

BIO-PATH HOLDINGS INC

Form 10-K

April 03, 2009

---

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

FORM 10-K

✓ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2008

OR

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

Commission file number 000-53404

BIO-PATH HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

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

3293 Harrison Boulevard, Suite 230, 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

-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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer

Accelerated filer

Smaller reporting company

Edgar Filing: BIO-PATH HOLDINGS INC - Form 10-K

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  No

The Issuer's revenues for the fiscal year ended December 31, 2008 were \$-0-.

As of March 24, 2009, there were 41,923,602 shares of the Issuer's common stock issued and outstanding of which 22,581,026 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 24, 2009 was approximately \$3,838,774.

DOCUMENTS INCORPORATED BY REFERENCE: NONE

---

## TABLE OF CONTENTS

	Page
PART I	<u>1</u>
Item 1. Description of Business	<u>2</u>
Item 1A. Risk Factors	<u>14</u>
Item 2. Properties	<u>27</u>
Item 3. Legal Proceedings	<u>27</u>
Item 4. Submission of Matters to a Vote of Security Holders	<u>27</u>
PART II	<u>27</u>
Item 5. Market for the Registrant's Common Stock and Related Security Holder Matters	<u>27</u>
Item 6. Selected Consolidated Financial Data	<u>29</u>
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operation	<u>29</u>
Item 7A. Quantitative and Qualitative Disclosures About Market Risk.	<u>36</u>
Item 8. Financial Statements and Supplementary Data	<u>36</u>
Item 9. Changes and Disagreements with Accountants on Accounting and Financial Disclosure	<u>36</u>
Item 9A. Controls and Procedures	<u>37</u>
Item 9B. Other Information	<u>38</u>
PART III	<u>38</u>
Item 10. Directors, Executive Officers and Corporate Governance	<u>38</u>
Item 11. Executive Compensation	<u>41</u>
Item 12. Security Ownership of Certain Beneficial Owners and Management	<u>43</u>
Item 13. Certain Relationships and Related Party Transactions	<u>45</u>
Item 14. Principal Accountant Fees and Services	<u>45</u>
Item 15. Exhibits	<u>46</u>



## PART I

Unless the context requires otherwise, references in this report to “we,” “our,” “us,” “Company” and “Bio-Path” refer to Bio-Path Holdings, Inc. and its subsidiaries. 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, and
  - assessment of impact of recent accounting pronouncements.

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 engaged in the business of financing and facilitating the development of novel cancer therapeutics. Our initial plan has been 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. We have two exclusive licenses (“License Agreements”) from M. D. Anderson 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.

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.

### 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, we will attempt to validate our business model by in-licensing additional products to broaden the drug product pipeline.

We anticipate that over the next 36 months, we will need to raise approximately \$11,500,000 to completely implement our business plan. Since its inception, Bio-Path Subsidiary completed several financings raising net proceeds of \$3,131,460. Our short term plan is to achieve three key milestones:

- (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;
- (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.

### 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. The Company is currently working on the requested changes. The final package submission to the FDA must include the manufacturing and chemistry control test data from an engineering test batch that will use the same manufacturing procedures to be used to manufacture the drug product to be used on human patients in the Phase I clinical trial. The clinical batch of drug product is currently scheduled to be manufactured in mid May, 2009 and the Company expects to have the final data submitted to the FDA by the end of April, 2009. Based on this timetable, the Company anticipates having the IND approved and commencement of patient enrollment for the Phase I clinical trial to start the end of May 2009. 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 Phase I clinical trial of BP-100-1.01 is budgeted for \$1,675,000. A significant portion of this budget is for acquisition of the drug material to be tested, a majority of which has been paid by the Company. Commencement of the Phase I clinical trial depends on the Federal Drug Administration ("FDA") approving the IND for BP-100-1.01.

We have entered into a supply agreement with Althea Technologies, Inc. for the manufacture of BP-100-1.01 for our upcoming Phase I Clinical Trial. Althea is a contract manufacturer who will formulate and lyophilize our BP-100-1.01 product requirements according to current Good Manufacturing Practices (cGMP). The contract includes payments by Bio-Path of approximately \$700,000 for process development and manufacture of cGMP product suitable for use in human patients in the Company's Phase I clinical trial. Bio-Path has the right to terminate the 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.

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 we will need to raise an additional \$11,500,000 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-100-2.01 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 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 additional capital raised will also allow Bio-Path 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 \$11,500,000 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 one full year 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 two exclusive License Agreements with M. D. Anderson. M. D. Anderson's stated mission is to "make cancer history" ([www.mdanderson.org](http://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.

#### 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 two licenses with M. D. Anderson for late stage preclinical molecules, and intends to use our relationship with M. D. Anderson to develop these 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

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 Agreement

We have entered into two Patent and Technology License Agreements (the “Licenses”) with M. D. Anderson relating to its technology. A summary of certain material terms of each 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 its rights to the licensed technology, we must meet certain development and funding milestones.

#### Description of Technologies

The 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

#### 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.

#### 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; Assistant Professor, Department of Experimental Therapeutics, M.D. Anderson Cancer Center.

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 it 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 timeframe 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.

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 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 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 approximately \$15,000,000 from the sale of our securities. Bio-Path Subsidiary has raised approximately \$3,573,150. We anticipate we currently have sufficient capital to fund our operations for the next nine (9) 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.

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 the Company 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 the Company; 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. As described through this Memorandum, Bio-Path Subsidiary has entered into two 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.

18

---



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 no 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 may not be able to obtain authority from the FDA or other equivalent foreign regulatory agencies to complete these trials or commence and complete any other clinical trials.

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.

Regulatory and legal uncertainties could result in significant costs or otherwise harm the business of the Company.

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 its 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](http://www.clinicaltrials.gov). Federal legislation was introduced in the fall of 2004 to expand [www.clinicaltrials.gov](http://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, 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 stockholders 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, 2008, the closing sales price of our common stock fluctuated from a low of \$0.50 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 stockholders 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 stockholders 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 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, 2008.

