BIO-PATH HOLDINGS INC
Form 10-K
March 31, 2010

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U.S. SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

ý ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THESECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2009
OR
¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THESECURITIES 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.) |

3293 Harrison Boulevard, Suite 220, Ogden, UT 84403
(Address of principal executive offices)

Issuer's telephone no., including area code: (801) 399-5500

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 ý
-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 ý
-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 ý 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. ý

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 ¨ |
| | Smaller reporting company ý |

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

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

The Issuer's revenues for the fiscal year ended December 31, 2009 were $-0-.

As of March 22, 2010, there were 46,509,602 shares of the Issuer's common stock issued and outstanding of which 30,134,466 were held by non-affiliates. The aggregate market value of the common stock held by non-affiliates of the registrant based upon the last sales price of the common stock reported on the OTCBB on March 22, 2010 was approximately $15,368,578.

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-P Holdings, Inc. and its subsidiary. Our wholly-owned subsidiary, Bio-Path, Inc., is sometime 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 to:

- the potential benefits and commercial potential of our potential products,
- level of future sales, if any,
- collections, costs, expenses and capital requirements, cash outflows,
- the safety and efficacy of our product candidates,
- estimates of the potential markets and estimated trial dates,
- sales and marketing plans,
- any changes in the current or anticipated market demand or medical need 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,
- 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,
- our ability to obtain additional financing,
- 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 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 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 Securities and Exchange Commission.

## ITEM 1. DESCRIPTION OF BUSINESS

Bio-Path Holdings, Inc. through Bio-Path, Inc., our wholly-owned subsidiary ("Bio-Path Subsidiary") is a biotechnology company engaged in the business of financing and facilitating the development of novel cancer therapeutics. Our initial plan has been (i) to acquire licenses for drug technologies from The University of Texas M. D. Anderson Cancer Center ("M. D. Anderson"), (ii) to fund clinical and other trials for such technologies and (iii) to commercialize such technologies. We have three exclusive licenses ("License Agreements") from M. D. Anderson for three lead products and nucleic acid delivery technology including tumor targeting technology. These licenses specifically provide drug delivery platform technology with composition of matter intellectual property that enables systemic delivery of antisense, small interfering RNA ("siRNA") and small molecules for treatment of cancer.

Our business plan is to act efficiently as an intermediary in the process of translating newly discovered drug technologies into authentic therapeutic drugs products. Our strategy is to selectively license potential drug candidates for certain cancers, and, primarily utilizing the comprehensive drug development capabilities of M. D. Anderson, to advance these candidates into initial human efficacy trials (Phase IIA), and out-license each successful potential drug to a pharmaceutical company.

### Research and Development

Our research and development is currently conducted through agreements we have with M. D. Anderson.

### Recent Updated Information

On March 12, 2010, we issued a press release announcing that the US Food and Drug Administration (FDA) has allowed an IND (Investigational New Drug) for our 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 Bio-Path covering pre-clinical studies, safety, chemistry, manufacturing and controls, and the protocol for the Phase I clinical trial. Bio-Path is developing a neutral lipid-based liposome delivery technology for nucleic acid cancer drugs (including antisense and siRNA molecules). Bio-Path's drug candidate liposomal BP-100-1.01 is an antisense drug substance targeted to treat several types of cancer. The FDA's clearance of the IND allows Bio-Path to proceed with a Phase I clinical trial in patients with chronic myelogenous leukemia (CML), acute myeloid leukemia (AML), acute lymphoblastic leukemia (ALL) and myelodysplastic syndrome (MDS). Commencement of the trial will occur after patients are enrolled and administrative details are finalized. Bio-Path does not expect significant delays for these steps and expect our Phase I clinical trials to commence in 2010.

### Plan of Operation

Our plan of operation over the next 36 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 products to broaden our drug product pipeline.

We anticipate that over the next 36 months, we will need to raise approximately $10,000,000 to completely implement our current business plan. We have completed several financings for use in our Bio-Path operations and have received total net proceeds of $3,776,403. Our short term plan is to achieve three key milestones:

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(1) conduct 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 including siRNA. As described above we recently received FDA clearance to commence Phase I clinical trials of our BP-100-1.01 drug;

(2) perform necessary pre-clinical studies in our lead liposomal siRNA drug candidate, BP-100-2.01 to enable the filing of an Investigational New Drug ("IND") for a Phase I clinical trial; and

(3) out-license (non-exclusively) our delivery technology for either antisense or siRNA to a pharmaceutical partner to speed development applications of our technology.

In June 2008, we entered into a Project Plan Agreement with Althea Technologies, Inc. ("Althea") relating to supply of drug product for our first Phase I clinical trials of our BP-100-1.01 drug. In September 2008 we executed a definitive agreement with Althea. Althea is a San Diego-based contract developer and manufacturer of biologic and injectable products, with fully integrated services to support clients with product development expertise and finished cGMP product from pre-clinical development through commercial supply.

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 modify the genetic material RNA to treat disease. RNA is essential in the process of creating proteins. The "i" in RNAi stands for "interference." We intend to develop drugs and drug delivery systems that are intended to work by using RNA to interfere with the production of proteins associated with disease. The discovery of RNAi, in 1998, has led not only to its widespread use in the research of biological mechanisms and target validation, but also to its application in down-regulating the expression of certain disease-causing proteins found in a wide spectrum of diseases including inflammation, cancer, and metabolic dysfunction. RNAi-based therapeutics work through a naturally occurring process within cells that has the effect of reducing levels of messenger RNA (mRNA) required for the production of proteins. At this time, several RNAi-based therapeutics are being evaluated in human clinical trials.

The historical perspective of cancer treatments has been 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 and siRNA, are two of the most promising fields of targeted therapy. Development of antisense and siRNA, 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 RNAi drug, which will be clinically tested for validation in Acute Myeloid Leukemia (AML), Myelodysplastic Syndrome (MDS) and Chronic Myelogenous Leukemia (CML). If this outcome is 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 of 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 US Food and Drug Administration (FDA) has allowed an IND (Investigational New Drug) 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. We anticipate that patient enrollment and final preparations for the Phase I clinical trial will start sometime during Fiscal Year 2010. We believe the trial will commence by the end of the second quarter, but there can be no assurance or exact time estimates. 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. An additional key objective of the trial is to assess that the effectiveness of the delivery technology.

The clinical trial will be conducted at the M. D. Anderson Cancer Center and is expected to last approximately one year. The primary objective of the Phase I trial is to demonstrate the safety of the Company's drug candidate liposomal BP-100-1.01 for use in human patients. Additional objectives are to demonstrate the effectiveness of our drug delivery technology similar to that experienced in pre-clinical treatment of animals, and further, 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 clinical trial is structured to test five rounds of patients, with each round comprising treatment of three patients. Each succeeding round in the study has a higher dose of the drug candidate test article being administered to the patients.

We will reimburse M. D. Anderson at the rate of approximately $13,000 per patient for treating patients in the study. We currently expect to reimburse M. D. Anderson a total of approximately $250,000 spread out over one year for patient treatment costs.

We are also required to supply M. D. Anderson with the actual drugs to be administered to the patients in the study. We have entered into a drug supply contract with Althea Technologies which will produce sufficient drugs for testing through two rounds. We expect to pay no more than $150,000 to Althea to complete payments under the current contract. Drug costs for the entire study could cost an additional $1 million including requirements for drug candidate test article for additional treatments of the patients if the drug is having a positive effect on the patients' disease. We have sufficient cash resources to fund the trial through the initial two or three rounds of the study. We plan to attempt to raise additional cash resources through the sale of common stock in 2010. We have the right to terminate the Althea agreement at any time, subject to payment of a termination fee to Althea. The termination fee is not material.

BP-100-2.01

BP-100-2.01 is our lead siRNA drug, which will be clinically tested for validation as a novel, targeted ovarian cancer therapeutic agent. The Company prepared a review package of the testing material for this drug product and reviewed the information with the FDA. Based on this review and feedback, performing the remaining pre-clinical development work for BP-100-2.01 expected to be required for an IND is budgeted for $225,000. The additional pre-clinical work is expected to include two toxicity studies in mice and primates.

Definitions

The following definitions are intended to assist you in understanding certain matters discussed in this Business Section:

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 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 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 Liposomes are 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. The new technology, being licensed in the field of neutral lipid-based liposome delivery of antisense technologies and siRNA, will 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).[1] 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. Nucleic acid base sequence of proteins plays 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.

siRNA. Small interfering RNA (siRNA), sometimes known as short interfering RNA or silencing RNA, is a class of 20-25 nucleotide-long double-stranded RNA molecules that play a variety of roles in biology. Most notably, siRNA is involved in the RNA interference (RNAi) pathway, where it interferes with the expression of a specific gene. A therapeutic siRNA drug is designed to block the cell's ability to produce a disease causing protein, effectively controlling the disease.

Projected Financing Needs

We anticipate that will need to raise an additional $10,000,000 in the next 36 months to complete our $15 million fund raising objectives, which will enable us to conduct additional clinical trials in other Bio-Path drug candidates and extend operations through 36 months.

