of financial statements, including the following:

***Principles of Consolidation*** — The consolidated financial statements include our accounts and the accounts of our wholly-owned subsidiary, Bio-Path, Inc. All intercompany accounts and transactions have been eliminated in consolidation.

***Related Party —*** Based on its stock ownership in us, MD Anderson meets the criteria to be deemed a related party of us. For the years ending December 31, 2014 and 2013, MD Anderson related party research and development expense was approximately $197,000 and $116,000, respectively. MD Anderson related party research and development expense for the year ending December 31, 2014 included license expense of approximately $50,000 for the license annual maintenance fee and approximately $31,000 for license patent expenses not capitalized in the technology license other asset and clinical trial hospital expense of approximately $116,000. As of December 31, 2014, we had

approximately $67,000 in accrued research and development related expense for the clinical trial and approximately $100,000 in accrued license payments for past patent expenses and the annual license maintenance fee. See Notes 4, 5, and 6 to the financial statements included elsewhere in this Annual Report on Form 10-K. For the year ended December 31, 2013, we had approximately $116,000 in research and development related party expense, which consisted of clinical trial hospital expense of approximately $52,000 and license expense of approximately $63,700, including license maintenance fees of approximately $50,000 and approximately $13,700 in patent expenses not capitalized in the technology license other asset. For the year ended December 31, 2012, we had approximately $464,000 in research and development related party expense for the clinical trial, license maintenance fee and technology impairment; accounts payable related party of approximately $9,000 for patent expenses not capitalized in the technology license and accrued license payments payable related party of approximately $100,000 for the annual maintenance fee and past patent expenses, and approximately $26,000 accrued expense related party for clinical trial hospital expenses.

***Cash and Cash Equivalents —*** We consider all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents.

***Concentration of Credit Risk —*** Financial instruments that potentially subject us to a significant concentration of credit risk consist of cash. The Company maintains its cash balances with one major commercial bank, JPMorgan Chase Bank. The balances are insured by the Federal Deposit Insurance Corporation (the “FDIC”) up to $250,000. As a result, as of December 31, 2014, approximately $13.61 million of our cash balances was not covered by the FDIC. As of December 31, 2013 we had approximately $3.55 million in cash on-hand, of which approximately $3.3 million was not covered by the FDIC. As of December 31, 2012, we had approximately $534,000 in cash on-hand, of which approximately $284,000 was not covered by the FDIC.

***Furniture, fixtures and equipment —*** Furniture, fixtures and equipment are stated at cost and depreciated using the straight line method over the estimated useful lives of the assets. Depreciation expense was approximately $10,000, $0 and $0 for the years ended December 31, 2014, 2013 and 2012, respectively.

The estimated useful lives are as follows:

Furniture – 3 years

Fixtures – 3 years

Equipment – 3 years

Major additions and improvements are capitalized, while costs for minor replacements, maintenance, and repairs that do not increase the useful life of an asset are expensed as incurred.

***Long Lived Assets*** — Our long lived assets consist of furniture, fixtures and equipment, and a technology license. Long lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of the asset is measured by a comparison of the asset's carrying amount to the estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated undiscounted future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the asset.

***Intangible Assets/Impairment of Long-Lived Assets —*** As of December 31, 2014, other assets totaled approximately $1.25 million for our technology license, comprised of approximately $2.5 million in value acquiring our technology license and our intellectual property, less accumulated amortization of approximately $1.25 million. The technology value consists of approximately $836,200 in cash paid or accrued to be paid to MD Anderson, plus 3,138,889 shares of common stock granted to MD Anderson valued at approximately $2.35 million less approximately $690,000 for impairment expense taken in December of 2011 and June of 2012. This value is being amortized over a 15 year period from November 7, 2007, the date that the technology license became effective. We account for the impairment and disposition of our long-lived assets in accordance with GAAP. Long-lived assets are reviewed for events of changes in circumstances which indicate that their carrying value may not be recoverable. We estimate that approximately $160,000 will be amortized per year for each future year for the current value of the technology licenses acquired until approximately 2022. As of December 31, 2013 other assets totaled approximately $1.41 million, comprised of approximately $2.5 million in value acquiring our technology licenses and our intellectual property, less accumulated amortization of approximately $1.09 million. As of December 31, 2012 other assets totaled approximately $1.57 million, comprised of approximately $2.5 million in value acquiring our technology licenses and our intellectual property, less accumulated amortization of approximately $0.93 million.

***Research and Development Costs —*** Costs and expenses that can be clearly identified as research and development are charged to expense as incurred in accordance with GAAP. Advance payments, including nonrefundable amounts, for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts will be recognized as an expense as the related goods are delivered or the related services

are performed. If the goods will not be delivered, or services will not be rendered, then the capitalized advance payment is charged to expense. For the year 2014, we had approximately $1.63 million of costs classified as research and development expense and approximately $197,000 of related party research and development expense. Of the research and development expense totaling approximately $1.63 million, approximately $160,600 was for amortization of the technology license, approximately $83,100 was for stock options expense for individuals involved in research and development activities, approximately $729,000 was for drug material manufactured to be used in clinical trials, approximately $12,000 was for drug storage, approximately $194,000 was for clinical trial expense, approximately $90,300 was for advisory services, approximately $292,000 was for manufacturing development and drug product testing, approximately $40,500 was for preclinical studies and approximately $29,200 was for other research and development activities. Of the approximate $197,000 related party research and development expense, approximately $50,000 was comprised of technology license maintenance fees, approximately $31,000 was for patent expenses not capitalized in technology license-Other Assets and approximately $116,000 was comprised of clinical trial hospital costs. For the year 2013, we had approximately $1.52 million of costs classified as research and development expense and approximately $116,000 of related party research and development expense. For the year 2012, we had approximately $1.13 million of costs classified as research and development expense and approximately $464,000 of related party research and development expense.

***Stock-Based Compensation —*** We have accounted for stock-based compensation under the provisions of GAAP. The provisions require us to record an expense associated with the fair value of stock-based compensation. We currently use the Black-Scholes option valuation model to calculate stock based compensation at the date of grant. Option pricing models require the input of highly subjective assumptions, including the expected price volatility. Changes in these assumptions can materially affect the fair value estimate.

***Net Loss Per Share —*** Basic net loss per common share is computed by dividing net loss for the period by the weighted average number of common shares outstanding during the period. Although there were warrants and stock options outstanding during 2014, 2013 and 2012, no potential common shares shall be included in the computation of any diluted per-share amount when a loss from continuing operations exists. Consequently, diluted net loss per share as presented in the financial statements is equal to basic net loss per share for the years 2014, 2013 and 2012. The calculation of basic and diluted earnings per share for 2014 did not include 4,734,861 shares and 10,000 shares issuable pursuant to the exercise of vested common stock options and vested warrants, respectively, as of December 31, 2014 as the effect would be anti-dilutive. The calculation of basic and diluted earnings per share for 2013 did not include 4,848,298 shares and 10,000 shares issuable pursuant to the exercise of vested common stock options and vested warrants, respectively, as of December 31, 2013 as the effect would be anti-dilutive. The calculation of basic and diluted earnings per share for 2012 did not include 3,296,354 shares and 10,000 shares issuable pursuant to the exercise of vested common stock options and vested warrants, respectively, as of December 31, 2012 as the effect would be anti-dilutive.

***Comprehensive Income —*** Comprehensive income (loss) is defined as all changes in a company's net assets, except changes resulting from transactions with shareholders. At December 31, 2014, 2013 and 2012, we had no reportable differences between net loss and comprehensive loss.

***Use of Estimates —*** The preparation of consolidated financial statements in conformity with GAAP in the United States requires management to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes. On an ongoing basis, we evaluate our estimates and judgments, which are based on historical and anticipated results and trends and on various other assumptions that we believe to be reasonable under the circumstances. By their nature, estimates are subject to an inherent degree of uncertainty and, as such, actual results may differ from our estimates.

***Income Taxes —*** Deferred income tax assets and liabilities are determined based upon differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse.

***New Accounting Pronouncements*** — From time to time, new accounting pronouncements are issued by the Financial Standards Accounting Board ("FASB") that are adopted by us as of the specified effective date. If not discussed, management believes that the impact of recently issued standards, which are not yet effective or will not have a material impact on our consolidated financial statements upon adoption. Recently, FASB issued ASU 2014-10 to eliminate the concept of a development stage entity (a "DSE") from GAAP. This change rescinds certain financial reporting requirements that have historically applied to DSEs. The amendments are effective for annual reporting periods beginning after December 15, 2014 and interim periods therein. Early adoption is permitted for financial statements that have not yet been issued or made available for issuance. We elected to early adopt ASU 2014-10 as of September 30, 2014.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

***Interest Rate Risk***. We had cash and cash equivalents of approximately $13.86 million as of December 31, 2014. Although this cash account is subject to fluctuations in interest rates and market conditions, no significant gain or loss on this account is expected to be recognized in earnings. We do not invest in derivative securities.

***Capital Market Risk***. We currently have no product revenues and depend on funds raised through other sources. One source of funding is through future debt or equity offerings. Our ability to raise funds in this manner depends upon capital market forces affecting our stock price.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMETARY DATA

Our consolidated financial statements, together with the report of our independent registered public accounting firm, are set forth beginning on page F-1 of this Annual Report on Form 10-K. In the calendar year 2008, our fiscal year end was changed from June 30th to December 31st.

ITEM 9. CHANGES AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

It is management's responsibility to establish and maintain adequate internal control over all financial reporting pursuant to Rule 13a-15 under the Exchange Act. Our management, including our Chief Executive Officer and our Chief Financial Officer, have reviewed and evaluated the effectiveness of our disclosure controls and procedures, as defined in Section 240.13a-15(e) or Section 240.15d-15(e) of the Exchange Act, as of the end of the period covered by this Annual Report on Form 10-K. Following this review and evaluation, management collectively determined that our disclosure controls and procedures are effective and that they ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act (i) is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and (ii) is accumulated and communicated to management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting, as defined in Exchange Act Rule 13a-15(f), is a process designed by, or under the supervision of, our principal executive officer and our principal financial officer, and effected by our Board, management, and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and disposition of our assets;

- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and

- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Management's assessment of the effectiveness of our internal controls is based principally on our financial reporting as of December 31, 2014. In making our assessment of internal control over financial reporting, management used the criteria set forth in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Our management, with the participation of our Chief Executive Officer (who is also our acting Chief Financial Officer), has evaluated the effectiveness of our internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, as of December 31, 2014. Based on this evaluation, management believes that, as of December 31, 2014, our internal control over financial reporting was effective.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. 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. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. The scope of management's assessment of the effectiveness of internal control over financial reporting includes our consolidated subsidiary.

The effectiveness of our internal control over financial reporting as of December 31, 2014 has been audited by Mantyla McReynolds LLC, an independent registered public accounting firm, as stated in their report which is included elsewhere in this Annual Report on Form 10-K.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the period covered by this Annual Report on Form 10-K that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Identification of Directors and Executive Officers

Our current directors and officers are set forth below:

| Name | Age | Position - Committee |
|---|---|---|
| Peter H. Nielsen | 66 | Chief Executive Officer; President; Chief Financial Officer; Treasurer; Chairman of the Board; Director |
| Ulrich W. Mueller, Ph.D. | 48 | Chief Operating Officer; Secretary |
| Michael J. Garrison | 45 | Director – Audit Committee; Compensation Committee; Nominating/Corporate Governance Committee |
| Amy P. Sing, M.D. | 57 | Director – Audit Committee; Compensation Committee; Nominating/Corporate Governance Committee |
| Heath W. Cleaver, CPA | 41 | Director – Audit Committee; Compensation Committee; Nominating/Corporate Governance Committee |
| Douglas P. Morris | 59 | Director |

Our current directors will serve until the next annual meeting of stockholders or until their successors are elected or appointed and qualified.

Background Information

***Peter H. Nielsen***. Mr. Nielsen is a co-founder of Bio-Path, serving as its Chief Executive Officer, President and Chief Financial Officer/Treasurer and Chairman of the Board since 2008. Mr. Nielsen has developed a close working relationship over the last six years with key individuals at The University of Texas MD Anderson Cancer Center and

its suppliers. Mr. Nielsen has a broad management background in senior management, leading turnarounds of several large companies. He also has experience in finance, product development, cost and investment analysis, manufacturing and planning. He has also worked with several other biotech companies developing and executing on strategies for growth and previously served as a director of Synthecon, Inc., a manufacturer of 3D bioreactors. Prior to joining Bio-Path, Mr. Nielsen served as Chief Financial Officer of Omni Energy Services Corp., a NASDAQ traded energy services company. Mr. Nielsen was a Lieutenant in the U.S. Naval Nuclear Power program where he was Director of the Physics Department and was employed at Ford Motor Company in product development. He holds engineering and M.B.A. finance degrees from the University of California-Berkeley.

***Ulrich W. Mueller, Ph.D.*** Dr. Mueller has served as Bio-Path's Chief Operating Officer and Secretary since March 2014. Between 2007 and 2014, Dr. Mueller most recently served as Vice President, Industry Relations and Clinical Research Support, of Fred Hutchinson Cancer Research Center, a leading research center for cancer and other life-threatening diseases. At Fred Hutchinson Cancer Research Center Dr. Mueller managed various administrative departments. Between 2000 and 2007, Dr. Mueller served in various capacities at MD Anderson, including as Managing Director, Director of Licensing, and Assistant Director of Business Development. Dr. Mueller holds a Ph.D. in Cell and Molecular Biology from Baylor College of Medicine, a Master's degree in Biology from Texas A&M University, and a Bachelor of Science in Microbiology from New Mexico State University.

***Douglas P. Morris***. Mr. Morris is a co-founder of Bio-Path and has served as a director of Bio-Path since 2007 and served as an officer from 2007 to June 2014. Mr. Morris currently serves as a co-founder, Managing Member, and Secretary of nCAP Holdings, LLC (nCAP), a privately held technology based company. Between 1993 and 2010, Mr. Morris was an officer and director of Celtic Investment, Inc., a financial services company. Since 1990, Mr. Morris owns and operates Hyacinth Resources, LLC ("Hyacinth"), a business-consulting firm and is also a Managing Member of Sycamore Ventures, LLC, a privately held consulting firm. Mr. Morris has a B.A. from Brigham Young University, and attended the University of Southern California Masters program in public administration.

