BIO-PATH HOLDINGS INC
Form 10-K
April 01, 2013

U.S. 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, 2012

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)

Utah	87-0652870
(State or other jurisdiction of incorporation)	(I.R.S. employer identification No.)

2626 South Loop, Suite 180, Houston, Texas

(Address of principal executive offices)

Registrant's telephone no., including area code: (832) 971-6616

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

Securities registered pursuant to Section 12(g) of the Exchange Act: Common Stock $0.001 par value

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. x

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 ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ¨ Nox

As of March 20, 2013, there were 62,219,050 of the registrant's common stock issued and outstanding. The aggregate market value of the voting stock held by non-affiliates of the Issuer was approximately $16,684,748 as of June 30, 2012, the last business day of the registrant's most recently completed second fiscal quarter, based on the last sales price of the Issuer’s common stock as reported on the OTCQX on such date of $0.37 per share. For purposes of the preceding sentence only, all directors, executive officers and beneficial owners of ten percent or more of the shares of the Issuer’s common stock are assumed to be affiliates.

DOCUMENTS INCORPORATED BY REFERENCE: NONE

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PART I

Unless the context requires otherwise, references in this report to “we,” “our,” “us,” “Company” and “Bio-Path” refer to Bio-Pa
Holdings, Inc. and its subsidiary. Our wholly-owned subsidiary, Bio-Path, Inc., is sometimes hereafter referred to as
“Bio-Path Subsidiary”.

Note Regarding Forward-Looking Statements

This annual report on Form 10-K contains forward-looking statements that have been made pursuant to the provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements are based on current expectations, estimates and projections about our industry, management’s beliefs, and certain assumptions made by our management, and may include, but are not limited to statements regarding:

- the potential benefits and commercial potential of our potential products,
- our clinical trials, commencement dates for new clinical trials, clinical trial results, evaluation of our clinical trial results by regulatory agencies in other countries,
- our ability to obtain additional financing,
- the safety and efficacy of our product candidates,
- estimates of the potential markets and estimated trial dates,
- any changes in the current or anticipated market demand or medical need of our potential products,
- need for additional research and testing,
- the uncertainties involved in the drug development process and manufacturing,
- our future research and development activities,
- assessment of competitors and potential competitors,
- potential costs resulting from product liability or other third-party claims,
- the sufficiency of our existing capital resources and projected cash needs,
- assessment of impact of recent accounting pronouncements, and
- government regulation and approvals.

Words such as “anticipates,” “expects,” “intends,” “plans,” “believes,” “seeks,” “estimates,” variations of such words and simil
expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements are not guarantees of future performance and are subject to certain risks, uncertainties, and assumptions that are difficult to predict; therefore, actual results may differ materially from those expressed or forecasted in any such forward-looking statements. Such risks and uncertainties include, but are not limited to, those discussed later in this annual report under the section entitled “Risk Factors.” Unless required by law, we undertake no obligation to update publicly any forward-looking statements, whether because of new information, future events or otherwise. However, readers 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”).

ITEM 1. DESCRIPTION OF BUSINESS

The “Company is a development stage company with its lead cancer drug candidate, Liposomal Grb-2 (“L-Grb-2” or “BP-100-1.01”), 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 lead liposomal antisense drug candidates are targeted to treat acute myeloid leukemia, myelodysplastic syndrome, chronic myelogenous leukemia, acute lymphoblastic leukemia and follicular lymphoma, and if successful, could potentially be used in treating many other indications of cancer.

Research and Development

Our research and development is currently conducted through agreements we have with MD Anderson. We anticipate that new research and development relationships will be added in the future for pre-clinical testing services and future sites for clinical trials that require multiple sites for patient testing. Research and development related expenses incurred for the years ended December 31, 2012 and December 31, 2011 were $1,132,712 and 596,802, respectively.

Recent Updated Information

In November of 2012, the Company announced that it was requesting the U.S. Food and Drug Administration ("FDA") to allow for higher doses of L-Grb-2 in patients because there had been no evidence of significant toxicity from treatment of patients with L-Grb-2. The Principal Investigator for the Phase I clinical trial, in consultation with Bio-Path's Board of Directors (the "Board"), advised that with the absence of any real toxicity barriers, the Company should continue to evaluate higher doses of Liposomal Grb-2. The absence of significant toxicity provides a significant opportunity for the Company 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 is in place allowing higher dosing. The Company is currently enrolling and treating patients in Cohort 5 at a dose of 60 mg/m^2. The clinical trial is being conducted at MD Anderson.

In December 2012 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.

At the end of January 2012, the Company's Board held a strategic planning session. Among several topics was a discussion of the Company's liposomal siRNA technology. The siRNA discussion covered a broad range of topics including intellectual property, the amount of development that would be needed and the overall impression of diminishing acceptance of siRNA technology by the pharmaceutical industry and equity market investors. The Board compared this to our core liposomal antisense technology, which has a stronger intellectual property position, a method of action blocking expression of disease-causing proteins that is better understood in the scientific community and a much easier path for development than liposomal siRNA technology. Since both antisense and siRNA are means to block expression of disease-causing proteins, the Board concluded that there was no apparent reason to develop a second, higher-risk siRNA method of blocking protein expression when the development of the liposomal antisense method is now much further along and showing promising results. After this discussion the Board decided to discontinue development of the licensed liposomal siRNA technology and the Company commenced discussions regarding this decision with MD Anderson to determine with them whether to modify the license to include other products, postpone the license or simply abandon the license. As an interim step pending final resolution of this matter, the Company took a charge of $345,000 at the end of the fiscal year ending December 31, 2011 to reduce the carrying value of the siRNA license by fifty percent (50%). This amount represented one half of the value of the

Company's common stock given to MD Anderson when the original siRNA license was finalized. In June 2012, the Company decided to write-off the balance of the carrying value of the siRNA license, representing $345,000, and cancel the license.

An important milestone was achieved for the Company in the second quarter, 2012 when Bio-Path's common stock began trading on the quality-controlled OTCQX. OTCQX is the highest tier, premier trading platform for OTC companies. The Company also announced that it had retained Roth Capital Partners to serve as the Company's Designated Advisor for Disclosure ("DAD") on OTCQX, responsible for providing guidance on OTCQX requirements.

On October 1, 2012, the Company's Board increased the size of the Board from three to four members and elected Michael J. Garrison as a director of the Company to fill the vacancy created by such increase.

In the first quarter of 2013, the Company entered into a supply agreement with its drug product manufacturer for the manufacture of the Company's drug product for delivery in May of 2013. The agreement calls for the Company to pay approximately $150,000 in various stages until the final drug product is manufactured, successfully tested and delivered to the Company.

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

The Company's strategy consists of five principle steps:

1) Complete the Phase I clinical trial of the Company's 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 the Company's 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 30 months is focused on achievement of milestones with the intent to demonstrate clinical proof-of-concept of our drug delivery technology and lead drug products. 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. We also intend to raise 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.

Previously, we developed a business plan with milestones that we currently anticipate will require us to raise approximately $7,000,000 to completely implement our current business plan. The milestones include completion of the Phase I clinical trial of L-Grb-2, a Phase I clinical trial in an additional liposomal antisense drug product in addition to the drug product L-Grb-2 currently in a Phase I clinical trial and a multi-site Phase II clinical trial of L-Grb-2. In addition, our previous plan of operation included funds to in-license up to four new protein targets for development as liposomal antisense drug product candidates to add to our product pipeline for development. However, as previously noted, the results seen to date in the Phase I clinical trial of Liposomal Grb-2 have created the opportunity to conduct multi-site Phase II clinical trials of Liposomal Grb-2 in three separate blood cancers (specifically, AML, MDS and CML), a significant opportunity for the Company. 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. As a result of these two developments over the past year, Bio-Path has revised its business plan over the next 30 months to include (i) milestones for the additional two Phase II clinical trials for Liposomal Grb-2 and (ii) development of Liposomal Grb-2 treatments for triple negative and inflammatory breast cancer, including a pre-clinical program and a Phase I clinical trial. The Company believes that the potential to enhance the value of the Company from these two project additions is significant; however, these projects are expected to cause the capital requirements for the Company over the next 30 months to increase to $12,700,000.

We have completed several financings for use in our operations and have received total net proceeds of $8,459,384 through December 31, 2012. In addition, the Company is continuing its capital raising efforts through the sale of shares of its common stock. Our near term plan is to achieve three key milestones:

(1) conduct and conclude a Phase I clinical trial of our lead drug BP-100-1.01, which if successful, will validate our liposomal delivery technology for nucleic acid drug products. We anticipate completing the Phase I clinical trial by the middle of 2013, assuming that only two additional dose levels are required.

(2) complete plans to initiate Phase II clinical trials in our lead drug BP-100-1.01 and initiate pre-clinical development of BP-100-1.01 for triple negative and inflammatory breast cancers.

(3) after achieving sufficient proof of concept that validates our delivery technology, 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.

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 drugs, 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 have shown a 10-fold to 30-fold increase in tumor cell uptake with this technology compared to other delivery methods.

BP-100-1.01

BP-100-1.01 is our lead lipid delivery antisense drug candidate, which is being clinically tested in patients having Acute Myeloid Leukemia (AML), Chronic Myelogenous Leukemia (CML), Myelodysplastic Syndrome (MDS) and Acute Lymphoblastic Leukemia (ALL). If the results of the clinical tests are favorable, we expect there will be opportunities to negotiate non-exclusive license applications involving upfront cash payments with pharmaceutical companies developing antisense drugs that need systemic delivery technology.

The IND for BP-100-1.01 was submitted to the 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 Investigational New Drug ("IND") for Bio-Path's lead cancer drug candidate liposomal BP-100-1.01 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 is a dose-escalating study to determine the safety and tolerance of escalating doses of L-Grb-2. The study will also determine the optimal biologically active dose for further development. The pharmacokinetics of L-Grb-2 in patients will be studied, making it possible to investigate whether the delivery technology performs as expected based on pre-clinical studies in animals. In addition, patient blood samples from the trial will be tested using a new assay developed by the Company to measure down-regulation of the target protein, the critical scientific data that will demonstrate that 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 trial will evaluate five doses of L-Grb-2 and patients will be enrolled in the study to achieve 18 to 30 evaluable patients. An evaluable patient is a patient who is able to complete the four-week treatment cycle. The clinical trial is being conducted at MD Anderson.

Patients eligible for enrollment into the Phase I clinical trial have refractory or relapsed Acute Myeloid Leukemia ("AML"), Philadelphia Chromosome Positive Chronic Myelogenous Leukemia ("CML") and Acute Lymphoblastic Leukemia ("ALL"), or Myelodysplastic Syndrome ("MDS") and who have failed other approved treatments. These are patients with very advanced stages of the disease, and consequently, not all patients enrolled are able to complete the four-week treatment cycle because of progressive disease, which is unrelated to the treatment with Liposomal-Grb-2.

At the end of July 2011, the Company completed requirements for treating patients in the first cohort. The Company, its medical advisors and the Principal Investigator agreed that the data from the first cohort demonstrated that Liposomal Grb-2 was safe enough to proceed to the next cohort of the trial, which treated patients in the trial with a dose that was double the dose used in the first cohort. As a result of this review, the first cohort was closed and the second cohort was opened for recruiting patients into the clinical trial. In January 2012, the Company completed requirements for treating patients in the second cohort. The Company, its medical advisors and the Principal Investigator agreed that the data from the second cohort demonstrated that Liposomal Grb-2 was safe enough to proceed to the third cohort of the trial, which treated patients with a dose of 20 mg/m^2, double the dose used in the second cohort. Significantly, in the third cohort, all three patients completed the treatment cycle and were evaluable and, because of apparent stabilization from treatment with Liposomal Grb-2, had received or anticipated to receive extended treatment cycles. The Company, its medical advisors and the Principal Investigator agreed that the data from the third cohort demonstrated that Liposomal Grb-2 was safe enough to proceed to the fourth cohort of the trial, which treated patients with a dose of 40 mg/m^2, double the dose used in the third cohort.

Based on the experience treating patients in the third cohort, when all three patients benefited from treatment with Liposomal Grb-2 and were apparently stabilized, the assumption for drug requirements for the fourth cohort and beyond have increased significantly. Specifically, the assumption now is that all patients will benefit from treatment with the drug candidate Liposomal Grb-2 and be eligible to receive up to six months of treatments. In this regard, the Company increased the capacity of its drug supply chain, adding new suppliers for the Liposomal Grb-2 drug substance and for the final drug product. Substantially increased supplies of the drug candidate Liposomal Grb-2 were delivered in July 2012.

In November 2012, the Company announced that since there had been no evidence of significant toxicity from treatment of patients with L-Grb-2, the Company was proceeding with requesting the FDA to allow higher dosing in patients. The Principal Investigator for the clinical trial, in consultation with Bio-Path's Board, advised that with the absence of any real toxicity barriers, the Company should continue to evaluate higher doses of Liposomal Grb-2. The absence of significant toxicity provides a significant opportunity for the Company 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 is in place allowing higher dosing. The Company is currently enrolling and treating patients in the fifth cohort at a dose of 60 mg/m^2. The clinical trial is being conducted at MD Anderson.

The Principal Investigator for the Phase I clinical trial, Dr. Jorge Cortes (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 and he presented such results at the annual meeting of the American Society of Hematology in December of 2011. Results from the second cohort also demonstrated potential anti-leukemia benefits in treated patients and such results were included in the presentation to the American Society of Hematology. Bio-Path and the Principal Investigator plan to present information at leading industry scientific conferences in the future as results become available.

Bio-Path has also been working with the Principal Investigator to finalize plans for Phase II clinical trials in Liposomal Grb-2. Significantly, these plans include three Phase II trials, one each for CML, AML and MDS, of the drug candidate Liposomal Grb-2 in combination with the respect frontline treatment for each disease in salvage therapy for advanced patients. The opportunity for three drug approvals in a relatively moderate timeframe could be significant for Bio-Path's shareholders. The Company expects to update investors on its development plans in the very near future. An update for timelines and budgets is anticipated to given at that time.

An important outcome for the Phase I clinical trial is the ability to assess for the first time the performance of the Company's delivery technology platform in human patients. The Company has 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.

Being platform technology, a successful demonstration of the delivery technology in this study will allow the Company to begin expanding Bio-Path's drug candidates by simply applying the delivery technology template to multiple new drug product targets. In this manner, Bio-Path 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, the Company is researching potential targets for which it can apply its liposomal antisense drug delivery technology.

BP-100-1.02

BP-100-1.02 ("Bcl-2" or "BP-100-1.02") is Bio-Path's co-lead compound. The scientific name for BP-100-1.02 is Liposomal Bcl-2, a liposome delivered antisense cancer drug that targets the lymphoma and certain solid tumor markets. 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 percent 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.

Clinical targets for BP-100-1.02 include lymphoma, breast cancer, colon cancer, prostate cancer and leukemia.

Other Liposomal Antisense Products

As noted previously, the Company intends to apply its 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 the Company’s 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 “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 is 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.

Liposomal Tumor Targeting is a new technology, being licensed in the field of neutral lipid-based liposome delivery of antisense technologies and siRNA, that will likely enhance the Company’s liposome delivery technology by adding vectors to the liposomes targeted to a receptor that is specifically over-expressed on a majority of solid and hematological tumors and on eighty percent (80%) of metastatic epithelial tumors. The Company believes this liposome tumor-targeting technology for antisense and siRNA delivery is a highly promising strategy for treating primary and metastatic cancers.

Myelodysplastic Syndromes 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 (AML). 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.

Projected Financing Needs

We anticipate that will need to raise approximately an additional $12,700,000 to complete our revised planned clinical trials and other activities described herein.

The remaining cost of the Phase I clinical trial of BP-100-1.01 is expected to be approximately $500,000, provided that the trial is completed after the next two dose levels. If the Phase I clinical trial in BP-100-1.01 is successful, we expect to follow with multi-site Phase II trials in BP-100-1.01. Successful Phase I and II trials of BP-100-1.01 is expected to provide clinical evidence to support BP-100-1.01 as a potential therapeutic drug product for treatment of AMLMDS and CML. The Phase II clinical trials in BP-100-1.01 are expected to cost approximately $2,000,000 each, or approximately $6,000,000 for all three.

Development of BP-100-1.01 to treat triple negative and inflammatory breast cancers over the 30 month plan horizon is expected to require approximately $1,500,000. This amount is expected to fund the preclinical program and the Phase I clinical trial. It is anticipated that the Phase I clinical trial will cost less than a typical Phase I trial because the safety profile will have already been established upon conclusion of BP-100-1.01’s current clinical trial. This is expected to result in fewer patients being tested and a more efficient progression to an optimal biological dose.

The Phase I clinical trial of BP-100-1.02 (L-Bcl-2) is expected to cost approximately $2,000,000. Commencement of the Phase I clinical trial depends on the FDA approving the IND for BP-100-1.02. Success in the Phase I clinical trial will be based on the demonstration that the drug is well tolerated and other key outcomes. The Phase I clinical trial will likely be a dose-escalating study to determine the safety and tolerance of escalating doses of BP-100-1.02. The study will also likely determine the optimal biologically active dose for further development. The pharmacokinetics of BP-100-1.02 in patients will be studied, as well as down-regulation of the target protein to corroborate any positive anti-cancer effects in addition to confirming effectiveness of the delivery technology.

Approximately $300,000 has been allocated to identifying other protein targets for development into liposomal antisense drug candidates. The balance of the $12,700,000 in funding needs from our revised plan over 30 months is approximately $2,400,000, which is planned to fund patent expenses, licensing fees, pre-clinical costs to MD Anderson’s Pharmaceutical Development Center, consulting fees and management and administration. Of the projected total of $12,700,000 in funding needs, approximately $10,000,000 in project costs is projected to be spent on clinical trials of our drug candidates and developing new drug candidates, and the balance is projected to be spent on period costs for professionals, management and license costs.