The Phase I clinical trial of BP-100-1.01 is expected to cost $1,675,000. If the Phase I clinical trial in BP-100-1.01 is successful, we will follow with a Phase IIa trial in BP-100-1.01. Successful Phase I and IIA trials of BP-100-1.01 will demonstrate clinical proof-of-concept that BP-100-1.01 is a viable therapeutic drug product for treatment of AML, MDS and CML. The Phase IIA clinical trial in BP-100-1.01 is expected to cost approximately $1,600,000.

The Phase I clinical trial of BP-100-2.01 is expected to cost $2,000,000. Commencement of the Phase I clinical trial depends on the FDA approving the IND for BP-100-2.01. Success in the Phase I clinical trial will be based on the demonstration that the delivery technology for siRNA has the same delivery characteristics seen in our pre-clinical studies of the drug in animals.

If we are able to raise the entire $10,000,000, we anticipate that such capital raised will also allow us to conduct a Phase I clinical trial of BP-100-1.02, which is an anti-tumor drug that treats a broad range of cancer tumors. This trial is budgeted to cost $2,500,000 and is higher than the Phase I clinical trial for BP-100-1.01 due to expected higher hospital, patient monitoring and drug costs. Similar to the case with BP-100-1.01, commencement of the Phase I clinical trial of BP-100-1.02 requires that the FDA approve the IND application for BP-100-1.02.

We have currently budgeted approximately $3,000,000 out of the total $10,000,000 in net proceeds to be raised for additional drug development opportunities. The balance of the funding is planned to fund patent expenses, licensing fees, pre-clinical costs to M. D. Anderson's Pharmaceutical Development Center, consulting fees and management and administration.

We have generated approximately two full years of financial information and have not previously demonstrated that we will be able to expand our business through an increased investment in our technology and trials. We cannot guarantee that plans as described in this report will be successful. Our business is subject to risks inherent in growing an enterprise, including limited capital resources and possible rejection of our new products and/or sales methods. If financing is not available on satisfactory terms, 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 M. D. Anderson

We anticipate that our initial drug development efforts will be pursuant to three exclusive License Agreements with M. D. Anderson. M. D. 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. M. D. 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 M. D. Anderson as one of 2 best hospitals for 16 consecutive years. M. D. Anderson will treat more than 100,000 patients this year, of which approximately 11,000 will participate in therapeutic clinical research exploring novel treatments the largest such program in the nation. M. D. Anderson employs more than 15,000 people including more than 1,000 M. D. and Ph.D clinicians and researchers, and is routinely conducting more than 700 clinical trials at any one time.

Each year, researchers at M. D. 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.

Over the past several years M. D. 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 M. D. 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 Investigational New Drug Application ("IND") with the FDA, which is required to initiate clinical trials. These studies include pharmacokinetics ("pK"), tissue distribution, metabolism studies and toxicology studies.

We anticipate being able to use the PDC as a 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 M. D. Anderson

Bio-Path was founded to focus on bringing the capital and expertise needed to translate drug candidates developed at M. D. Anderson (and potentially other research institutions) into real treatment therapies for cancer patients. To carry out this mission, Bio-Path plans to negotiate several agreements with M. D. Anderson that will:

- give Bio-Path ongoing access to M. D. 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 working with M. D. Anderson and its personnel. Bio-Path believes that if Bio-Path obtains adequate financing, Bio-Path will be positioned to translate current and future M. D. Anderson technology into real treatments for cancer patients. This in turn is expected to provide a steady flow of cancer drug candidates for out-licensing to pharmaceutical partners.

Licenses

Bio-Path Subsidiary has negotiated and signed three licenses with M. D. Anderson for late stage preclinical molecules, and intends to use our relationship with M. D. Anderson to develop these drug compounds 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 product ourselves. Our basic guide to a decision 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 36-40 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 adequate capital, we intend to develop a steady series of drug candidates through Phase IIa clinical trials and then to engage in a series of out-licensing transactions to the pharmaceutical and biotechnology companies. These 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.

In addition to this source of revenue and value, we may forward integrate 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. Hence, "marketing and distribution" becomes a realistic possibility for select products. These candidates may be eligible for Orphan Drug Status 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 a unique and greatly needed solution to the delivery of small molecules, DNA and siRNA and their efficient uptake by targeted physiological tissues is a very important technological asset that may be commercialized in other areas of medicine.

License Agreements

We have entered into three Patent and Technology License Agreements (the "Licenses") with M. D. Anderson relating to its technology. A summary of certain material terms of the first two of the Licenses is as follows:

| | |
|---|---|
| Licensor: | The Board of Regents of the University of Texas System on behalf of The University of Texas M.D. Anderson Cancer Center |
| Licensee: | Bio-Path, Inc. |
| License: | A royalty bearing, exclusive license to manufacture, use and sell the Licensed Products |
| Territory: | Worldwide |
| Retained Rights: | Certain research and academic rights are retained by Licensor |
| License Fees: | Documentation Fee - $40,000 for the first license and $60,000 for the second license; annual maintenance fee - $25,000 for years 1, 2 & 3 increasing to $100,000 in the eighth year. After the first sale, increasing to $125,000 |
| Royalties: | Three percent of net sales |
| Milestone Payments: | One-time payments range from $150,000 to $2,000,000. Total up to $8,150,000 |
| Securities Issuance: | 1,883,333 shares of Bio-Path for first License and 1,255,556 shares for secondLicense |
| Expense: | Bio-Path will reimburse M. D. Anderson for expenses |
| Term: | Full term of patents |

To maintain our rights to the licensed technology, we must meet certain development and funding milestones.

Description of Technologies

The two above described License Agreements relate to the following technologies:

1) a lead siRNA drug product
2) two single nucleic acid (antisense) drug products
3) delivery technology platform for nucleic acids

August 2009 License

Effective August 27, 2009, we entered into an exclusive License Agreement (the "Agreement") with The University of Texas M. D. Anderson Cancer Center to develop liposome tumor targeting technology. Bio-Path is currently developing a neutral-lipid based liposome delivery technology for nucleic acid cancer drugs (including antisense and siRNA molecules). The new technology, being licensed in the field of neutral lipid-based liposome delivery of antisense technologies and FAK siRNA, is projected to enhance our 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 80 percent of metastatic epithelial tumors. We believe this liposome tumor-targeting technology for antisense and FAK siRNA delivery is a highly promising strategy for treating primary and metastatic cancers.

The historical perspective of cancer treatments has been 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 and siRNA, are two of the most promising fields of targeted therapy. Development of antisense and siRNA, 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 tenfold to thirtyfold increase in tumor cell uptake with this technology compared to other delivery methods. Our first drug with this delivery technology is scheduled to commence a Phase I clinical trial in 2011.

FAK (facal adhesion kinase) is a cancer protein target that we intend our SIRNA to block. Accordingly, the FAK SIRNA is a drug candidate that is intended to treat forms of cancer involving abnormal or over-expression of the FAK gene including ovarian, colon, breast, thyroid, head and neck and metastatic cancer.

The new liposome tumor targeting technology being licensed will be developed as an extension of our current delivery technology, with a goal toward more powerfully focusing delivery of the antisense and FAK siRNA cancer treatments to the tumor tissue. Adding a vector to the liposome that targets a receptor that is highly expressed on the surface of tumor cells is expected to drive uptake of the liposomes into the tumor tissue, enhancing relative deposition in the target tumor tissue. In animal studies conducted at M. D. Anderson Cancer Center, researchers demonstrated an ability for vector targeted neutral lipid-based liposomes to increase transfection efficiency and siRNA molecule uptake fivefold to eightfold into cancer cells compared to those of untargeted liposomes and controls. These efficiencies are in addition to the delivery efficiencies noted above from the core neutral lipid-based liposome delivery technology.

Pursuant to the License Agreement, we are obligated to various one time and recurring fees, expenses, royalties, milestone payments, and other compensation and expenses to the licensor.

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 IIA.

- 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 M. D. Anderson's pre-clinical and clinical development capabilities, including using the PDC for pre-clinical studies as well as clinical pharmacokinetics and pharmacodynamics and the institution's world-renowned clinics, 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 laboratories. This should also allow us to operate in an essentially virtual fashion, thereby avoiding the expense of setting up and operating laboratory facilities, without losing control over timing or quality or IP contamination.

- Use our Scientific Advisory Board to supplement our Management Team to critically monitor existing programs and evaluate new technologies and/or compounds discovered or developed at M. D. 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.

Manufacturing

We have no manufacturing capabilities and intend to outsource our manufacturing function. 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. In September 2008, we executed a Supply Agreement with Althea Technologies, Inc., a cGMP manufacturer of pharmaceutical products, for the supply of drug product needed for Bio-Path's upcoming clinical trials.

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., started serving as our Medical Officer and medical liaison for the conduct of our 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).

Employees

We currently employ two (2) full time employees. We also have contractual relationships with 4 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 Advisory Board

Our Scientific Advisory Board consists of the following scientists and oncologists:

Gabriel Lopez-Berestein, M.D. – Chairman of the Scientific Advisory Board and founder of Bio-Path; Professor of Medicine and Internist, Director, Cancer Therapeutics Discovery Program, Chief, Section of Immunobiology and Drug Carriers at M. D. Anderson Cancer Center.