## 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, 2007		
First Fiscal Quarter	\$ .90	\$ .61
Second Fiscal Quarter	\$ .90	\$ .35
Third Fiscal Quarter	\$ .50	\$ .35
Fourth Fiscal Quarter	\$ .87	\$ .50
Fiscal Year Ended December 31, 2008		
First Fiscal Quarter	\$ .90	\$ .52
Second Fiscal Quarter	\$5.00	\$ .90



Edgar Filing: BIO-PATH HOLDINGS INC - Form 10-K

	High Bid	Low Bid
Third Fiscal Quarter	\$2.60	\$1.50
Fourth Fiscal Quarter	\$1.65	\$1.40
Fiscal Year Ended December 31, 2009		
First Fiscal Quarter (Through March 30, 2007)	\$ .90	\$ .11

Shares Issued in Unregistered Transactions

During the fiscal year ended December 31, 2008 we issued 458,994 shares of our common stock in unregistered transactions. A total of 38,023,578 shares were issued in the merger wherein we acquired Bio-Path Subsidiary. 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	78,970
Strategic Consultants	80,000
Firm for Services Finding Merger Partner	200,000
Investor Relations Firm	100,000
Share Rounding Per NASDAQ Rules	24
Total	458,994

Holdings

As of March 24, 2009 there were 41,923,602 shares of common stock outstanding and approximately 232 stockholders of record.

Dividends

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

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

None

Equity Compensation Plan Information

Plan Category	Number of Shares of common stock to be issued upon exercise of	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
---------------	---	---	---	---

Edgar Filing: BIO-PATH HOLDINGS INC - Form 10-K

	outstanding options			under equity compensation plans
Equity compensation plans approved by stockholders (1)	3,850,620	\$1.21	9.2 yrs.	3,149,380
Equity compensation plans not approved by stockholders	---	---	---	---



(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 24, 2009.

#### 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 stockholders 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 stockholders 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 stockholders (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 stockholders 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 stockholders.

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 S. 700 E., 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 two 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, 2008.

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, 2008 and period from inception (May 10, 2007) to December 31, 2007.

We have no operating revenues since our inception. Our operating expenses for the twelve months ended December 31, 2008 were \$2,893,828 and consisted of general and administrative expenses of \$587,163, stock issued for services of \$300,000, cost of stock options and warrants of \$1,501,239 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.

Our operating expenses for the period of inception (May 10, 2007) to December 31, 2007 were \$307,006 and consisted of general and administrative expenses of \$271,280, and amortization expense of \$27,551 for our technology licenses. We expended \$8,175 on research and development costs during the year ended December 31, 2007.



We had interest income of \$ 41,061 for the twelve months ended December 31, 2008 compared to interest income of \$25,609 for the period of inception (May 10, 2007) to December 31, 2007. Our interest income was derived from cash and cash equivalents net of bank fees.

Our net loss was \$2,852,767 for the twelve months ended December 31, 2008 compared to a net loss of \$281,397 for the period of inception (May 10, 2007) to December 31, 2007. Net loss per share, both basic and diluted was \$.07 for the twelve months ended December 31, 2008 and \$0.01 for the period of inception (May 10, 2007) to December 31, 2007.

#### Liquidity and Capital Resources as of December 31, 2008

At December 31, 2008, we had cash of \$1,507,071 compared to \$1,219,358 at December 31, 2007. We currently have no lines of credit or other arranged access to debt financing.

Net cash used in operations during the year ended December 31, 2008 was \$930,600 compared to \$251,107 from inception to December 31, 2007. 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.

Currently all of our cash is, and has been, generated from financing activities. Cash provided by financing activities was \$1,368,313 compared to \$1,670,465 from inception to December 31, 2007. Since inception we have net cash from financing activities of \$3,038,779. 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 fiscal year ending December 31, 2009. However, we believe that we will need to raise approximately an additional \$11,500,000 in net proceeds to completely implement our business plan. We do need to raise additional capital during 2009, in order to fund our operations in 2010. There can be no assurance that we will be able to raise cash when it is needed to fund our operations.

#### Liquidity and Capital Resources as of December 31, 2007

At December 31, 2007, we had cash of \$1,219,358. Cash used in operations since inception to December 31, 2007 totaled \$251,107. Since inception, we have net cash from financing activities of \$1,670,465. 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 current fiscal year ending December 31, 2008. However, we believe that we will need to raise approximately \$15,000,000 in gross proceeds to completely implement our business plan.

#### 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 1,615,000 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 24, 2009, a total of 1,458,332 of these options are now vested, and the remaining 1,041,668 vest over a three year period from October 2008 based on one-thirty six per month for services rendered as employees. The exercise price is \$1.40 per share.

#### 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 two 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, JPMorgan Chase Bank. The balances are insured by the Federal Deposit Insurance Corporation up to \$250,000. As a result, \$1,257,071 of the Company's cash balances is not covered by the FDIC.

**Intangible Assets/Impairment of Long-Lived Assets** -- As of December 31, 2008, Other Assets totals \$2,504,662 for the Company's two technology licenses, comprised of \$2,704,167 in value acquiring the Company's technology licenses and its intellectual property, less accumulated amortization of \$199,505. The technology value consists of \$350,000 in cash paid or accrued to be paid to MD Anderson, plus 3,138,889 shares of common stock granted to M.D. Anderson valued at \$2,354,167. 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, 2008 accrued payments to be made to M. D. Anderson totaled \$125,000, and such payments are expected to be made in 2009. The Company accounts for the impairment and disposition of its long-lived assets in accordance with Statement of Financial Accounting Standards ("SFAS") No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets. In accordance with SFAS No. 144, 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 \$175,000 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 SFAS No. 2, "Accounting for Research and Development Costs." For the year 2008, the Company had \$333,472 of costs classified as research and development expense. Of this amount, approximately \$225,000 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 Statement of Financial Accounting Standards No. 123(R), "Share-Based Payment." This statement 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.