***Amy P. Sing, M.D.*** Dr. Sing has served as a director of Bio-Path since November 2014. She also currently serves as Senior Director of Medical Affairs at Genomic Health, Inc., a leading publicly held biotechnology company that assists physicians and patients in making personalized cancer treatment decisions. From 2004 to 2006, Dr. Sing led oversight of the approved breast cancer drug Avastin Investigator Sponsored Trials (IST) program at Genentech, Inc., a public biotechnology firm providing major contributions to the understanding and development of cancer research. From 2004 to 2011, Dr. Sing worked in various other leadership and research positions at Genentech, Inc. Dr. Sing also led research teams for Seattle Genetics, Inc. from 1999 to 2003 and has received awards from the National Cancer Institute, American Cancer Society and Stanford University. Dr. Sing holds a B.A. from Amherst College and an M.D. from Stanford University.

***Michael J. Garrison***. Mr. Garrison has served as a director of Bio-Path since 2012. Mr. Garrison is a principal and President of Body Sculpt International, LLC, which operates plastic surgery clinics under the trade name Sono Bello. Prior to founding Body Sculpt International, LLC, Mr. Garrison spent 10 years in a variety of executive roles with Dell, Inc. His most recent role at Dell was Director of Marketing, Americas Small and Medium Business. Prior to joining Dell, Inc., Mr. Garrison held general management and corporate development positions with ITT Industries, a leading industrial manufacturer. Mr. Garrison holds a Master's degree in Business Administration from Harvard Business School and a Bachelor of Science in Mechanical Engineering from Purdue University.

***Heath W. Cleaver, CPA.*** Mr. Cleaver has served as a director of Bio-Path since February 2014. Mr. Cleaver currently serves as the Chief Financial Officer of Global Fabrication Services, Inc., a US based steel and flame cutting company. From October 2014 to December 2014, Mr. Cleaver served as Chief Financial Officer at Tarka Resources, Inc. From February 2011 until May 2014, Mr. Cleaver served as Chief Financial Officer of Porto Energy Corp. From August 2010 until February 2011, Mr. Cleaver served as Chief Accounting Officer of Porto Energy Corp. Mr. Cleaver served as Corporate Controller and then as Vice President and Chief Accounting Officer for BPZ Energy from October 2006 to mid-2010. Beginning in November 1997 through August 2004, Mr. Cleaver served in various accounting roles, including Financial Controller, at Horizon Offshore Contractors, Inc. Mr. Cleaver is a Certified Public Accountant in the state of Texas and holds a Bachelor's Degree in Business Administration - Accounting from Texas A&M University.

Board of Directors

Our operations are managed under the broad supervision of the Board, which has ultimate responsibility for the establishment and implementation of our general operating philosophy, objectives, goals and policies. Our Board is currently comprised of three independent directors and two non-independent directors. The Board has determined that current directors Michael J. Garrison, Heath W. Cleaver and Amy P. Sing, M.D. are "independent" as independence is defined under the listing standards for the NASDAQ Stock Market. The Board based these determinations primarily on a review of the responses our directors provided to questions regarding employment and compensation history, affiliations and family and other relationships.

**Codes of Ethics**

We have adopted the Employee Code of Business Conduct and Ethics, which applies to all of our employees, including our executive officers, and the Code of Business Conduct and Ethics for Members of the Board, which applies to members of the Board.

Board Committees

The Board has a standing audit committee (the "Audit Committee"), compensation committee (the "Compensation Committee") and nominating/corporate governance committee (the "Nominating/Corporate Governance Committee"). The Board may also establish other committees from time to time as necessary to facilitate the management of the business and affairs of the Company. The information below summarizes the functions of each of the committees in accordance with their charters.

***Audit Committee***

The Audit Committee has been structured to comply with the requirements of Section 3(a)(58)(A) of the Exchange Act. The Board has determined that the Audit Committee members have the appropriate level of financial understanding and industry specific knowledge to be able to perform the duties of the position and are financially literate and have the requisite financial sophistication as required by the applicable listing standards of the NASDAQ Stock Market.

The Audit Committee, as permitted by, and in accordance with, its charter, is responsible to periodically assess the adequacy of procedures for the public disclosure of financial information and review on behalf of the Board, and report to the Board, the results of its review and its recommendation regarding all material matters of a financial reporting and audit nature, including, but not limited to, the following main subject areas:

- financial statement, including management's discussion and analysis thereof;
- financial information in any annual information form, proxy statement, prospectus or other offering document, material change report, or business acquisition report;
- press releases regarding annual and interim financial results or containing earnings guidance;
- internal controls;
- audits and reviews our financial statements; and
- filings with securities regulators containing financial information, including our Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q.

The Audit Committee is responsible to appoint and set the compensation for the independent registered public accounting firm annually and to review and evaluate such external auditor. This external auditor reports directly to the Audit Committee. The Audit Committee is responsible to establish our hiring policies regarding current and former partners and employees of the external auditor. In addition, the Audit Committee is responsible to pre-approve all audit and non-audit services undertaken by the external auditor.

The Audit Committee has direct responsibility for overseeing the work of the external auditor engaged for the purpose of preparing or issuing an auditor's report or performing other audit, review or attest services, including the resolution of disagreements between the external auditor and management.

The Audit Committee meets at least once per fiscal quarter to fulfill its responsibilities under its charter and in connection with the review of the Company's quarterly and annual financial statements. The Audit Committee was established on February 11, 2014. The Audit Committee is comprised of Messrs. Garrison and Cleaver and Dr. Sing. Mr. Cleaver is the chair of the Audit Committee. The Board has determined that Mr. Cleaver qualifies as an "audit committee financial expert" under the Exchange Act and that each member of the Audit Committee is an independent director.

***Compensation Committee***

The Compensation Committee's role is to assist the Board in fulfilling its responsibilities relating to matters of human resources and compensation, including equity compensation, and to establish a plan of continuity and development for our senior management. The Compensation Committee operates under a written charter adopted by the Board. The Compensation Committee periodically assesses compensation of our executive officers in relation to companies of comparable size, industry and complexity, taking the performance of the Company and such other companies into consideration. All decisions with respect to the compensation of our Chief Executive Officer are determined and approved either solely by the Compensation Committee or together with other independent directors, as directed by the Board. All decisions with respect to non-CEO executive compensation, and incentive-compensation and equity based plans are first approved by the Compensation Committee and then submitted, together with the Compensation Committee's recommendation, to the members of the Board for final approval. In addition, the Compensation Committee will, as appropriate, review and approve public or regulatory disclosure respecting compensation, including the Compensation Disclosure and Analysis, and the basis on which performance is measured. The Compensation Committee has the authority to retain and compensate any outside adviser as it determines necessary to permit it to carry out its duties. The Compensation Committee has not to date engaged the services of any executive compensation consultant. The Compensation Committee may not form or delegate authority to subcommittees without the prior approval of the Board.

The Compensation Committee is comprised of Messrs. Garrison and Cleaver and Dr. Sing, all of whom are independent under the rules of the NASDAQ Stock Market. The Compensation Committee meets as necessary. Mr. Garrison is the chair of the Compensation Committee.

***Nominating/Corporate Governance Committee***

The Nominating/Corporate Governance Committee's charter provides that the responsibilities of such committee include:

- evaluating, identifying and recommending nominees to the Board;

- considering written recommendations from our stockholders for nominees to the Board;
- recommending directors to serve as committee members and chairs;
- reviewing and developing corporate governance guidelines, policies and procedures for the Board;
- reviewing disclosure by us of matters within the Nominating/Corporate Governance Committee's mandate; and
- reviewing and evaluating the Nominating/Corporate Governance Committee's charter and efficacy.

The Nominating/Corporate Governance Committee is responsible for, among other things, identifying and recommending potential candidates for nomination to the Board. The Nominating/Corporate Governance Committee receives advice from the Board and will consider written recommendations from the stockholders of the Company respecting individuals best suited to serve as directors, and, when necessary, develops its own list of appropriate candidates for directorships.

The Nominating/Corporate Governance Committee is comprised of Messrs. Garrison and Cleaver and Dr. Sing, all of whom are independent under the rules of the NASDAQ Stock Market. The Nominating/Corporate Governance Committee was established on February 11, 2014. The Nominating/Corporate Governance Committee meets at least annually, and otherwise as necessary. Mr. Garrison is the chair of the Nominating/Corporate Governance Committee.

**Availability of Committee Charters and Other Information**

The charters for our Audit Committee, Compensation Committee, and Nominating/Corporate Governance Committee, as well as our Corporate Governance Guidelines, Employee Code of Business Conduct and Ethics and Code of Business Conduct and Ethics for Members of the Board, are available under the section titled "Corporate Governance" on the Investor/Media page of the Company's website, *www.biopathholdings.com*. We intend to disclose any changes to or waivers from the Employee Code of Business Conduct and Ethics that would otherwise be required to be disclosed under Item 5.05 of Form 8-K on our website. The information on our website is not, and shall not be deemed to be, a part of this Annual Report on Form 10-K or incorporated into any other filings we make with the SEC.

We also make available on our website, free of charge, access to our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments to those reports, as well as other documents that we file with or furnish to the SEC pursuant to Sections 13(a) or 15(d) of the Exchange Act, as soon as

reasonably practicable after such documents are filed with, or furnished to, the SEC.

**Nomination Process**

It is our Board's responsibility to nominate members for election to the Board and to fill vacancies on the Board that may occur between annual meetings of stockholders. The Nominating/Corporate Governance Committee assists the Board by identifying and reviewing potential candidates for Board membership consistent with criteria approved by the Board. The Nominating/Corporate Governance Committee also annually recommends qualified candidates (which may include existing directors) for approval by the Board of a slate of nominees to be proposed for election to the Board at the annual meeting of stockholders.

In the event of a vacancy on the Board between annual meetings of our stockholders, the Board may request that the Nominating/Corporate Governance Committee identify, review and recommend qualified candidates for Board membership for Board consideration to fill such vacancies, if the Board determines that such vacancies will be filled. Our Bylaws allow for up to fifteen directors. The Board is permitted by the Bylaws to change the number of directors by a resolution adopted by the Board. In February 2014, the size of the Board was increased from four to five members and Mr. Cleaver was appointed to fill the vacancy. In addition, Ms. Gillian Ivers-Read resigned as a member of the Board effective October 28, 2014 and Dr. Sing was appointed as a member of the Board to fill the vacancy created by Ms. Ivers-Read's resignation. Both Mr. Cleaver and Dr. Sing, along with the other members of our Board, were subsequently elected to the Board at the Company's 2014 annual meeting of stockholders held on December 30, 2014.

When formulating its recommendations for potential Board nominees, the Nominating/Corporate Governance Committee seeks and considers advice and recommendations from management, other members of the Board and may seek or consider advice and recommendations from consultants, outside counsel, accountants, or other advisors as the Nominating/Corporate Governance committee or the Board may deem appropriate.

Board membership criteria are determined by the Board, with input from the Nominating/Corporate Governance Committee. The Board is responsible for periodically determining the appropriate skills, perspectives, experiences, and characteristics required of Board candidates, taking into account our needs and current make-up of the Board. This assessment should include appropriate knowledge, experience, and skills in areas deemed critical to understanding the Company and our business; personal characteristics, such as integrity and judgment; and the candidate's commitments to the boards of other companies. Each Board member is expected to ensure that other existing and planned future commitments do not materially interfere with the member's service as a director and that he or she devotes the time necessary to discharge his or her duties as a director.

**Nominations for Directors**

The Nominating/Corporate Governance Committee will consider candidates for director nominees that are recommended by our stockholders in the same manner as Board recommended nominees, in accordance with the procedures set forth in our Bylaws. Any such nominations should be submitted to the Nominating/Corporate Governance Committee c/o Secretary, Bio-Path Holdings, Inc., 4710 Bellaire Boulevard, Suite 201, Bellaire, Texas 77401 before the deadline set forth in the Bylaws and should be accompanied by the following information:

- appropriate biographical information, a statement as to the qualifications of the nominee and any other information relating to such nominee that is required to be disclosed pursuant to Regulation 14A under the Exchange Act (including such person's written consent to being named in the proxy statement as a nominee and to serving as a director if elected); and
- the Proposing Stockholder Information (as defined in the Bylaws).

**Key Consultants**

***Bradley G. Somer, MD.*** Dr. Somer is employed by ACORN CRO, a full service, oncology-focused CRO. Under our agreement with ACORN CRO, Dr. Somer serves as our Medical Officer and medical liaison for the conduct of our Phase I clinical study of liposomal BP1001 in refractory or relapsed acute myeloid leukemia, chronic myelogenous leukemia, acute lymphoblastic leukemia and myelodysplastic syndrome.

***Kevin Rando, MBA.*** Mr. Rando serves as monitor and CRO for our clinical trial. Mr. Rando has nearly twenty years' experience in the pharmaceutical industry as a clinical research professional in clinical trial operations and as a monitor of clinical trials. He has experience in clinical research associate staffing, management, & training and protocol site management in pharmacy audit. Mr. Rando also performs protocol and CRF design/review and database review.

***Thomas A. Walker, Ph.D***. Dr. Walker serves as our Chemistry, Manufacturing and Controls CMC Development Specialist. Dr. Walker has more than twenty years of broad analytical chemistry experience in the pharmaceutical industry. His experience in drug development includes preparation of regulatory filings for pharmaceutical drug products and experience managing preformulation, analytical methods development/validation and drug delivery departments.

***Alan MacKenzie, Ph.D.*** Dr. MacKenzie serves as a manufacturing process consultant to us. Dr. MacKenzie is a leading lyophilization expert with a particular emphasis on developing lyophilization processes for solvents based products. Dr. MacKenzie has been a Professor at the University of Washington.

***Ana Tari, Ph.D.*** Dr. Tari serves as our Director of Preclinical Operations and Research. Dr. Tari is the lead researcher who has developed our lead cancer drug, BP1001. Dr. Tari is also an Associate Professor at the University of Florida at Gainesville. Previously, Dr. Tari was an Associate Professor at MD Anderson.

Involvement in Certain Legal Proceedings

There have been no events under any bankruptcy act, no criminal proceedings and any judgments or injunctions material to the evaluation of the ability and integrity of any director or executive officer during the last five years.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors and officers, and persons who own more than 10% of our common stock, to file initial reports of ownership and reports of changes in ownership (Forms 3, 4, and 5) of common stock with the SEC. Officers, directors and greater than 10% stockholders are required by SEC regulation to furnish us with copies of all such forms that they file.