Anil Sood, M.D. -- Member of the Scientific Advisory Board and co-founder of Bio-Path; Professor, Department of Gynecologic Oncology & Professor, Department of Cancer Biology M. D. Anderson Cancer Center; Director, Ovarian Cancer Research & Director, Blanton-Davis Ovarian Cancer Research Program; Faculty Scholar Award, M. D. Anderson Cancer Center.

Ana M. Tari, Ph.D., M.S. – Member of the Scientific Advisory Board and co-founder of Bio-Path; Associate Professor at the University of Florida at Gainsville.

We anticipate that additional scientists and clinicians will join the Scientific Advisory Board once additional funding has been secured to expend 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, substantially all 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 entering into out-license agreements with pharmaceutical licensee partners who will be responsible for post-Phase IIA clinical testing and working with the FDA on necessary regulatory submissions resulting in approval of new drug applications for 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. A successful Phase IIA drug typically is afforded significant value by investors in the public stock markets.

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 Agreements with M. D. 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.

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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 PDC 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 U.S. Food and Drug Administration ("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. Our business plan calls for us to raise an additional approximately $10,000,000 from the sale of our securities. We have raised approximately $3,776,403. We anticipate that we have sufficient capital to fund our operations for the next six (6) months. 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, 2009, we had a cumulative loss of $5,103,903. 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.

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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 recent FDA approval of our application to commence Phase 1 clinical trials, we plan to commence Phase 1 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 recently received FDA approval to start 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, unblinded 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. However, "out-license" pharmaceutical partners will likely be responsible for manufacturing of those drug requirements.

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 Althea Technologies, Inc. for the manufacture of our drug requirements for our drug BP-100-1.01. Althea 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, Althea 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 have entered into three license agreements with M. D. Anderson. 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, it will 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.

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 M. D. Anderson. Our license agreements with M. D. Anderson provide M. D. Anderson the right to terminate the agreements upon written notice to us if we do not meet all of our requirements under the license agreements which require 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 licenses or any other agreements we enter into with M. D. Anderson is terminated for any reason, our business will be adversely and perhaps materially adversely affected, and our business may fail. In addition, our relationship with M. D. Anderson is not exclusive to us. It is possible that M. D. Anderson could enter into an exclusive relationship with one of our future competitors. If this were to occur it could adversely affect our competitive position and depending on the terms of any such agreement, could make it difficult for us to succeed.

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 have recently received FDA approval to start Phase I clinical trials for our 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, nor 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.

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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, including California, Vermont, Maine, Minnesota, New Mexico and West Virginia 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, or 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, on a quarterly basis, 11% 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) 15.1% 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. Our patents and 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 of directors 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 of directors. The board of directors, 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 "OTC Bulletin Board". 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 regulators approval of our products. In particular, between February 15, 2008 and December 31, 2009, the closing sales price of our common stock fluctuated from a low of $0.27 per share to a high of $6.00 per share. 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" if it meets one or more of the definitions in Rules 15g-2 through 15g-6 promulgated under Section 15(g) of the Securities Exchange Act of 1934, as amended. These include, but are not limited to the following: (i) the stock trades at a price less than $5.00 per share; (ii) it is NOT traded on a "recognized" national exchange; (iii) it is NOT quoted on the NASDAQ Stock Market, or even if so, has a price less than $5.00 per share; or (iv) 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. The principal result or effect of being designated a "penny stock" is that securities broker-dealers cannot recommend the stock but must trade in it on an unsolicited basis.

Additionally, Section 15(g) of the Securities Exchange Act of 1934, as amended, and Rule 15g-2 promulgated there under by the SEC require broker-dealers dealing in penny stocks to provide potential investors with a document disclosing the risks of penny stocks and to obtain a manually signed and dated written receipt of the document before effecting any transaction in a penny stock for the investor's account.

Potential investors in our common stock are urged to obtain and read such disclosure carefully before purchasing any Units that are deemed to be "penny stock." Moreover, Rule 15g-9 requires broker-dealers in penny stocks to approve the account of any investor for transactions in such stocks before selling any penny stock to that investor. This procedure requires the broker-dealer to (i) obtain from the investor information concerning his or her financial situation, investment experience and investment objectives; (ii) reasonably determine, based on that information, that transactions in penny stocks are suitable for the investor and that the investor has sufficient knowledge and experience as to be reasonably capable of evaluating the risks of penny stock transactions; (iii) provide the investor with a written statement setting forth the basis on which the broker-dealer made the determination in (ii) above; and (iv) receive a signed and dated copy of such statement from the investor, confirming that it accurately reflects the investor's financial situation, investment experience and investment objectives. Compliance with these requirements may make it more difficult for holders of our common stock to resell their Units to third parties or to otherwise dispose of them in the market or otherwise.

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 2. PROPERTIES

We currently do not have any significant facilities. We lease two small offices in Ogden, Utah and Houston, Texas. The offices will be expanded as additional employees join Bio-Path. Due to the anticipated use of the PDC or another laboratory company for pre-clinical development of our sponsored drug candidates, Bio-Path does not foresee at this time the need to lease laboratory space.

## ITEM 3. LEGAL PROCEEDINGS

We are not a party to any legal proceedings.

## ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matters were submitted to our shareholders for a vote during the last quarter of the year ended December 31, 2009.

# PART II

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

Our common stock is quoted on the OTCBB under the symbol "BPTH". There has only 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, 2008 | | |
| First Fiscal Quarter | $ .90 | $ .61 |
| Second Fiscal Quarter | $ .90 | $ .35 |
| Third Fiscal Quarter | $ .50 | $ .35 |
| Fourth Fiscal Quarter | $1.65 | $1.40 |

| | High Bid | Low Bid |
|---|---|---|
| Fiscal Year Ended December 31, 2009 | | |
| First Fiscal Quarter | $ .90 | $ .61 |
| Second Fiscal Quarter | $ .90 | $ .35 |
| Third Fiscal Quarter | $ .87 | $ .50 |
| Fourth Fiscal Quarter | $ .87 | $ .50 |
| Fiscal Year Ended December 31, 2010 | | |
| First Fiscal Quarter (Through March 22, 2010) | $ .71 | $ .27 |

Shares Issued in Unregistered Transactions

During the fiscal year ended December 31, 2009 and carrying over to January 2010 we sold 3,360,000 shares of our common stock in unregistered transactions. All of the shares of common stock issued were issued in non registered transactions in reliance on Section 4(2) of the Securities Act of 1933, as amended (the "Securities Act"). The shares of common stock issued were as follows:

| | |
|---|---|
| Placement Agent | 336,000 |
| Private Placement investors | 3,360,000 |
| Total | 3,696,000 |

Although these shares were sold in 2009, only 726,000 of these shares were actually issued by our transferred agent in 2009. The balance of shares was physically issued in 2010. For purpose of the MDA contained herein, all of such shares were deemed to be issued in 2009 because such shares were in fact sold in 2009. However, the December 31, 2009 amounts for issued and outstanding shares in the financial statements contained in Item 8 do not include 2,700,000 unissued common shares represented by proceeds received prior to December 31, 2009 amounting to $675,000. These proceeds are recorded as additional paid-in capital for shares to be issued on the Balance Sheet as of December 31, 2009.

Holders

As of March 22, 2010 there were 46,509,602 shares of common stock outstanding and approximately 232 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.

Purchases of Equity Securities by the Small Business Issuer and Affiliated Purchasers

None

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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) | 3,765,000 | $1.22 | 8.6 yrs. | 3,235,000 |
| 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 22, 2010.

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 1933 Act may be permitted to our directors and officers, we have been advised that in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the 1933 Act 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 required by smaller reporting companies.

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 Item 1A "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. 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 Securities and Exchange Commission 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 initial plan was to acquire licenses for drug technologies from The University of Texas M. D. Anderson Cancer Center ("M. D. Anderson"), to fund clinical and other trials for such technologies and to commercialize such technologies. Bio-Path has negotiated and executed three exclusive licenses ("License Agreements") for three lead products and nucleic acid delivery technology. These licenses specifically provide drug delivery platform technology with composition of matter intellectual property that enables systemic delivery of antisense, small interfering RNA ("siRNA") and small molecules for treatment of cancer. 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 M. D. Anderson, to advance these candidates into initial human efficacy trials (Phase IIa), and out-license each successful potential drug to a pharmaceutical company.

Plan of Operation

See Item 1 of this Form 10-K.

Results of Operations for Year Ended December 31, 2009.

Except as discussed below, a discussion of our past financial results is not pertinent to the business plan of the Company on a going forward basis, due to the change in our business which occurred upon consummation of the Merger on February 14, 2008.

Results of Operations for the twelve months ended December 31, 2009 and December 31, 2008.

We have no operating revenues since our inception. Our operating expenses for the twelve months ended December 31, 2009 were $1,973,122 and included general and administrative expenses of $721,029, fair value expense of stock options and warrants of $ 588,857 and amortization expense of $182,981 for our technology licenses. We expended $480,255 on research and development costs during the year ended December 31, 2009.

Our operating expenses for the year ended December 31, 2008 were $2,893,828 and included general and administrative expenses of $587,163, fair value expense of stock options, warrants and stock issued for services of $1,801,239 and amortization expense of $171,954 for our technology licenses. We expended $333,472 on research and development costs during the year ended December 31, 2008.