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 1,615,000 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 service period 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 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 service period 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 vesting schedule.

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.

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 SFAS No. 128, Earnings Per Share, 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. Under SFAS No. 128, diluted net income (loss) per share is computed by dividing the net income (loss) for the period by the weighted average number of common and common equivalent shares, such as stock options and warrants, outstanding during the period.

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, 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.

#### Recent Accounting Pronouncements:

In September 2006, the FASB issued SFAS No. 157 “Fair Value Measurements.” SFAS 157 defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. SFAS 157 applies under other accounting pronouncements that require or permit fair value measurements and does not require any new fair value measurements. The provisions of SFAS 157 were originally to be effective beginning January 1, 2008. Subsequently, the FASB provided for a one-year deferral of the provisions of SFAS 157 for non-financial assets and liabilities that are recognized or disclosed at fair value in consolidated financial statements on a non-recurring basis. We are currently evaluating the input of adopting the provisions of SFAS 157 for non-financial assets and liabilities that are recognized or disclosed on a non-recurring basis.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities — Including an amendment of FASB Statement No. 115, which is effective for fiscal years beginning after November 15, 2007. The statement permits entities to choose to measure many financial instruments and certain other items at fair value. The Company has not elected to account for any of its assets or liabilities using the fair value option under SFAS No. 159 and accordingly, the adoption of SFAS No. 159 did not have a material impact on the Company's financial position or results of operations.

In July 2007, the Emerging Issues Task Force (EITF) issued EITF 07-3, "Accounting for Nonrefundable Advance Payments for Goods or Services to be Used in Future Research and Development Activities" (EITF 07-3). EITF 07-3 clarifies the accounting for non-refundable advance payments for goods or services that will be used or rendered for research and development activities. EITF 07-3 states that such payments should be capitalized and recognized as an expense as the goods are delivered or the related services are performed. If an entity does not expect the goods to be delivered or the services rendered, the capitalized advance payment should be charged to expense. EITF 07-3 is effective for fiscal years beginning after December 15, 2007. We adopted EITF 07-3 on January 1, 2008. The adoption of EITF 07-3 did not have a material effect on our financial position or the results of our operations.

In December 2007, the FASB completed the second phase of its business combination project and issued the following two accounting standards: (i) Statement No. 141(R), "Business Combinations;" and (ii) Statement No. 160, "Noncontrolling Interests in Consolidated Financial Statements" — an amendment of ARB No. 51. These statements dramatically change the way companies account for business combinations and noncontrolling interests. Compared with their predecessors, Statements 141(R) and 160 will require:

- More assets acquired and liabilities assumed to be measured at fair value as of the acquisition date;
- Liabilities related to contingent consideration to be remeasured at fair value in each subsequent reporting period;
  - An acquirer in preacquisition periods to expense all acquisition related costs; and
- Noncontrolling interests in subsidiaries initially to be measured at fair value and classified as a separate component of equity.

Statements 141(R) and 160 should both be applied prospectively for fiscal years beginning on or after December 15, 2008. However, Statement 160 requires entities to apply the presentation and disclosure requirements retrospectively to comparative financial statements if presented. Both standards prohibit early adoption. We are currently assessing the impact these new standards will have on our consolidated financial statements.

In December 2007, the FASB ratified a consensus opinion reached by the EITF on EITF Issue 07-1, "Accounting for Collaborative Arrangements" (EITF 07-1). The guidance in EITF 07-1 defines collaborative arrangements and establishes presentation and disclosure requirements for transactions within a collaborative arrangement (both with third parties and between participants in the arrangement). The consensus in EITF 07-1 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2008. The consensus requires retrospective application to all collaborative arrangements existing as of the effective date, unless retrospective application is impracticable. The impracticability evaluation and exception should be performed on an arrangement-by-arrangement basis. We are evaluating the impact EITF 07-1 will have on our financial statements. We currently do not believe that the adoption of EITF 07-1 will have a significant effect on our financial statements.

In December 2007, the SEC staff issued Staff Accounting Bulletin (SAB) 110, "Share-Based Payment" (SAB 110) which amends SAB 107, "Share-Based Payment," to permit public companies, under certain circumstances, to use the simplified method in SAB 107 for employee option grants after December 31, 2007. Use of the simplified method after December 2007 is permitted only for companies whose historical data about their employees' exercise behavior does not provide a reasonable basis for estimating the expected term of the options. We are currently evaluating the potential impact that the adoption of FSP 142-3 may have on our consolidated financial statements. We currently use the simplified method to estimate the expected term for employee option grants, as adequate historical experience is not available to provide a reasonable estimate. SAB 110 is effective for employee options granted after December 31, 2007. We adopted SAB 110 on January 1, 2008 and will continue to apply the simplified method until enough historical experience is readily available to provide a reasonable estimate of the expected term for employee option grants.

In April 2008, the FASB issued FASB Staff Position No. 142-3, Determination of the Useful Life of Intangible Assets ("FSP 142-3"). FSP 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under Statement of Financial Accounting Standards No. 142, Goodwill and Other Intangible Assets ("SFAS 142"). The objective of this FSP is to improve the consistency between the useful life of a recognized intangible asset under SFAS 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS 141R. This FSP is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years.

In November 2008, the FASB issued EITF Issue No. 08-7, "Accounting for Defensive Intangible Assets," or EITF 08-7. EITF 08-7 seeks to clarify how to account for defensive intangible assets, or those intangible assets acquired in a business combination that an entity does not intend to actively use but does intend to prevent others from using, subsequent to initial measurement. EITF 08-7 is effective for all intangible assets acquired during the first fiscal year beginning on or after December 15, 2008. Early adoption is not permitted. The impact of the adoption of EITF 08-7 will be dependent upon the type and structure of any transactions that the Company may make in the future.