To our knowledge, based solely on our review of the copies of such reports received by us and on written representations by certain reporting persons that no reports on Form 5 were required, we believe that during the fiscal year ended December 31, 2014, all Section 16(a) filing requirements applicable to our officers, directors and 10% stockholders were complied with in a timely manner.

ITEM 11. EXECUTIVE COMPENSATION

**Compensation Discussion and Analysis**

The Compensation Committee oversees our compensation programs for executives and all employees. The Compensation Committee understands that for the Company and its stockholders to achieve long-term success, the compensation programs need to attract, retain, develop and motivate a strong leadership team. As a result, our executive compensation programs are designed to pay for performance, enable talent attraction, retain top talent and closely align the interests of our executives with those of our stockholders. All decisions with respect to the compensation of our Chief Executive Officer are determined and approved either solely by the Compensation Committee or together with other independent directors, as directed by the Board. All decisions with respect to non-CEO executive compensation, and incentive-compensation and equity based plans are first approved by the Compensation Committee and then submitted, together with the Compensation Committee's recommendation, to the members of the Board for final approval.

This Compensation Discussion and Analysis provides important information on our executive compensation programs and explains the compensation decisions made during 2014 by the Compensation Committee for our named executive officers ("NEOs"). In fiscal year 2014, we had the following NEOs:

- Peter H. Nielsen, Chairman of the Board, Chief Executive Officer and President;
- Ulrich W. Mueller, Chief Operating Officer and Secretary (Mr. Mueller began serving in such capacities in March 2014); and
- Douglas P. Morris, Director and Vice President of Corporate Development (Mr. Morris ceased serving in such officer capacity in June 2014).

***Compensation Philosophy***

Our primary objective with respect to executive compensation is to design a reward system that will align executive compensation with our overall business strategies and attract and retain highly qualified executives. We intend to stay competitive in the marketplace with companies of comparable size, industry and complexity. Our compensation philosophy for executives is guided by the following principles:

- Goal-Oriented Pay for Performance. In making compensation decisions, we consider annual and long-term Company performance and assess compensation of our executive officers in relation to companies of comparable size, industry and complexity, taking the performance of the Company and such other companies into consideration at the individual and corporate levels.

- Reviewed Annually. The Compensation Committee annually reviews compensation levels to ensure we remain competitive and continues to attract, retain and motivate top-tier talent.

- Alignment with Stockholder Interests. Our compensation is intended to closely align the interests of our NEOs with those of our stockholders in an effort to create long-term stockholder value. In developing our compensation philosophy, the Compensation Committee has considered the most recent stockholder advisory vote on executive compensation in which an overwhelmingly positive percentage of the votes cast were in favor of our executive compensation. The Compensation Committee is continuously mindful of stockholders' views on executive compensation and remains focused on ensuring proper alignment with stockholder interests.

Our compensation philosophy rewards demonstrated performance and encourages behavior that is in the long-term best interests of the Company and its stockholders.

***Elements and Mix of our 2014 Compensation Program***

The following elements made up the fiscal year 2014 compensation program for our NEOs:

| Element | Form of Compensation | Purpose, Basis and Performance Criteria |
|---|---|---|
| Base Salary | Cash | Ÿ Base salary is intended to provide a market competitive level of fixed compensation in recognition of responsibilities, skills, capabilities, experience and leadership.<br><br>Ÿ Base salary is not generally performance based, but reflective of competencies and experience. |
| Annual Performance Incentive Awards (considered "at-risk" compensation) | Cash | Ÿ Annual cash performance incentive awards are intended to motivate and reward performance achievement.<br><br>Ÿ Payments are discretionary and approved annually by the Compensation Committee. |
| Long-Term Incentive Awards (considered "at-risk" compensation) | Stock Options | Ÿ Long-term incentive awards are intended to recognize and reward the achievement of long-term corporate goals and objectives, recognize promotions, motivate retention of our leadership talent and align executives' interests with our stockholders.<br><br>Ÿ The Compensation Committee determines the amount of long-term incentive awards to be granted to each executive officer. The Compensation Committee also may make isolated awards to recognize promotions, new hires or individual performance achievements.<br><br>Ÿ In 2014, the long-term incentive awards included time-vested equity awards that vest over a four-year period.<br><br>Ÿ The Compensation Committee provides time-vested long-term incentives (i) to build a consistent ownership stake and retention incentive, (ii) to create a meaningful tie to the Company's relative long-term stockholder returns and (iii) to motivate consistent improvement over a longer-term horizon. |
| Change of Control Severance | Eligible to receive severance payments and post-termination health benefits in connection with involuntary termination | Ÿ Employment agreements are intended to provide financial security and an industry-competitive compensation package for NEOs. This additional security helps ensure that officers remain focused on our performance and the continued creation |

| | |
|---|---|
| within three months before or twelve months after a change of control | of stockholder value throughout any change of control transaction rather than on the potential uncertainties associated with their own employment. Currently, our only NEO with whom we have entered into an employment agreement is Mr. Nielsen. |

***Evaluation Process, Compensation Consultant, Peer Comparisons and Officers***

*Evaluation Process*. The Compensation Committee oversees the administration of the compensation programs applicable to our employees, including our NEOs. The Compensation Committee generally makes its decisions regarding the annual compensation of our NEOs at its regularly-scheduled meeting in the first quarter of each year. These decisions include adjustments to base salary, grants of annual incentive awards and grants of long-term incentive awards. The Compensation Committee also makes compensation adjustments as necessary at other times during the year, such as in the case of promotions, changes in employment status and for competitive purposes.

Each year for the Compensation Committee meeting, our CEO prepares an evaluation of each of the other executive officers and makes compensation recommendations to the Compensation Committee based upon our performance against our corporate performance metrics and the individual's performance against his or her goals. In addition to considering the CEO's recommendations, the Compensation Committee assesses the applicable executive officer's impact during the year and his or her overall value to the Company, specifically by considering the individual leadership skills, impact on strategic initiatives, performance in his or her primary area of responsibility, his or her role in succession planning and development, and other intangible qualities that contribute to corporate and individual success.

*Compensation Consultant and Peer Comparisons.* For the 2014 performance period, the Compensation Committee did not engage an external consultant to review the compensation of our executive officers. The Compensation Committee relied upon peer executive compensation data from proxies and compensation surveys of the Industry Peer Group (as defined below) for comparison purposes. Based on these comparisons, the Compensation Committee targeted base salary compensation for our NEOs at below the twenty-fifth ($25^{th}$) percentile of salaries for executives in our Industry Peer Group.

The Compensation Committee reviewed executive compensation data from the Industry Peer Group to benchmark competitive pay levels and compensation practices. In identifying companies to include in the Industry Peer Group, the Compensation Committee considered, among other things, the following:

- the industry of the companies;
- the annual revenue, market value and total assets of the companies;
- the market data sources that are available with respect to the companies; and
- the number of employees of the companies.

For 2014, Industry Peer Group consisted following companies (the "Industry Peer Group"):

- BioTime, Inc. (BTX)
- Sunesis Pharmaceuticals, Inc. (SNSS)
- Curis, Inc. (CRIS)
- Threshold Pharmaceuticals, Inc. (THLD)
- Verastem, Inc. (VSTM)
- Achillion Pharmaceuticals, Inc. (ACHN)

- ZIOPHARM Oncology, Inc. (ZIOP)
- Ampio Pharmaceuticals, Inc. (AMPE)
- Synta Pharmaceuticals Corp. (SNTA)
- Omeros Corp. (OMER)
- Cempra, Inc. (CEMP)
- Immunomedics, Inc. (IMMU)
- Repros Therapeutics, Inc. (RPRX)
- Endocyte, Inc. (ECYT)
- Merrimack Pharmaceuticals, Inc. (MACK)
- BioCryst Pharmaceutical,s Inc. (BCRX)
- Geron Corp. (GERN)

*Role of the Chief Executive Officer.* Annually, our CEO provides the Compensation Committee with an evaluation of his performance that is based, in large part, upon performance of the Company and as our lead representative to the investment community. The Compensation Committee evaluates our CEO on these and other criteria. The total compensation package for our CEO is based on the Compensation Committee's evaluation, and reflects his performance, the performance of the Company and competitive industry practices.

*Role of Other Executive Officers.* Our CEO makes recommendations to the Compensation Committee on all compensation actions (other than his own compensation) affecting our executive officers. In developing his recommendation for an executive officer, our CEO considers the self-evaluation prepared by the executive officer, the recommendations of his executive team, as well as his own evaluation. Our CEO's evaluation includes an assessment of the impact that the executive officer has had on the Company during the award year and their overall value to the Company as a senior leader.

The Compensation Committee is provided with our CEO's evaluation of each executive officer's performance and contributions to the Company. The Compensation Committee considers the information and recommendations provided by our CEO and provides a recommendation to the Board for non-CEO executive officer the base salary, annual cash incentive awards and grants of long-term incentive awards, which are subject to Board approval.

***2014 Performance Analysis and Compensation Decisions***

In its meeting in the first quarter of each year, the Compensation Committee determines base salaries for the current year, the annual performance incentive awards for prior-year performance and the long-term incentive awards for the current year. Each element is reviewed annually, as well as at the time of a promotion, other change in responsibilities, other significant corporate events or a material change in market conditions. Variances in the amount of compensation awarded to each executive officer generally reflect differences in individual responsibility and experience as well as the competitive levels provided to officers in comparable positions in our industry. Overall, our CEO's compensation is higher than the compensation of the other executive officers. This difference in compensation is supported by industry benchmark data from our Industry Peer Group, and is indicative of the greater responsibility the CEO position entails for the strategic direction, financial condition, operating results and image of the Company.

*Base Salary*. In recent years, the Compensation Committee has adjusted executive base salaries to be more competitive with the salaries for comparable positions within companies of comparable size, industry and complexity, with the goal of providing a stable base of competitive cash compensation while rewarding corporate and individual performance through annual performance incentive awards. During 2014, the annual base salaries for our NEOs were adjusted between (50)% and 60% compared to 2013 base salaries. The base salary adjustments made during 2014 are reflected in the following table:

| | 2013 Base Salary | 2014 Base Salary | % Increase/(Decrease) |
|---|---|---|---|
| Mr. Nielsen (1) | $ 250,000 | $ 400,000 | 60 % |
| Mr. Morris (2) | $ 120,000 | $ 60,000 | (50)% |
| Mr. Mueller | $ - | $ 285,000 | N/A |

(1) Mr. Nielsen's annual salary increased from $250,000 in 2012 and 2013 to $400,000 in 2014. The increase in Mr. Nielsen's salary reflects his contributions to the Company's success and achievement of numerous milestones, including development of manufacturing processes and supplier base for our proprietary liposomal delivery technology, recruiting key individuals to build our organization, raising over $30 million in cash for the Company and leading the Company to becoming listed on the NASDAQ Capital Market. Mr. Nielsen's current salary is below the twenty-fifth ($25^{th}$) percentile of salaries of comparable executives within our Industry Peer Group.

(2)

Mr. Morris decided to reduce his role with the Company in order to devote time to another venture. The effect of the salary decrease was to transition this change and his eventual departure from the Company.

Mr. Mueller began serving as our Chief Operating Officer in March 2014 and Mr. Morris ceased serving in his officer capacities in June 2014. Accordingly, for the fiscal year ended 2014, both Mr. Mueller and Mr. Morris received only prorated portions of their base salaries, which were based on their respective starting and ending dates of employment in 2014, as disclosed in the Summary Compensation Table, below.

*Annual Performance Incentive Awards*. During 2014, the Compensation Committee approved discretionary annual cash performance incentive awards for Mr. Nielsen in the amount of $125,000 and for Mr. Morris in the amount of $12,000, which were intended to motivate and reward performance achievement.

*Long-term Incentive Awards*. The Compensation Committee believes that long-term incentive awards should provide for a retention incentive with the strong tie to relative long-term stockholder return. Accordingly, the Compensation Committee grants stock option awards that typically vest over a four-year period. On May 1, 2014, we granted Mr. Mueller a time-vested stock option award to purchase 125,000 shares of our common stock. The terms of the stock option grant require, among other things, that Mr. Mueller continues to provide services over the vesting period of the option. The option vests over four equal one-fourth (1/4) increments on the first, second, third and fourth anniversaries of May 1, 2014.

**Compensation Committee Report**

The Compensation Committee has reviewed and discussed the Compensation Discussion and Analysis required by Item 402(b) of Regulation S-K with management and, based on the review and discussion referenced above, the Compensation Committee recommended to the Board that the Compensation Discussion and Analysis referred to above be included in this Annual Report on Form 10-K.

The Compensation Committee of the Board,

Michael J. Garrison, Chairman

Heath W. Cleaver

Dr. Amy P. Sing

**Summary Compensation Table**

The following table sets forth information with respect to the compensation of our NEOs for the fiscal years ended December 31, 2014, 2013 and 2012.

| Name and Principal Position | Year | Salary ($) | Bonus ($) | Stock Option ($)(1) | Total ($) |
|---|---|---|---|---|---|
| Peter H. Nielsen, CEO, CFO, | 2014 | $400,000 | $125,000 | — | $525,000 |
| President, Chairman, | 2013 | $250,000 | $125,000 | 675,000 | $1,050,000 |
| Director | 2012 | $250,000 | $— | — | $250,000 |
| Douglas P. Morris, VP | 2014 | $40,000 (2) | $12,000 | — | $52,000 |
| Corporate Development, | 2013 | $120,000 | $60,000 | 450,000 | $630,000 |
| Director | 2012 | $120,000 | $— | — | $120,000 |
| Ulrich W. Mueller, COO, | 2014 | $190,000 (2) | $— | 294,875 | $484,875 |
| Secretary | 2013 | $— | $— | — | $— |
| | 2012 | $— | $— | — | $— |

(1) The amounts reported in this column reflect the aggregate grant date fair value of equity awards granted during the year computed in accordance with FASB ASC Topic 718. See Note 8 to our consolidated financial statements

included elsewhere in this Annual Report on Form 10-K for assumptions made by us in such valuation.

(2) The amounts reported represent prorated portions of the base salaries of Messrs. Morris and Mueller, which was based on their respective starting and ending dates of employment in 2014.