We had interest income of $3,384 for the twelve months ended December 31, 2009 compared to interest income of $41,061 for the year ended December 31, 2008. Our interest income was derived from cash and cash equivalents net of bank fees.

Our net loss was $1,969,738 for the twelve months ended December 31, 2009 compared to a net loss of $2,852,767 for the year ended December 31, 2008. Net loss per share, both basic and diluted was $.05 for the twelve months ended December 31, 2009 and $.07 for the twelve months ended December 31, 2008.

Liquidity and Capital Resources as of December 31, 2009

At December 31, 2009, we had cash of $567,249 compared to $1,507,071 at December 31, 2008. We currently have no lines of credit or other arranged access to debt financing.

Net cash used during the year ended December 31, 2009 was $939,822 compared to a surplus of $287,713 for the year ended December 31, 2008. Inasmuch as we have not yet generated revenues, our entire expenses of operations are funded by our cash assets.

In the year ended December 31, 2008, we paid $150,000 for the cash portion of the purchase price of the licenses we acquired from M. D. Anderson. In 2009 we paid or incurred $110,000 in license fees to M. D. Anderson.

Currently all of our cash is, and has been, generated from financing activities. Net cash provided by financing activities in 2009 was $737,624 compared to $1,368,313 for 2008. Since inception we have net cash from financing activities of $3,776,403. As discussed in our Plan of Operation above, we believe that our available cash will be sufficient to fund our liquidity and capital expenditure requirements through the second quarter of 2010. We believe that we will need to raise approximately $2,500,000 in net proceeds to fund our operations in 2010 and approximately $10,000,000 in net proceeds to completely implement our current business plan. We do need to raise additional capital during 2010, in order to fund our operations in 2010 and 2011. There can be no assurance that we will be able to raise cash when it is needed to fund our operations.

Future capital needs

We anticipate that the total cost of additional needed funds for Phase I Clinical trials of our BP-100-1.01 will range from $1,500,000 to $2,000,000. We anticipate that we must raise additional funds for substantially that entire amount. Inasmuch as we have received no 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 attempt to raise additional capital in the second and/or third quarter of 2010.

Other Events

In April of 2008 we granted stock options for services to be performed over the next three years, to purchase in the aggregate 1,165,000 shares of our 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 April of 2008 we awarded warrants for services to purchase in the aggregate 85,620 shares of our common stock. The exercise price is $0.90 a share. In April of 2008, we issued 200,000 shares of our common stock to a firm in connection with introducing Bio-Path, Inc. to its merger partner Ogden Golf. In October, 2008 we granted a total of 2,500,000 employee stock options to our two corporate officers, Peter Nielsen and Douglas Morris.

As of March 22, 2010, a total of 1,985,937of these options are now vested, and the remaining 1,779,063 vest over an average of a eight year period with a weighted average price of $1.22.

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 has recently entered into three Patent and Technology License Agreements (the “Licenses”) with M. D. Anderson relating to its technology. (See” Business of Bio-Path”)

In September 2008, Bio-Path entered into a Supply Agreement with Althea Technologies, Inc. for the supply of drug product for the Company’s upcoming clinical trial of the drug BP-100-1.01 in human patients.

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, $317,249 of the Company's cash balances is not covered by the FDIC.

Intangible Assets/Impairment of Long-Lived Assets. As of December 31, 2009, Other Assets totals $2,431,680 for the Company's three technology licenses, comprised of $2,814,166 in value acquiring the Company's technology licenses and its intellectual property, less accumulated amortization of $382,486. The technology value consists of $460,000 in cash paid or accrued to be paid to M. D. Anderson, plus 3,138,889 shares of common stock granted to M. D. Anderson valued at $2,354,166. This value is being amortized over a fifteen year (15 year) period from November 7, 2007, the date that the technology licenses became effective. As of December 31, 2009 accrued payments to be made to M. D. Anderson totaled $125,000, and such payments are expected to be made in 2010. 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 $190,000 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. For the year 2009, the Company had $480,255 of costs classified as research and development expense. Of this amount, approximately $280,000 is comprised of raw materials and costs for the Company's raw material suppliers and contract drug manufacturer to perform unplanned additional engineering test runs of the Company's lead drug product in advance of manufacturing a current Good Manufacturing Practice (cGMP) clinical batch of this drug for use in an upcoming Phase I Clinical Trial.

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 of 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. 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 will be expensed over the next three years based on the stock option service period.

In December of 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 2008 being reported on totaled $1,465,189. There were no stock option awards granted in 2009. Total stock option expense for the year 2009 being reported on totaled $588,857.

Warrant Grants. In April of 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 2008, 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 year 2009. The calculation of Basic and Diluted earnings per share for 2009 did not include 1,985,937 shares and 745,620 shares issuable pursuant to the exercise of vested common stock and vested warrants, respectively, as of December 31, 2009 as the effect would be anti-dilutive. The calculation of Basic and Diluted earnings per share for 2008 did not include 1,250,000 shares and 85,620 shares issuable pursuant to the exercise of vested common stock and vested warrants, respectively, as of December 31, 2008 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, 2009, 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.

Recent Accounting Pronouncements:

In June 2009, the FASB issued FASB ASC 860-10-05 (Prior authoritative literature: FASB Statement 166, Accounting for Transfers of Financial Assets). FASB ASC 860-10-05 is effective for fiscal years beginning after November 15, 2009. The Company is currently assessing the impact of FASB ASC 860-10-05 on its financial position and results of operations.

In June 2009, the FASB issued FASB ASC 810-10-25 (Prior authoritative literature: FASB Statement 167-Amendment to FIN 46(R), Consolidation of Variable Entities). FASB ASC 810-10-25 eliminates the quantitative approach previously required for determining the primary beneficiary of a variable interest entity and requires a qualitative analysis to determine whether an enterprise's variable interest gives it a controlling financial interest in a variable interest entity. FASB ASC 810-10-25 contains certain guidance for determining whether an entity is a variable interest entity. This statement also requires ongoing reassessments of whether an enterprise is the primary beneficiary of a variable interest entity. FASB ASC 810-10-25 will be effective as of the beginning of the Company's 2010 fiscal year. The Company is currently evaluating the impact of the adoption of FASB ASC 810-10-25.

In October 2009, the FASB issued ASU No. 200-13, Revenue Recognition – Multiple Deliverable Revenue Arrangements ("ASU 2009-13"). ASU 2009-13 updates the existing multiple-element revenue arrangements guidance currently included in FASB ASC 605-25. The revised guidance provides for two significant changes to the existing multiple-element revenue arrangements guidance. The first change relates to the determination of when the individual deliverables included in a multiple-element arrangement may be treated as separate units of accounting. This change will result in the requirement to separate more deliverables within an arrangement, ultimately leading to less revenue deferral. The second change modifies the manner in which the transaction consideration is allocated across the separately identified deliverables. Together, these changes will result in earlier recognition of revenue and related costs for multiple-element arrangements than under previous guidance. This guidance expands the disclosures required for multiple-element revenue arrangements. Effective for interim and annual reporting periods beginning after December 15, 2009. The Company is currently evaluating the potential impact, if any, of this guidance on its financial statements.

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

Information not required for smaller reporting companies.

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 30th to December 31st.

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

On February 14, 2008, Bio-Path Holdings, Inc. (fka Ogden Golf Co. Corporation) acquired Bio-Path, Inc in a merger transaction. Such transaction is further described in a Form 8-K filed on February 19, 2008. Subsequent to the merger transaction, the Board of Directors of Bio-Path Holdings, Inc. (the "Registrant") determined that it was in the best interests of the Registrant to appoint the accounting firm of Bio-Path, Inc., as the independent registered public accounting firm of the Registrant in place of the Registrant's previous accounting firm. Disclosure regarding such change of accounting firm was contained in our Form 10-K for the year ended December 31, 2008. No additional disclosure regarding such change of accounting firm is included in this Form 10-K pursuant to Instructions to Regulation S-K Section 304:1.

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 a date within ninety (90) days of the filing date of this Form 10-K annual report. 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 of Directors, 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, 2009. 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, 2009. 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 generally accepted accounting principles ("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, 2009. 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 temporary rules of the Securities and Exchange Commission 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 | 60 | Chief Executive Officer/President/Chief Financial Officer/Treasurer/ Chairman of the Board and Director |
| Douglas P. Morris | 54 | Vice President of Corporate Development/ Secretary/Director |
| Dr. Thomas Garrison | 51 | Director |
| Gillian Ivers-Read | 56 | 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 of Directors. Mr. Nielsen has developed a close working relationship over the last five years with key individuals at M. D. 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. Since 1993, Mr. Morris has been 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.

Dr. Thomas Garrison is a practicing medical doctor with over twenty years experience in the clinical medical field with extensive administration responsibilities. He is residency trained and board certified in emergency medicine. He has extensive experience in high-acuity, high-volume emergency departments with large trauma referral bases. He has co-authored several textbooks on emergency medicine. In addition to his professional medical career, he has been involved in a number of successful entrepreneurial pursuits. He is currently involved as the Medical Director of Sono Bello Body Contour Centers and has ownership in several of the centers. Sono Bello is a nationally growing Company, specializing in minimally invasive liposuction and non-invasive body contouring. He is responsible for medical oversight, written policies, regulatory input, equipment selection, pharmaceuticals, training and other medically relevant issues.