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

Information not required for smaller reporting companies.

#### ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY 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.

(a) Effective March 3, 2008, Spector & Wong, LLP (“Spector & Wong”) was notified that it was no longer the independent registered public accounting firm of the Registrant. The reports of Spector & Wong on the financial statements of the Registrant as of and for the years ended June 30, 2007 and 2006 did not contain an adverse opinion or a disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope or accounting principles, except for the addition of an explanatory paragraph expressing substantial doubt about the Registrants ability to continue as a going concern.

During the years ended June 30, 2007 and 2006 and through March 3, 2008, there were no disagreements with Spector & Wong on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure which disagreements, if not resolved to the satisfaction of Spector & Wong, would have caused Spector & Wong to make a reference to the subject matter of the disagreement in its reports on the Registrant’s financial statements for such periods. There were no reportable events (as defined in Regulation S-B Item 304(a)(1)(iv)) during the years ended June 30, 2007 and 2006 or the subsequent interim period through March 3, 2008.

The Registrant requested that Spector & Wong furnish it with a letter addressed to the Securities and Exchange Commission stating whether or not it agrees with the above statements. A copy of such letter, dated March 6, 2008 was filed as an exhibit to the Form 8-K which was filed to report on the change of independent registered public accounting firm.

(b) On February 21, 2008, upon the authorization and approval of the full Board of Directors acting as the audit committee of the Registrant, the Registrant appointed the accounting firm of Mantyla McReynolds, LLC (“Mantyla”) as the Company’s independent registered public accounting firm. No consultations occurred between the Registrant and Mantyla during the years ended June 30, 2007 and 2006 and through February 21, 2008 regarding either (i) the application of accounting principles to a specific completed or contemplated transaction, the type of audit opinion that might be rendered on the Registrant’s financial statements, or other information provided that was an important factor considered by the Registrant in reaching a decision as to an accounting, auditing or financial reporting issue, or (ii) any matter that was the subject of disagreement or a reportable event requiring disclosure under Item 304(a)(1)(iv) of Regulation S-B.

#### ITEM 9A. CONTROLS AND PROCEDURES

(a) Evaluation of disclosure controls and procedures. Under the supervision and with the participation of our management, including our principal executive officer/ principal financial officer, we conducted an evaluation of the effectiveness of the design and operations of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as of December 31, 2008. Based on this evaluation, our Chief Executive Officer/Chief Financial Officer concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed in the reports submitted under the Securities and Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission (“SEC”) rules and forms, including to ensure that information required to be disclosed by the Company is accumulated and communicated to management, including the principal executive officer/principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

(b) Evaluation of disclosure controls and procedures. We are responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act). Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes of accounting principles generally accepted in the United States.



Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance of achieving their control objectives.

Our Chief Executive Officer and Chief Financial Officer evaluated the effectiveness of our internal control over financial reporting as of December 31, 2008. In making this assessment, we used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework. Based on this evaluation, our Chief Executive Office/ Chief Financial Officer concluded that, as of December 31, 2008, 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 SEC that permit us to provide only management's report in this annual report.

(c) Changes in internal controls over financial reporting. The Company's Chief Executive Officer/ Chief Financial Officer has determined that there have been no changes in the Company's internal control over financial reporting during the period covered by this report identified in connection with the evaluation described in the above paragraph that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

#### 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	59	Chief Executive Officer/President/Chief Financial Officer/Treasurer/ Chairman of the Board and Director
Douglas P. Morris	53	Vice President of Corporate Development/ Secretary/Director
Dr. Thomas Garrison	51	Director
Dr. Gillian Ivers-Read	55	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. Mr. Morris has recently 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 continues to be Chief or Chair person over hospital Emergency Departments and 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 in Advanced Laser Clinics, Inc., serving as Corporate Medical Director for this growing national company. He is responsible for medical oversight, written policies, regulatory input, equipment selection, pharmaceuticals, training and other medically relevant issues. 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.

Dr. Gillian Ivers-Read. Dr. Ivers-Read is and has been since April 2002, Executive Vice President, Development Operations of Pharmion Corp., a publicly held biotech company. From 1996 to 2001, Dr. 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, Dr. 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 Dr. 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

Dai-Shan Wong. Mr. Wong was appointed as Bio-Path's Director of Regulatory Affairs and Quality Control in July 2008. Mr. Wong was Director of Regulatory Affairs with Applied Logic Associates and is a certified regulatory consultant with over 20 years of diversified regulatory and clinical oversight of U. S. Food and Drug Administration (FDA) regulated medical products. He has extensive experience in Quality System Regulations implementation and in performing quality audits. In addition, Mr. Wong has held project and general management positions. Dai-Shan Wong has a B.S. in Biology from Oklahoma Baptist University and has done graduate work in biochemistry at the University of Texas Medical Branch, Galveston, Texas. Mr. Wong is a Certified Regulatory Affairs Professional (RAC).

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 Assistant Professor at the M. D. Anderson Cancer Center. 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](http://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 stockholders 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	2007	\$133,333	\$20,000	-0-	\$153,333
Chairman	2008	\$250,000	-0-	-0-	\$250,000
Douglas P. Morris, VP Corporate Development/Drector	2007	\$ 80,000	-0-	-0-	\$ 80,000
Corporate Development Director	2008	\$120,000	-0-	-0-	\$120,000

## Stock Option Grants and Exercises During the Fiscal Year Ended December 21, 2008

The following table sets forth information concerning stock option grants made during the fiscal year ended December 31, 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 (\$/Sh)	Grant Date Fair Value of Option Awards (\$/Sh)
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, 2008.