We have generated approximately five 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 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 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.

There can be no assurance of the following:

1) That the actual costs of a particular trial will come within our budgeted amount.
2) That any trials will be successful or will result in drug commercialization opportunities.
3) That we will be able to raise the sufficient funds to allow us to operate for three years or to complete our trials.

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 mission is to "make 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 a "big deal" 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 the Company 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

Bio-Path was 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, Bio-Path negotiated or plans to negotiate several agreements with MD Anderson that will:

¨allow Bio-Path to develop MD Anderson's neutral lipid delivery technology;
¨give Bio-Path ongoing access to MD Anderson's Pharmaceutical Development Center for drug development;
¨provide rapid communication to Bio-Path of new drug candidate disclosures in the Technology Transfer Office;
¨standardize clinical trial programs sponsored by Bio-Path; and
¨standardize sponsored research under a master agreement addressing intellectual property sharing.

Bio-Path's Chief Executive Officer is experienced in working with MD Anderson and its personnel. Bio-Path believes that if we obtain adequate financing, Bio-Path 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 for out-licensing to pharmaceutical partners.

Licenses

Bio-Path Subsidiary had originally negotiated and executed three exclusive license agreements for three lead products and nucleic acid delivery technology; however, the Company has determined to maintain only one of these license agreements (the “License Agreement”). We intend to use our relationship with MD Anderson to develop drug compounds covered by such 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 biotech 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: Does Bio-Path 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 Bio-Path 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 "Big Pharma" criteria 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 shareholder value to add to the economic value of drug candidates fully developed and marketed by the Company, 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 forty in the US and perhaps two hundred 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.

License Agreements

We are currently maintaining the License Agreement with MD Anderson. 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. Accounts payable related party totaled $8,582 for current patent expenses and accrued license payments totaling $100,000 for accrued past patent expenses and the license annual maintenance fee are included in Current Liabilities as of December 31, 2012. Past patent expenses represent patent expenses incurred by MD Anderson prior to executing the License Agreement with Bio-Path that is being amortized in quarterly payments. As of December 31, 2012, the Company estimates remaining reimbursable past patent expenses total approximately $75,000 for the antisense license. The Company will be required to pay when invoiced these patent expenses at the rate of $25,000 per quarter when invoiced by MD Anderson. In addition, accrued expense-related party of $26,000 was included in current liabilities as of December 31, 2012 representing accrued hospital expense for MD Anderson services treating patients in Bio-Path’s clinical trial of BP-100-1.01. This expense is unrelated to the License Agreement.

Bio-Path is currently developing a neutral-lipid based liposome delivery technology of antisense for the treatment of cancer. The liposome targeting technology previously licensed was developed based on testing of tumor targeting of liposomal siRNA FAK drug candidate. Tumor targeting was a technology that was needed much more for liposomal siRNA technology than for liposomal antisense technology. As a result, with the Board’s decision in 2012 not to proceed with developing the siRNA technology at this time, tumor targeting will be developed at a later time with potentially another targeting technology.

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 commercialization strategy based on the following concepts:

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

¨Manage trials as if they were being done by Big Pharma: seamless transition; quality systems; documentation; and disciplined program management recognized by Big Pharma diligence teams; trials conducted, monitored and data collected consistent with applicable FDA regulations to maximize Bio-Path's credibility and value 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 Medical Advisory Board 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. Bio-Path will not need to invest its resources in building functions where it does not add substantial value or differentiation. Instead, it 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 have no manufacturing capabilities and intend to outsource our manufacturing function in the near future. The most likely outcome of the out-license of a Bio-Path drug to a pharmaceutical partner will be that the pharmaceutical partner will be responsible for manufacturing drug product requirements. However, in the event Bio-Path is required to supply a drug product to a distributor or pharmaceutical partner for commercial sale, Bio-Path will need to develop, contract for, or otherwise arrange for the necessary manufacturing capabilities. There are a limited number of manufacturers that operate under the FDA's current good manufacturing practices (cGMP) regulations capable of manufacturing our future products. As noted previously, 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.

Intellectual Property

Patents, trademarks, trade secrets, technology, know-how, and other proprietary rights are important to our business. Our success will depend in part on our ability to develop and maintain proprietary aspects of our technology. To this end, we intend to have an intellectual property program directed at developing proprietary rights in technology that we believe will be important to our success.

We will actively seek patent protection in the U.S. and, as appropriate, abroad and closely monitor patent activities related to our business. In addition to patents, we will rely on trade secrets and proprietary know-how, which we seek to protect, in part, through confidentiality and proprietary information agreements.

Agreement with Acorn CRO

On April 23, 2009, we announced that had we entered into an agreement with ACORN CRO, a full service, oncology-focused clinical research organization (CRO), to provide us with a contract medical officer and potentially other clinical trial support services. Under such agreement, Bradley G. Somer, M. D., commenced serving as our Medical Advisor and medical liaison for the conduct of our Phase I clinical study of liposomal BP-100-1.01 in refractory or relapsed Acute Myeloid Leukemia (AML), Chronic Myelogenous Leukemia (CML), Acute Lymphoblastic Leukemia (ALL) and Myelodysplastic Syndrome (MDS).

Employees

We currently employ two full time employees. We also have contractual relationships with six additional professionals who perform medical officer, regulatory and drug development duties. We expect to hire additional employees once additional funding has been secured that will enable additional clinical programs to be undertaken.

Scientific Advisors

Our Scientific Advisors consist of the following scientists and drug development professionals:

Ana M. Tari, Ph.D., M.S. Co-founder of Bio-Path; Associate Professor, at the University of Florida at Gainsville. In addition to her position at the University of Florida, Dr. Tari currenlty is also Director, Preclinical Operations and Research for Bio-Path Holdings, Inc. Previously, Dr. Tari was Associate Professor at the University of Texas MD Anderson Cancer Center.

Bradley G Somer, M.D. Medical Advisor to Bio-Path on a contract basis. Practicing oncologist in hematology, member of the Executive Committee with the West Hospital in Memphis Tennessee. Former site principal investigator for several clinical trial studies in CML.

Gillian Ivers-Read, BSc. Member of Bio-Path's Board and consultant for drug development strategy and operations. Currently Executive Vice President and co-founder of Clovis Oncology and formerly senior executive management with Cellgene, Pharmion and Aventis.

We anticipate that additional scientists and clinicians will join the Scientific Advisory Board once additional funding has been secured to expand Bio-Path's operations.

Competition

We are engaged in fields characterized by extensive research efforts, rapid technological progress, and intense competition. There are many public and private companies, including pharmaceutical companies, chemical companies, and biotechnology companies, engaged in developing products for the same human therapeutic applications that we are targeting. Currently, all or most of our competitors have substantially greater financial, technical and human resources than Bio-Path and are more experienced in the development of new drugs than Bio-Path. In order for us to compete successfully, we may need to demonstrate improved safety, efficacy, ease of manufacturing, and market acceptance of our products over the products of our competitors. We will face competition based on the safety and efficacy of our drug candidates, the timing and scope of regulatory approvals, the availability and cost of supply, marketing and sales capabilities, reimbursement coverage, price, patent position and other factors. Our competitors may develop or commercialize more effective, safer or more affordable products than we are able to develop or commercialize or obtain more effective patent protection. As a result, our competitors may commercialize products more rapidly or effectively than we may be able to, which would adversely affect our competitive position, the likelihood that our drug candidates, if approved, will achieve initial market acceptance and our ability to generate meaningful revenues from those drugs. Even if our drug candidates are approved and achieve initial market acceptance, competitive products may render such drugs obsolete or noncompetitive.

If any such drug is rendered obsolete, we may not be able to recover the expenses of developing and commercializing that drug. With respect to all of our drugs and drug candidates, Bio-Path is aware of existing treatments and numerous drug candidates in development by our competitors.

Government Regulation

Regulation by governmental authorities in the United States and foreign countries is a significant factor in the development, manufacturing, and expected marketing of our future drug product candidates and in its ongoing research and development activities. The nature and extent to which such regulations will apply to Bio-Path will vary depending on the nature of any drug product candidates developed. We anticipate that all of our drug product candidates will require regulatory approval by governmental agencies prior to commercialization.

In particular, human therapeutic products are subject to rigorous pre-clinical and clinical testing and other approval procedures of the FDA and similar regulatory authorities in other countries. Various federal statutes and regulations also govern or influence testing, manufacturing, safety, labeling, storage, and record-keeping related to such products and their marketing. The process of obtaining these approvals and the subsequent compliance with the appropriate federal statutes and regulations requires substantial time and financial resources. Any failure by us or our collaborators to obtain, or any delay in obtaining, regulatory approval could adversely affect the marketing of any drug product candidates developed by us, our ability to receive product revenues, and our liquidity and capital resources.

The steps ordinarily required before a new drug may be marketed in the United States, which are similar to steps required in most other countries, include:

- pre-clinical laboratory tests, pre-clinical studies in animals, formulation studies and the submission to the FDA of an investigational new drug application;
- adequate and well-controlled clinical trials to establish the safety and efficacy of the drug;
- the submission of a new drug application or biologic license application to the FDA; and
- FDA review and approval of the new drug application or biologics license application.

Bio-Path's business model relies on developing drug product candidates through Phase II 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 product candidate through commercialization.

Non-clinical tests include laboratory evaluation of drug product candidate chemistry, formulation and toxicity, as well as animal studies. The results of pre-clinical testing are submitted to the FDA as part of an investigational new drug application. A 30-day waiting period after the filing of each investigational new drug application is required prior to commencement of clinical testing in humans. At any time during the 30-day period or at any time thereafter, the FDA may halt proposed or ongoing clinical trials until the FDA authorizes trials under specified terms. The investigational new drug application process may be extremely costly and substantially delay the development of our drug product candidates. Moreover, positive results of non-clinical tests will not necessarily indicate positive results in subsequent clinical trials in humans. The FDA may require additional animal testing after an initial investigational new drug application is approved and prior to Phase III trials.

Clinical trials to support new drug applications are typically conducted in three sequential phases, although the phases may overlap. During Phase I, clinical trials are conducted with a small number of subjects to assess metabolism, pharmacokinetics, and pharmacological actions and safety, including side effects associated with increasing doses. Phase II usually involves studies in a limited patient population to assess the efficacy of the drug in specific, targeted indications; assess dosage tolerance and optimal dosage; and identify possible adverse effects and safety risks.

If a compound is found to be potentially effective and to have an acceptable safety profile in Phase II evaluations, Phase III trials are undertaken to further demonstrate clinical efficacy and to further test for safety within an expanded patient population at geographically dispersed clinical trial sites.

After successful completion of the required clinical trials, a new drug application is generally submitted. The FDA may request additional information before accepting the new drug application for filing, in which case the new drug application must be resubmitted with the additional information. Once the submission has been accepted for filing, the FDA reviews the new drug application and responds to the applicant. The FDA’s request for additional information or clarification often significantly extends the review process. The FDA may refer the new drug application to an appropriate advisory committee for review, evaluation, and recommendation as to whether the new drug application should be approved, although the FDA is not bound by the recommendation of an advisory committee.

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 new drug application and authorization of commercial marketing of the drug for certain indications. The FDA may also refuse to approve the new drug application or issue a “not approvable” letter outlining the deficiencies in the submission and often requiring additional testing or information.

Sales outside the United States of any drug product candidates Bio-Path develops will also be subject to foreign regulatory requirements governing human clinical trials and marketing for drugs. The requirements vary widely from country to country, but typically the registration and approval process takes several years and requires significant resources.

To date, we have not submitted a marketing application for any product candidate to the FDA or any foreign regulatory agency, and none of our proposed product candidates have been approved for commercialization in any country. We have no experience in designing, conducting and managing the clinical testing necessary to obtain such regulatory approval. In addition to our internal resources and our Scientific Advisory Board, Bio-Path will depend on regulatory consultants for assistance in designing preclinical studies and clinical trials and drafting documents for submission to the FDA. If we are not able to obtain regulatory consultants on commercially reasonable terms, we may not be able to conduct or complete clinical trials or commercialize our future product candidates. We intend to establish relationships with multiple regulatory consultants for our future clinical trials, although there is no guarantee that the consultants will be available for future clinical trials on terms acceptable to us.

Under the FDA Modernization Act of 1997, the FDA may grant “Fast Track” designation to facilitate the development of a drug intended for the treatment of a serious or life-threatening condition if the drug demonstrates, among other things, the potential to address an unmet medical need. The benefits of Fast Track designation include scheduled meetings with the FDA to receive input on development plans, the option of submitting an NDA in sections (rather than submitting all components simultaneously), and the option of requesting evaluation of trials using surrogate endpoints. Fast Track designation does not necessarily lead to a priority review or accelerated approval of a drug candidate by the FDA.

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	Evaluate safety in humans; study how the drug candidate works, metabolizes, and interacts with other drugs	1 to 2 years
Phase II	Establish effectiveness of the drug candidate and its optimal dosage; continue safety evaluation	2 to 4 years
Phase III	Confirm efficacy, dosage regime, and safety profile of the drug candidate; submit NDA	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.

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

Post-approval Studies

Even after FDA approval has been obtained, further studies, including post-approval trials, may be required to provide additional data on safety and will be required to gain approval for the sale of a product as a treatment for clinical indications other than those for which the product initially was approved. Also, the FDA will require post-approval reporting to monitor the side effects of the drug. Results of post-approval programs may limit or expand the indications for which the drug product may be marketed. Further, if there are any requests for modifications to the initial FDA approval for the drug, including changes in indication, manufacturing process, labeling or manufacturing facilities, a supplemental NDA may be required to be submitted to the FDA or we may elect to seek changes and submit a supplemental NDA to obtain approval.

Other Regulations

Pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, 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 statute also allows a patent owner to extend the term of the patent for a period equal to one-half the period of time elapsed between the submission of an IND and the filing of the corresponding NDA plus the period of time between the filing of the NDA and FDA approval. We intend to seek the benefits of this statute, but there can be no assurance that Bio-Path will be able to obtain any such benefits.

Whether or not FDA approval has been obtained, approval of a drug product by regulatory authorities in foreign countries must be obtained prior to the commencement of commercial sales of the product in such countries. Historically, the requirements governing the conduct of clinical trials and product approvals, and the time required for approval, have varied widely from country to country.

The FDA may grant orphan drug designation to drugs intended to treat a “rare disease or condition” that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting an application for marketing authorization. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. If a product that has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years; except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Also, competitors may receive approval of different drugs or biologics for the indications for which the orphan product has exclusivity. As a result of our License Agreement with MD Anderson, we have the rights to drug BP-100-1.01. This drug has been granted orphan drug status by the FDA.

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.

In addition to the statutes and regulations described above, Bio-Path is also subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other federal, state, local and foreign regulations, now or hereafter in effect.

We currently do not have any significant facilities. We lease a small office in Houston, Texas. Our facilities will be expanded as additional employees join Bio-Path. Due to the anticipated use of the outside testing firms for pre-clinical development of our sponsored drug candidates, Bio-Path does not foresee at this time the need to lease laboratory space.

ITEM 1A. RISK FACTORS

Bio-Path is a development stage company with no revenue. We are a holding company. Our operations are conducted by our subsidiary Bio-Path Subsidiary which is a development stage company that was formed on May 10, 2007. Bio-Path Subsidiary has generated no revenues from its contemplated principal business activity. We currently have no products available for sale, no product revenues, and may not succeed in developing or commercializing any drug products that will generate product or licensing revenues. We do not expect to have any products on the market for several years. In addition, development of any of our product candidates will require a process of pre-clinical and clinical testing, and submission to and approval by the FDA or other regulatory agencies, during which our products could fail. Whether profitability is achieved may depend on success in developing, manufacturing and marketing our product candidates or in finding suitable partners to commercialize these candidates.

No revenues in the foreseeable future. Bio-Path Subsidiary has never generated revenues and does not expect any revenues to be generated in the foreseeable future. The drug development process is a lengthy process and no revenues from product sales will be generated for several years, if ever.

Need for additional capital. We anticipate that we have sufficient capital to fund our operations through the second quarter of 2013. We will be required to raise substantial additional financing at various intervals for development

programs, including significant requirements for clinical trials, for operating expenses including intellectual property protection and enforcement, for pursuit of regulatory approvals and for establishing or contracting out manufacturing, marketing and sales functions. We intend to seek additional funding from product-based collaborations, federal grants, technology licensing, and public or private financings, but there is no assurance that such additional funding will be available on terms acceptable to us, or at all. Accordingly, we may not be able to secure the significant funding which is required to maintain and continue development programs at their current levels or at levels that may be required in the future. We may be forced to accept funds on terms or pricing that is highly dilutive or otherwise onerous to other equity holders. If we cannot secure adequate financing, we may be required to delay, scale back or eliminate one or more of our development programs or to enter into license or other arrangements with third parties to commercialize products or technologies that we would otherwise seek to further develop ourselves.

We have had a history of operating losses and we may never achieve profitability. If we continue to incur operating losses, we may be unable to continue our operations. From inception on May 10, 2007 through December 31, 2012, we had a cumulative net loss of $12,131,283. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. In the absence of substantial revenue from the sale of products or other sources, the amount, timing, nature or source of which cannot be predicted, our losses will continue as we conduct our research and development activities.

Successful development of any of our product candidates is highly uncertain. Only a small minority of all research and development programs ultimately result in commercially successful drugs. Even if clinical trials demonstrate safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates will depend upon their acceptance by patients, the medical community, and third-party payers and on our partners' ability to successfully manufacture and commercialize our product candidates. If our products are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business would be severely harmed.