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He was formally involved with Advanced Laser Clinics, Inc., serving as Corporate Medical Director. He received his Doctor of Medicine, Uniformed Services University of the Health Sciences, Bethesda, Maryland in 1982, and his Bachelor of Science; Chemistry Major, Engineering Minor from the University of Utah in 1978.

Gillian Ivers-Read. Ms. Ivers-Read is currently head of Techinical 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.

Committees of the Board of Directors

We currently have a compensation committee of the Board of Directors consisting of Ms. Gillian Ivers-Read and Douglas P. Morris. We anticipate as our Board of Directors 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).

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. He was involved significantly with the start up and qualification of Quality Control laboratories and a Quality Assurance department for GEL Analytics, a pharmaceutical drug supplier. He also has provided oversight in setting up and qualifying current Good Manufacturing Practice (cGMP) analytical and Good Laboratory Practices (GLP) analytical and bioanalytical laboratories. 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. Dr. Walker has authored numerous articles and a book chapter covering various topics in analytical chemistry. Thomas Walker has a Ph.D. in Analytical Chemistry from The University of Iowa and a B.S. in Chemistry from Oral Roberts University.

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.

Other 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, or our 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 Global 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 Securities and Exchange Commissions.

Communications with Board Members

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

Compliance with Section 16(a)

No disclosure required

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 of directors has overall responsibility for the compensation program for our executive officers. Our compensation committee consists of an independent director 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, during fiscal 2008, 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 | Year | Salary ($) | Bonus ($) | Stock Option ($) | Total ($) |
|---|---|---|---|---|---|
| Peter Nielsen, CEO, President, | 2009 | $250,000 | -0- | -0- | $250,000 |
| Chairman | 2008 | $250,000 | -0- | $1,491,000* | $1,741,000 |
| | 2007 | $133,333 | $20,000 | -0- | $153,333 |
| Douglas P. Morris, VP Corporate Development/Director | 2009 | $120,000 | -0- | -0- | $120,000 |
| Corporate Development Director | 2008 | $120,000 | -0- | $994,000* | $1,114,000 |
| | 2007 | $ 80,000 | -0- | -0- | $ 80,000 |

*In 2008, we granted Mr. Nielsen options to purchase 1,500,000 shares of our common stock at $1.40 per share, the fair market value on the date of grant. In 2008 we granted Mr. Morris options to purchase 1,000,000 shares of our common stock at $1.40 per share, the fair market value on the date of grant. Each of these grants of options were ½ vested at the time of grant with the remaining ½ vesting monthly over a three year period. This column shows the grant date fair value of awards computed in accordance with stock-based compensation accounting rules.

Stock Option Grants and Exercises During the Fiscal Years Ended December 31, 2009 and 2008

The following table sets forth information concerning stock option grants made during the fiscal year ended December 31, 2009 and 2008, to our executive officers named in the "Summary Compensation Table" above. The fair value information in the far right column is for illustration purposes only and is not intended to predict the future price of our Common Stock. The actual future value of the stock options will depend on the market value of the Common Stock.

GRANTS OF PLAN-BASED AWARDS

| Name | Grant Date | All Other Options Awards: Number of Securities Underlying Options (#) | Exercise or Base Price of Option Awards (1) | Grant Date Fair Value of Option Awards |
|---|---|---|---|---|
| Peter Nielsen | 10/7/08 | 1,500,000 | $1.40 | $ .99 |
| Douglas Morris | 10/7/08 | 1,000,000 | $1.40 | $ .99 |

(1) This column shows the exercise price for the stock options granted, which was the closing price of our Common Stock on October 7, 2008, the date of grant.

For the fiscal year ended December 31, 2007 neither of the persons listed in the Summary Compensation Table were granted options or other rights to purchase shares of our common stock. 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. The options are exercisable for a term of ten years from the date of grant.

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, 2009.

OUTSTANDING EQUITY AWARDS AT DECEMBER 31, 2009

| | Option/Warrant Awards | | | | |
|---|---|---|---|---|---|
| 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) Except as indicated, the options granted vest and become exercisable in monthly installments over a three year period, commencing on the date of grant.

Option Exercises

No officer or director exercised any option during the fiscal year ended December 31, 2009.

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 22, 2010 by: (1) 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 Units of its common stock.

| Shareholder | Shares Owned | Percentage |
|---|---|---|
| Peter Nielsen (1) (2) | 6,289,433 | 13.20% |
| Douglas P. Morris (1) (3) | 2,383,911 | 5.04% |
| Dr. Tom Garrison (1) (4) | 3,421,767 | 7.24% |
| Gillian Ivers-Read (1) (5) | 52,083 | * |
| M. D. Anderson | 6,930,025 | 12.03% |
| Tom Fry (6) | 5,593,334 | 13.20% |
| All officers and directors as a group (7) | 12,147,194 | 24.68% |
| Total | 46,509,602 | 100.00% |

*Less than 1%

(1) These are the officers and directors of Bio-Path.

(2) Includes 5,164,433 shares owned of record and 1,125,000 shares issuable upon the exercise of options that are currently exercisable or will be exercisable within 60 days Mr. Nielsen's additional options vest monthly over the next 24 months. If such option were to fully vest, he would have the right to purchase a total of 1,500,000 shares at $1.40 per share.

(3) Includes 1,633,911 shares owned of record and 750,000 shares issuable upon the exercise of options that are currently exercisable or will be exercisable within 60 days. Mr. Morris's additional options vest monthly over the next 24 months. If such option were to fully vest, he would have the right to purchase a total of 1,000,000 shares at $1.40 per share.

(4) Includes 2,646,767 shares owned of record and 25,000 shares issuable upon the exercise of options that are currently exercisable and 750,000 shares issuable upon the exercise of currently exercisable warrants at a price of $1.50 per share. Dr. Garrison's owns additional options which vest monthly over the next 36 months.

(5) Ms. Ivers-Read has vested a total of 52,083 options, exercisable at $.90 per share. Ms. Ivers-Read has a total, if fully vested, to purchase an additional 397,917 shares of common stock at a price of $0.90 per share. These options vest over a period of 36 months.

(6) Includes 2,649,3555 shares owned of record by Amy fry, the spouse of Tom fry and 2,943,729 shares owned of record by Brick & Mortar, LLC, an affiliate of Tom Fry.

(7) Includes 9,445,111 shares of record and 2,702,083 shares issuable upon the exercise of currently vested options and warrants.

Stock Options

In April of 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. 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. The total value of stock options granted through December 31, 2009 was determined using this methodology is $761,590, which will be expensed over the next six years based on the stock option vesting schedule.

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. The options are exercisable for a term of ten years from the date of grant.

Warrants

We have a total of 85,620 outstanding warrants that are fully vested and which were expensed in the second quarter of 2008.

Equity Compensation Plan Information

We have no Equity Compensation Plans except for our Stock Incentive Plan.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

During 2009, director Thomas Garrison purchased 750,000 shares of Bio-Path's common stock for a total of $187,500. These shares were purchased in connection with a private offering and were on the same terms and conditions applicable to all other purchasers. Each purchaser was issued one warrant for each share purchased and accordingly, Dr. Garrison was issued Warrants to purchase 750,000 shares. The exercise price of such warrants is $1.50 per share and are exercisable until November 30, 2011.

As part of the license agreements with M. D. Anderson, Bio-Path Subsidiary issued M. D. Anderson 3,138,889 shares of our common stock. In addition, M. D. Anderson researchers purchased shares of our subsidiary's common stock at par value. These shares issued to M. D. Anderson and such researchers were converted into a total of 8,858,873 shares of our common stock in the merger.

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 2009 and 2008, the Audit Committee pre-approved all services described below in the captions "Audit Fees", "Audit-Related Fees", "Tax Fees" and "All Other Fees". For fiscal year 2009 and 2008, no hours expended on Mantyla McReynolds' engagement to audit the Company's financial statements were attributed to work performed by persons other than full-time, permanent employees of Mantyla McReynolds.

The aggregate fees billed for professional services by Mantyla McReynolds in fiscal year 2009 and 2008:

| Type of Fees | 2008 | 2009 |
|---|---|---|
| Audit Fees | $49,940 | $43,950 |
| Audit-Related Fees | - | - |
| Tax Fees | 887 | 4,746 |
| All Other Fees | | |
| Total | $50,827 | $48,696 |

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). |
| 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) |
| 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 | Drug Product Development and Clinical Supply Agreement (incorporated by reference to exhibit 10.1 to the registrant's current report on Form 8-K filed on October 16, 2008). |
| 10.4 | 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). |
| 14.1 | Code of Ethics |

| | |
|---|---|
| 21.1 | Subsidiaries of Bio-Path Holdings, Inc. |
| 23.1 | Consent of Independent Registered Public Accounting Firm |
| 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. |

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: March 30, 2010

By: /s/ Peter Nielsen
Peter Nielsen
President
Chief Executive Officer
Chief Accounting Officer/Principal Financial 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 |
|---|---|---|
| March 30, 2010 | Chief Executive Officer/Principal Financial Officer/President/ Director | /s/ Peter Nielsen |
| | Director | Peter Nielsen |
| March 30, 2010 | Secretary and Director | /s/ Douglas P. Morris |
| | | Douglas P. Morris |
| March 30, 2010 | Director | /s/ Dr. Thomas Garrison |
| | | Dr. Thomas Garrison |
| March 30, 2010 | Director | |
| | | Dr. Gillian Ivers-Read |

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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 balance sheets of Bio-Path Holdings, Inc. [a development stage company] as of December 31, 2009 and 2008, and the related statements of operations, cash flows, and stockholders' equity, for the years ended December 31, 2009 and 2008, and the period from inception to December 31, 2009. 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, 2009 and 2008, and the results of their operations and their cash flows for the years ended December 31, 2009 and 2008, and the period from inception to December 31, 2009 in conformity with accounting principles generally accepted in the United States of America.