**Grants of Plan-Based Awards Table**

The following table contains information about grants of plan-based stock options to our NEOs during fiscal year 2014:

| Name | Grant Date | Estimated Future Payouts Under Non-Equity Incentive Plan Awards | | | All Other Stock Awards: Number of Shares of Stock or Units (#) | All Other Option Awards: Number of Securities Underlying Options (#) | Exercise or Base Price of Option Awards ($/Sh) | Grant Date Fair Value of Stock Awards ($)(2) |
|---|---|---|---|---|---|---|---|---|
| | | Threshold ($) | Target ($) | Maximum ($) | | | | |
| Mr. Mueller (1) | 5/1/2014 | — | — | — | — | 125,000 | $ 2.40 | $ 294,875 |

(1) Reflects a time-vested stock option awarded under our 2007 Stock Incentive Plan. The option vests over four equal one-fourth (1/4) increments on the first, second, third and fourth anniversaries of May 1, 2014.

(2) The amounts in this column reflect the aggregate grant date fair value of equity awards granted during the year computed in accordance with FASB ASC Topic 718. See Note 8 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for assumptions made by us in such valuation.

**Narrative Disclosure to Summary Compensation Table and Grants of Plan-Based Awards Table**

Please see the discussion under the heading "2014 Performance Analysis and Compensation Decisions" in this Annual Report on Form 10-K, above.

**Outstanding Equity Awards at December 31, 2014**

The following table sets forth certain information with respect to outstanding stock option awards of the NEOs for the fiscal year ended December 31, 2014.

| Name | Number of Securities Underlying Unexercised Options Exercisable (#)(1) | Number of Securities Underlying Unexercised Options Unexercisable (#) | Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#) | Option Exercise Price ($) | Option Expiration Date |
|---|---|---|---|---|---|
| Peter H. Nielsen (1) | 1,500,000 | - | - | $ 1.40 | Oct 2018 |
| Douglas P. Morris (1) | 1,000,000 | - | - | $ 1.40 | Oct 2018 |
| Peter H. Nielsen (2) | 1,104,167 | 395,833 | - | $ 0.46 | Aug 2023 |
| Douglas P. Morris (3) | 652,778 | - | - | $ 0.46 | Aug 2023 |
| Ulrich W. Mueller (4) | - | 125,000 | - | $ 2.40 | May 2024 |

(1) All of these options granted are fully vested.

(2) One-half of such option shares were fully vested on the date of grant and the remaining one-half of such option shares vest in 36 equal monthly increments from the date of such grant.

(3)

A portion of the original options granted lapsed and never vested as a result of Mr. Morris ceasing to serve as an officer of the Company.

(4) Such options vest over four years in equal, one-fourth (1/4) increments on the first, second, third and fourth anniversaries of May 1, 2014, based on continuing service to the Company.

**Employment Agreement and Potential Payments Upon Termination or Change of Control**

Bio-Path Subsidiary has entered into an employment agreement with its Chief Executive Officer, Peter H. Nielsen, dated May 1, 2007 (the “Nielsen Employment Agreement”). The employment agreement with Douglas P. Morris was terminated on June 30, 2014. We have not entered into employment agreements with any of our other NEOs.

The Nielsen Employment Agreement provides for a base salary, as approved by the Compensation Committee, of $400,000. In addition, the Nielsen Employment Agreement provides that Mr. Nielsen is entitled to certain severance payments and benefits in the event he is terminated without Cause (as defined in the Nielsen Employment Agreement) or resigns for Good Reason (as defined in the Nielsen Employment Agreement) within three months before or 12 months following a Change in Control (as defined in the Nielsen Employment Agreement), subject to Mr. Nielsen’s continued compliance with the Confidentiality Agreement (as defined in the Nielsen Employment Agreement) and execution of a general release of all claims against us.

The severance payments and benefits include the following: (i) any unvested stock or stock options awarded to Mr. Nielsen shall immediately vest upon the occurrence of Mr. Nielsen's termination of employment; (ii) Mr. Nielsen's base salary will be paid through the termination date, and any accrued but untaken vacation days of Mr. Nielsen will be paid to the extent not yet paid; (iii) Mr. Nielsen's normal post-termination benefits will be paid in accordance with our retirement, insurance and other benefit plan arrangements (including non-qualified deferred compensation plans); (iv) the equivalent of Mr. Nielsen's base salary will be paid for a period of three months; (v) subject to certain restrictions, for six months after Mr. Nielsen's date of termination, or such longer period as may be provided by the terms of the appropriate plan, program, practice of policy, Mr. Nielsen's health care, dental, disability and life insurance benefits will be provided on the same basis as immediately prior to the date of termination; and (vi) subject to certain restrictions and to the extent not otherwise paid or provided, we will pay or provide any other amounts or benefits required to be paid or provided or which Mr. Nielsen is eligible to receive following his termination of employment under any of our plans, programs, policies, practices, contracts or agreements.

Director Compensation

The following table presents summary information for the year ended December 31, 2014 regarding the compensation of the non-employee members of our Board.

| Name | Fees Earned or Paid in Cash (1) | Stock Awards | Option Awards(2) | Non-Equity Incentive Plan Compensation | Change in pension value and nonqualified deferred compensation earnings | All Other Compensation | Total |
|---|---|---|---|---|---|---|---|
| Michael J. Garrison | $7,100 | — | $45,150 | — | — | — | $52,250 |
| Amy P. Sing | $1,000 | — | — | — | — | — | $1,000 |
| Heath W. Cleaver | $10,500 | — | $104,425 | — | — | — | $114,925 |
| Gillian Ivers-Read, BSc(3) | $10,000 | — | $57,425 | — | — | — | $67,425 |

(1) All of the amounts in this column reflect cash fees paid to or earned by our non-employee directors for attending Board or committee meetings during the year ended December 31, 2014.

(2) During 2014, our non-employee directors who were eligible earned or received an annual grant of an option to purchase 25,000 shares of our common stock which was the only grant received by such directors during 2014. The amounts in this column reflect the aggregate grant date fair value of equity awards granted during the year computed in accordance with FASB ASC Topic 718. See Note 8 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for assumptions made by us in such valuation.

The following table reflects the aggregate number of outstanding options (including unexercisable options) held by our non-employee directors as of December 31, 2014:

| Director | Number of shares underlying outstanding options |
|---|---|
| Michael J. Garrison | 75,000 |
| Amy P. Sing | — |
| Heath W. Cleaver | 25,000 |

(3) Ms. Ivers-Read resigned from her position as a member of our Board on October 28, 2014.

**Narrative to Director Compensation Table**

In 2014, our non-employee directors received cash compensation of $2,000 for each required meeting of the Board attended in person, $1,500 for each telephonic meeting of the Board in which they participated of duration of 15 minutes or longer and $500 for each telephonic meeting of the Board in which they participated of duration of less than 15 minutes. In addition, in 2014, our non-employee directors received cash compensation of $1,500 for each required meeting of any Board committee attended in person, $1,000 for each telephonic meeting of any Board committee in which they participated of duration of 15 minutes or longer and $500 for each telephonic meeting of any Board committee in which they participated of duration of less than 15 minutes. Furthermore, Mr. Garrison, Mr. Cleaver and Ms. Ivers-Read (the latter no longer serving as a member of our Board) each received a stock option grant of 25,000 shares of our common stock, which vest on the one-year anniversary of each respective grant based on continued service.

Currently, our compensation structure for all non-employee directors is as follows:

***Board Compensation***

Non-employee directors receive as compensation the following amounts: (i) $2,000 for each required meeting of the Board attended in person; (ii) $1,500 for each meeting of the Board conducted by telephonic or other electronic communications of duration of 15 minutes or longer; and (iii) $500 for each meeting of the Board of duration less than 15 minutes conducted by telephonic or other electronic communications. Board members must attend meetings in person or by telephonic or other electronic communications to receive the applicable compensation.

Each non-employee director of the Board also receives as compensation an annual stock option grant (a “Grant”) of 25,000 shares of our common stock (the “Option Shares”). The exercise price of the Option Shares is determined by the Board and the Option Shares vest over a four-year period from the date of the Grant, with one-fourth (1/4) of the Option Shares vesting on the first anniversary of each such Grant (i.e., 6,250 Option Shares), and the remaining Option Shares vesting thereafter in equal monthly increments equal to one-forty-eighth (1/48) of the Option Shares over the next three years (i.e., approximately 520.83 Option Shares per month), based on continuing service to the Company.

***Committee Compensation***

Each non-employee director of the Board who is a member of a Board committee will also receive as compensation the following amounts: (i) $1,500 for each committee meeting attended in person; (ii) $1,000 for each committee meeting conducted by telephonic or other electronic communications of duration of 15 minutes or longer; and (iii) $500 for each committee meeting of duration less than 15 minutes conducted by telephonic or other electronic communications. Committee members must attend meetings in person or by telephonic or other electronic communications to receive the applicable compensation.

**Compensation Committee Interlocks and Insider Participation**

All present members of the Compensation Committee are independent directors, and none of them are present or past employees of the Company. Douglas P. Morris served as a member of the Compensation Committee during the fiscal year 2014, but ceased to serve on such committee as of February 11, 2014 in preparation for our initial listing on the

NASDAQ Capital Market, which was effective March 10, 2014. During the time Mr. Morris served on the Compensation Committee, he also served as one of our executive officers.

No present or past member of the Compensation Committee has had any relationship with us requiring disclosure under Item 404 of Regulation S-K under the Exchange Act. None of our present or past executive officers have served on the board or compensation committee (or other committee serving an equivalent function) of any other entity, one of whose executive officers served on our Board or Compensation Committee.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth information regarding shares of our common stock beneficially owned at February 27, 2015 by: (i) each of our NEOs and directors; (ii) all NEOs and directors as a group; and (iii) each person known by us to beneficially own 5% or more of the outstanding shares of our common stock. The information in this table is based solely on statements in filings with the SEC or other reliable information.

| Name of Beneficial Owner | Amount and Nature of Beneficial Ownership | Percent of Class |
|---|---|---|
| Peter H. Nielsen (1) (2) | 7,831,100 | 8.47% |
| Douglas P. Morris (1) (3) | 3,286,689 | 3.60% |
| Ulrich W. Mueller (1) | -- | * |
| Amy P. Sing, M.D. (1) | -- | * |
| Michael J. Garrison (1) (4) | 881,667 | * |
| Heath W. Cleaver (1) (5) | 25,000 | * |
| All officers and directors as a group (6) | 12,024,456 | 12.77% |

*Less than 1%

(1) These are our NEOs and directors.

(2) Includes 5,164,433 shares owned of record and 2,666,667 shares issuable upon the exercise of options that are that are exercisable within 60 days.

(3) Includes 1,633,911 shares owned of record and 1,652,778 shares issuable upon the exercise of options that are that are exercisable within 60 days.

(4) Includes 50,000 shares issuable upon the exercise of options that are exercisable within 60 days. Also includes 83,333 shares owned of record, 75,000 shares held by Cosmo Capital Partners, LLC and 673,334 shares held by Garrison Capital, LLC. Mr. Garrison is a managing member of Cosmo Capital Partners, LLC and, thus, may be deemed to beneficially own the shares held by Cosmo Capital Partners, LLC. Mr. Garrison disclaims beneficial ownership of these securities except to the extent of his pecuniary interest therein.

(5) All 25,000 shares are issuable upon the exercise of options that are that are exercisable within 60 days.

(6) Includes 7,630,011 shares owned of record and 4,394,445 shares issuable upon the exercise of options and warrants currently exercisable or will be exercisable within 60 days.

Please see the table disclosed under the heading “Equity Compensation Plan Information” disclosed in “Item 5. Market for the Registrant’s Common Stock and Related Security Holder Matters” of this Annual Report on Form 10-K.

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

**Related Party Transactions**

It is our policy that we will not enter into any transactions required to be disclosed under Item 404 of Regulation S-K promulgated by the SEC unless the Audit Committee first reviews and approves the transactions. The Audit Committee is required to review on an ongoing basis, and pre-approve all related party transactions before they are entered into, including those transactions that are required to be disclosed under Item 404 of Regulation S-K. Related party transactions involving a director must also be approved by the disinterested members of the Audit Committee. It is the responsibility of our employees and directors to disclose any significant financial interest in a transaction between the Company and a third party, including an indirect interest. All related party transactions shall be disclosed in our filings with the SEC as required under SEC rules.

In addition, pursuant to our codes of ethics, all employees, officers and directors of ours and our subsidiaries are prohibited from engaging in any relationship or financial interest that is an actual or potential conflict of interest with us without approval. Employees and officers are required to provide written disclosure to their supervisors as soon as they have any knowledge of a transaction or proposed transaction with an outside individual, business or other organization that would create a conflict of interest or the appearance of one. Directors are required to disclose such information to the Board or as otherwise required by law.

Other than the reimbursements and other expenses paid to MD Anderson as described elsewhere in this Annual Report on Form 10-K, since the beginning of our last fiscal year, there has not been nor is there currently proposed any transaction or series of similar transactions to which we were or are to be a party in which the amount involved exceeds the lesser of $120,000 or 1% of the average of our total assets at the end of our last two fiscal years, and in which any of our directors, executive officers, persons who we know hold more than 5% of our common stock, or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest other than: (i) compensation agreements and other arrangements, which are described elsewhere in this Annual Report on Form 10-K and (ii) the transactions described in the following paragraph.

We have has entered into indemnity agreements with certain of our officers and directors which provide, among other things, that we will indemnify such officer or director, under the circumstances and to the extent provided for therein, for expenses, damages, judgments, fines and settlements he or she may be required to pay in actions or proceedings which he or she is or may be made a party by reason of his or her position as a director, officer or other agent of the Company, and otherwise to the fullest extent permitted under applicable law, our Certificate of Incorporation and our Bylaws.

**Director Independence**

The following members of the Board have been identified as independent under the standards of the NASDAQ Stock Market: Michael J. Garrison, Heath W. Cleaver and Amy P. Sing. In addition, Gillian C. Ivers-Read served as a member of the Board during the fiscal year ended December 31, 2014. Ms. Ivers-Read was independent under the standards of the NASDAQ Stock Market and resigned from her position on October 28, 2014.