OUTSTANDING EQUITY AWARDS AT DECEMBER 31, 2008

Name	Option/Warrant Awards					
	Number of Securities Underlying Unexercised Options/Warrants Exercisable (#)(1)		Number of Securities Underlying Unexercised Options (#)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option/Warrant Exercise Price (\$)	Option/Warrant Expiration Date (2)
Peter Nielsen	1,500,000	0	-	-	\$1.40	7/24/2008
Douglas P. Morris	1,000,000	0	-	-	\$1.40	2/2/2014

(1) Except as indicated, the options granted vest and become exercisable in monthly installments over a two year period, commencing on the date of grant.

(2) The amount represents the shares of Common Stock issuable upon exercise of the vested warrants.

Option/Warrant Exercises

No officer or director exercised any option during the fiscal year ended December 31, 2008

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 as of March 24, 2009 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)	5,956,100	14.21%
Douglas P. Morris (1) (3)	2,157,588	5.15%
Dr. Tom Garrison (1)	1,761,324	4.20%
Dr. Gillian Ivers-Read (1) (4)	-0-	-0-%
M. D. Anderson	6,930,025	16.51%
Tom Fry	5,533,334	13.20%
All officers and directors as a group (5)	9,875,012	23.55%
Total	41,923,602	100.00%

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

(2) Includes 5,164,434 shares owned of record and 791,666 shares issuable upon the exercise of options that are currently exercisable or will be exercisable within 60 days. In addition to the vested options of Mr. Nielsen, additional options vest monthly over the next 36 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 1,629,811 shares owned of record and 527,777 shares issuable upon the exercise of options that are currently exercisable or will be exercisable within 60 days. In addition to the vested options of Mr. Morris, additional options vest monthly over the next 36 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) Dr. Ivers-Read owns options which are not currently vested. These options, if fully vested would, entitled her to purchase 450,000 shares of common stock at a price of \$0.90 per share. These options vest over a period of three years.

(5) Includes 8,555,569 shares of record and 1,319,443 shares issuable upon the exercise of currently vested options.

### Stock Options

In April of 2008 the Company made stock option grants for services over the next three years to purchase in the aggregate 1,615,000 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, 2008 was determined using this methodology is \$761,590, which will be expensed over the next six years based on the stock option vesting schedule. The expense for the three months ended June 30, 2008 was \$42,216.



In August 2008, Ulrich Mueller resigned as a Director of the Company and withdrew from his consulting agreement as an advisor to the Company. As a result, the Company cancelled stock options granted to Dr. Mueller to purchase 450,000 shares of 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 fair market value of these options has not been determined as of the date of this Memorandum.

#### 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

Prior to the merger, Bio-Path, Inc. issued shares of its common stock to Peter Nielsen, Douglas P. Morris and Dr. Thomas Garrison at a price of \$.001 per share. These individuals are officers and/or directors of the Company. These shares were converted into a total of 8,555,569 shares of our common stock in the merger transaction

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.

We granted director Gillian Ivers-Read options to purchase 450,000 shares of our common stock at a price of \$0.90 per share. These options vest over a period of four years.

We recently granted to Peter Nielsen and Douglas P. Morris options to purchase a total of 2,500,000 shares of our common stock at a price of \$1.40 per share. These individuals are officers and directors of the Company.

#### 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, PC. 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 2008 and 2007, 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 2008 and 2007, 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 2008 and 2007:

Type of Fees	2008	2007
Audit Fees	\$49,940	\$3,327
Audit-Related Fees	-	-
Tax Fees	887	-
All Other Fees	-	-
Total	\$50,827	\$3,327

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

Edgar Filing: BIO-PATH HOLDINGS INC - Form 10-K

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: April 2, 2009

By: /s/  
 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
April 2, 2009	Chief Executive Officer/Principal F i n a n c i a l / s / Officer/President/ Director Director	Peter Nielsen
April 2, 2009	Secretary and Director	/s/ Douglas P. Morris
April 2, 2009	Director	/s/ Dr. Thomas Garrison
April 2, 2009	Director	/s/ Dr. Gillian Ivers-Read



Index to Financial Statements

Bio-Path Holdings, Inc. Financial Statements	Page
Report of Independent Registered Public Accounting Firm	<u>F-2</u>
Consolidated Balance Sheet	<u>F-3</u>
Consolidated Statement of Operations	<u>F-4</u>
Consolidated Statement of Cash Flows	<u>F-5</u>
Consolidated Statement of Shareholders' Equity	<u>F-6</u>
Notes to Financial Statements	<u>F-7</u>

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of Bio-Path Holdings, Inc. [a development stage company] as of December 31, 2008 and 2007, and the related consolidated statements of operations, stockholders' equity, and cash flows for the period ended December 31, 2008 and the period from inception to December 31, 2007 and 2008. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. 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 audits 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 audits provide 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, 2008 and 2007, and the results of their operations and their cash flows for the period ended December 31, 2008 and the period from inception to December 31, 2007 and 2008 in conformity with accounting principles generally accepted in the United States of America.

Mantyla McReynolds, LLC  
Salt Lake City, Utah  
March 31, 2009

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

CONSOLIDATED BALANCE SHEET  
December 31, 2008 and 2007

	December 31,	
	2008	2007
<b>ASSETS</b>		
Current assets		
Cash	\$ 1,507,071	\$ 1,219,358
Restricted cash	-	208,144
Drug product for testing	292,800	-
Other current assets	82,772	27,434
<b>Total current assets</b>	<b>1,882,643</b>	<b>1,454,936</b>
Other assets		
Technology licenses	2,704,167	2,554,167
Less Accumulated Amortization	(199,505)	(27,551)
	2,504,662	2,526,616
<b>TOTAL ASSETS</b>	<b>\$ 4,387,305</b>	<b>\$ 3,981,552</b>
<b>LIABILITIES &amp; SHAREHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable	185,843	21,998
Escrow cash payable	-	208,144
Accrued expense	16,442	8,175
Accrued license payments	125,000	-
<b>Total current liabilities</b>	<b>327,285</b>	<b>238,317</b>
Long term debt	-	-
<b>TOTAL LIABILITIES</b>	<b>327,285</b>	<b>238,317</b>
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	41,923	15,484
41,923,602 and 15,484,050 shares issued and outstanding		
as of 12/31/08 and 12/31/07, respectively		
Additional paid in capital	7,152,261	4,009,148
Accumulated deficit during development stage	(3,134,164)	(281,397)
<b>Total shareholders' equity</b>	<b>4,060,020</b>	<b>3,743,235</b>