/s/ Mantyla McReynolds LLC
Mantyla McReynolds LLC
Salt Lake City, Utah
March 30, 2010

BIO-PATH HOLDINGS, INC.
(A Development Stage Company)

CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2009 AND 2008

| | December 31, | |
|---|---|---|
| | 2009 | 2008 |
| ASSETS | | |
| Current assets | | |
| Cash | $567,249 | $1,507,071 |
| Drug product for testing | 608,440 | 292,800 |
| Other current assets | 74,297 | 82,772 |
| Total current assets | 1,249,986 | 1,882,643 |
| | | |
| Other assets | | |
| Technology licenses | 2,814,166 | 2,704,167 |
| Less Accumulated Amortization | (382,486 ) | (199,505 ) |
| | 2,431,680 | 2,504,662 |
| TOTAL ASSETS | $3,681,666 | $4,387,305 |
| | | |
| LIABILITIES & SHAREHOLDERS' EQUITY | | |
| Current liabilities | | |
| Accounts payable | 6,453 | 185,843 |
| Accrued expenses | 133,450 | 16,442 |
| Accrued license payments | 125,000 | 125,000 |
| Total current liabilities | 264,903 | 327,285 |
| Long term debt | - | - |
| TOTAL LIABILITIES | 264,903 | 327,285 |
| | | |
| 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 | 42,649 | 41,923 |
| 42,649,602 and 41,923,602 shares issued and outstanding | | |
| as of 12/31/09 and 12/31/08, respectively | | |
| Additional paid in capital | 7,803,016 | 7,152,261 |
| Additional paid in capital for shares to be issued * | 675,000 | |
| Accumulated deficit during development stage | (5,103,902) | (3,134,164) |
| | | |
| Total shareholders' equity | 3,416,763 | 4,060,020 |
| | | |
| TOTAL LIABILITIES & SHAREHOLDERS' EQUITY | $3,681,666 | $4,387,305 |
| | | |
| * Represents 2,700,000 shares of common stock | | |

SEE ACCOMPANYING NOTES TO FINANCIAL STATEMENTS

BIO-PATH HOLDINGS, INC.
(A Development Stage Company)
CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE YEARS ENDED DECEMBER 31, 2009 AND 2008 AND THE PERIOD
FROM INCEPTION (MAY 10, 2007) THROUGH DECEMBER 31, 2009

| | 2009 | 2008 | From inception 05/10/07 to 12/31/09 |
|---|---|---|---|
| Revenue | $- | $- | $- |
| Operating expense | | | |
| Research and development | 480,255 | 333,472 | 821,901 |
| General & administrative | 721,029 | 587,163 | 1,579,473 |
| Stock issued for services | - | 300,000 | 300,000 |
| Stock options & warrants | 588,857 | 1,501,239 | 2,090,096 |
| Amortization | 182,981 | 171,954 | 382,486 |
| Total operating expense | 1,973,122 | 2,893,828 | 5,173,956 |
| Net operating loss | $(1,973,122 ) | $(2,893,828 ) | $(5,173,956 ) |
| Other income | | | |
| Interest income | 3,384 | 41,061 | 70,054 |
| Total Other Income | 3,384 | 41,061 | 70,054 |
| Net Loss | $(1,969,738 ) | $(2,852,767 ) | $(5,103,902 ) |
| Loss per share | | | |
| Net loss per share, basic and diluted | $(0.05 ) | $(0.07 ) | $(0.14 ) |
| Basic and diluted weighted average number of common shares outstanding | 42,347,102 | 41,162,099 | 37,352,654 |

SEE ACCOMPANYING NOTES TO FINANCIAL STATEMENTS

BIO-PATH HOLDINGS, INC.
(A Development Stage Company)

CONSOLIDATED STATEMENT OF CASH FLOWS
FOR THE YEARS ENDED DECEMBER 31, 2009 AND 2008 AND THE PERIOD
FROM INCEPTION (MAY 10, 2007) THROUGH DECEMBER 31, 2009

| | 2009 | 2008 | From inception 05/10/2007 to 12/31/2009 |
|---|---|---|---|
| CASH FLOW FROM OPERATING ACTIVITIES | | | |
| Net loss | $(1,969,738) | $(2,852,767) | $(5,103,902) |
| Adjustments to reconcile net loss to net cash used in operating activities | | | |
| Amortization | 182,981 | 171,954 | 382,486 |
| Common stock issued for services | | 300,000 | 300,000 |
| Stock options and warrants | 588,857 | 1,501,239 | 2,090,096 |
| (Increase) decrease in assets | | | |
| Restricted escrow cash | | 208,144 | |
| Drug product for testing | (315,640) | (292,800) | (608,440) |
| Other current assets | 8,475 | (55,338) | (74,298) |
| Increase (decrease) in liabilities | | | |
| Accounts payable and accrued expenses | (62,381) | 297,112 | 264,904 |
| Escrow cash payable | | (208,144) | |
| Net cash used in operating activities | (1,567,446) | (930,600) | (2,749,154) |
| | | | |
| CASH FLOW FROM INVESTING ACTIVITIES | | | |
| Purchase of exclusive license | (110,000) | (150,000) | (460,000) |
| Net cash used in investing activities | (110,000) | (150,000) | (460,000) |
| | | | |
| 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 | 737,624 | 1,368,313 | 3,356,403 |
| Net cash from financing activities | 737,624 | 1,368,313 | 3,776,403 |
| | | | |
| NET INCREASE/(DECREASE) IN CASH | (939,822) | 287,713 | 567,249 |
| Cash, beginning of period | 1,507,071 | 1,219,358 | - |
| Cash, end of period | $567,249 | $1,507,071 | $567,249 |
| | | | |
| SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION | | | |
| Cash paid for | | | |
| Interest | $- | $- | $- |
| Income taxes | $- | $- | $- |
| Non-cash financing activities | | | |
| Common stock issued upon conversion of convertible notes | | | $420,000 |

| | | |
|---|---|---|
| Common stock issued to Placement Agent | $78,970 | $294,845 |
| Common stock issued to M.D. Anderson for technology license | | $2,354,167 |

SEE ACCOMPANYING NOTES TO FINANCIAL STATEMENTS

BIO-PATH HOLDINGS, INC.
(A Development Stage Company)

CONSOLIDATED STATEMENT OF SHAREHOLDERS' EQUITY

| Date | Description | Common Stock Shares | Common Stock 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 | 78,970 | 79 | 78,891 | | | 78,970 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | Placement Agent | | | | | | |
| 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 Odgen 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 | | | | | - |
| | 2nd Quarter fund raising expense | | | (6,243 ) | | | (6,243 ) |
| | 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 ) |
| | | | | | | (596,694 ) | (596,694 ) |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | Net loss 1st Quarter 2009 | | | | | | |
| 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 |
| | 2nd Quarter fund raising expense | | | (34,841 ) | | | (34,841 ) |
| | 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 |

SEE ACCOMPANYING NOTES TO FINANCIAL STATEMENTS

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

Notes to Financial Statements
December 31, 2009

1. Organization and Business

Bio-Path Holdings, Inc. ("Bio-Path" or the "Company") is a development stage company founded with technology from The University of Texas, M. D. Anderson Cancer Center ("M. D. Anderson") dedicated to developing novel cancer drugs under an exclusive license arrangement. The Company has drug delivery platform technology with composition of matter intellectual property that enables systemic delivery of antisense, small interfering RNA ("siRNA") and small molecules for treatment of cancer. Bio-Path recently licensed new liposome tumor targeting technology, which has the potential to be applied to augment the Company's current delivery technology to improve further the effectiveness of its antisense and siRNA drugs under development as well as future liposome-based delivery technology drugs in the future. In addition to its existing technology under license, the Company expects to have a close working relationship with key members of the M. D. Anderson's staff, which should provide Bio-Path with a strong pipeline of promising drug candidates in the future. Bio-Path expects the program with M. D. Anderson to enable the Company to broaden its technology to include cancer drugs other than antisense and siRNA.

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 drug candidates treat acute myeloid leukemia, chronic myelogenous leukemia, acute lymphoblastic leukemia and follicular lymphoma, and if successful, could potentially be used in treating many other indications of cancer. These two lead drug candidates will be ready for clinical trials after receiving an investigational new drug ("IND") status from the FDA. The Company has filed an IND application for its lead drug candidate liposomal Grb-2 (BP-100-1.01) and received notice from the FDA subsequent to December 31, 2009 that the IND has been allowed for commencement of a Phase I clinical trial of this drug.

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 its lead drug product candidate BP-100-1.01 for a Phase I clinical trial.