As a result of the FDA approval of our application to commence Phase I clinical trials, we commenced Phase I clinical trials for our BP -100-1.01 in 2010. Clinical trials may not demonstrate statistically sufficient effectiveness and safety to obtain the requisite regulatory approvals for this product candidate.

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is highly uncertain. If any of our drug trials are delayed or yield unfavorable results, we will have to delay or may be unable to obtain regulatory approval for our product candidates. We have commenced dosing patients in our Phase I clinical trials on our BP-100-1.01. We must conduct extensive testing of our product candidates before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting these trials is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining subjects in the clinical trial, lack of sufficient supplies of the product candidate or comparator drug, and the failure of clinical investigators, trial monitors, contractors, consultants, or trial subjects to comply with the trial plan or protocol. A clinical trial may fail because it did not include a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting. Many of clinical trials are conducted under the oversight of Independent Data Monitoring Committees (or IDMCs). These independent oversight bodies are made up of external experts who review the progress of ongoing clinical trials, including available safety and efficacy data, and make recommendations concerning a trial's continuation, modification, or termination based on interim, un-blinded data. Any of ongoing clinical trials may be discontinued or amended in response to recommendations made by responsible IDMCs based on their review of such interim trial results.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new trials, which are expensive and time consuming, or abandon the drug development program. Even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Many companies in the biopharmaceutical industry have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials. The failure of clinical trials to demonstrate safety and effectiveness for the desired indication(s) could harm the development of our product candidate(s), and our business, financial condition, and results of operations may be materially harmed.

We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use. Changes in product formulations and manufacturing processes may be required as product candidates' progress in clinical development and are ultimately commercialized. If we are unable to develop suitable product formulations or manufacturing processes to support large scale clinical testing of our product candidates, we may be unable to supply necessary materials for our clinical trials, which would delay the development of our product candidates. Similarly, if we are unable to supply sufficient quantities of our product or develop product formulations suitable for commercial use, we will not be able to successfully commercialize our product candidates.

Reliance on collaboration agreements. Our business strategy depends upon our ability to enter into collaborative relationships for the development and commercialization of products based on licensed compounds. We will face significant competition in seeking necessary and appropriate collaborators. Moreover, these arrangements are complex to negotiate and time-consuming to document. We may not be successful in our efforts to establish or maintain our existing collaborative relationships, if any, or other alternative arrangements on commercially reasonable terms. We have not entered into any collaborative agreements and there can be no assurance that we will ever enter into such agreements. If we are unable to enter into collaborative agreements, our business model must change and we will be required to raise even greater capital to fund the costs of services that we anticipate having provided by collaborators. This will make an investment in Bio-Path an even greater risk to investors.

If we do enter into collaborative agreements, of which there can be no assurance, the success of collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Our collaborators will have significant discretion in determining the efforts and resources that they will apply to these collaborations. The risks that we face in connection with these collaborations include, but are not limited to, the following:

- disputes may arise in the future 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;
- we may have difficulty enforcing the contracts if one of our collaborators fails to perform;

- our collaborators may terminate their collaborations with us, 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 will have considerable discretion in electing whether to pursue the development of any additional drugs 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 or products that are the subject of the collaboration with Bio-Path; and
- our collaborators may change the focus of their development and commercialization efforts. Pharmaceutical and biotechnology companies historically have re-evaluated their priorities following mergers and consolidations, which have been common in recent years in these industries. The ability of our products to reach their potential could be limited if our collaborators decrease or fail to increase spending relating to such products.

Given these risks, it is possible that any collaborative arrangements into which we enter may not be successful. The failure of any of our collaborative relationships could delay drug development or impair commercialization of our products.

Reliance on third parties for manufacturing. We have no manufacturing experience and no commercial scale manufacturing capabilities and we do not expect to manufacture any products in the foreseeable future. In order to continue to develop products, apply for regulatory approvals and ultimately commercialize products, we will need to develop, contract for, or otherwise arrange for the necessary manufacturing capabilities. The Company may evaluate developing its own manufacturing facility(ies at an appropriate time in the future; however, there is no assurance that we will ever develop our own manufacturing facility(ies).

We intend to rely upon third parties to produce material for preclinical and clinical testing purposes. We expect that our out-license pharmaceutical partners, to the extent we have such partners, will produce materials that may be required for the commercial production of our products.

We have entered into a supply agreement with Lyophilization Services of New England, Inc. (LSNE) for the manufacture of our drug requirements for our drug BP-100-1.01. LSNE is a manufacturer that operates under the FDA's current good manufacturing practices ("cGMP") regulations and is capable of manufacturing our products in the foreseeable future. If our pharmaceutical company partners are unable to arrange for third party manufacturing of our products on a timely basis, LSNE could potentially manufacture their requirements.

Reliance on third party manufacturers will entail risks to which we would not be subject if we manufactured our own products, including, but not limited to:

- reliance on the third party for regulatory compliance and quality assurance;
- the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control;

- the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for Bio-Path;
- the potential that third party manufacturers will develop know-how owned by such third party in connection with the production of our products that is necessary for the manufacture of our products; and
- reliance upon third party manufacturers to assist us in preventing inadvertent disclosure or theft of Bio-Path's proprietary knowledge.

Reliance on key members of scientific and management staff. Our success depends on the availability and contributions of members of our current and future scientific team and our current and future senior management teams and other key personnel that we currently have or which we may develop in the future. The loss of services of any of these persons could delay or reduce our product development and commercialization efforts. Furthermore, recruiting and retaining qualified scientific personnel to perform future research and development work will be critical to our success. The loss of members of our management team, key clinical advisors or scientific personnel, or our inability to attract or retain other qualified personnel or advisors, could significantly weaken our management, harm our ability to compete effectively and harm our business.

Need for intellectual property protection. We had originally entered into three exclusive license agreements with MD Anderson; however, the Company has determined to maintain only the License Agreement. The patents underlying the licensed intellectual property and positions, and those of other biopharmaceutical companies, are generally uncertain and involve complex legal, scientific and factual questions.

Our ability to develop and commercialize drugs depends in significant part on our ability to:

- obtain and/or develop broad, protectable intellectual property;
- obtain additional licenses to the proprietary rights of others on commercially reasonable terms;

¨operate without infringing upon the proprietary rights of others;
¨prevent others from infringing on our proprietary rights; and
¨protect trade secrets.

We do not know whether any of those patent applications which we may have licensed will result in the issuance of any patents. Patents that we may acquire and those that might be issued in the future, may be challenged, invalidated or circumvented, and the rights granted thereunder may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies or duplicate any technology we develop. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thus reducing any advantage of the patent.

Because patent applications in the United States and many foreign jurisdictions are typically not published until at least 12 months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, neither Bio-Path nor our licensors can be certain that either Bio-Path or our licensors were the first to make the inventions claimed in issued patents or pending patent applications, or that Bio-Path was the first to file for protection of the inventions set forth in these patent applications.

Reliance on third party patents. We may not have rights under some patents or patent applications related to products we may develop in the future. Third parties may own or control these patents and patent applications in the United States and abroad. Therefore, in some cases, to develop, manufacture, sell or import some of our future products, Bio-Path or our collaborators may choose to seek, or be required to seek, licenses under third party patents issued in the United States and abroad or under patents that might be issued from United States and foreign patent applications. In instances in which Bio-Path must obtain a license for third party patents, we may be required to pay license fees or royalties or both to the licensor. If licenses are not available to us on acceptable terms, we or our collaborators may not be able to develop, manufacture, sell or import these products.

Exposure to patent litigation. There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industry. We may become a party to various types of patent litigation or other proceedings regarding intellectual property rights from time to time even under circumstances where we are not using and do not intend to use any of the intellectual property involved in the proceedings.

The cost of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the cost of such litigation or proceedings more effectively than we will be able to because our competitors may have substantially greater financial resources. If any patent litigation or other proceeding is resolved against us, we or our collaborators may be enjoined from developing, manufacturing, selling or importing our drugs without a license from the other party and we may be held liable for significant damages. We may not be

able to obtain any required license(s) on commercially acceptable terms or at all.

Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

The Company does have patent product litigation liability insurance in place. However, it may not be sufficient to cover litigations circumstances.

Competition. The pharmaceutical and biotechnology industry is highly competitive and characterized by rapid and significant technological change. We will face intense competition from organizations such as pharmaceutical and biotechnology companies, as well as academic and research institutions and government agencies. Some of these organizations are pursuing products based on technologies similar to our future technologies. Other of these organizations have developed and are marketing products, or are pursuing other technological approaches designed to produce products that are competitive with our future product candidates in the therapeutic effect these competitive products have on diseases targeted by our product candidates. Our competitors may discover, develop or commercialize products or other novel technologies that are more effective, safer or less costly than any that we may develop. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our products.

Many of our competitors are substantially larger than we are and have greater capital resources, research and development staffs and facilities than we have. In addition, many of our competitors are more experienced in drug discovery, development and commercialization, obtaining regulatory approvals, and drug manufacturing and marketing.

We anticipate that the competition with our products and technologies will be based on a number of factors including product efficacy, safety, availability, and price. The timing of market introduction of our future products and competitive products will also affect competition among products. We expect the relative speed with which we can develop products, complete the initial Phase I and IIa clinical trials, establish a strategic partner and supply appropriate quantities of the products for late stage trials to be important competitive factors. Our competitive position will also depend upon our ability to attract and retain qualified personnel, to obtain patent protection or otherwise develop proprietary products or processes and to secure sufficient capital resources for the period between technological conception and commercial sales or out-license to a pharmaceutical partner.

Market reception. The commercial success of any of our future products for which we may obtain marketing approval from the FDA or other regulatory authorities will depend upon their acceptance by the medical community and third party payors as clinically useful, cost-effective and safe. Many of the products that we will develop will be based upon technologies or therapeutic approaches that are relatively new and unproven. As a result, it may be more difficult for us to achieve regulatory approval or market acceptance of our products. Our efforts to educate the medical community on these potentially unique approaches may require greater resources than would be typically required for products based on conventional technologies or therapeutic approaches. The safety, efficacy, convenience and cost-effectiveness of our future products as compared to competitive products will also affect market acceptance.

Changes in Bio-Path relationships with MD Anderson. Our License Agreement with MD Anderson provides MD Anderson the right to terminate the agreement upon written notice to us if we do not meet all of our requirements under the License Agreement, which requires us to file an Investigational New Drug Application with the FDA or have a commercial sale of a licensed product within an agreed upon period of time. If either of the License Agreement or any other agreements we enter into with MD Anderson is terminated for any reason, our business will be adversely and materially adversely affected.

No sales, marketing and distribution capabilities. We currently have no sales, marketing, or distribution capabilities and do not intend to develop such capabilities in the foreseeable future. If we are unable to establish sales, marketing, or distribution capabilities either by developing our own sales, marketing and distribution organization or by entering into agreements with others, we may be unable to successfully sell any products that we are able to begin to commercialize. If we, and our strategic partners, are unable to effectively sell our products, our ability to generate revenues will be harmed. We may not be able to hire, in a timely manner, the qualified sales and marketing personnel for our needs, if at all. In addition, we may not be able to enter into any marketing or distribution agreements on acceptable terms, if at all. If we cannot establish sales, marketing and distribution capabilities as we intend, either by developing our own capabilities or entering into agreements with third parties, sales of future products, if any, will be harmed.

Exposure to product liability claims or recall. Our business will expose us to potential product liability risks inherent in the clinical testing and manufacturing and marketing of pharmaceutical products, and we may not be able to avoid significant product liability exposure. A product liability claim or recall could be detrimental to our business. In addition**,** we do not currently have any product liability or clinical trial insurance**,** and we may not be able to obtain

or maintain such insurance on acceptable terms, or we may not be able to obtain any insurance to provide adequate coverage against potential liabilities. Our inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or limit the commercialization of any products that we develop.

Rapid technology change and obsolescence. New products and technological developments in the healthcare field may adversely affect our ability to complete the necessary regulatory requirements and introduce the proposed products in the market. The healthcare field, which is the market for our products, is characterized by rapid technological change, new and improved product introductions, changes in regulatory requirements, and evolving industry standards. Our future success will depend to a substantial extent on our ability to identify new market trends on a timely basis and develop, introduce and support proposed products on a successful and timely basis. If we fail to develop and deploy our proposed products on a successful and timely basis, we may not be competitive.

Risks Relating to Governmental Approvals

Extensive regulatory requirements. The testing, manufacturing, labeling, advertising, promotion, exporting, and marketing of our products are subject to extensive regulation by governmental authorities in Europe, the United States and elsewhere throughout the world.

To date, we have not submitted a marketing application for any product candidate to the FDA or any foreign regulatory agency, and none of our product candidates have been approved for commercialization in any country. Prior to commercialization, each product candidate would be subject to an extensive and lengthy governmental regulatory approval process in the United States and in other countries. We may not be able to obtain regulatory approval for any product candidate we develop or, even if approval is obtained, the labeling for such products may place restrictions on their use that could materially impact the marketability and profitability of the product subject to such restrictions. Any regulatory approval of a product may also contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Any product for which we or our pharmaceutical company out-license partner obtain marketing approval, along with the facilities at which the product is manufactured, any post-approval clinical data and any advertising and promotional activities for the product will be subject to continual review and periodic inspections by the FDA and other regulatory agencies.

We have limited experience in designing, conducting, and managing the clinical testing necessary to obtain such regulatory approval. Satisfaction of these regulatory requirements, which includes satisfying the FDA and foreign regulatory authorities that the product is both safe and effective for its intended therapeutic uses, typically takes several years depending upon the type, complexity and novelty of the product and requires the expenditure of substantial resources. In addition to our internal resources, we will depend on regulatory consultants and our proposed Scientific Advisory Board for assistance in designing our preclinical studies and clinical trials and drafting documents for submission to the FDA. If we are not able to obtain regulatory consultants on commercially reasonable terms, we may not be able to conduct or complete clinical trials or commercialize our product candidates. We intend to establish relationships with multiple regulatory consultants for our existing clinical trials, although there is no guarantee that the consultants will be available for future clinical trials on terms acceptable to us.

In addition, submission of an application for marketing approval to the relevant regulatory agency following completion of clinical trials may not result in the regulatory agency approving the application if applicable regulatory criteria are not satisfied, and may result in the regulatory agency requiring additional testing or information.

Both before and after approval is obtained, violations of regulatory requirements may result in:

¨the regulatory agency's delay in approving, or refusal to approve, an application for approval of a product;
¨restrictions on such products or the manufacturing of such products;
¨withdrawal of the products from the market;
¨warning letters;
¨voluntary or mandatory recall;
¨fines;
¨suspension or withdrawal of regulatory approvals;
¨product seizure;
¨refusal to permit the import or export of our products;
¨injunctions or the imposition of civil penalties; and
¨criminal penalties.

Clinical trials. In order to obtain regulatory approvals for the commercial sale of our products, we will be required to complete extensive clinical trials in humans to demonstrate the safety and efficacy of our drug candidates. We are currently dosing patients in our Phase I clinical trials for BP-100-1.01. We may not be able to obtain authority from the FDA or other equivalent foreign regulatory agencies to move on to Phase II or Phase III clinical trials or commence and complete any other clinical trials for any other products.

The results from preclinical testing of a drug candidate that is under development may not be predictive of results that will be obtained in human clinical trials. In addition, the results of early human clinical trials may not be predictive of results that will be obtained in larger scale, advanced stage clinical trials. A failure of one or more of our clinical trials

can occur at any stage of testing. Further, there is to date no data on the long-term clinical safety of our lead compounds under conditions of prolonged use in humans, or on any long-term consequences subsequent to human use. We may experience numerous unforeseen events during, or as a result of, preclinical testing and the clinical trial process that could delay or prevent its ability to receive regulatory approval or commercialize our products, including:

- regulators or institutional review boards may not authorize us to commence a clinical trial 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;
- the timing of our clinical trials may be longer than we currently anticipate; and
- the effects of our products may not be the desired effects or may include undesirable side effects or the products may have other unexpected characteristics.

The rate of completion of clinical trials is dependent in part upon the rate of enrollment of patients. Patient accrual is a function of many factors, including:

- the size of the patient population;
- the proximity of patients to clinical sites;
- the eligibility criteria for the study;
- the nature of the study;
- the existence of competitive clinical trials; and
- the availability of alternative treatments.

We may not be able to successfully complete any clinical trial of a potential product within any specified time period. In some cases, we may not be able to complete the trial at all. Moreover, clinical trials may not show our potential products to be both safe and efficacious. Thus, the FDA and other regulatory authorities may not approve any of our potential products for any indication.

Our clinical development costs will increase if we experience delays in our clinical trials. We do not know whether planned clinical trials will begin as planned, will need to be restructured or will be completed on schedule, if at all. Significant clinical trial delays could also allow our competitors to bring products to market before we do and impair our ability to commercialize our products.

Pricing and reimbursement. If our future strategic partners succeed in bringing our product candidates to the market, they may not be considered cost-effective, and coverage and adequate payments may not be available or may not be sufficient to allow us to sell our products on a competitive basis. In both the United States and elsewhere, sales of medical products and therapeutics are dependent, in part, on the availability of reimbursement from third party payors, such as health maintenance organizations and other private insurance plans, and governmental programs such as Medicare.

Third party payors are increasingly challenging the prices charged for pharmaceutical products and medical devices. Our business will be affected by the efforts of government and third party payors to contain or reduce the cost of health care through various means. In the United States, there have been and will continue to be a number of federal and state proposals to implement government controls on pricing. Similar government pricing controls exist in varying degrees in other countries. In addition, the emphasis on managed care in the United States has increased, and will continue to increase the pressure on the pricing of pharmaceutical products and medical devices. We cannot predict whether any legislative or regulatory proposals will be adopted or the effect these proposals or managed care efforts may have on our business.