Presently, there are no directors on any of our committees who are not independent under the standards of the NASDAQ Stock Market. Douglas P. Morris served as a member of the Compensation Committee during the fiscal year 2014, but ceased to serve on such committee as of February 11, 2014 in preparation for our initial listing on the NASDAQ Capital Market, which was effective March 10, 2014. During the time Mr. Morris served on the Compensation Committee, he also served as one of our executive officers.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

For the fiscal years ended December 31, 2013 and December 31, 2014, Mantyla McReynolds LLC, as our independent registered public accounting firm, billed the approximate fees set forth below. Our Board has considered the services provided by Mantyla McReynolds LLC as disclosed below in the captions “Audit Fees,” “Tax Fees” and “All Other Fees” and has concluded that such services are compatible with the independence of Mantyla McReynolds LLC as our principal accountants.

For the fiscal years 2013 and 2014, the Board pre-approved all services described below in the captions “Audit Fees,” “Audit-Related Fees,” “Tax Fees” and “All Other Fees.” For fiscal year 2013 and 2014, no hours expended on Mantyla McReynolds LLC’s engagement to audit our financial statements were attributed to work performed by persons other than full-time, permanent employees of Mantyla McReynolds LLC.

**Audit Fees**

Aggregate fees consist of fees billed for professional services rendered for the audit of our consolidated financial statements and internal control over financial reporting, reviews of the interim condensed consolidated financial statements included in quarterly filings, and services that are normally provided by Mantyla McReynolds LLC in connection with statutory and regulatory filings or engagements, including consents, except those not required by statute or regulation. Aggregate fees billed for audit services were $44,050 and $55,125 for the years ended December 31, 2013 and December 31, 2014, respectively.

**Audit-Related Fees**

We were billed no audit-related fees by Mantyla McReynolds LLC for the years ended December 31, 2013 or December 31, 2014.

**Tax Fees**

Tax fees consist of fees billed for professional services rendered by Mantyla McReynolds LLC for state and federal tax compliance and advice, and tax planning. Aggregate fees for tax services were $1,600 and $2,911during the years ended December 31, 2013 and 2014, respectively.

**All Other Fees**

Other fees consist of fees billed by Mantyla McReynolds LLC for professional services other than those relating to audit fees, audit-related fees and tax fees. These fees include services provided in conjunction with registration statements and equity financing transactions. Aggregate other fees billed by Mantyla McReynolds LLC were $8,630 and $7,700 during the years ended December 31, 2013 and December 31, 2014, respectively.

**Pre-Approval Policies and Procedures**

The Audit Committee, has not adopted any blanket pre-approval policies and procedures. Instead, the Audit Committee will pre-approve the provision by Mantyla McReynolds LLC of all audit or non-audit services.

ITEM 15. EXHIBITS

| Exhibit Number | Exhibit |
|---|---|
| 2.1 | Agreement and Plan of Merger and Reorganization dated September 27, 2007, by and among the Company, Biopath Acquisition Corp., a Utah corporation and wholly owned subsidiary of the registrant, and Bio-Path, Inc., a Utah corporation (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed on September 27, 2007). |
| 3.1 | Certificate of Incorporation (incorporated by reference to Exhibit 3.3 to the Company's Current Report on Form 8-K filed on January 6, 2015). |
| 3.2 | Bylaws (incorporated by reference to Exhibit 3.4 to the Company's Current Report on Form 8-K filed on January 6, 2015). |
| 3.3 | Articles of Merger relating to the merger of Biopath Acquisition Corp. with and into Bio-Path, Inc. (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed on February 19, 2008). |
| 3.4 | Certificate of Conversion (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed on January 6, 2015). |
| 3.5 | Articles of Transfer (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on January 6, 2015). |
| 4.1* | Form of Common Stock Certificate. |
| 4.2 | Warrant Agreement, dated April 25, 2008, by and between the Company and Randeep Suneja, M.D. (incorporated by reference to Exhibit 4.2 to the Company's Annual Report on Form 10-K filed on March 31, 2014). |
| 4.3 | Form of Warrant issued to Maxim Group LLC, Sabby Healthcare Volatility Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd. (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K on January 21, 2014). |
| 10.1+ | Employment Agreement – Peter H. Nielsen (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed on February 19, 2008). |
| 10.2+ | Amended 2007 Stock Incentive Plan (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-8 filed on December 10, 2008). |
| 10.3+ | First Amendment to First Amended 2007 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on August 14, 2013). |
| 10.4 | |

| | |
|---|---|
| | Placement Agent Agreement, dated as of April 13, 2012, by and between the Company and ACAP Financial, Inc. (incorporated by reference to Exhibit 10.5 to the Company's Annual Report on Form 10-K filed on April 1, 2013). |
| 10.5 | Patent and Technology License Agreement, dated as of November 2, 2007, by and between the Company and the Board of Regents of The University of Texas System on behalf of The University of Texas M.D. Anderson Cancer Center (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on May 15, 2013). |
| 10.6 | Amendment No. 1 to the Patent and Technology Agreement, dated as of May 11, 2009, by and between the Company and the Board of Regents of the University of Texas System on behalf of The University of Texas M.D. Anderson Cancer Center (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on May 15, 2013). |

| | |
|---|---|
| 10.7 | Form of Purchase Agreement by and between the Company and certain investors party thereto (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on May 15, 2013). |
| 10.8 | Placement Agent Agreement, dated as of December 9, 2013, by and between the Company and Maxim Group LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 21, 2014). |
| 10.9 | Form of Securities Purchase Agreement by and between the Company, Sabby Healthcare Volatility Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 21, 2014). |
| 10.10 | Form of Waiver, Consent and Amendment to that certain Securities Purchase Agreement by and between Sabby Healthcare Volatility Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd. (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K on January 21, 2014). |
| 10.11+ | First Amendment to Employment Agreement, dated March 26, 2014 – Peter H. Nielsen (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on March 26, 2014). |
| 10.12 | Lease Agreement dated April 16, 2014 by and between the Company and Pin Oak North Parcel TT, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 18, 2014). |
| 21.1* | Subsidiaries of Bio-Path Holdings, Inc. |
| 23.1* | Consent of Mantyla McReynolds LLC. |
| 31* | Certification of Principal Executive Officer/Principal Financial Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 Sarbanes Oxley Act of 2002. |
| 32* | Certification of Principal Executive Officer/Principal Financial Officer pursuant to Section 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002. |
| 101.INS* | XBRL Instance Document |
| 101.SCH* | XBRL Taxonomy Extension Schema Document |
| 101.CAL* | XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF* | XBRL Taxonomy Extension Definition Linkbase Document |
| 101.LAB* | XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE* | XBRL Taxonomy Extension Presentation Linkbase Document |

* Filed herewith.

+ Management contract or compensatory plan.

SIGNATURES

In accordance with Section 13 or 15(d) of the Securities Exchange Act of 1934, the Company caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

BIO-PATH HOLDINGS, INC.

Dated: March 16, 2015 By: /s/ Peter H. Nielsen
Peter H. Nielsen
President
Chief Executive Officer
Chief Financial Officer

Principal Accounting Officer

In accordance with the Securities Exchange Act, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the Company and in the capacities and on the dates indicated.

| Date | Title | Signature |
|---|---|---|
| March 16, 2015 | President/Chief Executive Officer/ Chief Financial Officer/Principal Accounting Officer/ Director | /s/ Peter H. Nielsen<br>Peter H. Nielsen |
| March 16, 2015 | Director | /s/ Michael J. Garrison<br>Michael J. Garrison |
| March 16, 2015 | Director | /s/ Amy P. Sing<br>Amy P. Sing |
| March 16, 2015 | Director | /s/ Heath W. Cleaver<br>Heath W. Cleaver |
| March 16, 2015 | Director | /s/ Douglas P. Morris<br>Douglas P. Morris |

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders

Bio-Path Holdings, Inc.

Bellaire, Texas

We have audited the accompanying consolidated balance sheets of Bio-Path Holdings, Inc. (the "Company") as of December 31, 2014 and 2013 and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2014. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated 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 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 financial statement presentation. 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 financial position of the Company at December 31, 2014 and 2013, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2014**,** in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2014, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated March 16, 2015 expressed an unqualified opinion thereon.

/s/ Mantyla McReynolds, LLC

Salt Lake City, Utah

March 16, 2015

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders

Bio-Path Holdings, Inc.

Bellaire, Texas

We have audited Bio-Path Holdings, Inc.'s (the "Company") internal control over financial reporting as of December 31, 2014, based on criteria established in the *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Bio-Path Holdings, Inc.'s management is responsible 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 the Company's internal control over financial reporting based on our audit.

We conducted our audit 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 effective internal control over financial reporting was maintained in all material respects. Our audit 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 audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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, Bio-Path Holdings, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2014, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of the Company as of December 31, 2014 and 2013, and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2014 and our report dated March 16, 2015 expressed an unqualified opinion thereon.

/s/ Mantyla McReynolds, LLC

Salt Lake City, Utah

March 16, 2015

**BIO-PATH HOLDINGS, INC.**

**CONSOLIDATED BALANCE SHEETS**

**DECEMBER 31, 2014 AND 2013**

| | December 31 2014 | 2013 |
|---|---|---|
| ASSETS | | |
| Current assets | | |
| Cash | $13,858,798 | $3,551,832 |
| Prepaid drug product for testing | 154,667 | 51,364 |
| Other current assets | 100,494 | 64,117 |
| Total current assets | 14,113,959 | 3,667,313 |
| Fixed assets | | |
| Furniture, fixtures & equipment | 123,410 | - |
| Less Accumulated Depreciation | (10,284) | - |
| | 113,126 | - |
| Other assets | | |
| Technology licenses - related party | 2,500,374 | 2,500,374 |
| Less Accumulated Amortization | (1,249,481) | (1,088,856) |
| | 1,250,893 | 1,411,518 |
| TOTAL ASSETS | $15,477,978 | $5,078,831 |
| LIABILITIES & SHAREHOLDERS' EQUITY | | |
| Current liabilities | | |
| Accounts payable | 41,026 | 76,109 |
| Accounts payable - related party | 100,450 | - |
| Accrued expense | 253,445 | 66,739 |
| Accrued expense - related party | 67,050 | 52,050 |
| Accrued license payments - related party | 100,000 | 100,000 |
| Total current liabilities | 561,971 | 294,898 |
| Long term debt | - | - |

| | | |
|---|---|---|
| TOTAL LIABILITIES | 561,971 | 294,898 |
| | | |
| Shareholders' Equity | | |
| Preferred Stock, $.001 par value 10,000,000 shares authorized, no shares issued and outstanding | - | - |
| Common Stock, $.001 par value, 200,000,000 shares authorized 89,762,872 and 84,237,872 shares issued and outstanding as of 12/31/14 and 12/31/13, respectively | 89,763 | 84,238 |
| Additional paid in capital | 34,743,489 | 20,096,991 |
| Accumulated deficit | (19,917,245) | (15,397,296) |
| | | |
| Total shareholders' equity | 14,916,007 | 4,783,933 |
| | | |
| TOTAL LIABILITIES & SHAREHOLDERS' EQUITY | $15,477,978 | $5,078,831 |

SEE ACCOMPANYING NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**BIO-PATH HOLDINGS, INC.**

**CONSOLIDATED STATEMENTS OF OPERATIONS**

**FOR THE YEARS ENDED DECEMBER 31, 2014, 2013 AND 2012**

| | 2014 | 2013 | 2012 |
|---|---|---|---|
| Revenue | $- | $- | $- |
| Operating expense | | | |
| Research and development a/ | 1,630,439 | 1,518,885 | 1,132,712 |
| Research and development - related party b/ | 196,661 | 115,705 | 463,870 |
| General and administrative c/ | 2,715,146 | 1,634,650 | 986,097 |
| Total operating expense | 4,542,246 | 3,269,240 | 2,582,679 |
| Net operating loss | $(4,542,246) | $(3,269,240) | $(2,582,679) |
| Other income (expense) | | | |
| Interest income | 22,632 | 4,037 | 779 |
| Other expense | (335) | (810) | (637) |
| Total Other Income (Expense) | 22,297 | 3,227 | 142 |
| Net Loss Before Income Taxes | (4,519,949) | (3,266,013) | (2,582,537) |
| Income tax expense | - | - | - |
| Net Loss | $(4,519,949) | $(3,266,013) | $(2,582,537) |
| Loss per share | | | |
| Net loss per share, basic and diluted | $(0.05) | $(0.05) | $(0.04) |
| Basic and diluted weighted average number of common shares outstanding | 89,281,622 | 71,372,672 | 59,317,779 |

a/ Research and development expense includes stock option expense of $83,139, $32,879 and $53,645 for the years ending 12/31/2014, 12/31/2013 and 12/31/2012, respectively. Research and development expense also includes amortization expense of $160,625 for the years ending 12/31/2014 and 12/31/2013, and $185,271 for the year ending 12/31/2012.

b/ Includes $345,000 technology impairment charge for the year ending 12/31/2012.

c/ General & administrative expense includes stock option expense of $321,011, $671,601 and $9,740 for the years ending 12/31/2014, 12/31/2013 and 12/31/2012, respectively. General & administrative expense also includes depreciation expense of $10,284 for the year ended 12/31/2014.