Bio-Path raised an additional $675,000 of funds for operations in the fourth quarter of 2009 through a private placement sale of shares of the Company's common stock and associated warrants. The private placement offering remained open at the end of the year, and subsequent to December 31, 2009, the Company raised an additional $225,000 through sale of shares of the Company's common stock and associated warrants (see Footnote 13.). Subsequent to December 31, 2009, the IND was granted for Bio-Path's drug candidate BP-100-1.01, and Management believes there will be sufficient liquidity to commence the Phase I clinical trial in BP-100-1.01 and continue testing into the summer of 2010. The Company will need to raise additional capital to continue beyond in 2010 to complete this clinical trial. The Company's strategy has been to minimize the amount of funds raised at the current lower, pre-Phase I trial share prices to avoid excessive dilution and raise larger amounts of new capital with anticipated higher valuation of the Company's common stock after commencement of the Phase I trial when the Company's technology is expected to be further validated.

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.

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, $317,249 of the Company's cash balances is not covered by the FDIC.

Intangible Assets/Impairment of Long-Lived Assets -- As of December 31, 2009, Other Assets totals $2,431,680 for the Company's three technology licenses, comprised of $2,814,166 in value acquiring the Company's technology licenses and its intellectual property, less accumulated amortization of $382,486. The technology value consists of $460,000 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 $2,354,166. This value is being amortized over a fifteen year (15 year) period from November 7, 2007, the date that the technology licenses became effective. As of December 31, 2009 accrued payments to be made to M. D. Anderson totaled $125,000, and such payments are expected to be made in 2010. 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 $190,000 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 -- Costs and expenses that can be clearly identified as research and development are charged to expense as incurred in accordance with GAAP For the year 2009, the Company had $480,255 of costs classified as research and development expense. Of this amount, approximately $280,000 is comprised of raw materials and costs for the Company's raw material suppliers and contract drug manufacturer to perform unplanned additional engineering test runs of the Company's lead drug product in advance of manufacturing a current Good Manufacturing Practice (cGMP) clinical batch of this drug for use in an upcoming Phase I Clinical Trial.

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

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 2008, 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 year 2009. The calculation of Basic and Diluted earnings per share for 2009 did not include 1,985,937 shares and 745,620 shares issuable pursuant to the exercise of vested common stock and vested warrants, respectively, as of December 31, 2009 as the effect would be anti-dilutive. Further, the calculation of Basic and Diluted earnings per share for 2009 did not include 2,700,000 shares that are to be issued subsequent to December 31, 2009 relating to private placement proceeds received prior to that date, nor did it include the 270,000 shares to be issued to the placement agent once these shares are issued. The calculation of Basic and Diluted earnings per share for 2008 did not include 1,250,000 shares and 85,620 shares issuable pursuant to the exercise of vested common stock and vested warrants, respectively, as of December 31, 2008 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, 2009 and 2008, 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 -- In June 2009, the FASB issued FASB ASC 860-10-05 (Prior authoritative literature: FASB Statement 166, Accounting for Transfers of Financial Assets). This Statement removes the concept of a qualifying special-purpose entity from Statement 140 and removes the exception from applying FASB Interpretation No. 46 (revised December 2003), Consolidation of Variable Interest Entities, to qualifying special-purpose entities. FASB ASC 860-10-05 is effective for fiscal years beginning after November 15, 2009. The Company is currently assessing the impact of FASB ASC 860-10-05 on its financial position and results of operations.

In June 2009, the FASB issued FASB ASC 810-10-25 (Prior authoritative literature: FASB Statement 167-Amendment to FIN 46(R), Consolidation of Variable Entities). FASB ASC 810-10-25 eliminates the quantitative approach previously required for determining the primary beneficiary of a variable interest entity and requires a qualitative analysis to determine whether an enterprise's variable interest gives it a controlling financial interest in a variable interest entity. FASB ASC 810-10-25 contains certain guidance for determining whether an entity is a variable interest entity. This statement also requires ongoing reassessments of whether an enterprise is the primary beneficiary of a variable interest entity. FASB ASC 810-10-25 will be effective as of the beginning of the Company's 2010 fiscal year. The Company is currently evaluating the impact of the adoption of FASB ASC 810-10-25.

In October 2009, the FASB issued ASU No. 200-13, Revenue Recognition – Multiple Deliverable Revenue Arrangements ("ASU 2009-13"). ASU 2009-13 updates the existing multiple-element revenue arrangements guidance currently included in FASB ASC 605-25. The revised guidance provides for two significant changes to the existing

multiple-element revenue arrangements guidance.

The first change relates to the determination of when the individual deliverables included in a multiple-element arrangement may be treated as separate units of accounting. This change will result in the requirement to separate more deliverables within an arrangement, ultimately leading to less revenue deferral. The second change modifies the manner in which the transaction consideration is allocated across the separately identified deliverables. Together, these changes will result in earlier recognition of revenue and related costs for multiple-element arrangements than under previous guidance. This guidance expands the disclosures required for multiple-element revenue arrangements. Effective for interim and annual reporting periods beginning after December 15, 2009. The Company is currently evaluating the potential impact, if any, of this guidance on its financial statements.

3. Restricted Cash

As of December 31, 2007, Current Assets included $208,144 of restricted cash. This represented funds deposited in an escrow account pursuant to an ongoing placement memorandum for the sale of the Company's common stock. Since the conditions of the offering required that a minimum of $500,000 of common stock be sold to enable closing of the round and release of the funds to the Company, the $208,144 was classified as a Current Liability on the December 31, 2007 Balance Sheet. Subsequently, in February of 2008 these funds were released to the Company when the private placement sales of common stock exceeded the $500,000 minimum.

4. Drug Product for Testing

The Company has paid installments to its contract drug manufacturing and raw material suppliers totaling $292,800 during 2008 and $315,640 during 2009 pursuant to a Project Plan and Supply Agreement (see Note 11.) for the manufacture and delivery of the Company's lead drug product for testing in a Phase I clinical trial. This amount is carried on the Balance Sheet as of December 31, 2009 at cost as Drug Product for Testing and will be expensed as the drug product is used during the Phase I clinical trial.

5. Accounts Payable

As of December 31, 2009 and 2008, Current Liabilities included accounts payable of $6,453 and $185,843, respectively. These amounts were subsequently paid in the first quarter of each succeeding year.

6. Accrued Expense

As of December 31, 2009 and 2008, Current Liabilities included accrued expense of $133,450 and $16,442, respectively. For December 31, 2009, the bonus pool accrual comprised $92,500 of this amount and accrued expense for payments to the Company's contract manufacturing supplier totaled $24,000.

7. Convertible Debt

The Company issued $435,000 in notes convertible into common stock at a rate of $.25 per common share. As of December 31, 2007, $15,000 of the convertible notes had been repaid in cash and $420,000 of the convertible notes had been 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.

8. Accrued License Payments

Accrued license payments totaling $125,000 were included in Current Liabilities as of December 31, 2009 and 2008. These amounts represent patent expenses for the licensed technology expected to be invoiced from M. D. Anderson and maintenance fees needed to keep the licenses underlying patents in current good standing with the institution. It is expected that the accrued license payments will be made to M. D. Anderson in 2010.

9. Stockholder's 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. As of December 31, 2009, there were 42,649,602 shares of common stock issued and outstanding. There are no preferred shares outstanding as of December 31, 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. However, when issued investors will receive 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 connection with this private placement, the Company will issue 270,000 shares of common stock to the Placement Agent as commission for the shares of common stock sold to investors.

10. 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.

There were no stock options or compensation-based warrants granted in the year 2009 being reported on. Stock option and 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 the period using the Black-Scholes option-pricing model on the date of grant. In addition, for all stock options and 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 for the year ended December 31, 2008 the following weighted average assumptions were used in determining fair value:

| | 2008 |
|---|---|
| Risk-free interest rate | 3.10% |
| Dividend yield | -% |
| Expected volatility | 80% |
| Expected term in months | 76 |

The Company determines the expected term of its stock option and warrant awards based on the numerical average of the length of the vesting period and the term of the exercise period. Expected volatility is determined by weighting the volatility of the Company's historical stock price with the volatility of a group of peer group stock over the expected term of the grant, which method compensates for the limited trading history of the Company's share price. 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, 2009 and 2008, was as follows:

| | Options | Weighted-Average Exercise Price | Weighted Average Remaining Contractual Term (In years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Year Ended December 31, 2008 | | | | |
| Outstanding at December 31, 2007 | - | - | - | - |
| Granted | 3,765,000 | $1.22 | | |
| Exercised | - | - | | |
| Forfeited/expired | - | - | | |
| Outstanding at December 31, 2008 | 3,765,000 | $1.22 | 9.6 | $25,000 |
| Vested and expected to vest December 31, 2008 | 1,250,000 | $1.40 | 9.8 | - |
| Exercisable at December 31, 2008 | - | - | - | - |

| | Options | Weighted-Average Exercise Price | Weighted Average Remaining Contractual Term (In years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Year Ended December 31, 2009 | | | | |
| Outstanding at December 31, 2008 | 3,765,000 | $1.22 | 9.6 | $25,000 |
| Granted | - | | | |
| Exercised | - | - | | |
| Forfeited/expired | - | - | | |
| Outstanding at December 31, 2009 | 3,765,000 | $1.22 | 8.6 | $13,000 |
| Vested and expected to vest December 31, 2009 | 1,985,937 | $1.34 | 8.7 | $4,130 |
| Exercisable at December 31, 2009 | 31,771 | $0.30 | 7.9 | $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 the year 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, 2009. 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, 2009:

| | 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 | 100,000 | 7.7 | $0.30 | 31,771 | $0.30 |
| $0.90 | 1,165,000 | 8.3 | $0.90 | - | - |
| $1.40 | 2,500,000 | 8.8 | $1.40 | - | - |
| | 3,765,000 | 8.6 | $1.22 | 31,771 | $0.30 |