TOTAL LIABILITIES & SHAREHOLDERS' EQUITY	\$ 4,387,305	\$ 3,981,552
--	--------------	--------------

SEE ACCOMPANYING NOTES TO THE FINANCIAL STATEMENTS

F-3

---

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

CONSOLIDATED STATEMENT OF OPERATIONS  
FOR THE YEAR ENDED DECEMBER 31, 2008 AND FOR THE PERIOD  
FROM INCEPTION (MAY 10, 2007) THROUGH DECEMBER 31, 2008 AND 2007

	2008	From inception 05/10/07 to 12/31/07	From inception 05/10/07 to 12/31/08
Revenue	\$ -	\$ -	\$ -
Operating expense			
Research and development	333,472	8,175	341,647
General & administrative	587,163	271,280	858,443
Stock issued for services	300,000	-	300,000
Stock options & warrants	1,501,239	-	1,501,239
Amortization	171,954	27,551	199,505
Total operating expense	2,893,828	307,006	3,200,834
Net operating loss	\$ (2,893,828)	\$ (307,006)	\$ (3,200,834)
Other income			
Interest income	41,061	25,609	66,670
Total Other Income	41,061	25,609	66,670
Net Loss	\$ (2,852,767)	\$ (281,397)	\$ (3,134,164)
Loss per share			
Net loss per share, basic and diluted	\$ (0.07)	\$ (0.01)	\$ (0.09)
Basic and diluted weighted average number of common shares outstanding	41,162,099	26,514,573	34,355,984

SEE ACCOMPANYING NOTES TO THE FINANCIAL STATEMENTS

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

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

	2008	From inception 05/10/2007 to 12/31/2007	From inception 05/10/2007 to 12/31/2008
<b>CASH FLOW FROM OPERATING ACTIVITIES</b>			
Net loss	\$ (2,852,767)	\$ (281,397)	\$ (3,134,164)
Adjustments to reconcile net loss to net cash used in operating activities			
Amortization	171,954	27,551	199,505
Common stock issued for services	300,000	-	300,000
Stock options and warrants	1,501,239	-	1,501,239
(Increase) decrease in assets			
Restricted escrow cash	208,144	(208,144)	
Drug product for testing	(292,800)	-	(292,800)
Other current assets	(55,338)	(27,434)	(82,772)
Increase (decrease) in liabilities			
Accounts payable and accrued expenses	297,112	30,173	327,285
Escrow cash payable	(208,144)	208,144	
Net cash used in operating activities	(930,600)	(251,107)	(1,181,707)
<b>CASH FLOW FROM INVESTING ACTIVITIES</b>			
Purchase of exclusive license	(150,000)	(200,000)	(350,000)
Net cash used in investing activities	(150,000)	(200,000)	(350,000)
<b>CASH FLOW FROM FINANCING ACTIVITIES</b>			
Proceeds from convertible notes		435,000	435,000
Cash repayment of convertible notes		(15,000)	(15,000)
Net proceeds from sale of common stock	1,368,313	1,250,465	2,618,778
Net cash from financing activities	1,368,313	1,670,465	3,038,778
<b>NET INCREASE IN CASH</b>	<b>287,713</b>	<b>1,219,358</b>	<b>1,507,071</b>
Cash, beginning of period	1,219,358	-	-
Cash, end of period	\$ 1,507,071	\$ 1,219,358	\$ 1,507,071
<b>SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION</b>			
Cash paid for			
Interest	\$ -	\$ -	\$ -
Income taxes	\$ -	\$ -	\$ -
Non-cash financing activities			
Common stock issued upon conversion of convertible notes		\$ 420,000	\$ 420,000
Common stock issued to Placement Agent	\$ 78,970	\$ 199,375	\$ 278,345
Common stock issued to M.D. Anderson for technology license		\$ 2,354,167	\$ 2,354,167

SEE ACCOMPANYING NOTES TO THE FINANCIAL STATEMENTS

F-5

---

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

CONSOLIDATED STATEMENT OF SHAREHOLDERS' EQUITY  
FOR THE YEAR ENDED DECEMBER 31, 2008 AND THE PERIOD  
FROM INCEPTION (MAY 2007) THROUGH DECEMBER 31, 2008

Date	Description	Common Stock		Additional Paid in Capital	Accumulated Deficit	Total
		Shares	Amount			
May-07	Common stock issued for cash	6,480,994	\$ 6,481	\$ -	\$ -	\$ 6,481
Jun-07	Common stock issued for cash	25,000	25			25
	2nd Quarter fund raising expense			(26,773)		(26,773)
	Net loss 2nd Quarter 2007				(56,210)	(56,210)
	Balances at June 30, 2007	6,505,994	6,506	(26,773)	(56,210)	(76,477)
Aug-07	Common stock issued for cash in seed round	3,975,000	3,975	989,775		993,750
Aug-07	Common stock issued for cash in second round	1,333,334	1,333	998,667		1,000,000
Aug-07	Common stock issued to Placement Agent for services	530,833	531	198,844		199,375
	3rd Quarter fund raising expense			(441,887)		(441,887)
	Net loss 3rd Quarter 2007				(81,986)	(81,986)
	Balances at September 30, 2007	12,345,161	12,345	1,718,626	(138,196)	1,592,775
Nov-07	Common stock issued MD Anderson for License	3,138,889	3,139	2,351,028		2,354,167
	4th Quarter fund raising expense			(60,506)		(60,506)
	Net loss 4th Quarter 2007				(143,201)	(143,201)
	Balances at December 31, 2007	15,484,050	\$ 15,484	\$ 4,009,148	\$ (281,397)	\$ 3,743,235
Feb-08	Common stock issued for cash in 3rd round	1,579,400	1,579	1,577,821		1,579,400
Feb-08	Common stock issued to Placement Agent	78,970	79	78,891		78,970
Feb-08		80,000	80	79,920		80,000