Changes in laws and regulations affecting the healthcare industry could adversely affect our business. All aspects of our business, including research and development, manufacturing, marketing, pricing, sales, litigation, and intellectual property rights, are subject to extensive legislation and regulation. Changes in applicable federal and state laws and agency regulations could have a material adverse effect on our business. These include:

- changes in the FDA and foreign regulatory processes for new therapeutics that may delay or prevent the approval of any of our current or future product 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 Good Manufacturing Practice, or cGMPs, that make it more difficult for us to manufacture our marketed product and clinical candidates in accordance with cGMPs.

Regulatory and legal uncertainties could result in significant costs or otherwise harm our business. In order to manufacture and sell our products, we must comply with extensive international and domestic regulations. In order to sell its products in the United States, approval from the FDA is required. The FDA approval process is expensive and time-consuming. We cannot predict whether our products will be approved by the FDA. Even if they are approved, we cannot predict the time frame for approval. Foreign regulatory requirements differ from jurisdiction to jurisdiction and may, in some cases, be more stringent or difficult to obtain than FDA approval. As with the FDA, we cannot predict if or when we may obtain these regulatory approvals. If we cannot demonstrate that our products can be used safely and successfully in a broad segment of the patient population on a long-term basis, our products would likely be denied approval by the FDA and the regulatory agencies of foreign governments.

Our product candidates are based on new technology and, consequently, are inherently risky. Concerns about the safety and efficacy of our products could limit our future success. We are subject to the risks of failure inherent in the development of product candidates based on new technologies. These risks include the possibility that the products we create will not be effective, that our product candidates will be unsafe or otherwise fail to receive the necessary regulatory approvals or that our product candidates will be hard to manufacture on a large scale or will be uneconomical to market.

Many pharmaceutical products cause multiple potential complications and side effects, not all of which can be predicted with accuracy and many of which may vary from patient to patient. Long term follow-up data may reveal additional complications associated with our products. The responses of potential physicians and others to information about complications could materially affect the market acceptance of our future products, which in turn would materially harm our business.

Unsuccessful or delayed regulatory approvals required to exploit the commercial potential of our future products could increase our future development costs or impair our future sales. No Bio-Path technologies have been approved by the FDA for sale in the United States or in foreign countries. To exploit the commercial potential of our technologies, we are conducting and planning to conduct additional pre-clinical studies and clinical trials. This process is expensive and can require a significant amount of time. Failure can occur at any stage of testing, even if the results are favorable. Failure to adequately demonstrate safety and efficacy in clinical trials would prevent regulatory approval and restrict our ability to commercialize our technologies. Any such failure may severely harm our business. In addition, any approvals obtained may not cover all of the clinical indications for which approval is sought, or may contain significant limitations in the form of narrow indications, warnings, precautions or contraindications with respect to conditions of use, or in the form of onerous risk management plans, restrictions on distribution, or post-approval study requirements.

State pharmaceutical marketing compliance and reporting requirements may expose us to regulatory and legal action by state governments or other government authorities. In recent years, several states have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs and file periodic reports on sales, marketing, pricing and other activities. Similar legislation is being considered in other states. Many of these requirements are new and uncertain, and available guidance is limited. Unless we are in full compliance with these laws, we could face enforcement actions and fines and other penalties and could receive adverse publicity, all of which could harm our business.

We may be subject to new federal and state legislation to submit information on our open and completed clinical trials to public registries and databases. In 1997, a public registry of open clinical trials involving drugs intended to treat serious or life-threatening diseases or conditions was established under the Food and Drug Administration Modernization Act(the “FDMA”), in order to promote public awareness of and access to these clinical trials. Under the FDMA, pharmaceutical manufacturers and other trial sponsors are required to post the general purpose of these trials, as well as the eligibility criteria, location and contact information of the trials. Since the establishment of this registry, there has been significant public debate focused on broadening the types of trials included in this or other registries, as

well as providing for public access to clinical trial results. A voluntary coalition of medical journal editors has adopted a resolution to publish results only from those trials that have been registered with a no-cost, publicly accessible database, such as www.clinicaltrials.gov. Federal legislation was introduced in the fall of 2004 to expand www.clinicaltrials.gov and to require the inclusion of study results in this registry. The Pharmaceutical Research and Manufacturers of America has also issued voluntary principles for its members to make results from certain clinical studies publicly available and has established a website for this purpose. Other groups have adopted or are considering similar proposals for clinical trial registration and the posting of clinical trial results. Failure to comply with any clinical trial posting requirements could expose us to negative publicity, fines and other penalties, all of which could materially harm our business.

We face uncertainty related to pricing and reimbursement and health care reform. In both domestic and foreign markets, sales of our future products will depend in part on the availability of reimbursement from third-party payors such as government health administration authorities, private health insurers, health maintenance organizations and other health care-related organizations. Reimbursement by such payors is presently undergoing reform and there is significant uncertainty at this time as to how this will affect sales of certain pharmaceutical products.

Medicare, Medicaid and other governmental healthcare programs govern drug coverage and reimbursement levels in the United States. Federal law requires all pharmaceutical manufacturers to rebate a percentage of their revenue arising from Medicaid-reimbursed drug sales to individual states. Generic drug manufacturers' agreements with federal and state governments provide that the manufacturer will remit to each state Medicaid agency a certain percentage of the average manufacturer price for generic products marketed and sold under abbreviated new drug applications covered by the state's Medicaid program. For proprietary products, which are marketed and sold under new drug applications, manufacturers are required to rebate the greater of (a) a certain percentage of the average manufacturer price or (b) the difference between the average manufacturer price and the lowest manufacturer price for products sold during a specified period.

Both the federal and state governments in the United States and foreign governments continue to propose and pass new legislation, rules and regulations designed to contain or reduce the cost of health care. Existing regulations that affect the price of pharmaceutical and other medical products may also change before any products are approved for marketing. Cost control initiatives could decrease the price that we receive for any product developed in the future. In addition, third-party payors are increasingly challenging the price and cost-effectiveness of medical products and services and litigation has been filed against a number of pharmaceutical companies in relation to these issues. Additionally, some uncertainty may exist as to the reimbursement status of newly approved injectable pharmaceutical products. Our products, if any, may not be considered cost effective or adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an adequate return on our investment.

Other companies may claim that we infringe their intellectual property or proprietary rights, which could cause us to incur significant expenses or prevent us from selling products. Our success will depend in part on our ability to operate without infringing the patents and proprietary rights of third parties. The manufacture, use and sale of new products have been subject to substantial patent rights litigation in the pharmaceutical industry. These lawsuits generally relate to the validity and infringement of patents or proprietary rights of third parties. Infringement litigation is prevalent with respect to generic versions of products for which the patent covering the brand name product is expiring, particularly since many companies which market generic products focus their development efforts on products with expiring patents. Other pharmaceutical companies, biotechnology companies, universities and research institutions may have filed patent applications or may have been granted patents that cover aspects of our products or its licensors' products, product candidates or other technologies.

Future or existing patents issued to third parties may contain patent claims that conflict with our future products. We expect to be subject to infringement claims from time to time in the ordinary course of business, and third parties could assert infringement claims against us in the future with respect to products that we may develop or license. Litigation or interference proceedings could force us to:

- stop or delay selling, manufacturing or using products that incorporate or are made using the challenged intellectual property;
- pay damages; or
- enter into licensing or royalty agreements that may not be available on acceptable terms, if at all.

Any litigation or interference proceedings, regardless of their outcome, would likely delay the regulatory approval process, be costly and require significant time and attention of key management and technical personnel.

Any inability to protect intellectual property rights in the United States and foreign countries could limit our ability to manufacture or sell products. We will rely on trade secrets, unpatented proprietary know-how, and continuing technological innovation and, in some cases, patent protection to preserve a competitive position. The patents underlying the License Agreement or our licensed patent rights may be challenged, invalidated, infringed or circumvented, and the rights granted in those patents may not provide proprietary protection or competitive

advantages to us. We and our licensors may not be able to develop patentable products. Even if patent claims are allowed, the claims may not issue, or in the event of issuance, may not be sufficient to protect the technology owned by or licensed to us. Third party patents could reduce the coverage of the patent's license, or that may be licensed to or owned by us.

If patents containing competitive or conflicting claims are issued to third parties, we may be prevented from commercializing the products covered by such patents, or may be required to obtain or develop alternate technology. In addition, other parties may duplicate, design around or independently develop similar or alternative technologies.

We may not be able to prevent third parties from infringing or using our intellectual property, and the parties from whom we may license intellectual property may not be able to prevent third parties from infringing or using the licensed intellectual property. We generally will attempt to control and limit access to, and the distribution of, our product documentation and other proprietary information. Despite efforts to protect this proprietary information, however, unauthorized parties may obtain and use information that we may regard as proprietary. Other parties may independently develop similar know-how or may even obtain access to these technologies.

The laws of some foreign countries do not protect proprietary information to the same extent as the laws of the United States, and many companies have encountered significant problems and costs in protecting their proprietary information in these foreign countries.

The U.S. Patent and Trademark Office and the courts have not established a consistent policy regarding the breadth of claims allowed in pharmaceutical patents. The allowance of broader claims may increase the incidence and cost of patent interference proceedings and the risk of infringement litigation. On the other hand, the allowance of narrower claims may limit the value of our proprietary rights.

We may be required to defend lawsuits or pay damages for product liability claims. Product liability is a major risk in testing and marketing biotechnology and pharmaceutical products. We may face substantial product liability exposure in human clinical trials and for products that sell after regulatory approval. Product liability claims, regardless of their merits, could exceed policy limits, divert management's attention, and adversely affect our reputation and the demand for our products.

Other Corporate Risks

Our articles of incorporation grant 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 articles of incorporation, and on approval from our Board. The Board , without any action by our shareholders, may designate and issue shares in such classes or series as the Board of directors 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.

Furthermore, any issuances of additional stock (common or preferred) will dilute the percentage of ownership interest of then-current holders of our capital stock and may dilute the book value per share of our common stock.

We do not intend to pay dividends on our common stock for the foreseeable future. We do not anticipate that we will have any revenues for the foreseeable future and accordingly, we do not anticipate that we will pay any dividends for the foreseeable future. Accordingly, any return on an investment in our Company will be realized, if at all, only when you sell shares of our common stock.

Our common stock trades only in an illiquid trading market . Trading of our common stock is conducted on the "OTCQX". This could have an adverse effect on the liquidity of our common stock, not only in terms of the number of shares that can be bought and sold at a given price, but also through delays in the timing of transactions and reduction in security analysts' and the media's coverage of Bio-Path and our common stock. This may result in lower prices for our common stock than might otherwise be obtained and could also result in a larger spread between the bid and asked

prices for our common stock.

If the trading price of our common stock continues to fluctuate in a wide range, our shareholders will suffer considerable uncertainty with respect to an investment in our common stock. The trading price of our common stock has been volatile and may continue to be volatile in the future. Factors such as announcements of fluctuations in our or our competitors' operating results or clinical or scientific results, fluctuations in the trading prices or business prospects of our competitors and collaborators, changes in our prospects, and market conditions for biopharmaceutical stocks in general could have a significant impact on the future trading prices of our common stock and our convertible senior notes. In particular, the trading price of the common stock of many biopharmaceutical companies, including ours, has experienced extreme price and volume fluctuations, which have at times been unrelated to the operating performance of the companies whose stocks were affected. This is due to several factors, including general market conditions, the announcement of the results of our clinical trials or product development and the results of our efforts to obtain regulatory approval of our products. While we cannot predict our future performance, if our stock price continues to fluctuate in a wide range, an investment in our common stock may result in considerable uncertainty for an investor.

Penny stock. Our common stock is considered to be a "penny stock." The SEC has adopted rules under Section 15(g) of the Securities Exchange Act of 1934, as amended, which generally defines "penny stock" to be any equity security that meets one or more of the following: (i) has a market price less than $5.00 per share, or an exercise price of less than $5.00 per share, subject to certain exceptions; (ii) is NOT traded on a national securities exchange; or (iii) is issued by a company with net tangible assets less than $2.0 million, if in business more than a continuous three years, or with average revenues of less than $6.0 million for the past three years. Our securities are covered by the penny stock rules, which impose additional sales practice requirements on broker-dealers who sell to persons other than established customers and institutional accredited investors. The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document in a form prepared by the SEC which provides information about penny stocks and the nature and level of risks in the penny stock market. The broker-dealer also must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and its salesperson in the transaction and monthly account statements showing the market value of each penny stock held in the customer's account. The bid and offer quotations, and the broker- dealer and salesperson compensation information, must be given to the customer orally or in writing prior to effecting the transaction and must be given to the customer in writing before or with the customer's confirmation. In addition, the penny stock rules require that prior to a transaction in a penny stock not otherwise exempt from these rules, the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written agreement to the transaction. These disclosure requirements may have the effect of reducing the level of trading activity in the secondary market for the stock that is subject to these penny stock rules. Consequently, these penny stock rules may affect the ability of broker-dealers to trade our securities. We believe that the penny stock rules discourage investor interest in and limit the marketability of our common stock. Potential investors in our common stock are urged to obtain and read such disclosure documents and information carefully before purchasing any securities that are deemed to be "penny stock."

In addition to the "penny stock" rules promulgated by the SEC, the Financial Industry Regulatory Authority, or FINRA, has adopted rules that require that in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending speculative low priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives and other information. Under interpretations of these rules, the FINRA believes that there is a high probability that speculative low priced securities will not be suitable for at least some customers. The FINRA requirements make it more difficult for broker-dealers to recommend that their customers buy our common stock, which may limit your ability to buy and sell our stock.

Limitation on director liability. As permitted by Utah law, our Articles of Incorporation limit the liability of directors to the Company or its shareholders for monetary damages for breach of a director’s fiduciary duty except for liability in certain instances. As a result of such Articles of Incorporation and Utah law, our shareholders may have limited rights to recover against directors for breach of fiduciary duty.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We lease a small office in Houston, Texas. The office will be expanded as additional employees join Bio-Path or as otherwise needed.

ITEM 3. LEGAL PROCEEDINGS

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

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PART II

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

Our common stock is quoted on the OTCQX under the symbol "BPTH". There has been limited trading in our common stock. The prices reported below reflect inter-dealer prices and are without adjustments for retail markups, markdowns or commissions, and may not necessarily represent actual transactions.

	High Bid	Low Bid
Fiscal Year Ended December 31, 2011		
First Fiscal Quarter	$.85	$.35
Second Fiscal Quarter	$.45	$.30
Third Fiscal Quarter	$.50	$.26
Fourth Fiscal Quarter	$.36	$.25
Fiscal Year Ended December 31, 2012		
First Fiscal Quarter	$.38	$.13
Second Fiscal Quarter	$.42	$.24
Third Fiscal Quarter	$.42	$.32
Fourth Fiscal Quarter	$.41	$.26
Fiscal Year Ending December 31, 2013		
First Fiscal Quarter (January 1st through March 20th)	$.41	$.30

Holders

As of March 20, 2013, there were 62,219,050 shares of common stock of the Company outstanding and approximately 379 shareholders 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

Plan Category	Number of Shares of common stock to be issued upon exercise of outstanding options	Weighted-average exercise price of outstanding options	Weighted-average term to expiration of options outstanding	Number of shares of common stock remaining available for future issuance under equity compensation plans
Equity compensation plans approved by shareholders (1)	3,482,188	$ 1.19	6.2yrs.	3,517,812
Equity compensation plans not approved by shareholders	—	—	—	—

(1) Reflects number of shares of common stock to be issued upon exercise of outstanding options and warrants under all of our equity compensation plans, including our 2007 Stock Incentive Plan. No shares of common stock are available for future issuance under any of our equity compensation plans, except the 2007 Stock Incentive Plan. The outstanding options and restricted shares are not transferable for consideration and do not have dividend equivalent rights attached. Remaining average term to expiration of options outstanding is as of March 20, 2013.

Unregistered Sales of Equity Securities and Use of Proceeds

From October 1, 2012 through December 31, 2012, the Company sold to accredited investors a total of 2,362,001 shares of common stock. The Company received net proceeds from these sales of $708,600.

The capital raised from such sales will be used for general working capital purposes. The Company sold these unregistered securities in accordance with Rule 506 of Regulation D under the Securities Act of 1933, as amended.

Limitation on Directors' Liability, Charter Provisions and Other Matters

Utah law authorizes corporations to limit or eliminate the personal liability of directors to corporations and their shareholders for monetary damages for breach of directors' fiduciary duty of care. The duty of care requires that, when acting on behalf of the corporation, directors must exercise an informed business judgment based on all material information reasonably available to them. Absent the limitations authorized by Utah law, directors are accountable to corporations and their shareholders for monetary damages for conduct constituting gross negligence in the exercise of their duty of care. Utah law enables corporations to limit available relief to equitable remedies such as injunction or rescission. Our Articles of Incorporation limits the liability of our directors to us or to our shareholders (in their capacity as directors but not in their capacity as officers) to the fullest extent permitted by Utah law.

The inclusion of this provision in our Articles of Incorporation may have the effect of reducing the likelihood of derivative litigation against directors and may discourage or deter shareholders or management from bringing a lawsuit against directors for breach of their duty of care, even though such an action, if successful, might otherwise have benefited the Company and its shareholders.

Our Bylaws provide indemnification to our officers and directors and certain other persons with respect to certain matters. Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, may be permitted to our directors and officers, we have been advised that in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act of 1933, as amended, and is, therefore, unenforceable.

Transfer Agent and Registrar

Our transfer agent is Fidelity Transfer Company, 8915 South 700 East, Suite 102, Sandy, Utah 84070; telephone (801) 562-1300.

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

Not applicable.