SEE ACCOMPANYING NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**BIO-PATH HOLDINGS, INC.**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

**FOR THE YEARS ENDED DECEMBER 31, 2014, 2013 AND 2012**

| | 2014 | 2013 | 2012 |
|---|---|---|---|
| CASH FLOW FROM OPERATING ACTIVITIES | | | |
| Net loss | $(4,519,949) | $(3,266,013) | $(2,582,537) |
| Adjustments to reconcile net loss to net cash used in operating activities | | | |
| Amortization | 160,625 | 160,625 | 185,271 |
| Depreciation | 10,284 | - | - |
| Technology impairment | - | - | 345,000 |
| Common stock issed for services | - | - | 18,500 |
| Stock options and warrants | 404,150 | 704,480 | 63,385 |
| (Increase) decrease in assets | | | |
| Prepaid drug product for testing | (103,303) | 143,636 | (42,000) |
| Other current assets | (36,377) | (21,542) | 5,864 |
| Increase (decrease) in liabilities | | | |
| Accounts payable and accrued expenses | 267,073 | (34,346) | 13,113 |
| Net cash used in operating activities | (3,817,497) | (2,313,160) | (1,993,404) |
| CASH FLOW FROM INVESTING ACTIVITIES | | | |
| Purchase of exclusive license - related party | - | - | (25,000) |
| Purchase furniture, fixtures & equipment | (123,410) | - | - |
| Net cash used in investing activities | (123,410) | - | (25,000) |
| CASH FLOW FROM FINANCING ACTIVITIES | | | |
| Net proceeds from sale of common stock | 13,812,373 | 5,330,946 | 1,600,198 |
| Net proceeds from exercise of common stock options | 435,500 | - | - |
| Net cash from financing activities | 14,247,873 | 5,330,946 | 1,600,198 |
| ` | | | |
| NET INCREASE (DECREASE) IN CASH | 10,306,966 | 3,017,786 | (418,206) |
| Cash, beginning of period | 3,551,832 | 534,046 | 952,252 |
| Cash, end of period | $13,858,798 | $3,551,832 | $534,046 |

SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION

| | | | |
|---|---|---|---|
| Cash paid for | | | |
| Interest | $- | $- | $- |
| Income taxes | $- | $- | $- |
| | | | |
| Non-cash financing activities | | | |
| Common stock issued to Placement Agent | $- | $771,047 | $- |
| Due diligence and commitment shares issued | $- | $- | $1,750 |

SEE ACCOMPANYING NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**BIO-PATH HOLDINGS, INC.**

**CONSOLIDATED STATEMENT OF SHAREHOLDERS' EQUITY**

| Date | Description | **Common** Stock Shares | Amount | Additional Paid in Capital | Additional Paid in Capital Shares to be Issued | Accumulated Deficit | Total |
|---|---|---|---|---|---|---|---|
| Balances at December 31, 2011 | | 58,325,169 | $58,325 | $12,405,395 | $ - | $(9,548,746 ) | $2,914,974 |
| Mar-12 | Common stock for cash Lincoln | 166,667 | 167 | 49,833 | | | 50,000 |
| Mar-12 | Commitment Shares issued to Lincoln | 2,084 | 2 | 623 | | | 625 |
| Apr-12 | Common stock for cash Lincoln | 89,286 | 89 | 24,911 | | | 25,000 |
| Apr-12 | Commitment Shares issued to Lincoln | 1,042 | 1 | 291 | | | 292 |
| Apr-12 | Common stock for cash Lincoln | 96,154 | 96 | 24,904 | | | 25,000 |
| Apr-12 | Commitment Shares issued to Lincoln | 1,042 | 1 | 270 | | | 271 |
| Apr-12 | Common stock for cash Lincoln | 185,185 | 185 | 49,815 | | | 50,000 |
| Apr-12 | Commitment Shares issued to Lincoln | 2,084 | 2 | 561 | | | 563 |
| Jun-12 | Common stock sold shares to be issued | | | | 150,000 | | 150,000 |
| Jul-12 | Common stock sold shares to be issued | | | | 171,900 | | 171,900 |
| Aug-12 | Common stock sold shares to be issued | | | | 140,000 | | 140,000 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Aug-12 | Common stock issued for services | 50,000 | 50 | 18,450 | | | 18,500 |
| Sep-12 | Common stock sold shares to be issued | | | | 73,000 | | 73,000 |
| Sep-12 | Common stock sold shares to be issued | | | | 250,100 | | 250,100 |
| Sep-12 | Common stock sold shares to be issued | | | | 160,000 | | 160,000 |
| Nov-12 | Common stock sold shares to be issued | | | | 59,100 | | 59,100 |
| Nov-12 | Common stock sold shares to be issued | | | | 148,200 | | 148,200 |
| Nov-12 | Shares issued for common stock previously sold | 3,300,337 | 3,300 | 986,801 | (990,101 ) | | - |
| Nov-12 | Common stock Placement Agent shares to be issued | | | | 99,011 | | 99,011 |
| Dec-12 | Common stock sold shares to be issued | | | | 501,300 | | 501,300 |
| Dec-12 | Full year 2012 stock option vesting | | | 63,385 | | | 63,385 |
| Dec-12 | Full year 2012 fund raising expense | | | (304,164 ) | | | (304,164 ) |
| Dec-12 | Full year 2012 net loss | | | | | (2,582,537 ) | (2,582,537 ) |
| Balances at December 31, 2012 | | 62,219,050 | $62,218 | $13,321,075 | $ 762,510 | $(12,131,283) | $2,014,520 |
| Feb-13 | Common stock sold shares to be issued | | | | 197,002 | | 197,002 |
| Mar-13 | Common stock sold shares to be issued | | | | 149,200 | | 149,200 |
| Apr-13 | Common stock sold shares to be issued | | | | 853,050 | | 853,050 |
| May-13 | | | | | 1,636,649 | | 1,636,649 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | Common stock sold shares to be issued | | | | | | |
| Jun-13 | Common stock issued to Placement Agent | 330,034 | 330 | 98,681 | (99,011) | | - |
| Jun-13 | Shares issued for common stock previously sold | 11,664,665 | 11,665 | 3,487,735 | (3,499,400) | | - |
| Jun-13 | Common stock issued to Placement Agent | 1,166,465 | 1,166 | 348,774 | | | 349,940 |
| Sep-13 | Common stock sold to investors shares to be issued | | | | 3,220,966 | | 3,220,966 |
| Nov-13 | Shares issued for common stock previously sold | 8,052,416 | 8,053 | 3,212,913 | (3,220,966) | | - |
| Nov-13 | Common stock issued to Placement Agent | 805,242 | 806 | 321,290 | | | 322,096 |
| Dec-13 | Full year 2013 stock option vesting | | | 704,480 | | | 704,480 |
| Dec-13 | Full year 2013 fund raising expense | | | (1,397,957) | | | (1,397,957) |
| Dec-13 | Full year 2013 net loss | | | | | (3,266,013) | (3,266,013) |
| Balances at December 31, 2013 | | 84,237,872 | $84,238 | $20,096,991 | $ - | $(15,397,296) | $4,783,933 |
| Jan-14 | Common stock sold to institutional investor | 5,000,000 | 5,000 | 14,995,000 | | | 15,000,000 |
| Dec-14 | Exercise of stock options | 525,000 | 525 | 434,975 | | | 435,500 |
| Dec-14 | Full year 2014 stock option vesting | | | 404,150 | | | 404,150 |
| Dec-14 | Full year 2014 fund raising expense | | | (1,187,627) | | | (1,187,627) |
| Dec-14 | Full year 2014 net loss | | | | | (4,519,949) | (4,519,949) |
| Balances at December 31, 2014 | | 89,762,872 | $89,763 | $34,743,489 | $ - | $(19,917,245) | $14,916,007 |

SEE ACCOMPANYING NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**Bio-Path Holdings, Inc.**

**Notes to Consolidated Financial Statements**

**December 31, 2014**

## 1. Organization and Business

Bio-Path Holdings, Inc. ("Bio-Path" or the "Company") is a biotechnology company with its lead cancer drug candidate, Liposomal Grb-2 ("L-Grb-2" or "BP-100-1.01"), currently in clinical trials. The planned principal operations are described in the following paragraphs. The Company was founded with technology from The University of Texas, MD Anderson Cancer Center ("MD Anderson") and is dedicated to developing novel cancer drugs under an exclusive license arrangement (the "License Agreement"). The Company has drug delivery platform technology with composition of matter intellectual property for systemic delivery of its proprietary antisense. Bio-Path also plans to investigate developing liposome tumor targeting technology, which has the potential to be developed to augment the Company's current delivery technology to improve further the effectiveness of its antisense. In addition to its existing technology under license the Company expects to maintain a close working relationship with key members of the MD Anderson staff, which has the potential to provide Bio-Path with additional drug candidates in the future. Bio-Path also expects to broaden its technology to include cancer drugs other than antisense, including drug candidates licensed from institutions other than MD Anderson.

Bio-Path believes that its core technology, if successful, will enable it to be at the center of emerging genetic and molecular target-based therapeutics that require systemic delivery of DNA and RNA-like material. The Company's two lead liposomal antisense drug candidates are targeted to treat Acute Myeloid Leukemia ("AML"), Myelodysplastic Syndrome ("MDS"), Philadelphia Chromosome Positive Chronic Myelogenous Leukemia ("CML"), Acute Lymphoblastic Leukemia ("ALL") and follicular lymphoma, and if successful, could potentially be used in treating many other indications of cancer. For example, in July of 2013 Bio-Path announced that it was initiating development of its lead cancer drug Liposomal Grb-2 to treat triple negative breast cancer (TNBC) and inflammatory breast cancer (IBC), two cancers characterized by formation of aggressive tumors and relatively high mortality rates.

The Company was founded in May of 2007 as a Utah corporation. In February of 2008, Bio-Path completed a reverse merger with Ogden Golf Co. Corporation, a public company traded over the counter that had no current operations. The name of Ogden Golf was changed to Bio-Path Holdings, Inc. and the directors and officers of Bio-Path, Inc. became the directors and officers of Bio-Path Holdings, Inc. Bio-Path became a publicly traded company as a result of this merger. The Company's operations to date have been limited to organizing and staffing the Company, acquiring, developing and securing its technology and undertaking product development for a limited number of product candidates including readying and now conducting a Phase I clinical trial in its lead drug product candidate Liposomal Grb-2.

On November 5, 2013, the Company filed a shelf registration statement on Form S-3 with the SEC, which was declared effective by the SEC on January 13, 2014. The shelf registration statement was filed to register the offering and sale of up to $100 million of our common stock, preferred stock, warrants to purchase common stock or preferred stock or any combination thereof, either individually or in units. The foregoing does not constitute an offer to sell or the solicitation of an offer to buy securities, and shall not constitute an offer, solicitation or sale in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of that jurisdiction.

On January 15, 2014, the Company entered into a securities purchase agreement, as amended, with two dedicated healthcare funds (collectively, the “Sabby Investors”) that are managed by Sabby Management, pursuant to which the Company agreed to sell an aggregate of 5,000,000 shares of its common stock and warrants to purchase a total of 2,500,000 shares of its common stock to the Sabby Investors for gross proceeds of approximately $15,000,000. The net proceeds to the Company from the registered direct public offering, after deducting the placement agent’s fees and expenses, the Company’s estimated offering expenses, and excluding the proceeds from the exercise of the warrants issued in the offering, were approximately $13.8 million. The Company is using the net proceeds from this offering and sale of securities for working capital and general corporate purposes.

On March 5, 2014, the NASDAQ Stock Market LLC informed the Company that it had approved the listing of the Company's common stock on the NASDAQ Capital Market. The Company's common stock ceased trading on the OTCQX and commenced trading on the NASDAQ Capital Market on March 10, 2014 under the ticker symbol "BPTH."

In April 2014 the Company entered in a lease for a larger office space. The new, expanded size office is required for the core organization the Company has added.

In December of 2014, a former Director of the Company exercised stock options on 525,000 shares of the Company's common stock for aggregate gross proceeds of $435,500.

As of December 31, 2014, Bio-Path had $13,858,798 in cash on hand.

At the December 30, 2014 annual shareholder meeting, shareholders approved a change in incorporation to the State of Delaware. This was subsequently completed effective December 31, 2014.

As the Company has not begun its planned principal operations of commercializing a product candidate, the Company's activities are subject to significant risks and uncertainties, including the potential requirement to secure additional funding, the outcome of the Company's clinical trials, and failing to operationalize the Company's current drug candidates before another company develops similar products.

## 2. Summary of Significant Accounting Policies

***Principles of Consolidation*** — The consolidated financial statements include the accounts of Bio-Path Holdings, Inc., and its wholly-owned subsidiary Bio-Path, Inc. All intercompany accounts and transactions have been eliminated in consolidation.

***Related Party*** — Based on its stock ownership in the Company, MD Anderson Cancer Center meets the criteria to be deemed a related party of Bio-Path Holdings. For the years ending December 31, 2014 and 2013, MD Anderson related party research and development expense was $196,661 and $115,705, respectively. MD Anderson related party research and development expense for the year ending December 31, 2014 included license expense of $50,000 for the license annual maintenance fee and $31,211 for license patent expenses not capitalized in the technology license other asset and clinical trial hospital expense of $115,450. As of December 31, 2014, the Company had $67,050 in accrued R&D related expense for the clinical trial and $100,000 in accrued license payments for past patent expenses and the

annual license maintenance fee. See Notes 4, 5, and 6. For the year ended December 31, 2013, the Company had $115,705 in R&D related party expense for clinical trial hospital expense of $52,050 and license expense of $63,655 including license maintenance fees of $50,000 and $13,655 in patent expenses not capitalized in the technology license other asset. For the year ended December 31, 2012, the Company had $463,870 in R&D related party expense for the clinical trial, license maintenance fee and technology impairment, accounts payable related party of $8,582 for patent expenses not capitalized in the technology license and accrued license payments payable related party of $100,000 for the annual maintenance fee and past patent expenses, and $26,000 accrued expense related party for clinical trial hospital expenses.

***Cash and Cash Equivalents*** — The Company considers all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents.

***Concentration of Credit Risk —*** Financial instruments that potentially subject the Company to a significant concentration of credit risk consist of cash. The Company maintains its cash balances with one major commercial bank, JPMorgan Chase Bank. The balances are insured by the Federal Deposit Insurance Corporation up to $250,000. As a result, as of December 31, 2014, $13,608,798 of the Company’s cash balances were not covered by the FDIC. As of December 31, 2013 the Company had $3,551,832 in cash on-hand, of which $3,301,832 was not covered by Federal Deposit Insurance Corporation insurance and as of December 31, 2012 the Company had $534,046 in cash on-hand, of which $284,046 was not covered by Federal Deposit Insurance Corporation insurance.

***Furniture, fixtures and equipment —*** Furniture, fixtures and equipment are stated at cost and depreciated using the straight-line method over the estimated useful lives of the assets. Depreciation expense was $10,284, $0 and $0 for the years ended December 31, 2014, 2013 and 2012, respectively.

The estimated useful lives are as follows:

Furniture – 3 years

Fixtures – 3 years

Equipment – 3 years

Major additions and improvements are capitalized, while costs for minor replacements, maintenance, and repairs that do not increase the useful life of an asset are expensed as incurred.

***Long-Lived Assets —*** The Company's long-lived assets consist of furniture, fixtures and equipment, and a technology license. Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of the asset is measured by a comparison of the asset's carrying amount to the estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated undiscounted future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the asset.