Edgar Filing: BIO-PATH HOLDINGS INC - Form 10-K

	Common stock issued for services						
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
Dec-08	Common stock issued for services	100,000	100	39,900			40,000
Dec-08	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

SEE ACCOMPANYING NOTES TO THE FINANCIAL STATEMENTS

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

Notes to Financial Statements  
December 31, 2008

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. In addition to its existing technology under license, the Company has a blanket disclosure agreement with M. D. Anderson, which in addition to a close working relationship with key members of the University’s staff, is expected to provide Bio-Path with a strong pipeline of promising drug candidates on a continuing basis. Bio-Path expects the program with MD Anderson, with additional funding, 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. In total, the Company expects that with additional funding it will be able to have up to six (6) drug candidates under license at various stages of development. The Company’s two lead drug candidates potentially treat a large segment of cancer patients. The Company’s primary lead drug candidate, which is expected to enter a Phase I clinical trial in the second quarter 2009, will treat patients in the trial with chronic myelogenous leukemia, acute myeloid leukemia, acute lymphoblastic leukemia and myelodysplastic syndrome. There is also pre-clinical evidence that this drug can be used to treat late-stage breast cancer patients and other forms of cancer. A second lead drug candidate is expected to be tested initially in patients with follicular lymphoma, and if successful, could potentially be used in treating up to forty percent (40%) of cancer tumors. These two drug candidates will be ready to commence clinical trials after receiving investigational new drug (“IND”) status from the FDA. The Company has filed an IND application for its lead drug candidate and expects to be granted an IND for this drug product in the second quarter of 2009.

The Company was founded in May of 2007 as Bio-Path, Inc., a Utah corporation. In February of 2008, Bio-Path, Inc. completed a reverse merger with Ogden Golf Co. Corporation, a public company traded over the counter that had no current operations at the time of the reverse merger. The name of Ogden Golf was changed to Bio-Path Holdings, Inc. and the directors and officers of Bio-Path, Inc. became the directors and officers of Bio-Path Holdings, Inc. Bio-Path became a publicly traded company (symbol 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. 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, \$1,257,071 of the Company's cash balances is not covered by the FDIC.

**Intangible Assets/Impairment of Long-Lived Assets --** As of December 31, 2008, Other Assets totals \$2,504,662 for the Company's two technology licenses, comprised of \$2,704,167 in value acquiring the Company's technology licenses and its intellectual property, less accumulated amortization of \$199,505. The technology value consists of \$350,000 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 \$2,354,167. 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, 2008 accrued payments to be made to M. D. Anderson totaled \$125,000, and such payments are expected to be made in 2009. The Company accounts for the impairment and disposition of its long-lived assets in accordance with Statement of Financial Accounting Standards ("SFAS") No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets. In accordance with SFAS No. 144, 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 \$175,000 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 SFAS No. 2, "Accounting for Research and Development Costs." For the year 2008, the Company had \$333,472 of costs classified as research and development expense. Of this amount, approximately \$225,000 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 Statement of Financial Accounting Standards No. 123(R), "Share-Based Payment." This statement 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 SFAS No. 128, Earnings Per Share, 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, under SFAS No. 128, 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 2008. 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, 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** -- The Company accounts for income taxes under FASB Statement No. 109, Accounting for 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 September 2006, the FASB issued SFAS No. 157 “Fair Value Measurements.” SFAS 157 defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. SFAS 157 applies under other accounting pronouncements that require or permit fair value measurements and does not require any new fair value measurements. The provisions of SFAS 157 were originally to be effective beginning January 1, 2008. Subsequently, the FASB provided for a one-year deferral of the provisions of SFAS 157 for non-financial assets and liabilities that are recognized or disclosed at fair value in consolidated financial statements on a non-recurring basis. We are currently evaluating the input of adopting the provisions of SFAS 157 for non-financial assets and liabilities that are recognized or disclosed on a non-recurring basis.

In December 2007, the FASB issued SFAS No. 141(R), “Business Combinations.” SFAS No. 141(R) changes the accounting for and reporting of business combination transactions in the following way: Recognition with certain exceptions, of 100% of the fair values of assets acquired, liabilities assumed, and non controlling interests of acquired businesses; measurement of all acquirer shares issued in consideration for a business combination at fair value on the acquisition date; recognition of contingent consideration arrangements at their acquisition date fair values, with subsequent changes in fair value generally reflected in earnings; recognition of pre-acquisition gain and loss contingencies at their acquisition date fair value; capitalization of in-process research and development (IPR&D) assets acquired at acquisition date fair value; recognition of acquisition-related transaction costs as expense when incurred; recognition of acquisition-related restructuring cost accruals in acquisition accounting only if the criteria in Statement No. 146 are met as of the acquisition date; and recognition of changes in the acquirer’s income tax valuation allowance resulting from the business combination separately from the business combination as adjustments to income tax expense.



SFAS No. 141(R) is effective for the first annual reporting period beginning on or after December 15, 2008 with earlier adoption prohibited. The adoption of SFAS No. 141(R) will affect valuation of business acquisitions made in 2009 and forward.