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

In addition to historical information, this report contains forward-looking statements that involve 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 the section entitled "Risk Factors," and the "Note Regarding Forward-Looking Statements," included in the beginning of this 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 should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this Form 10-K.

Overview

We were formed 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. ("Bio-Path Subsidiary") in a reverse merger transaction (the "Merger"). In connection with the Merger, we changed our name to Bio-Path Holdings, Inc., we acquired Bio-Path Subsidiary as a wholly owned subsidiary and we appointed new officers and directors. In connection with the Merger, we also increased our authorized capital stock and adopted a Stock Incentive Plan. The Merger and related matters are further described in a 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.

Bio-Path Subsidiary was formed to finance and facilitate the development of novel cancer therapeutics. Our plan was to acquire licenses for drug technologies from MD Anderson, to fund clinical and other trials for such technologies and to commercialize such technologies. Bio-Path had originally negotiated and executed three exclusive license agreements for three lead products and nucleic acid delivery technology; however, the Company has determined to maintain only the License Agreement. The License Agreement specifically provides drug delivery platform technology with composition of matter intellectual property that enables systemic delivery of antisense. The Company is currently developing only the liposomal antisense delivery technology and products. Bio-Path's business plan is to act efficiently as an intermediary in the process of translating newly discovered drug technologies into authentic therapeutic drugs candidates. Its 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.

Plan of Operation

See Item 1 of this Form 10-K.

Results of Operations

Results of Operations for the twelve months ended December 31, 2012 and December 31, 2011.

Revenues. We have no operating revenues since our inception.

Research and Development Expenses. Our research and development expense was $1,132,712 for the twelve month period ending December 31, 2012; an increase of $535,910 over the twelve month period ending December 31, 2011. The increase in research and development expense for the twelve months ending December 31, 2012 compared to the comparable period ending December 31, 2011 was primarily due to a $503,000 increase in expense for drug product material to be used in our clinical trial, and approximately $40,000 in increased expenses for clinical trial operations and advisory services. Our research and development expense was $4,325,596 for the period from inception through December 31, 2012. Research and development expense-related party was $463,870 for the twelve month period ending December 31, 2012, a decrease of $80,130 compared to the comparable twelve month period ending December 31, 2011. The decrease in research and development expense-related party was due primarily to a decrease in clinical trial hospital expenses. Research and development expense-related party $1,063,620 for the period from inception through December 31, 2012.

General and Administrative Expenses. Our general and administrative expenses were $986,097 for the twelve month period December 31, 2012; a decrease of $238,716 compared to the 12 month period ended December 31, 2011. The decrease in general and administrative expense for the twelve month period ending December 31, 2012 compared to the 21 month period ending December 31, 2011 was due to lower management and administrative stock option expense totaling $320,000, which more than offset increases in public company expense and expenses for industry conferences and communications. General and administrative expenses were $7,059,463 for the period from inception through December 31, 2012.

Net Loss. Our net loss was $2,582,537 for the twelve month period ended December 31, 2012 compared to a loss of $2,363,344 for the twelve month period ended December 31, 2011. The increase in the net loss for the twelve month period ending December 31, 2012 compared to the comparable twelve month period ending December 31, 2011 was due to an increase in research and development expense more than offsetting a decrease in research and development expense-related and general administrative expense during the same periods. Net loss per share, both basic and diluted was $0.04 per share, for both of the respective twelve month periods. Our net loss was $12, 131,283 for the period from inception through December 31, 2012, and net loss per share, both basic and diluted, was $0.26 for the period from inception through December 31, 2012. Included in the net loss for the period from inception through December 31, 2012 is other income of $317,396, comprised of $77,091 in interest income and other income of $244,479 representing a grant received from the U.S. Government.

Liquidity and Capital Resources as of December 31, 2012

At December 31, 2012, we had cash of $534,046 compared to $952,252 at December 31, 2011. We currently have no lines of credit or other arranged access to debt financing.

Net cash used in operating activities during the twelve months ending December 31, 2012 was $1,993,404 compared to net cash used in operating activities of $1,149,911 for the comparable twelve month period ending December 31, 2011. Inasmuch as we have not yet generated revenues in 2012, substantially all of our expenses of operation in 2012 have been funded by proceeds from the sale of shares of the Company's common stock.

Net cash provided by financing activities in 2012 was $1,600,198 compared to $2,033,654 for 2011. Since inception we have net cash provided from financing activities of $8,459,384. We believe that our available cash and our ongoing capital raising efforts will be sufficient to fund our liquidity and capital expenditure requirements through the second quarter of 2013. We will need approximately $1.3 million from our ongoing capital raising efforts to fund our operations through the second quarter of 2013, at which time we anticipate that we will complete dosing in our Phase I clinical trial. We believe that we will need to raise approximately $12,700,000 in net proceeds to completely implement our current business plan over the next 30 months.

Future Capital Needs

We anticipate that the total cost of additional needed funds to complete the Phase I clinical trial of our BP-100-1.01 drug candidate will be$500,000, provided that only two additional does levels are required to complete the trial . We anticipate that we must raise additional funds to continue our business model. Inasmuch as we have received limited income from operations, we are required to depend upon the sale of our securities as our principal sources of cash for the foreseeable future. There can be no assurance that we will be able to continue to raise cash through the sale of our securities in the future. The amount and pace of research and development work that we can do or sponsor, and our ability to commence and complete the clinical trials that are required in order for us to obtain FDA and foreign regulatory approval of products, depend upon the amount of money we have. We have attempted to reduce overhead expenses due to the limited amount of funds available. Future research and clinical study costs are not presently determinable due to many factors, including the inherent uncertainty of these costs and the uncertainty as to timing, source, and amount of capital that will become available for these projects. We intend to raise additional capital in the second and/or third quarter of 2013.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

Contractual Obligations and Commitments

Bio-Path had originally entered into three exclusive license agreements with MD Anderson; however, the Company has determined to maintain only the License Agreement See Item 1 of this Form 10-K.

In the first quarter of 2013, Bio-Path entered into a supply agreement with its drug product manufacturer for the manufacture of the Company's drug product for delivery in May 2013. The agreement calls for the Company to pay approximately $150,000 in various stages until the final drug product is manufactured, successfully tested and delivered to the Company.

Inflation

The Company does not believe that inflation will negatively impact its business plans.

Critical Accounting Policies

The preparation of financial statements in conformity with generally accepted accounting principles ("GAAP") in the United States has required the management of the Company 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. The Company considers its critical accounting policies to be those that require the more significant judgments and estimates in the preparation of financial statements, including the following:

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, J. P. Morgan Chase Bank. The balances are insured by the Federal Deposit Insurance Corporation up to $250,000. As a result, a total of $284,046 of the Company's cash balances on December 31, 2012 is not covered by the FDIC.

Intangible Assets/Impairment of Long-Lived Assets. As of December 31, 2012, Other Assets totals $1,572,143 for the Company's technology licenses, comprised of $2,500,374 in value acquiring the Company's technology licenses and its intellectual property, less accumulated amortization of $928,231. 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. This value is being amortized over a fifteen year (15 year) period from November 7, 2007, the date that the technology licenses became effective. The Company accounts for the impairment and disposition of its 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. The Company estimates that approximately $200,000 will be amortized per year for each future year for the current value of the technology licenses acquired until approximately 2022.

Research and Development. 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 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. Of the research and development expense totaling $1,132,712, $185,271 was for amortization of the technology license, $53,645 was for stock options expense for individuals involved in research and development activities, $594,440 for drug product material expensed, $124,685 for clinical trial expense and the balance of approximately $174,671 was for drug product testing, advisory services and other R&D activities. Of the $463,870 related party research and development expense, $37, 300 was comprised of costs for clinical trial and hospital costs, $50,000 for technology license maintenance fees and $31,170 in siRNA patent costs not capitalized in technology license-Other Assets and $345,000 in technology license impairment expense (See Note 2. Related Party). For the year 2011, the Company had $596,802 of costs classified as research and development expense and $544,000 of related party research and development expense.

Stock-Based Compensation. The Company has accounted for stock-based compensation under the provisions of GAAP, which requires 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.

In October 2008 the Company made stock option grants to management and officers to purchase in the aggregate 2,500,000 shares of the Company's common stock. Terms of the stock option grants require that the individuals continue employment with the Company over the vesting period of the option, fifty percent (50%) of which vested upon the date of the grant of the stock options and fifty percent (50%) of which will vest over 3 years from the date that the options were granted. As of the end of 2012 all of the 2,500,000 options are fully vested. The exercise price of the options is $1.40 a share. The Company determined the fair value of the stock options granted using the Black Scholes model and expenses this value monthly based upon the vesting schedule for each stock option award.

For purposes of determining fair value, the Company used an average annual volatility of eighty four percent (84%), which was calculated based upon taking a weighted average of the volatility of the Company's common stock and the volatility of similar biotechnology stocks. The risk free rate of interest used in the model was taken from a table of the market rate of interest for U. S. Government Securities for the date of the stock option awards and interpolated as necessary to match the appropriate effective term for the award. The total value of stock options granted to management and officers was determined using this methodology to be $2,485,000, half of which was expensed at the date of grant and the balance fully vested during the fourth quarter of 2012.

In December 2008 the Company made stock option grants for services over the next three years to purchase in the aggregate 100,000 shares of the Company's common stock. Terms of the stock option grants require, among other things, that the individual continues to provide services over the vesting period of the option, which is three or four years from the date that each option granted to the individual becomes effective. The exercise price of the options is $0.30 a share. None of these stock options grants were for current management and officers of the Company. The Company determined the fair value of the stock options granted using the Black Scholes model and expenses this value monthly based upon the vesting schedule for each stock option award. For purposes of determining fair value, the Company used an average annual volatility of eighty four percent (84%), which was calculated based upon taking a weighted average of the volatility of the Company's common stock and the volatility of similar biotechnology stocks. The risk free rate of interest used in the model was taken from a table of the market rate of interest for U. S. Government Securities for the date of the stock option awards and interpolated as necessary to match the appropriate effective term for the award. The total value of stock options granted was determined using this methodology to be $21,450, which will be expensed over the next four years based on the stock option vesting schedule.

Total stock option expense for the year 2012 being reported on totaled $63,385. Total stock option expense for the year 2011 being reported on totaled $383,928.

Warrant Grants. In April 2008 the Company awarded warrants for services to purchase in the aggregate 85,620 shares of the Company's common stock. The exercise price is $0.90 a share. The warrants were one hundred percent (100%) vested upon issuance and were expensed upfront as warrants for services. The fair value of the warrants expensed was determined using the same methodology as described above for stock options. The total value of the warrants granted was determined using this methodology to be $36,050, the total amount of which was expensed in the second quarter 2008.

Net Loss Per Share. In accordance with GAAP, and SEC Staff Accounting Bulletin ("SAB") No. 98, 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 2012 and 2011, 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 is not presented in the financial statements for the years 2012 and 2011.

Comprehensive Income. Comprehensive income (loss) is defined as all changes in a company's net assets, except changes resulting from transactions with shareholders. As of December 31, 2012, the Company had 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.

Recent Accounting Pronouncements.

From time to time, new accounting pronouncements are issued by FASB 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.

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

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMETARY DATA

The consolidated financial statements and supplementary data of the Company required in this item are set forth beginning on page F-1. In the calendar year 2008, our fiscal year end was changed from June 30 to December 31.

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 Securities Exchange Act of 1934 (the "Exchange Act"). Our management, including our principal executive officer, our principal operations officer, and our principal financial officer, have reviewed and evaluated the effectiveness of our disclosure controls and procedures 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 to 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, our chief operations officer, and our chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

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.

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, our principal operations 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 generally accepted accounting principles and includes those policies and procedures that:

Management's assessment of the effectiveness of our internal controls is based principally on our financial reporting as of December 31, 2012. In making our assessment of internal control over financial reporting, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control – Integrated Framework. Our management, with the participation of our Chief Executive Officer (who is also

the 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, 2012. Those rules define internal control over financial reporting as 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 GAAP and includes those policies and procedures that:

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.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2012. Based on this assessment, management believes that, as of that date, our internal control over financial reporting was effective.

This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to rules of the SEC that permit us to provide only management's report in this annual report.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE.

Identification of Directors and Executive Officers

The current directors and officers of Bio-Path Holdings, Inc. who will serve until the next annual meeting of shareholders or until their successors are elected or appointed and qualified, are set forth below:

Name	Age	Position - Committee
Peter Nielsen	62	Chief Executive Officer/President/Chief Financial Officer/Treasurer/ Chairman of the Board and Director
Douglas P. Morris	57	Vice President of Corporate Development/ Secretary/Director
Gillian Ivers-Read	59	Director
Michael J. Garrison	45	Director

Background Information

Peter Nielsen, CEO is a co-founder of Bio-Path, serving as its Chief Executive Officer, President and Chief Financial Officer/Treasurer and Chairman of the Board. Mr. Nielsen has developed a close working relationship over the last five years with key individuals at MD Anderson and 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 is currently 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 Dept. 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.

Douglas P. Morris is a co-founder of Bio-Path serving as its Vice President of Corporate Development, Secretary and a Director. Between 1993 and 2010, Mr. Morris served as an officer and director of Celtic Investment, Inc., a financial services company. Celtic Investment owns Celtic Bank, an FDIC insured industrial loan company chartered under the laws of the State of Utah. Since 1990, Mr. Morris owns and operates Hyacinth Resources, LLC ("Hyacinth"). Hyacinth is a privately held business consulting firm. Hyacinth consults with privately held and publicly held corporations relating to management, merger and acquisitions, debt and equity financing, capital market access, and market support for publicly traded securities. Hyacinth also holds investments purchased by Mr. Morris. In 2007, Mr. Morris formed Sycamore Ventures, LLC, a privately-held consulting firm. Mr. Morris has a BA from Brigham Young University and a Masters in Public Administration from the University of Southern California.

Gillian Ivers-Read. Ms. Ivers-Read is currently head of Technical Operations at Clovis Oncology, a recently formed bio-technology company. Since, April 2002, Ms. Ivers-Read had been Executive Vice President, Development Operations of Pharmion Corp., a publicly held biotech company. From 1996 to 2001, Ms. Ivers-Read held various regulatory positions with Hoechst Marion Roussel and its successor Aventis Pharmaceuticals, Inc., where she most recently held the position of Vice President, Global Regulatory Affairs. From 1994 to 1996, Ms. Ivers-Read was Vice President, Development and Regulatory Affairs for Argus Pharmaceuticals and from 1984 to 1994 she served as a regulatory affairs director for Marion Merrell Dow.

Michael J. Garrison. 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.

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 one independent director and two non-independent directors. The Board has determined that current directors, Gillian Ivers-Read and Michael J. Garrison 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.

Committees of the Board of Directors

We currently have a compensation committee of the Board consisting of Ms. Gillian Ivers-Read, Michael J. Garrison, and Douglas P. Morris. We anticipate as our Board increases in size, we will appoint an audit committee and a nominating and corporate governance committee.

Key Consultants

Bradley G. Somer, MD. Dr. Somer is employed by ACORN CRO, a full service, oncology-focused clinical research organization (CRO), under the agreement with ACORN, Dr. Somer will serve as Bio-Path's Medical Officer and medical liaison for the conduct of the Company's upcoming Phase I clinical study of liposomal BP-100-1.01 in refractory or relapsed Acute Myeloid Leukemia (AML), Chronic Myelogenous Leukemia (CML), Acute Lymphoblastic Leukemia (ALL) and Myelodysplastic Syndrome (MDS).

Kevin Rando, MBA. 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 was appointed as Bio-Path's Chemistry, Manufacturing and Controls CMC Development Specialist. Dr. Walker also 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 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 is an Associate Professor at the University of Florida at Gainsville. Dr. Tari was the lead researcher who has developed Bio-Path's lead cancer drug BP-100-1.01. In addition to her position at the University of Florida, Dr. Tari serves as Director of Preclinical Operations and Research for Bio-Path Holdings, Inc.

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.

Code of Ethics

We have adopted a code of ethics (the "Code of Ethics") that applies to directors, officers and employees and complies with the requirements of Item 406 of Regulation S-K and the listing standards of the NASDAQ Stock Market. Our Code of Ethics is located on our website (www.biopathholdings.com). Any amendments or waivers to our Code of Ethics will be promptly disclosed on our website and as required by applicable laws, rules and regulations of the SEC.

Communications with Board Members

We have not adopted a formal process by which shareholders may communicate with the Board.

Compliance with Section 16(a)

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, 2012, 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 (a) annually reviews and determines salaries, bonuses and other forms of compensation paid to our executive officers and management; (b) selects recipients of awards of incentive stock options and non-qualified stock options and establishes the number of shares and other terms applicable to such awards; and (c) construes the provisions of and generally administers the 2007 Stock Incentive Plan (the “2007 Plan”). We do not currently have a compensation committee charter.

The compensation committee of our Board has overall responsibility for the compensation program for our executive officers. Our compensation committee consists of two independent directors, and a non-independent director. The compensation committee is responsible for establishing policies and otherwise discharging the responsibilities of the Board with respect to the compensation of our executive officers, senior management, and other employees. In evaluating executive officer pay, the compensation committee may retain the services of an independent compensation consultant or research firm and consider recommendations from the chief executive officer and persons serving in supervisory positions over a particular officer or executive officer with respect to goals and compensation of the other executive officers. The compensation committee assesses the information it receives in accordance with its business judgment. The compensation committee also periodically is responsible for administering all of our incentive and equity-based plans.

All decisions with respect to executive compensation 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.

Elements of compensation for our executives generally include:

- £ base salary (typically subject to upward adjustment annually based on individual performance);
- £ stock option awards;
- £ health, disability and life insurance.