Warrant activity under the Plan for the years ended December 31, 2009 and 2008, was as follows:

| | Warrants | Weighted-Average Exercise Price | Weighted Average Remaining Contractual Term (In years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Year Ended December 31, 2008 | | | | |
| Outstanding at December 31, 2007 | - | - | - | - |
| Granted | 85,620 | $0.90 | | |
| Exercised | - | - | | |
| Forfeited/expired | - | - | | |
| Outstanding at December 31, 2008 | 85,620 | $0.90 | 4.9 | $- |
| Vested and expected to vest December 31, 2008 | 85,620 | $0.90 | 4.9 | $- |
| Exercisable at December 31, 2008 | - | - | - | - |

| | Warrants | Weighted-Average Exercise Price | Weighted Average Remaining Contractual Term (In years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Year Ended December 31, 2009 | | | | |
| Outstanding at December 31, 2008 | 85,620 | $0.90 | 4.9 | $- |
| Granted | - | - | | |
| Exercised | - | - | | |
| Forfeited/expired | - | - | | |
| Outstanding at December 31, 2009 | 85,620 | $0.90 | 3.9 | $- |
| Vested and expected to vest December 31, 2009 | 85,620 | $0.90 | 3.9 | $- |
| Exercisable at December 31, 2009 | - | - | - | - |

A summary of options outstanding and exercisable as of December 31, 2009:

| | 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 |
| $0.90 | 85,620 | 3.9 | $0.90 | - | - |
| | 85,620 | 3.9 | $0.90 | - | - |

Stock Option Grants - In April of 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. 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 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. The total value of stock options granted was determined using this methodology to be $761,590, which will be expensed over the next six years based on the stock option service period.

In October of 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. 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 will be expensed over the next three years based on the stock option service period.

In December of 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 2008 being reported on totaled $1,465,189.

There were no stock option awards granted in 2009. Total stock option expense for the year 2009 being reported on totaled $588,857.

Warrant Grants - In April of 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.

There were no warrants for services granted in 2009 and there was no warrant expense for the year 2009 being reported on. The warrants issued in connection with the sale of units of common stock were for cash value received and as such were not grants of compensation-based warrants.

11. Commitments and Contingencies

Technology License - The Company has negotiated exclusive licenses from M. D. Anderson to develop drug delivery technology for siRNA and antisense drug products and to develop liposome tumor targeting technology. These licenses require, among other things, the Company to reimburse M. D. Anderson for ongoing patent expense. Accrued license payments totaling $125,000 are included in Current Liabilities as of December 31, 2009. As of December 31, 2009, the Company estimates reimbursable patent expenses will total approximately $200,000. The Company will be required to pay when invoiced the patent expenses at the rate of $25,000 per quarter.

Drug Supplier Project Plan - In June of 2008, Bio-Path entered into a Project Plan agreement with a contract drug manufacturing supplier for delivery of drug product to support commencement of the Company's Phase I clinical trial of its first cancer drug product. The Company currently expects to start this trial in 2010. In 2009, the Company paid $315,640 to this manufacturer and its drug substance raw material supplier that is carried at cost as Drug Product for Testing on the balance sheet (see Note 4.). The Company expects to pay no more than $150,000 to its contract drug manufacturing supplier to complete payments under the current contract when the supplier delivers clinical grade drug product for testing in the Company's clinical trial. Future contracts will be required as the Company's requirement for clinical drug product increases.

Additional Paid In Capital For Shares To Be Issued - 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 as of the December 31, 2009 year end. However, the Company is committed to issuing 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.

Placement Agent Agreement – In the fourth quarter of 2009, the Company entered into a Placement Agent Agreement to raise additional capital. Under the terms of this Agreement, the Company is required to pay cash and stock commissions to the Placement Agent for funds raised. As of December 31, 2009 the Company sold shares and warrants under this Agreement totaling $675,000. The Placement Agent was paid $65,000 for cash commission, leaving a remaining obligation of $2,500. The 2,700,000 shares purchased by investors had not been issued as of December 31, 2009, however, when issued, the Company is committed to issuing Placement Agent 270,000 shares representing the stock commission.

12. Income Taxes

At December 31, 2009, the Company has a net operating loss carryforward for Federal income tax purposes of $3,009,065 which expires in varying amounts through 2029. The Company recorded an increase in the valuation allowance of $528,599 for the year ended December 31, 2009.

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

| | December 31, | |
|---|---|---|
| | 2009 | 2008 |
| Net Operating Loss (NOL) Carryover | $1,023,082 | $553,879 |
| Share Based Expense | 112,163 | 52,767 |
| Total Deferred Tax Asset | 1,135,245 | 606,646 |
| Less: Valuation Allowance | (1,135,245) | (606,646) |
| 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, | |
|---|---|---|
| | 2009 | 2008 |
| Loss Before Income Taxes | $(1,969,738) | $(2,852,767) |
| Tax Benefit @ Statutory Tax Rate | 669,711 | 969,941 |
| Effects of: | | |
| Exclusion of ISO Expense | (140,816) | (457,654) |
| (Increase)/Decrease in Valuation Allowance | (528,599) | (509,274) |
| Other | (296) | (3,013) |
| Provision (Benefit) for Income Taxes | $- | $- |

As of December 31, 2009 and 2008, the Company has no unrecognized income tax benefits. The Company is in process of completing an analysis of its tax credit carryforwards. Any uncertain tax positions identified in the course of this analysis will not impact its financial statements due to the full valuation allowance. A reconciliation of our unrecognized tax benefits for the years ending December 31, 2009 and 2008 is presented in the table below:

| | December 31, | |
|---|---|---|
| | 2009 | 2008 |
| Beginning balance | $0.0 | $0.0 |
| Additions based on tax positions related to current year | 0.0 | 0.0 |
| Reductions for tax positions of prior years | 0.0 | 0.0 |
| Reductions due to expiration of statute of limitations | 0.0 | 0.0 |
| Settlements with taxing authorities | 0.0 | 0.0 |
| Ending Balance | $0.0 | $0.0 |

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, 2009, and 2008.

The tax years from 2007 and forward remain open to examination by federal and Texas 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.

13. Subsequent Events

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 as of the December 31, 2009 year end. In the first quarter of 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, completing the Company's obligation to these investors. 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 of 2010, the Company paid the Placement Agent the balance of $2,500 for cash commissions owed for the sale of common stock and warrant in the fourth quarter of 2009. In addition, the Company issued 270,000 shares of common stock to the Placement Agent representing stock commission on shares of common stock sold.

In January of 2009, the Company issued 900,000 shares of common stock and warrants to purchase an additional 900,000 shares of common stock for $225,000 in cash to an investor in the Company pursuant to a private placement memorandum. In connection with this private placement, the Company paid $22,500 in cash commissions and issued 90,000 shares of common stock to the Placement Agent as commission for the shares of common stock sold to investors.

In March of 2010, the Company received written notification from the U. S. Food and Drug Administration (FDA) that it has allowed an IND (Investigational New Drug) for the Company's lead cancer drug candidate liposomal Grb-2 (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 the Company covering pre-clinical studies, safety, chemistry, manufacturing and controls, and the protocol for the Phase I clinical trial. The clinical trial will be conducted at the M. D. Anderson Cancer Center and is expected to last one year. The primary objective of the Phase I trial is to demonstrate the safety of the Company's drug candidate liposomal Grb-2 for use in human patients. Additional objectives are to demonstrate the effectiveness of the Company's delivery technology similar to that experienced in pre-clinical treatment of animals, and further, 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 clinical trial is structured to test five rounds of patients, with each round comprising treatment of three patients. Each succeeding round in the study has a higher dose of the drug candidate test article being administered to the patients. The Company will reimburse M. D. Anderson at the rate of approximately $13,000 per patient for treating patients in the study. In total, the Company currently expects to reimburse M. D. Anderson approximately $250,000 spread out over one year for patient treatment costs. The Company is also required to supply the drug candidate test article for administration to the patients in the study, for which the Company has in place a drug supply contract with Althea Technologies (see Note 11.) that will supply sufficient drug candidate test article for testing through two rounds. The Company expects to pay no more than $150,000 to its contract drug manufacturing supplier to complete payments under the current contract. Drug costs for the entire study could cost an additional $1 million including requirements for drug candidate test article for additional treatments of the patients if the drug is having a positive effect on the patients' disease. The Company has sufficient cash resources to fund the trial through the initial two or three rounds of the study. The Company plans to raise additional cash resources through the sale of common stock in an offering planned for early summer of 2010. Commencement of the trial will begin in 2010 after completion of final preparations and enrollment of patients into the study.