***Intangible Assets —*** As of December 31, 2014, Other Assets totaled $1,250,893 for the Company's technology license, comprised of $2,500,374 in value acquiring the Company's technology license and its intellectual property, less accumulated amortization of $1,249,481. The technology value consists of $836,207 in cash paid or accrued to be paid to MD Anderson, plus 3,138,889 shares of common stock granted to MD Anderson valued at $2,354,167 less $690,000 for impairment expense taken in December of 2011 and June of 2012. This value is being amortized over a 15 year period from November 7, 2007, the date that the technology license became effective. The Company accounts for the impairment and disposition of its long-lived assets in accordance with generally accepted accounting principles (GAAP). Long-lived assets are reviewed for events of changes in circumstances which indicate that their carrying value may not be recoverable. The Company estimates that approximately $160,000 will be amortized per year for each future year for the current value of the technology licenses acquired until approximately 2022. As of December 31, 2013 Other Assets totaled $1,411,518 comprised of $2,500,374 in value acquiring the Company's technology licenses and its intellectual property, less accumulated amortization of $1,088,856. As of December 31, 2012 Other Assets totaled $1,572,143 comprised of $2,500,374 in value acquiring the Company's technology licenses and its intellectual property, less accumulated amortization of $928,231.

***Research and Development Costs —*** Costs and expenses that can be clearly identified as research and development are charged to expense as incurred in accordance with GAAP. Advance payments, including nonrefundable amounts, for goods or services that will be used or rendered for future R&D activities are deferred and capitalized. Such amounts will be recognized as an expense as the related goods are delivered or the related services are performed. If the goods will not be delivered, or services will not be rendered, then the capitalized advance payment is charged to expense. For the year 2014, the Company had $1,630,439 of costs classified as research and development expense and $196,661 of related party research and development expense. Of the research and development expense totaling $1,630,439, $160,625 was for amortization of the technology license, $83,139 was for stock options expense for individuals involved in research and development activities, $729,031 for drug material manufactured to be used in the clinical trial, $11,965 for drug storage, $193,640 for clinical trial expense, $90,337 for advisory services, $291,993 for manufacturing development and drug product testing, $40,520 for preclinical studies and $29,189 for other R&D activities. Of the $196,661 related party research and development expense, $50,000 was comprised of technology license maintenance fees, $31,211 in patent expenses not capitalized in technology license-Other Assets and $115,450 was comprised of clinical trial hospital costs. For the year 2013, the Company had $1,518,885 of costs classified as research and development expense and $115,705 of related party research and development expense. For the year 2012, the Company had $1,132,712 of costs classified as research and development expense and $463,870 of related party research and development expense.

***Stock-Based Compensation —*** The Company has accounted for stock-based compensation under the provisions of GAAP. The provisions require us to record an expense associated with the fair value of stock-based compensation. We currently use the Black-Scholes option valuation model to calculate stock based compensation at the date of grant. Option pricing models require the input of highly subjective assumptions, including the expected price volatility. Changes in these assumptions can materially affect the fair value estimate.

***Net Loss Per Share –*** Basic net loss per common share is computed by dividing net loss for the period by the weighted average number of common shares outstanding during the period. Although there were warrants and stock options outstanding during 2014, 2013 and 2012, no potential common shares shall be included in the computation of any diluted per-share amount when a loss from continuing operations exists. Consequently, diluted net loss per share as presented in the financial statements is equal to basic net loss per share for the years 2014, 2013 and 2012. The calculation of Basic and Diluted earnings per share for 2014 did not include 4,734,861 shares and 10,000 shares issuable pursuant to the exercise of vested common stock options and vested warrants, respectively, as of December 31, 2014 as the effect would be anti-dilutive. The calculation of Basic and Diluted earnings per share for 2013 did not include 4,848,298 shares and 10,000 shares issuable pursuant to the exercise of vested common stock and vested warrants, respectively, as of December 31, 2013 as the effect would be anti-dilutive. The calculation of Basic and Diluted earnings per share for 2012 did not include 3,296,354 shares and 10,000 shares issuable pursuant to the exercise of vested common stock and vested warrants, respectively, as of December 31, 2012 as the effect would be anti-dilutive.

***Comprehensive Income —*** Comprehensive income (loss) is defined as all changes in a company's net assets, except changes resulting from transactions with shareholders. At December 31, 2014, 2013 and 2012, the Company has no reportable differences between net loss and comprehensive loss.

***Use of Estimates —*** The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the Company's consolidated financial statements and accompanying notes. On an ongoing basis, the Company evaluates its estimates and judgments, which are based on historical and anticipated results and trends and on various other assumptions that the Company believes to be reasonable under the circumstances. By their nature, estimates are subject to an inherent degree of uncertainty and, as such, actual results may differ from the Company's estimates.

***Income Taxes —*** Deferred income tax assets and liabilities are determined based upon differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse.

***New Accounting Pronouncements*** — From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board that are adopted by the Company as of the specified effective date. If not discussed,

management believes that the impact of recently issued standards, which are not yet effective, will not have a material impact on the Company's consolidated financial statements upon adoption. Recently, the FASB issued ASU 2014-10 to eliminate the concept of a development stage entity (DSE) from U.S. GAAP. This change rescinds certain financial reporting requirements that have historically applied to DSEs. The amendments are effective for annual reporting periods beginning after December 15, 2014 and interim periods therein. Early adoption is permitted for financial statements that have not yet been issued or made available for issuance. The Company elected to early adopt ASU 2014-10 as of September 30, 2014.

**3. Prepaid Drug Product for Testing**

Advance payments, including nonrefundable amounts, for goods or services that will be used or rendered for future R&D activities are deferred and capitalized. Such amounts will be recognized as an expense as the related goods are delivered or the related services are performed. The Company incurred installments to its contract drug manufacturing and raw material suppliers totaling $51,364 in late 2013 pursuant to a Drug Supply Contract (See Note 9) for the manufacture and delivery of the Company's lead drug product for testing in a Phase I clinical trial. This amount was carried on the Balance Sheet as of December 31, 2013 at cost as Prepaid Drug Product for Testing. The Company incurred additional installment costs with the total costs incurred totaling $154,667 being carried on the Balance Sheet as of December 31, 2014 as Prepaid Drug Product for Testing (See Note 9).

**4. Accounts Payable**

As of December 31, 2014, Current Liabilities included accounts payable of $41,026 comprised primarily of approximate amounts owed totaling $38,127 to the Company's drug product manufacturer, raw material suppliers and suppliers of services used in clinical trials as well as other miscellaneous items totaling $2,899. Current Liabilities as of December 31, 2014 also included accounts payable – related party totaling $100,450 for MD Anderson clinical trial hospital expense. By the first week of March 2015, the December 31, 2014 amounts included in accounts payable and accounts payable – related party had been substantially paid. As of December 31, 2013, Current Liabilities included accounts payable of $76,109 which were subsequently paid in 2014 and accounts payable – related party of $0.

**5. Accrued Expense**

As of December 31, 2014, Current Liabilities included accrued expense of $253,445 for bonus incentive accruals, unpaid vacation, legal fees, advisory fees, clinical trial costs, corporate communications and travel expenses. Current Liabilities as of December 31, 2014 also included accrued expense – related party of $67,050 for MD Anderson clinical trial hospital expense. (See Note 2). As of December 31, 2013, Current Liabilities included accrued expense of $66,739 and accrued expense related party of $52,050.

**6. Accrued License Payments – Related Party**

Accrued license payments – related party totaling $100,000 and $100,000 were included in Current Liabilities as of December 31, 2014 and 2013, respectively. The amount for 2014 and 2013 represent reimbursement of past patent expenses incurred by MD Anderson prior to the Bio-Path license and the annual license maintenance fee.

**7. Stockholders' Equity**

***Issuance of Common Stock*** – In March of 2012, the Company received $50,000 from LPC in exchange for 166,667 shares of the Company's common stock. LPC was also issued 2,084 shares of the Company's common stock as a commitment fee in connection with the purchase of the 166,667 shares of common stock. No warrants to purchase additional shares of common stock of the Company were issued to Lincoln in connection with the sale of the common stock.

In April of 2012, LPC made three separate purchases of the Company's common stock. The Company received $25,000 from LPC in exchange for 89,286 shares of the Company's common stock. LPC was also issued 1,042 shares of the Company's common stock as a commitment fee in connection with the purchase of the 89,286 shares of common stock. The Company received another $25,000 from LPC in exchange for 96,154 shares of the Company's common stock. LPC was also issued 1,042 shares of the Company's common stock as a commitment fee in connection with the purchase of the 96,154 shares of common stock. Finally, the Company received $50,000 from LPC in exchange for 185,185 shares of the Company's common stock. LPC was also issued 2,084 shares of the Company's common stock as a commitment fee in connection with the purchase of the 185,185 shares of common stock. No warrants to purchase additional shares of common stock of the Company were issued to Lincoln in connection with the sale of the common stock.

In June of 2012, the Company sold $150,000 in shares of its common stock pursuant to a private placement, with shares to be issued, and $18,500 in shares of its common stock for services with shares to be issued.

In August of 2012, the Company issued 50,000 shares of its common stock for the $18,500 shares for services previously recognized in June 2012.

In July through September of 2012, the Company sold $795,001 in shares of its common stock pursuant to a private placement, with shares to be issued.

In October through December of 2012, the Company sold $708,600 in shares of its common stock pursuant to a private placement, with shares to be issued.

As of December 31, 2012 the Company issued 3,300,337 shares of its common stock to investors who purchased shares of common stock from the period June through September of 2012.

As of December 31, 2012, there were 62,219,050 shares of common stock issued and outstanding. There are no preferred shares outstanding as of December 31, 2012.

In February and March of 2013, the Company sold $346,202 in shares of its common stock pursuant to a private placement, with shares to be issued.

In April and May of 2013, the Company sold $2,000,198 in shares of its common stock pursuant to a private placement, with shares to be issued, and $489,501 in shares of its common stock pursuant in a direct offering, with shares to be issued.

In June of 2013, the Company issued 11,664,665 shares of common stock to investors in connection with the private placement and direct offering. In June of 2013 the Company issued 1,496,499 shares of common stock to the Placement Agent as commission for the shares of common stock sold to investors. No warrants to purchase additional shares of common stock of the Company were issued to these investors or to the Placement Agent in connection with the sale of the common stock.

In August and September of 2013, the Company sold $3,220,966 in shares of its common stock pursuant to a private placement, with shares to be issued.

In November of 2013, the Company issued 8,052,416 shares of common stock to investors in connection with the private placement. In November of 2013 the Company issued 805,242 shares of common stock to the Placement Agent as commission for the shares of common stock sold to investors. No warrants to purchase additional shares of common stock of the Company were issued to these investors or to the Placement Agent in connection with the sale of the common stock.

As of December 31, 2013, there were 84,237,872 shares of common stock issued and outstanding. There are no preferred shares outstanding as of December 31, 2013.

In January of 2014, the Company issued a total of 5,000,000 shares of the Company’s common stock and warrants to purchase 2,500,000 shares of the Company’s common stock for aggregate gross proceeds of $15,000,000. The warrants are exercisable for a period of five years from the date of issuance. The exercise price of the warrants is $4.74 a share. The Company also issued warrants to purchase 250,000 shares of the Company’s common stock to the Placement Agent for the transaction with the same terms and conditions.

In December of 2014, a former Director of the Company exercised stock options on 525,000 shares of the Company’s common stock for aggregate gross proceeds of $435,500.

As of December 31, 2014, there were 89,762,872 shares of common stock issued and outstanding. There are no preferred shares outstanding as of December 31, 2014.

**8. Stock-Based Compensation Plans**

***The Plan*** - In 2007, the Company adopted the 2007 Stock Incentive Plan, as amended (the "Plan"). The Plan provides for the grant of Incentive Stock Options, Nonqualified Stock Options, Restricted Stock Awards, Restricted Stock Unit Awards, Performance Awards and other stock-based awards, or any combination of the foregoing to our key employees, non-employee directors and consultants. As of December 31, 2014 the total number of Shares reserved and available for grant and issuance pursuant to this Plan is 8,423,787 Shares, subject to the automatic annual Share increase as defined in the Plan. Under the Plan, the exercise price is determined by the compensation committee of the Board of Directors, and for options intended to qualify as qualified incentive stock options, may not be less than the fair market value as determined by the closing stock price at the date of the grant. Each option and award shall vest and expire as determined by the compensation committee. Options expire no later than ten years from the date of grant. All grants provide for accelerated vesting if there is a change of control, as defined in the Plan.

Stock option awards granted for the year 2014 were estimated to have a weighted average fair value per share of $2.51. Stock option awards granted for the years 2013 and 2012 were estimated to have weighted average fair values per share of $0.47 and $0.37, respectively. The fair value calculation is based on stock options and warrants granted during a period using the Black-Scholes option-pricing model on the date of grant. In addition, for all stock options and compensation-based warrants granted, exercise price was determined based on the fair market value as determined by the closing stock price at the date of the grant. For stock option and compensation-based warrants granted during 2012, 2013 and 2014 the following weighted average assumptions were used in determining fair value:

| | 2012 | 2013 | 2014 |
|---|---|---|---|
| Risk-free interest rate | 0.78% | 1.58% | 2.12% |
| Dividend yield | 0% | 0% | 0% |
| Expected volatility | 185% | 189% | 174% |
| Expected term in months | 61 | 69 | 80 |

The Company determines the expected term of its stock option and warrant awards using the simplified method based on the weighted average of the length of the vesting period and the term of the exercise period. Expected volatility is determined by the volatility of the Company's historical stock price over the expected term of the grant. The risk-free interest rate for the expected term of each option and warrant granted is based on the U.S. Treasury yield curve in effect at the time of grant.

Option activity under the Plan for the year ended December 31, 2014, was as follows:

| | Options | Weighted-Average Exercise Price | Weighted Average Remaining Contractual Term (In years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Year Ended December 31, 2014 | | | | |
| Outstanding at December 31, 2013 | 6,032,188 | $ 0.90 | 6.8 | $18,671,745 |
| Granted | 325,000 | 2.57 | 9.4 | |
| Exercised | (525,000 ) | 0.83 | | |
| Forfeited/expired | (404,410 ) | 0.68 | | |
| Outstanding at December 31, 2014 | 5,427,778 | $ 1.03 | 6.0 | $8,829,412 |
| Vested and expected to vest December 31, 2014 | 5,427,778 | $ 1.03 | 6.0 | $8,829,412 |
| Exercisable at December 31, 2014 | 4,734,861 | $ 0.99 | 5.6 | $7,930,757 |

The aggregate intrinsic value in the table above represents the total pretax intrinsic value (the difference between the Company's closing stock price on the last trading day of 2014 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on December 31, 2014. This amount changes based on the fair market value of the Company's stock. The aggregate pretax intrinsic value of exercises in 2014 totaled $914,824.