Our primary objective with respect to executive compensation is to design a reward system that will align executives' compensation with Bio-Path's overall business strategies and attract and retain highly qualified executives. The principle elements of executive compensation are salary, bonus and will, typically, include stock option grants. We intend to stay competitive in the marketplace with our peers. In considering the elements of compensation, Bio-Path considers its current cash position in determining whether to adjust salaries, bonuses and stock option grants. The following table sets forth summary information about the compensation paid to our officers.

Summary Compensation Table

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Option ($)	Total ($)
Peter Nielsen, CEO, President, Chairman, Director	2012	$250,000	$ -0-	-0-	$250,000
	2011	$250,000	62,500 a/	-0-	$312,500
Douglas P. Morris, VP Corporate Development, Director	2012	$120,000	$ -0-	-0-	$120,000
	2011	$120,000	$ 30,000 a/		$150,000

a/ In 2011, the Board's compensation committee awarded Mr. Nielsen and Mr. Morris each a bonus. During 2011, the Company paid these bonuses to Mr. Nielsen and Mr. Morris in the amounts of $62,500 and $30,000, respectively. Substantially all of this expense had been previously accrued as bonus expense in 2010 and in the first and second quarters of 2011.

OUTSTANDING EQUITY AWARDS AT DECEMBER 31, 2012

The following table sets forth certain information with respect to outstanding stock option and warrant awards of the named executive officers for the fiscal year ended December 31, 2012.

Name	Number of Securities Underlying Unexercised Options Exercisable (#)(1)	Number of Securities Underlying Unexercised Options Unexercisable (#)(1)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date)
Peter Nielsen	1,500,000	0	-	$ 1.40	Oct 2018
Douglas P. Morris	1,000,000	0	-	$ 1.40	Oct 2018

(1) All of the above options granted are fully vested.

Option Exercises

No officer or director exercised any option during the fiscal year ended December 31, 2012.

Employment Agreements

Bio-Path subsidiary has entered into employment agreements with its Chief Executive Officer, Peter Nielsen, and its Vice President of Corporate Development, Douglas P. Morris, dated May 1, 2007. The employment agreement for Mr. Nielsen provides for a base salary of $250,000. The employment agreement for Mr. Morris provides for a base salary of $120,000.

Director Compensation

Currently, outside directors received cash compensation of $500 for each Board meeting attended and $250 for each telephonic Board meeting that they participate in. Outside directors also receive annual stock options to purchase 25,000 shares of the Company's common stock for each 12 month period they serve as a director.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

Security Ownership of Certain Beneficial Owners

The following table sets forth information regarding shares of our common stock beneficially owned at March 20, 2013 by: (i) each of our officers and directors; (ii) all officers and directors as a group; and (iii) each person known by us to beneficially own five percent or more of the outstanding shares of our common stock.

Shareholder	Shares Owned	Percentage	
Peter Nielsen (1) (2)	6,664,433	10.5	%
Douglas P. Morris (1) (3)	2,633,911	4.2	%
Gillian Ivers-Read (1) (4)	422,915		*
Michael J. Garrison (1) (5)	491,667		*
MD Anderson 7515 S. Main, Suite 490, Unit 0510 Houston Texas 77030	6,930,025	11.1	%
All officers and directors as a group (6)	10,212,926	15.6	%

*Less than 1%

(1) These are the officers and directors of the Company.

(2) Includes 5,164,433 shares owned of record and 1,500,000 shares issuable upon the exercise of options that are currently exercisable through March 20, 2013.

(3) Includes 1,633,911 shares owned of record and 1,000,000 shares issuable upon the exercise of options that are currently exercisable through March 20, 2013.

(4) Includes 422,915 shares issuable upon the exercise of options that are currently exercisable through March 20, 2013.

(5) Includes 75,000 shares held by Cosmo Capital Partners, LLC and 333,334 shares held by Garrison Capital, LLC. Mr. Garrison is a managing member of Cosmo Capital Partners, LLC and, thus, may be deemed to be 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.

(6) Includes 6,881,677 shares of record and 3,331,249 shares issuable upon the exercise of options and warrants currently exercisable or will be exercisable within 60 days.

Stock Options

The Company determined the fair value of the stock options granted using the Black Scholes model and expenses this value monthly based upon the vesting schedule for each stock option award. For purposes of determining fair value, the Company used an average annual volatility of seventy two percent (72%), which was calculated based upon an average of volatility of similar biotechnology stocks. The risk free rate of interest used in the model was taken from a table of the market rate of interest for U. S. Government Securities for the date of the stock option awards and interpolated as necessary to match the appropriate effective term for the award. In April 2008 the Company made stock option grants for services over the next three years to purchase in the aggregate 1,165,000 shares of the Company's common stock. Terms of the stock option grants require, among other things, that the individual continues to provide services over the vesting period of the option, which is four or five years from the date that each option granted to the individual becomes effective. The exercise price of the options is $0.90 a share.

In October 2008 we granted our Chief Executive Officer, Peter Nielsen, an option to purchase 1,500,000 shares of our common stock at a price of $1.40 per share. In October 2008 we also granted our Vice President of Corporate Development, Douglas P. Morris, an option to purchase 1,000,000 shares of our common stock at a price of $1.40 per share. Each of the options provides that one-half of the option shares are immediately vested and the remaining one-half of the option shares vest in 36 equal monthly increments. All of these options are now fully vested. The options are exercisable for a term of ten years from the date of grant.

In June 2011 the Company made two stock option grants to purchase in the aggregate 125,000 shares of the Company's common stock for service as a director of the Company, 25,000 options, and for consulting services, 100,000 options. Terms of the stock option grant require, among other things, that the individual continues to provide services over the vesting period of the option, which is one year from the date of grant for the director service stock option and four years from the date of grant for the consulting service stock option. The exercise price of the options is $0.33 a share, which was the closing price of the common stock at the date of grant.

In May and October 2012 the Company made two stock option grants to purchase in the aggregate 50,000 shares of the Company's common stock for services for two directors, 25,000 respectively. Terms of the stock option grant require, among other things, that the individual continues to provide services over the vesting period of the option, which is one year from the date of grant for the director service stock option and four years from the date of grant for the consulting service stock option. The exercise prices of the options are $0.35, and $0.39, respectively which was the closing price of the common stock at the date of grant.

The total value of stock options granted through December 31, 2012, after adjusting for forfeitures and eliminations, is $3,029,504, which is being expensed based on the individual stock option vesting schedules.

Equity Compensation Plan Information

We have no Equity Compensation Plans, except for our 2007 Plan.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The Company had originally negotiated and executed three exclusive license agreements for three lead products and nucleic acid delivery technology; however, the Company has determined to maintain only the License Agreement. The License Agreement requires, among other things, the Company to reimburse MD Anderson for ongoing patent expense. Based on its stock ownership in the Company, MD Anderson meets the criteria to be deemed a related party of the Company. For the year ended December 31, 2012, MD Anderson related party research and development expense was $463,870, consisting of (i) clinical trial expense of $37,700, (ii) license maintenance fees of $50,000, (iii) siRNA patent expenses of $31,170 not capitalized in the technology license other asset and (iv) $345,000 in non-cash technology impairment expense related to the Company's siRNA license (see Note 2). As of December 31, 2012, the Company had (a) accounts payable and accrued license payments for current and past patent expenses to MD Anderson totaling $57,000and (b) $100,000 in accrued related party research and development expense for the clinical trial (see Notes 5and 7).

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Our entire Board currently serves as our audit committee. The Audit Committee has adopted policies and procedures to oversee the external audit process including engagement letters, estimated fees and solely pre-approving all permitted non-audit work performed by Mantyla McReynolds, LLC. The Committee has pre-approved all fees for work performed.

The Audit Committee has considered whether the services provided by Mantyla McReynolds as disclosed below in the captions “Audit-Related Fee”, “Tax Fees” and “All Other Fees” and has concluded that such services are compatible with the independence of Mantyla McReynolds as the Company’s principal accountants.

For the fiscal years 2011 and 2012 the Audit Committee pre-approved all services described below in the captions “Audit Fees”, “Audit-Related Fees”, “Tax Fees” and “All Other Fees”.

The aggregate fees billed for professional services by Mantyla McReynolds in fiscal year 2011 and 2012:

Type of Fees	2011	2012
Audit Fees	$41,025	$44,975
Audit-Related Fees	-	-
Tax Fees	2,870	2,300
All Other Fees	-	-
Total	$43,895	$47,275

ITEM 15. EXHIBITS

A. Exhibits

Exhibit

Number	Exhibit
2.1	Agreement and Plan of Merger and Reorganization dated September 27, 2007, by and among Ogden Golf Co. Corporation, a Utah corporation (the registrant), 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 registrant's current report on Form 8-K filed on September 27, 2007).
3.1	Restated Articles of Incorporation (incorporated by reference to exhibit 3.2 to the registrant's current report on Form 8-A filed on September 10, 2008).
3.2	Bylaws (incorporated by reference to exhibit 3.2 to the registrant's current report on Form 8-A filed on September 10, 2008)
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 registrant's current report on Form 8-K filed on February 19, 2008).
3.4	Amendment No. 1 to Bylaws (incorporated by reference to exhibit 3.2 to the registrant's current report on Form 8-K filed on June 21, 2010).
4.1	Specimen Stock certificate (incorporated by reference to exhibit 3.2 to the registrant's current report on Form 8-A filed on September 10, 2008).
4.2	Form of Warrant issued to Lincoln Park Capital Fund, LLC (incorporated by reference to exhibit 4.1 to the registrant's current report on Form 8-K filed on June 4, 2010).
10.1+	Employment Agreement – Peter Nielsen (incorporated by reference to exhibit 3.2 to the registrant's current report on Form 8-K filed on February 19, 2008).
10.2+	Employment Agreement – Douglas P. Morris (incorporated by reference to exhibit 3.2 to the registrant's current report on Form 8-K filed on February 19, 2008).
10.3+	Amended 2007 Stock Incentive Plan (incorporated by reference to exhibit 4.1 to the registrant's registration on Form S-8 filed on December 10, 2008).
10.4	Purchase Agreement, dated as of June 2, 2010, by and between the Company and Lincoln Park Capital Fund, LLC (incorporated by reference to exhibit 10.1 to the registrant's current report on Form 8-K filed on June 4, 2010).
10.5*	

	Placement Agent Agreement, dated as of April 13, 2012, by and between the Company and ACAP Financial, Inc.
21.1*	Subsidiaries of Bio-Path Holdings, Inc.
23.1*	Consent of Mantyla McReynolds LLC.
31*	Certificate of Chief Executive Officer/Chief Financial Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 Sarbanes Oxley Act of 2002.
32*	Certificate of Chief Executive Officer/ Chief Financial Officer pursuant to Section 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002.

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* Filed herewith.

+ Management contract or compensatory plan.

SIGNATURES

In accordance with Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BIO-PATH HOLDINGS, INC.

Dated: April 1, 2013 By: /s/ Peter Nielsen
Peter Nielsen
President
Chief Executive Officer
Chief Financial Officer

Principal Accounting Officer

In accordance with the Securities Exchange Act, this report 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
April 1, 2013	President/Chief Executive Officer/ Chief Financial Officer/Principal Accounting Officer/ Director	/s/ Peter Nielsen Peter Nielsen
April 1, 2013	Secretary and Director	/s/ Douglas P. Morris Douglas P. Morris
April 1, 2013	Director	/s/ Gillian Ivers-Read Gillian Ivers-Read
April 1, 2013	Director	/s/ Michael J. Garrison Michael J. Garrison

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders
Bio-Path Holdings, Inc.

We have audited the accompanying consolidated balance sheets of Bio-Path Holdings, Inc. [a development stage company] as of December 31, 2012 and 2011, and the related consolidated statements of operations, cash flows, and stockholders' equity, for the years ended December 31, 2012 and 2011, and the period from inception to December 31, 2012. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our 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 the financial statements are free of material misstatement. The Company has determined that it is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Bio-Path Holdings, Inc., as of December 31, 2012 and 2011, and the results of their operations and their cash flows for the years ended December 31, 2012 and 2011, and the period from inception to December 31, 2012 in conformity with accounting principles generally accepted in the United States of America.

/s/ Mantyla McReynolds LLC
Mantyla McReynolds LLC
Salt Lake City, Utah
April 1, 2013

BIO-PATH HOLDINGS, INC.

(A Development Stage Company)

CONSOLIDATED BALANCE SHEETS

DECEMBER 31, 2012 AND 2011

	December 31 2012	2011
ASSETS		
Current assets		
Cash	$534,046	$952,252
Prepaid drug product for testing	195,000	153,000
Other current assets	42,575	48,439
Total current assets	771,621	1,153,691
Other assets		
Technology licenses - related party	2,500,374	2,868,877
Less Accumulated Amortization	(928,231)	(791,463)
	1,572,143	2,077,414
TOTAL ASSETS	$2,343,764	$3,231,105
LIABILITIES & SHAREHOLDERS' EQUITY		
Current liabilities		
Accounts payable	57,000	121,540
Accounts payable - related party	8,582	67,971
Accrued expense	137,662	46,082
Accrued expense - related party	26,000	41,000
Accrued license payments - related party	100,000	39,538
Total current liabilities	329,244	316,131
Long term debt	-	-
TOTAL LIABILITIES	329,244	316,131
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 62,219,050 and 58,325,169 shares issued and outstanding as of 12/31/12 and 12/31/11, respectively	62,218	58,325
Additional paid in capital	13,321,075	12,405,395
Additional paid in capital for shares to be issued a/	762,510	-
Accumulated deficit during development stage	(12,131,283)	(9,548,746)
Total shareholders' equity	2,014,520	2,914,974
TOTAL LIABILITIES & SHAREHOLDERS' EQUITY	$2,343,764	$3,231,105

a/ Represents 2,541,700 shares of common stock

SEE ACCOMPANYING NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

BIO-PATH HOLDINGS, INC.

(A Development Stage Company)

CONSOLIDATED STATEMENTS OF OPERATIONS

FOR THE YEARS ENDED DECEMBER 31, 2012 AND 2011 AND THE PERIOD

FROM INCEPTION (MAY 10, 2007) THROUGH DECEMBER 31, 2012

	2012	2011	From inception 05/10/07 to 12/31/12
Revenue	$-	$-	$-
Operating expense			
Research and development a/	1,132,712	596,802	4,325,596
Research and development - related party b/	463,870	544,000	1,063,620
General & administrative c/	986,097	1,224,813	7,059,463
Total operating expense	2,582,679	2,365,615	12,448,679
Net operating loss	$(2,582,679)	$(2,365,615)	$(12,448,679)
Other income			
Interest income	779	2,907	77,091
Other income	-	-	244,479
Other expense	(637)	(636)	(4,174)
Total Other Income	142	2,271	317,396
Net Loss Before Income Taxes	(2,582,537)	(2,363,344)	(12,131,283)
Income tax expense	-	-	-
Net Loss	$(2,582,537)	$(2,363,344)	$(12,131,283)
Loss per share			
Net loss per share, basic and diluted	$(0.04)	$(0.04)	$(0.26)
Basic and diluted weighted average number of common shares outstanding	59,317,779	53,844,195	46,045,124

a/ Research and development expense includes stock option expense of $53,645 and $66,098 for the years ending 12/31/2012 and 12/31/2011, respectively; and $422,999 for the period from inception through 12/31/2012. Research and development expense also includes amortization expense of $185,271 and $211,709 for the years ending 12/31/2012 and 12/31/2011, respectively; and $976,734 for the period from inception through 12/31/2012.

b/ Includes $345,000 technology impairment charge for the year ending 12/31/2012 and $345,000 technology impairment for the year ending 12/31/2011; and technology impairment of $690,000 for the period from inception through 12/31/2012.

c/ General & administrative expense includes stock option expense of $9,740 and $316,820 for the years ending 12/31/2012 and 12/31/2011, respectively; and for the period from inception through 12/31/2012, $2,590,753 for stock option and warrant expense and $318,500 in stock for services.

SEE ACCOMPANYING NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

BIO-PATH HOLDINGS, INC.

(A Development Stage Company)

CONSOLIDATED STATEMENT OF CASH FLOWS

FOR THE YEARS ENDED DECEMBER 31, 2012 AND 2011 AND THE PERIOD

FROM INCEPTION (MAY 10, 2007) THROUGH DECEMBER 31, 2012

	2012	2011	From inception 05/10/2007 to 12/31/2012
CASH FLOW FROM OPERATING ACTIVITIES			
Net loss	$(2,582,537)	$(2,363,344)	$(12,131,283)
Adjustments to reconcile net loss to net cash used in operating activities			
Amortization	185,271	211,709	976,734
Technology impairment	345,000	345,000	690,000
Common stock issued for services	18,500	-	318,500
Stock options and warrants	63,385	382,918	3,013,752
(Increase) decrease in assets			
Grants receivable	-	244,479	-
Prepaid drug product for testing	(42,000)	(64,600)	(195,000)
Other current assets	5,864	24,554	(42,575)
Increase (decrease) in liabilities			
Accounts payable and accrued expenses	13,113	69,373	329,244
Net cash used in operating activities	(1,993,404)	(1,149,911)	(7,040,628)
CASH FLOW FROM INVESTING ACTIVITIES			
Purchase of exclusive license - related party	(25,000)	(170,056)	(884,710)
Net cash used in investing activities	(25,000)	(170,056)	(884,710)
CASH FLOW FROM FINANCING ACTIVITIES			
Proceeds from convertible notes	-	-	435,000
Cash repayment of convertible notes	-	-	(15,000)
Net proceeds from sale of common stock	1,600,198	2,033,654	8,039,384

Net cash from financing activities	1,600,198	2,033,654	8,459,384
NET INCREASE (DECREASE) IN CASH	(418,206)	713,687	534,046
Cash, beginning of period	952,252	238,565	-
Cash, end of period	$534,046	$952,252	$534,046
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION			
Cash paid for			
Interest	$-	$-	$445
Income taxes	$-	$-	$-
Non-cash financing activities			
Common stock issued upon conversion of convertible notes	$-	$-	$420,000
Common stock issued to Placement Agent	$-	$179,421	$591,566
Common stock issued to M.D. Anderson for technology license	$-	$-	$2,354,167
Due diligence and commitment shares issued to Lincoln	$1,750	$1,549	$210,755

SEE ACCOMPANYING NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

BIO-PATH HOLDINGS, INC.

(A Development Stage Company)

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
May-07	Common stock issued for cash	6,480,994	$6,481	$-	$ -	$-	$6,481
Jun-07	Common stock issued for cash	25,000	25				25
	2nd Quarter fund raising expense			(26,773)			(26,773)
	Net loss 2nd Quarter 2007					(56,210)	(56,210)
Balances at June 30, 2007		6,505,994	$6,506	$(26,773)	$ -	$(56,210)	$(76,477)
Aug-07	Common stock issued for cash in seed round	3,975,000	3,975	989,775			993,750
Aug-07	Common stock issued for cash in second round	1,333,334	1,333	998,667			1,000,000
Aug-07	Common stock issued to Placement Agent for services	530,833	531	198,844			199,375
	3rd Quarter fund raising expense			(441,887)			(441,887)
	Net loss 3rd Quarter 2007					(81,986)	(81,986)
Balances at September 30, 2007		12,345,161	$12,345	$1,718,626	$ -	$(138,196)	$1,592,775

Nov-07	Common stock issued MD Anderson for License	3,138,889	3,139	2,351,028			2,354,167
	4th Quarter fund raising expense			(60,506)			(60,506)
	Net loss 4th Quarter 2007					(143,201)	(143,201)
Balances at December 31, 2007		15,484,050	$15,484	$4,009,148	$ -	$(281,397)	$3,743,235
Feb-08	Common stock issued for cash in 3rd round	1,579,400	1,579	1,577,821			1,579,400
Feb-08	Common stock issued to Placement Agent	78,970	79	78,891			78,970
Feb-08	Common stock issued for services	80,000	80	79,920			80,000
Feb-08	Merger with 2.20779528 : 1 exchange ratio	20,801,158	20,801	(20,801)			-
Feb-08	Add merger partner Ogden Golf shareholders	3,600,000	3,600	(3,600)			-
	1st Quarter fund raising expense			(251,902)			(251,902)
	Net loss 1st Quarter 2008					(226,206)	(226,206)
Balances at March 31, 2008		41,623,578	$41,623	$5,469,477	$ -	$(507,603)	$5,003,497
Apr-08	Common stock issued to PCS, Inc. in connection with merger	200,000	200	179,800			180,000
Apr-08	Stock option awards			42,216			42,216
Apr-08	Warrants issued for services			36,050			36,050
Apr-08	Share rounding	24					-
				(6,243)			(6,243)

	2nd Quarter fund raising expense						
	Net loss 2nd Quarter 2008					(496,256)	(496,256)
Balances at June 30, 2008		41,823,602	$41,823	$5,721,300	$ -	$(1,003,859)	$4,759,264
	Stock option vesting			30,770			30,770
	3rd Quarter fund raising expense			(12,886)			(12,886)
	Net loss 3rd Quarter 2008					(239,049)	(239,049)
Balances at September 30, 2008		41,823,602	$41,823	$5,739,184	$ -	$(1,242,908)	$4,538,099
	Common stock issued for services	100,000	100	39,900			40,000
	Stock option vesting			1,392,202			1,392,202
	4th Quarter fund raising expense			(19,025)			(19,025)
	Net loss 4th Quarter 2008					(1,891,256)	(1,891,256)
Balances at December 31, 2008		41,923,602	$41,923	$7,152,261	$ -	$(3,134,164)	$4,060,020
	Stock option vesting			148,727			148,727
	1st Quarter fund raising expense			(4,069)			(4,069)
	Net loss 1st Quarter 2009					(596,694)	(596,694)
Balances at March 31, 2009		41,923,602	$41,923	$7,296,919	$ -	$(3,730,858)	$3,607,984
Jun-09	Common stock and warrants for cash 4th round	660,000	660	164,340			165,000
Jun-09	Common stock issued to Placement Agent	66,000	66	16,434			16,500
	Stock option vesting			150,156			150,156
				(34,841)			(34,841)

	2nd Quarter fund raising expense						
	Net loss 2nd Quarter 2009					(533,049)	(533,049)
Balances at June 30, 2009		42,649,602	$42,649	$7,593,008	$ -	$(4,263,907)	$3,371,750
	Stock option vesting			147,685			147,685
	3rd Quarter fund raising expense			(4,891)			(4,891)
	Net loss 3rd Quarter 2009					(407,200)	(407,200)
Balances at September 30, 2009		42,649,602	$42,649	$7,735,802	$ -	$(4,671,107)	$3,107,344
	Common stock sold shares to be issued				675,000		675,000
	Stock option vesting			142,288			142,288
	4th Quarter fund raising expense			(75,074)			(75,074)
	Net loss 4th Quarter 2009					(432,795)	(432,795)
Balances at December 31, 2009		42,649,602	$42,649	$7,803,016	$ 675,000	$(5,103,902)	$3,416,763
Jan-10	Shares issued for common stock sold 4Q09	2,700,000	2,700	672,300	(675,000)		-
Jan-10	Common stock and warrants for cash	900,000	900	224,100			225,000
Jan-10	Common stock issued to Placement Agent	360,000	360	89,640			90,000
May-10	Common stock and warrants for cash	780,000	780	272,220			273,000
May-10	Common stock issued to Placement Agent	78,000	78	27,222			27,300
Jun-10	Due diligence shares issued to Lincoln	12,000	12	4,188			4,200
Jun-10		571,429	572	199,428			200,000

	Common stock and warrants for cash Lincoln						
Jun-10	Commitment shares issued to Lincoln	566,801	567	197,813			198,380
Jul-10	Common stock for cash Lincoln	375,000	375	149,625			150,000
Jul-10	Commitment shares issued to Lincoln	6,251	7	2,493			2,500
Sep-10	Common stock for cash Lincoln	125,000	125	49,875			50,000
Sep-10	Commitment shares issued to Lincoln	2,084	2	832			834
Oct-10	Common stock for cash Lincoln	135,135	135	49,865			- 50,000
Oct-10	Commitment Shares issued to Lincoln	2,084	2	769			- 771
Nov-10	Common stock for cash Lincoln	135,135	135	49,865			- 50,000
Nov-10	Commitment Shares issued to Lincoln	2,084	2	769			- 771
Dec-10	Common stock sold shares to be issued				278,600		278,600
Dec-10	Full year 2010 stock option vesting			477,356			477,356
Dec-10	Full year 2010 fund raising expense			(552,229)			(552,229)
Dec-10	Full year 2010 Net Loss					(2,081,500)	(2,081,500)
Balances at December 31, 2010		49,400,605	$49,401	$9,719,147	$ 278,600	$(7,185,402)	$2,861,746
Feb-11	Common stock sold shares to be issued				332,200		332,200
Mar-11	Common stock sold shares to be issued				431,102		431,102

Apr-11	Common stock sold shares to be issued				454,203		454,203
May-11	Common stock sold shares to be issued				298,100		298,100
Jun-11	Shares issued for common stock sold 4Q10 thru 2Q11	5,980,685	5,980	1,788,225	(1,794,205)		-
Jun-11	Common stock issued to Placement Agent	598,069	598	178,823			179,421
Jun-11	Common stock for cash Lincoln	164,853	165	49,835			50,000
Jun-11	Commitment Shares issued to Lincoln	2,084	2	630			- 632
Oct-11	Common stock sold for investor warrant exercise	1,920,000	1,920	574,080			576,000
Nov-11	Common stock for cash Lincoln	83,333	84	24,916			25,000
Nov-11	Commitment Shares issued to Lincoln	1,042	1	312			313
Dec-11	Common stock for cash Lincoln	172,414	172	49,828			50,000
Dec-11	Commitment Shares issued to Lincoln	2,084	2	602			604
Dec-11	Full year 2011 stock option vesting			382,918			382,918
Dec-11	Full year 2011 fund raising expense			(363,921)			(363,921)
Dec-11	Full year 2011 net loss					(2,363,344)	(2,363,344)
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					99,011	99,011

	Common stock Placement Agent shares to be issued						
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	762,511	(12,131,283)	2,014,520

SEE ACCOMPANYING NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Bio-Path Holdings, Inc.
(A Development Stage Company)

Notes to Financial Statements
December 31, 2012

1. Organization and Business

Bio-Path Holdings, Inc. (“Bio-Path” or the “Company”) is a development stage company with its lead cancer drug candidate, Liposomal Grb-2 (“L-Grb-2” or “BP-100-1.01”), 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 lead liposomal antisense drug candidates are targeted to treat acute myeloid leukemia, myelodysplastic syndrome, chronic myelogenous leukemia, acute lymphoblastic leukemia and follicular lymphoma, and if successful, could potentially be used in treating many other indications of cancer. For example, recently in December of 2012 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.

Bio-Path is currently treating patients with its lead cancer drug candidate Liposomal Grb-2 in a Phase I clinical trial. In March of 2010, Bio-Path received written notification from the U.S. Food and Drug Administration (the “FDA”) that its application for Investigational New Drug (“IND”) status for L-Grb-2 had been granted. This enabled the Company to commence its Phase I clinical trial to study L-Grb-2 in human patients, which began in the third quarter 2010.

The Phase I clinical trial is a dose-escalating study to determine the safety and tolerance of escalating doses of L-Grb-2. The study will also determine the optimal biologically active dose for further development. The pharmacokinetics of L-Grb-2 in patients will be studied, making it possible to investigate whether the delivery technology performs as expected based on pre-clinical studies in animals. In addition, patient blood samples from the trial will be tested using a new assay developed by the Company to measure down-regulation of the target protein, the

critical scientific data that will demonstrate that 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 initial protocol for the trial required evaluation of five doses of L-Grb-2 and enrollment of a sufficient number of patients in the study to achieve 18 to 30 evaluable patients. An evaluable patient is a patient who is able to complete the four-week treatment cycle.

In November of 2012, the Company announced that since there had been no evidence of significant toxicity from treatment of patients with L-Grb-2, the Company was proceeding with requesting the FDA to allow higher dosing in patients. The Principal Investigator for the clinical trial, in consultation with Bio-Path's Board of Directors, advised that with the absence of any real toxicity barriers, the Company should continue to evaluate higher doses of Liposomal Grb-2. The absence of significant toxicity provides a significant opportunity for the Company 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 is in place allowing higher dosing. The Company is currently enrolling and treating patients in Cohort 5 at a dose of 60 mg/m^2. The clinical trial is being conducted at The University of Texas MD Anderson Cancer Center.

Patients eligible for enrollment into the Phase I clinical trial have refractory or relapsed Acute Myeloid Leukemia (AML), Philadelphia Chromosome Positive Chronic Myelogenous Leukemia (CML) and Acute Lymphoblastic Leukemia (ALL), or Myelodysplastic Syndrome (MDS) and who have failed other approved treatments. These are patients with very advanced stages of the disease, and consequently, not all patients enrolled are able to complete the four-week treatment cycle because of progressive disease, which is unrelated to the treatment with Liposomal-Grb-2.

At the end of July 2011, the Company completed requirements for treating patients in the first cohort. The Company, its medical advisors and the Principal Investigator agreed that the data from the first cohort demonstrated that Liposomal Grb-2 was safe enough to proceed to the next cohort of the trial, which treated patients in the trial with a dose that was double the dose used in the first cohort. As a result of this review, the first cohort was closed and the second cohort was opened for recruiting patients into the clinical trial. In January of 2012, the Company completed requirements for treating patients in the second cohort. The Company, its medical advisors and the Principal Investigator agreed that the data from the second cohort demonstrated that Liposomal Grb-2 was safe enough to proceed to the third cohort of the trial, which is treating patients with a dose of 20 mg/m^2, which is double the dose used in the second cohort. At the end of April 2012, there were three evaluable patients in Cohort 3. As a result, a meeting of the Company's medical advisory board was being scheduled to close the cohort and proceed to Cohort 4. Significantly, in the third cohort, all three patients completed the treatment cycle and were evaluable and, because of apparent stabilization from treatment with Bio-Path drug candidate Liposomal Grb-2, had received extended treatment cycles or were on hold for additional treatments pending increased supply of drug.

Based on the experience treating patients in Cohort 3, during which all three patients benefited from treatment with Liposomal Grb-2 and were apparently stabilized, the assumption for drug requirements for Cohort 4 and beyond were increased significantly. Specifically, the assumption now is that all patients will benefit from treatment with the drug candidate Liposomal Grb-2 and be eligible to receive up to six months of treatments. In this regard, the Company increased the capacity of its drug supply chain, adding new suppliers for the Grb-2 drug substance and for the final drug product. Substantially increased supplies of the drug candidate Liposomal Grb-2 were delivered in July of 2012.

The Principal Investigator for the Phase I clinical trial, Dr. Jorge Cortes, 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 annual meeting in December of 2011. Results from the second cohort also demonstrated potential anti-leukemia benefits in treated patients and were included in the presentation. Bio-Path and the Principal Investigator plan to present information at leading industry scientific conferences in the future as results become available.

Bio-Path has also been working with the Principal Investigator to finalize plans for Phase II clinical trials in Liposomal Grb-2. Significantly, these plans include three Phase II trials, one each for CML, AML and MDS, of the drug candidate Liposomal Grb-2 in salvage therapy for very advanced patients.An important outcome for the Phase I clinical trial is the ability to assess for the first time the performance of the Company's delivery technology platform in human patients. The Company has 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.

Being platform technology, a successful demonstration of the delivery technology in this study will allow the Company to begin expanding Bio-Path's drug candidates by simply applying the delivery technology template to multiple new drug product targets. In this manner, Bio-Path 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, the Company is researching potential targets for which it can apply its liposomal antisense drug delivery technology.

At the end of January 2012, the Company's Board of Directors held a strategic planning session. Among several topics was a discussion of Company's liposomal siRNA technology. The siRNA discussion covered a broad range of topics including intellectual property, the amount of development that would be needed and the overall impression of diminishing acceptance of siRNA technology by the pharmaceutical industry and equity market investors. The Board compared this to our core liposomal antisense technology, which has a stronger intellectual property position, a method of action blocking expression of disease-causing proteins that is better understood in the scientific community and a much easier path for development than liposomal siRNA technology. Since both antisense and siRNA are means to block expression of disease-causing proteins, the Board concluded that there was no apparent reason to develop a second, higher-risk siRNA method of blocking protein expression when the development of the liposomal antisense method is now much further along and showing promising results. After this discussion the Board decided to discontinue development of the licensed liposomal siRNA technology and the Company commenced discussions regarding this decision with MD Anderson to determine with them whether to modify the license to include other products, postpone the license or simply abandon the license. As an interim step pending final resolution of this matter, the Company took a charge of $345,000 at the end of the fiscal year ending December 31, 2011 to reduce the carrying value of the siRNA license by fifty percent (50%). This amount represented one half of the value of the common stock given to MD Anderson when the original siRNA license was finalized. In June 2012, the Company decided to write-off the balance of the carrying value of the siRNA license, representing $345,000, and cancel the license.

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 has become a publicly traded company (symbol OTCBB: BPTH) 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.

An important milestone was achieved for the Company in the second quarter, 2012 when Bio-Path's common stock began trading on the quality-controlled OTCQX. OTCQX is the highest tier, premier trading platform for OTC companies. The Company also announced that it had retained Roth Capital Partners to serve as the Company's Designated Advisor for Disclosure ("DAD") on OTCQX, responsible for providing guidance on OTCQX requirements

As of December 31, 2012, Bio-Path had $534,046 in cash on hand. During the year 2012, the Company raised approximately $1.6 million in net funds after Placement Agent commissions and fund raising expenses, through the sale of unregistered shares of its common stock to accredited investors through a private placement initiated by the Company in 2012. Based on the positive response from investors, the Company has extended the private placement through March 31, 2013. Bio-Path plans to begin raising significant amounts of additional development capital at anticipated higher share prices once there is demonstration of proof-of-concept of Bio-Path's technology in human patients.

As the Company has not begun its planned principal operations of commercializing a product candidate, the accompanying financial statements have been prepared in accordance with principles established for development stage enterprises.

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, 2012 and 2011, MD Anderson related party research and development expense was $463,870 and $544,000, respectively. MD Anderson related party research and development expense for the year ending December 31, 2012 included clinical trial expense of $37,700, license maintenance fees of $50,000 and $31,170 in siRNA patent expenses not capitalized in the technology license other asset, and $345,000 in non-cash technology impairment expense related to the Company's siRNA license (see Note 1.). As of December 31, 2012, the Company had accounts payable related party of $8,582, $100,000 in accrued license payments payable due to the related party for the annual maintenance fee and past patent expenses for the Company's Technology License, and $26,000 in accrued R&D related expense for the clinical trial. See Notes 5, 6 and 7.As of December 31, 2011, the Company had $544,000 in R&D related party expense for the clinical trial, license maintenance fee and technology impairment, accrued license payments payable related party of $39,538 for patent expenses, and $41,000 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, 2012, $284,046 of the Company's cash balances was not covered by the FDIC. As of December 31, 2011 the Company had $952,252 in cash on-hand, of which $702,252 was not covered by Federal Deposit Insurance Corporation insurance.

Intangible Assets/Impairment of Long-Lived Assets — As of December 31, 2012, Other Assets totals $1,572,143 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 $928,231. 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 (see Note 1). This value is being amortized over a fifteen year (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, 2011 Other Assets totaled $2,077,414 comprised of $2,868,877 in value acquiring the Company's technology licenses and its intellectual property, less accumulated amortization of $791,463.