Option activity under the Plan for the year ended December 31, 2013, was as follows:

| | Options | Weighted-Average Exercise Price | Weighted Average Remaining Contractual Term (In years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Year Ended December 31, 2013 | | | | |
| Outstanding at December 31, 2012 | 3,482,188 | $ 1.22 | 5.8 | $5,339 |
| Granted | 2,550,000 | $ 0.48 | 9.6 | |
| Exercised | - | - | | |
| Forfeited/expired | - | - | | |
| Outstanding at December 31, 2013 | 6,032,188 | $ 0.90 | 6.8 | $18,671,745 |
| Vested and expected to vest December 31, 2013 | 6,032,188 | $ 0.90 | 6.8 | $18,671,745 |
| Exercisable at December 31, 2013 | 4,848,298 | $ 1.0535 | 6.2 | $14,824,475 |

The aggregate intrinsic value in the table above represents the total pretax intrinsic value (the difference between the Company's closing stock price on the last trading day of 2013 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on December 31, 2013. This amount changes based on the fair market value of the Company's stock.

Option activity under the Plan for the year ended December 31, 2012, was as follows:

| | Options | Weighted-Average Exercise Price | Weighted Average Remaining Contractual Term (In years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Year Ended December 31, 2012 | | | | |
| Outstanding at December 31, 2011 | 3,432,188 | $ 1.23 | 6.8 | $ 2,839 |
| Granted | 50,000 | $ 0.37 | 9.5 | |

| | | | | |
|---|---|---|---|---|
| Exercised | - | - | | |
| Forfeited/expired | - | - | | |
| Outstanding at December 31, 2012 | 3,482,188 | $ 1.22 | 5.8 | $ 5,339 |
| Vested and expected to vest December 31, 2012 | 3,482,188 | $ 1.22 | 5.8 | $ 5,339 |
| Exercisable at December 31, 2012 | 181,771 | $ 0.32 | 7.0 | $ 4,130 |

The aggregate intrinsic value in the table above represents the total pretax intrinsic value (the difference between the Company’s closing stock price on the last trading day of 2012 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on December 31, 2012. This amount changes based on the fair market value of the Company’s stock.

A summary of options outstanding and exercisable as of December 31, 2014:

| | Options Outstanding | | | Options Exercisable | |
|---|---|---|---|---|---|
| Exercise Prices | Number Outstanding | Weighted Average Remaining Contractual Life (Years) | Weighted Average Exercise Price | Number Exercisable | Weighted Average Exercise Price |
| $ 0.30 | 50,000 | 3.9 | $ 0.30 | 50,000 | $ 0.30 |
| $ 0.33 | 100,000 | 6.5 | $ 0.33 | 89,583 | $ 0.33 |
| $ 0.39 | 25,000 | 7.8 | $ 0.39 | 25,000 | $ 0.39 |
| $ 0.46 | 2,152,778 | 8.6 | $ 0.46 | 1,756,945 | $ 0.46 |
| $ 0.53 | 20,000 | 6.1 | $ 0.53 | 18,333 | $ 0.53 |
| $ 0.90 | 270,000 | 3.3 | $ 0.90 | 270,000 | $ 0.90 |
| $ 1.40 | 2,500,000 | 3.8 | $ 1.40 | 2,500,000 | $ 1.40 |
| $ 1.95 | 25,000 | 8.8 | $ 1.95 | 25,000 | $ 1.95 |
| $ 1.96 | 25,000 | 9.8 | $ 1.96 | - | - |
| $ 2.28 | 15,000 | 9.7 | $ 2.28 | - | - |
| $ 2.37 | 15,000 | 9.7 | $ 2.37 | - | - |
| $ 2.40 | 150,000 | 9.3 | $ 2.40 | - | - |
| $ 2.42 | 5,000 | 9.7 | $ 2.42 | - | - |
| $ 2.71 | 50,000 | 9.3 | $ 2.71 | - | - |
| $ 4.30 | 25,000 | 9.1 | $ 4.30 | - | - |
| | 5,427,778 | 6.0 | $ 1.03 | 4,734,861 | $ 0.99 |

Warrant activity under the Plan for the year ended December 31, 2014, was as follows:

| | Warrants | Weighted-Average Exercise Price | Weighted Average Remaining Contractual Term (In years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Year Ended December 31, 2014 | | | | |
| Outstanding at December 31, 2013 | 10,000 | $ 0.90 | 4.3 | $ 31,000 |
| Granted | - | - | | |
| Exercised | - | - | | |
| Forfeited/expired | - | - | | |
| Outstanding at December 31, 2014 | 10,000 | $ 0.90 | 3.3 | $ 17,600 |
| Vested and expected to vest December 31, 2014 | 10,000 | $ 0.90 | 3.3 | $ 17,600 |
| Exercisable at December 31, 2014 | 10,000 | $ 0.90 | 3.3 | $ 17,600 |

Warrant activity under the Plan for the year ended December 31, 2013, was as follows:

| | Warrants | Weighted-Average Exercise Price | Weighted Average Remaining Contractual Term (In years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Year Ended December 31, 2013 | | | | |
| Outstanding at December 31, 2012 | 85,620 | $ 0.90 | 0.9 | $ - |
| Granted | - | - | | |
| Exercised | - | - | | |
| Forfeited/expired | (75,620 ) | 0.90 | | |
| Outstanding at December 31, 2013 | 10,000 | $ 0.90 | 4.3 | $ 31,000 |
| Vested and expected to vest December 31, 2013 | 10,000 | $ 0.90 | 4.3 | $ 31,000 |
| Exercisable at December 31, 2013 | 10,000 | $ 0.90 | 4.3 | $ 31,000 |

Warrant activity under the Plan for the year ended December 31, 2012, was as follows:

| | Warrants | Weighted-Average Exercise Price | Weighted Average Remaining Contractual Term (In years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Year Ended December 31, 2012 | | | | |
| Outstanding at December 31, 2011 | 85,620 | $ 0.90 | 1.9 | $ - |
| Granted | - | | | |
| Exercised | - | | | |
| Forfeited/expired | - | | | |
| Outstanding at December 31, 2012 | 85,620 | $ 0.90 | 0.9 | $ - |
| Vested and expected to vest December 31, 2012 | 85,620 | $ 0.90 | 0.9 | $ - |
| Exercisable at December 31, 2012 | - | - | - | - |

A summary of warrants outstanding and exercisable as of December 31, 2014:

| | Warrants Outstanding | | | Warrants Exercisable | |
|---|---|---|---|---|---|
| Range of Exercise Prices | Number Outstanding | Weighted Average Remaining Contractual Life (Years) | Weighted Average Exercise Price | Number Exercisable | Weighted Average Exercise Price |
| $ 0.90 | 10,000 | 3.3 | $ 0.90 | 10,000 | $ 0.90 |
| | 10,000 | 3.3 | $ 0.90 | 10,000 | $ 0.90 |

***Stock Option Grants -*** Total stock option expense for the years 2012 and 2013 totaled $63,385 and $704,480, respectively. Total stock option expense for the year 2014 totaled $404,150. Of this amount, $83,139 related to stock options for personnel involved in R&D activities and $321,011 related to stock options for outside directors and officers and management of the Company. As of December 31, 2014, total unrecognized compensation cost related to unexpensed stock option awards amounted to $705,387.

***Warrant Grants -*** There were no warrants for services granted in 2014 and there was no warrant expense for the year 2014. There were no warrants for services granted in the years 2012 and 2013 and there was no warrant expense for the years 2012 and 2013.

## 9. Commitments and Contingencies

***Technology License – Related Party -*** The Company has negotiated exclusive licenses from the MD Anderson Cancer Center to develop drug delivery technology for antisense and siRNA drug products. These licenses require, among other things, the Company to reimburse MD Anderson for ongoing patent expense. Related party accounts payable and accrued license payments attributable to the Technology License totaling $100,000 are included in Current Liabilities as of December 31, 2014. Related party accounts payable and accrued expense totaling $167,500 as of December 31, 2014 represent hospital costs for the clinical trial and are not related to the Technology License. As of December 31, 2014, the Company estimates reimbursable past patent expenses will total approximately $75,000 for the antisense license. The Company will be required to pay when invoiced the past patent expenses at the rate of $25,000 per quarter.

***Operating Lease -*** In April of 2014 the Company entered into a lease for a larger office space, which it occupied as of August 2014. The remaining lease payments due under this lease as of December 31, 2014 are approximately $382,000.

| | For the Year Ending December 31, |
|---|---|
| 2015 | $ 79,000 |
| 2016 | 81,000 |
| 2017 | 84,000 |
| 2018 | 87,000 |
| 2019 | 51,000 |
| Total | $ 382,000 |

***Drug Supplier Project Plan*** - In fourth quarter of 2014, Bio-Path entered into a project plan agreement with a new final drug product manufacturer for the manufacture and delivery of final drug product for expected delivery in the third quarter of 2015. This will be the second final drug product manufacturer that the Company can utilize for its drug supply requirements. The project plan requires the Company to pay approximately $250,000 in various stages as the final drug product is manufactured and delivered to the Company.

**10. Income Taxes**

At December 31, 2014, the Company has a net operating loss carryforward for Federal income tax purposes of $14,779,928 which expires in varying amounts during the tax years 2028 and 2034. The Company has a research and development tax credit carryforward of $668,611 for Federal tax purposes with no expiration date. The Company recorded an increase in the valuation allowance of $1,530,234 for the year ended December 31, 2014.

The components of the Company’s deferred tax asset are as follows:

| | December 31, 2014 | 2013 | 2012 |
|---|---|---|---|
| Current Deferred Tax Assets | | | |
| Accrued Bonuses | $48,408 | $15,725 | $39,131 |
| Noncurrent Deferred Tax Assets | | | |
| Net Operating Loss (NOL) Carryover | 5,025,174 | 3,727,259 | 2,914,697 |
| Technology Licenses | 66,697 | 69,859 | 73,021 |
| Research & Development Tax Credits | 668,611 | 520,891 | 383,067 |
| Share Based Expense | 256,568 | 201,490 | 179,779 |
| Total Deferred Tax Asset | 6,065,458 | 4,535,224 | 3,589,877 |
| Less: Valuation Allowance | (6,065,458) | (4,535,224) | (3,589,877) |
| Net Deferred Tax Asset | $- | $- | $- |

Reconciliation between income taxes at the statutory tax rate (34%) and the actual income tax provision for continuing operations follows:

| | December 31, | | |
|---|---|---|---|
| | 2014 | 2013 | 2012 |
| Loss Before Income Taxes | $4,560,481 ) | $(3,266,013) | $(2,582,537) |
| Tax (Benefit) @ Statutory Tax Rate | (1,550,564) | (1,110,444) | (878,063 ) |
| Effects of: | | | |
| Exclusion of ISO Expense | 82,333 | 217,813 | - |
| R&D Tax Credits | (131,722 ) | (90,964 ) | (179,779 ) |
| Increase in Valuation Allowance | 1,530,234 | 945,347 | 1,056,770 |
| Carryforward Adjustment | 21,439 | - | - |
| Other | 48,280 | 38,248 | 1,072 |
| Provision for Income Taxes | $- | $- | $- |

As of December 31, 2014, 2013 and 2012, the Company has no unrecognized income tax benefits. A reconciliation of our unrecognized tax benefits for the years ending December 31, 2014, 2013 and 2012 is presented in the table below:

| | December 31, | | |
|---|---|---|---|
| | 2014 | 2013 | 2012 |
| Beginning balance | $ - | $ - | $ - |
| Additions based on tax positions related to current year | - | - | - |
| Reductions for tax positions of prior years | - | - | - |
| Reductions due to expiration of statute of limitations | - | - | - |
| Settlements with taxing authorities | - | - | - |
| Ending Balance | $ - | $ - | $ - |

The Company’s policy for classifying interest and penalties associated with unrecognized income tax benefits is to include such items as tax expense. No interest or penalties have been recorded during the years ended December 31, 2014, 2013 and 2012 and no interest or penalties have been accrued as of December 31, 2014, 2013 and 2012.

The tax years from 2010 and forward remain open to examination by federal and state authorities due to net operating loss and credit carryforwards. The Company is currently not under examination by the Internal Revenue Service or any other taxing authorities.

**11. Subsequent Events**

In the first quarter of 2015 the Company entered into several contracts with its drug substance and final drug product manufacturers for drug requirements for the first half of 2015. Bio-Path entered into three agreements with its drug substance manufacturer including a contract for Grb-2 antisense for use in a clinical trial, a development contract for Bcl-2 antisense for its second drug candidate Liposomal Bcl-2 and a contract for Bcl-2 antisense for use in the drug product Liposomal Bcl-2 that would be used in a clinical trial. Bio-Path also entered into two contracts for manufacture of two batches of the Liposomal Grb-2 drug product for use in its Phase 2 clinical trial. Together these contracts total approximately $650,000, which will likely be paid over the first three quarters of 2015.

**12. Quarterly Results of Operations (Unaudited)**

Quarterly data for the years ended December 31, 2014 and 2013 is as follows:

| | Quarter Ended | | | |
|---|---|---|---|---|
| | March 31, | June 30, | September 30, | December 31, |
| 2014 | | | | |
| Total Revenues | $- | $- | $- | $- |
| Expenses | 510,210 | 1,274,801 | 1,154,108 | 1,603,127 |
| Loss From Operations | (510,210) | (1,274,801) | (1,154,108) | (1,603,127) |
| Other Income | 5,334 | 6,024 | 5,699 | 5,240 |
| Net Loss | (504,876) | (1,268,777) | (1,148,409) | (1,597,887) |
| Net Loss Per Common Share – Basic and Diluted | (0.01) | (0.01) | (0.01) | (0.02) |

| | Quarter Ended | | | |
|---|---|---|---|---|
| | March 31, | June 30, | September 30, | December 31, |
| 2013 | | | | |
| Total Revenues | $- | $- | $- | $- |
| Expenses | 655,910 | 428,646 | 1,393,728 | 790,956 |
| Loss From Operations | (655,910) | (428,646) | (1,393,728) | (790,956) |
| Other Income (Expense) | (92) | 1,402 | 521 | 1,396 |
| Net Loss | (656,002) | (427,244) | (1,393,207) | (789,560) |
| Net Loss Per Common Share – Basic and Diluted | (0.01) | (0.01) | (0.02) | (0.01) |