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 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. Of the research and development expense totaling $1,132,712, $185,271 was for amortization of the technology license, $53,645 was for stock options expense for individuals involved in research and development activities, $594,440 for drug product material expensed, 124,685 for clinical trial expense and the balance of approximately $174,671 was for drug product testing, advisory services and other R&D activities. Of the $463,870 related party research and development expense, $37,700 was comprised of costs for clinical trial hospital costs, $50,000 for technology license maintenance fees and $31,170 in siRNA patent costs not capitalized in technology license-Other Assets and $345,000 in technology license impairment expense (See Note 2. Related Party). For the year 2011, the Company had $596,802 of costs classified as research and development expense and $544,000 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 – In accordance with GAAP and SEC Staff Accounting Bulletin (“SAB”) No. 98, 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 2012 and 2011, 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 2012 and 2011. The calculation of Basic and Diluted earnings per share for 2012 did not include 3,296,354 shares and 85,620 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. The calculation of Basic and Diluted earnings per share for 2011 did not include 3,131,043 shares and 1,437,049 shares issuable pursuant to the exercise of vested common stock and vested warrants, respectively, as of December 31, 2011 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, 2012 and 2011, 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 FASB 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 financial statements upon adoption.

3. Grants Receivable

As of December 31, 2010, Current Assets included grants receivable of $244,479. This represents a grant award that Bio-Path received in October 2010 for its application to receive grant funding from the U.S. Government's Qualifying Therapeutic Discovery Project Program. The Company received these grant funds during the first week of February 2011.

4. 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 $195,000 during 2012 pursuant to a Drug Supply Contract (see Note 12) 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, 2012 at cost as Prepaid Drug Product for Testing and was expensed when the drug product was received by the Company in 2013. As of December 31, 2011 the Company had $153,000 of installments of costs carried on the Balance Sheet as Prepaid Drug Product for Testing for the manufacture and delivery of the Company's drug product for testing in its clinical trial.

5. Accounts Payable

As of December 31, 2012, Current Liabilities included accounts payable of $57,000 comprised primarily of amounts owed to the Company's drug contract manufacturer totaling $6,300, approximately $15,760 to the company providing clinical operations management for Bio-Path's clinical trial, $11,980 to the Company's attorneys and auditors and $14,940 for business wire and public filing expense; and accounts payable – related party of $8,582 comprised of siRNA patent expenses incurred during 2012. These amounts were subsequently paid in the first quarter of 2013. As of December 31, 2011, Current Liabilities included accounts payable $121,540 and accounts payable – related party of $67,971, which amounts were subsequently paid in 2012.

6. Accrued Expense

As of December 31, 2012, Current Liabilities included accrued expense of $137,662 including approximate amounts for research and development expense for clinical trial operations management of $10,000, $9,600 for advisors and consultants and $115,625 for management bonus accrual. Current Liabilities as of December 31, 2012 also included accrued expenses – related party of $26,000 for clinical trial hospital expense. As of December 31, 2011, Current Liabilities included accrued expense of $46,082 and accrued expense – related party of $41,000.

7. Accrued License Payments – Related Party

Accrued license payments – related party totaling $100,000 and $39,538 were included in Current Liabilities as of December 31, 2012 and 2011, respectively. The amount for 2012 represents reimbursement of past patent expenses incurred by MD Anderson prior to the Bio-Path license and the annual license maintenance fee.

8. Convertible Debt

In 2007, the Company issued $435,000 in notes convertible into common stock at a rate of $.25 per common share. In 2007, $15,000 of the convertible notes were repaid in cash and $420,000 of the convertible notes were converted into 1,680,000 shares of Bio-Path common stock and was included in the seed round completed in August of 2007. No interest was recorded because interest was nominal prior to conversion. No beneficial conversion feature existed as of the debt issuance date since the conversion rate was greater than or equal to the fair value of the common stock on the issuance date.

9. Additional Paid In Capital For Shares To Be Issued

During 2012, the Company sold shares of common stock for $762,510 in cash to investors pursuant to a private placement memorandum. These shares were not issued by the December 31, 2012 year end. The Company intends to close this offering at the end of the first quarter 2013 and issue 2,541,700 shares of common stock to these investors.

10. Stockholders' Equity

Issuance of Common Stock – In May and June of 2007, the Company issued 6,505,994 shares of common stock for $6,506 in cash to founders of the Company. In August of 2007, the Company issued 3,975,000 shares of common stock for $993,750 in cash to investors in the Company pursuant to a private placement memorandum. In August of 2007 the Company issued an additional 1,333,334 shares of common stock for $1,000,000 in cash to investors in the Company pursuant to a second round of financing. The Company issued 530,833 in common stock to the Placement Agent as commission for the shares of common stock sold to investors. In November of 2007, the Company issued 3,138,889 shares in common stock to MD Anderson as partial consideration for its two technology licenses from MD Anderson.

In February of 2008, the Company completed a reverse merger with Ogden Golf Co. Corporation and issued 38,023,578 shares of common stock of the public company Bio-Path Holdings (formerly Ogden Golf Co. Corporation) in exchange for pre-merger common stock of Bio-Path, Inc. In addition, shareholders of Ogden Golf Co. Corporation retained 3,600,000 shares of common stock of Bio-Path Holdings. In February of 2008 Bio-Path issued 80,000 shares of common stock to strategic consultants pursuant to executed agreements and the fair value was expensed upfront as common stock for services. In April of 2008, the Company issued 200,000 shares of common stock to a firm in connection with introducing Bio-Path, Inc. to its merger partner Ogden Golf Co. Corporation. The fair value of this stock issuance was expensed upfront as common stock for services valued at $180,000. In April of 2008, the Company recorded an additional 24 shares for rounding in accordance with FINRA rules. In December of 2008, the Company issued 100,000 shares of common stock to an investor relations firm for services. The fair value of this stock issuance was expensed upfront as common stock for services valued at $40,000. There were no issuances of shares during the first quarter of 2009. In June of 2009, the Company issued 660,000 shares of common stock and warrants to purchase an additional 660,000 shares of common stock for $165,000 in cash to investors in the Company pursuant to a private placement memorandum. The warrants must be exercised within two years from the date of issuance. The exercise price of the warrants is $1.50 a share. In connection with this private placement, the Company issued 66,000 shares of common stock to the Placement Agent as commission for the shares of common stock sold to investors. There were no issuances of shares during the fourth quarter of 2009.

In November and December of 2009, the Company sold shares of common stock and warrants to purchase shares of common stock for $675,000 in cash to investors pursuant to a private placement memorandum. These shares were not issued by the December 31, 2009 year end. In January 2010, the Company issued these investors 2,700,000 shares of common stock and warrants to purchase an additional 2,700,000 shares of common stock. The warrants must be exercised within two years from the date of issuance. The exercise price of the warrants is $1.50 a share. In January 2010, the Company also sold an additional 900,000 shares of common stock and warrants to purchase an additional 900,000 shares of common stock for $225,000 in cash to investors in the Company pursuant to a private placement memorandum. The warrants must be exercised within two years from the date of issuance and the exercise price is $1.50 a share. In connection with these private placement sales of equity, the Company issued 360,000 shares of common stock to the Placement Agent as commission for the shares of common stock sold to investors.

In May of 2010, the Company issued 780,000 shares of common stock and warrants to purchase an additional 780,000 shares of common stock for $273,000 in cash to investors in the Company pursuant to a private placement memorandum. The warrants must be exercised within two years from the date of issuance. The exercise price of the warrants is $1.50 a share. In connection with this private placement, the Company issued 78,000 shares of common stock to the Placement Agent as commission for the shares of common stock sold to investors.

In June of 2010, the Company signed an equity purchase agreement for up to $7 million with Lincoln Park Capital Fund, LLC (“LPC” or “Lincoln”), a Chicago-based institutional investor. Under the terms of the equity purchase agreement, the Company has the right to sell shares of its common stock to LPC from time to time over a 24-month period in amounts between $50,000 and $1,000,000 up to an aggregate amount of $7 million depending upon certain conditions set forth in the purchase agreement including that a registration statement related to the transaction has been declared effective by the U.S. Securities and Exchange Commission (“SEC”). As a result, a registration statement was filed and later declared effective by the SEC on July 12, 2010. Upon signing the agreement, the Company received $200,000 from LPC as an initial purchase in exchange for 571,429 shares (“Initial Purchase Shares”) of the Company’s common stock and warrants to purchase 571,429 shares of the Company’s common stock at an exercise price of $1.50 per share. Subsequent purchases of the Company’s common stock by Lincoln Park under the agreement do not include warrants. In connection with the signing of the LPC financing agreement, the Company issued LPC 12,000 shares of the Company’s common stock for its due diligence efforts and 566,801 shares of the Company’s common stock as a commitment fee for the balance of the $7 million equity purchase commitment.

In July of 2010, the Company received $150,000 from LPC in exchange for 375,000 shares of the Company’s common stock. LPC was also issued 6,251 shares of the Company’s common stock as a commitment fee in connection with the purchase of the 375,000 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 September of 2010, the Company received $50,000 from LPC in exchange for 125,000 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 125,000 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 October of 2010, the Company received $50,000 from LPC in exchange for 135,135 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 135,135 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 November of 2010, the Company received $50,000 from LPC in exchange for 135,135 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 135,135 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.

From November 2010 through April of 2011 the Company sold shares of common stock for $1,794,205 in cash to investors pursuant to a private placement memorandum. In June of 2011, the Company issued 5,980,685 shares of common stock to these investors. In connection with this private placement, in June of 2011 the Company issued 598,069 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 in connection with the sale of the common stock.

In June of 2011, the Company received $50,000 from LPC in exchange for 164,853 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 164,853 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 October of 2011, the Company issued 1,920,000 shares of common stock for $576,000 to investors who exercised warrants from September to October 2011.

In November of 2011, the Company received $25,000 from LPC in exchange for 83,333 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 83,333 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 December of 2011, the Company received $50,000 from LPC in exchange for 172,414 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 172,414 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 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 in 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.

11. 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. The total number of Shares reserved and available for grant and issuance pursuant to this Plan is 7,000,000 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 2012 were estimated to have a weighted average fair value per share of $0.37. None of the stock option awards granted in 2012 were made to current management. Stock option awards granted for the year 2011 were estimated to have a weighted average fair value per share of $0.34. There were no stock options or compensation-based warrants granted in the years 2010 and 2009. Stock option and compensation-based warrant awards granted for the year 2008 were estimated to have a weighted average fair value per share of $0.86. There were no stock options or warrants granted prior to 2008. 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 2008, 2011 and 2012 the following weighted average assumptions were used in determining fair value:

	2008	2011	2012
Risk-free interest rate	3.10%	2.30%	0.78%
Dividend yield	- %	- %	- %
Expected volatility	80 %	163 %	185 %
Expected term in months	76	81	61

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, 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 2011 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 or 2011, respectively. 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, 2012:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$ 0.30	56,771	5.3	$ 0.30	56,771	$ 0.30
$ 0.33	125,000	8.5	$ 0.33	125,000	$ 0.33
$ 0.35	25,000	8.3	$ 0.35	-	-
$ 0.39	25,000	8.8	$ 0.39	-	-
$ 0.53	20,000	8.1	$ 0.53	-	-
$ 0.90	730,417	5.3	$ 0.90	-	-
$ 1.40	2,500,000	5.8	$ 1.40	-	-
	3,482,188	5.8	$ 1.22	$ 181,771	$ 0.32

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, 2012:

	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	85,620	0.9	$ 0.90	-	-
	85,620	0.9	$ 0.90	-	-

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Stock Option Grants - Total stock option expense for the year 2011 totaled $382,918.

In October of 2012, the Company made a stock option grant to purchase 25,000 shares of the Company's common stock for service as a director of the Company. Terms of the stock option grant require, among other things, that the individual continues to provide services over the vesting period of the option, which is one year from the date of grant for the director service stock option. The exercise price of the option is $0.39 a share, which was the closing price of the common stock at the date of grant. The Company determined the fair value of the stock option granted using the Black Scholes model and expenses this value monthly based upon the vesting schedule of the stock option award. For purposes of determining fair value, the Company used an average annual volatility of one hundred eighty five percent (185%), which was calculated based on the closing price of the Company's stock over the preceding five years. The risk free rate of interest used in the model was taken from a table of the market rate of interest for U. S. Government Securities for the date of the stock option award and the effective term. The Company used the simplified method to determine the expected term of the options due to the lack of historical data. The total fair value of the stock option granted was determined using this methodology to be $9,725, which is being expensed following the date of grant based on the stock option vesting schedule.

In December of 2012, the Company made a stock option grant to purchase 25,000 shares of the Company's common stock for service as a director of the Company. Terms of the stock option grant require, among other things, that the individual continues to provide services over the vesting period of the option, which is one year from the date of grant for the director service stock option. The exercise price of the option is $0.35 a share, which was the closing price of the common stock at the date of grant being approved. The Company determined the fair value of the stock option granted using the Black Scholes model and expenses this value monthly based upon the vesting schedule of the stock option award. For purposes of determining fair value, the Company used an average annual volatility of one hundred eighty five percent (185%), which was calculated based on the closing price of the Company's stock over the preceding five years. The risk free rate of interest used in the model was taken from a table of the market rate of interest for U. S. Government Securities for the date of the stock option award and the effective term. The Company used the simplified method to determine the expected term of the options due to the lack of historical data. The total fair value of the stock option granted was determined using this methodology to be $8,700, which is being expensed following the date of grant based on the stock option vesting schedule.

The stock option grants in 2012 were not for current management of the Company.

Total stock option expense for the year 2012 totaled $63,385. Of this amount, $53,645 related to stock options for personnel involved in R&D activities and $9,740 related to stock options for outside directors of the Company. As of December 31, 2012, total unrecognized compensation cost related to nonvested stock option awards amounted to $62,439.

Warrant Grants - There were no warrants for services granted in 2011 and there was no warrant expense for the year 2011. There were no warrants for services granted in the year 2012 and there was no warrant expense for the year 2012.

12. 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 $108,582 are included in Current Liabilities as of December 31, 2012. Related party accrued expense totaling $26,000 as of December 31, 2012 represent hospital costs for the clinical trial and are not related to the Technology License. As of December 31, 2012, 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. In addition, the Company decided to discontinue development of its siRNA technology and subsequently canceled its siRNA license in June of 2012 (See Note 1).

Drug Supplier Project Plan - In August of 2012, Bio-Path entered into two project plan agreements with the Company's drug substance manufacturer and its final drug product manufacturer for the manufacture and delivery of final drug product incorporating the drug substance for expected delivery in the fourth quarter of 2012, with delivery subsequently revised to the first quarter of 2013. The project plans required the Company to pay approximately $340,000 in various stages as the drug substance and product are manufactured and delivered to the Company. Of this amount, $195,000 has been paid for by the Company, which is carried on the Balance Sheet as Prepaid Drug Product for Testing. This amount substantially represents the entire financial commitments to the drug substance and the drug product manufacturers for the new batch of drug product. The drug product was delivered to the Company in the first quarter of 2013 and the Balance Sheet item Prepaid Drug Product for Testing totaling $195,000 will be expensed in the first quarter 2013. Amounts owed to the Company's manufacturers for this drug batch have been paid subsequent to year end.

13. Income Taxes

At December 31, 2012, the Company has a net operating loss carryforward for Federal income tax purposes of $8,572,639 which expires in varying amounts during the tax years 2028 and 2032. The Company has a research and development tax credit carryforward of $383,067 for Federal tax purposes with no expiration date. The Company recorded an increase in the valuation allowance of $1,056,770 for the year ended December 31, 2012.

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

	December 31,	
	2012	2011
Current Deferred Tax Assets		
Accrued Bonuses	$39,313	$15,725
Noncurrent Deferred Tax Assets		
Net Operating Loss (NOL) Carryover	2,914,697	2,036,023
Technology Licenses	73,021	119,842
Research & Development Tax Credits	383,067	203,288
Share Based Expense	179,779	158,229
Total Deferred Tax Asset	3,589,877	2,533,107
Less: Valuation Allowance	(3,589,877)	(2,533,107)
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,	
	2012	2011
Loss Before Income Taxes	$(2,582,537)	$(2,363,344)
Tax (Benefit) @ Statutory Tax Rate	(878,063)	(803,537)
Effects of:		
Exclusion of ISO Expense	-	105,612
R&D Tax Credits	(179,779)	(24,928)
(Increase)/Decrease in Valuation Allowance	1,056,770	726,118
Other	1,072	(3,265)
Provision (Benefit) for Income Taxes	$-	$-

As of December 31, 2012 and 2011, the Company has no unrecognized income tax benefits. The Company is in process of completing an analysis of its tax credit carryforwards. A reconciliation of our unrecognized tax benefits for the years ending December 31, 2012 and 2011 is presented in the table below:

	December 31,	
	2012	2011

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, 2012, and 2011 and no interest or penalties have been accrued as of December 31, 2012 and 2011.

The tax years from 2009 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.

14. Subsequent Events

To date in the first quarter of 2013, the Company has sold approximately $350,000 to accredited investors in exchange for shares of the Company’s common stock pursuant to a private placement. The private placement has been amended to remain open until the end of the first quarter 2013.

The Company believes that it will sell a significant amount of common stock in the first quarter of 2013 prior to the closing of the private placement.

In the first quarter of 2013, the Company entered into a supply agreement with its drug product manufacturer for the manufacture of the Company’s drug product for delivery in May of 2013. The agreement calls for the Company to pay approximately $150,000 in various stages until the final drug product is manufactured, successfully tested and delivered to the Company.