In December 2007, the FASB issued SFAS No. 160 "Non-controlling Interest in Consolidated Financial Statements – an Amendment of ARB 51" (SFAS 160). SFAS 160 clarifies that a non-controlling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements. It also requires consolidated net income to be reported at amounts that include the amounts attributable to both the parent and the non-controlling interest, and requires disclosure, on the face of the consolidated statement of income, of the amounts of consolidated net income attributable to the parent and to the noncontrolling interest. SFAS 160 is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. Earlier adoption is prohibited. We do not anticipate a material impact upon adoption.

In December 2007, the FASB ratified a consensus opinion reached by the EITF on EITF Issue 07-1, "Accounting for Collaborative Arrangements" (EITF 07-1). The guidance in EITF 07-1 defines collaborative arrangements and establishes presentation and disclosure requirements for transactions within a collaborative arrangement (both with third parties and between participants in the arrangement). The consensus in EITF 07-1 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2008. The consensus requires retrospective application to all collaborative arrangements existing as of the effective date, unless retrospective application is impracticable. The impracticability evaluation and exception should be performed on an arrangement-by-arrangement basis. We are evaluating the impact EITF 07-1 will have on our financial statements. We currently do not believe that the adoption of EITF 07-1 will have a significant effect on our financial statements.

In December 2007, the SEC staff issued Staff Accounting Bulletin (SAB) 110, "Share-Based Payment" (SAB 110) which amends SAB 107, "Share-Based Payment", to permit public companies, under certain circumstances, to use the simplified method in SAB 107 for employee option grants after December 31, 2007. Use of the simplified method after December 2007 is permitted only for companies whose historical data about their employees' exercise behavior does not provide a reasonable basis for estimating the expected term of the options. We currently use the simplified method to estimate the expected term for employee option grants, as adequate historical experience is not available to provide a reasonable estimate. SAB 110 is effective for employee options granted after December 31, 2007. We adopted SAB 110 on January 1, 2008 and will continue to apply the simplified method until enough historical experience is readily available to provide a reasonable estimate of the expected term for employee option grants.

In March 2008, the FSAB issued FASS No. 161, "Disclosures about Derivative Instruments and Hedging Activities." SFAS 161 is intended to improve financial reporting about derivative instruments and hedging activities by requiring enhanced disclosures to enable investors to better understand their effects on an entity's financial position, financial performance, and cash flows. SFAS 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008, with early application encouraged. We do not anticipate a material impact upon adoption.

In April 2008, the FASB issued FASB Staff Position No. 142-3, Determination of the Useful Life of Intangible Assets ("FSP 142-3"). FSP 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under Statement of Financial Accounting Standards No. 142, Goodwill and Other Intangible Assets ("SFAS 142"). The objective of this FSP is to improve the consistency between the useful life of a recognized intangible asset under SFAS 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS 141R.



This FSP is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. We are currently evaluating the potential impact that the adoption of FSP 142-3 may have on our consolidated financial statements.

In November 2008, the FASB issued EITF Issue No. 08-7, "Accounting for Defensive Intangible Assets," or EITF 08-7. EITF 08-7 seeks to clarify how to account for defensive intangible assets, or those intangible assets acquired in a business combination that an entity does not intend to actively use but does intend to prevent others from using, subsequent to initial measurement. EITF 08-7 is effective for all intangible assets acquired during the first fiscal year beginning on or after December 15, 2008. Early adoption is not permitted. The impact of the adoption of EITF 08-7 will be dependent upon the type and structure of any transactions that the Company may make in the future.

### 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 supplier totaling \$292,800 during the third quarter and fourth quarters of 2008 pursuant to a Project Plan and Supply Agreement (see Note 10. below) 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, 2008 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, 2008, Current Liabilities included accounts payable of \$185,843. Of this amount, \$154,000 represents account balances owed to the Company's contract drug manufacturing supplier. The Company subsequently paid off these balances during the first quarter of 2009.

### 6. 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.



7. Accrued License Payments

Accrued license payments totaling \$125,000 were included in Current Liabilities as of December 31, 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 2009.

8. Stockholders' Equity

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

In February of 2008, the Company completed a reverse merger with Ogden Golf Co. Corporation and issued 38,023,578 shares of common stock of the public company Bio-Path Holdings (formerly Ogden Golf Co. Corporation) in exchange for pre-merger common stock of Bio-Path, Inc. In addition, shareholders of Ogden Golf Co. Corporation retained 3,600,000 shares of common stock of Bio-Path Holdings. In February of 2008 Bio-Path issued 80,000 shares of common stock to strategic consultants pursuant to executed agreements and the fair value was expensed upfront as common stock for services. In April of 2008, the Company issued 200,000 shares of common stock to a firm in connection with introducing Bio-Path, Inc. to its merger partner Ogden Golf Co. Corporation. The fair value of this stock issuance was expensed upfront as common stock for services valued at \$200,000. 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 \$100,000. As of December 31, 2008 there were 41,923,602 shares of common stock issued and outstanding. There are no preferred shares outstanding as of December 31, 2008.

9. Stock-Based Compensation Plans

The Plan - In 2007, the Company adopted the 2007 Stock Incentive Plan, as amended (the "Plan"). The Plan provides for the grant of Incentive Stock Options, Nonqualified Stock Options, Restricted Stock Awards, Restricted Stock Unit Awards, Performance Awards and other stock-based awards, or any combination of the foregoing to our key employees, non-employee directors and consultants. The total number of Shares reserved and available for grant and issuance pursuant to this Plan is 7,000,000 Shares, subject to the automatic annual Share increase as defined in the Plan. Under the Plan, the exercise price is determined by the compensation committee of the Board of Directors, and for options intended to qualify as qualified incentive stock options, may not be less than the fair market value as determined by the closing stock price at the date of the grant. Each option and award shall vest and expire as determined by the compensation committee. Options expire no later than ten years from the date of grant. All grants provide for accelerated vesting if there is a change of control, as defined in the Plan.

Stock option and warrant awards granted were estimated to have a weighted average fair value per share of \$0.86 for the year 2008. 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 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, 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	-	-	-	-

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 2008 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, 2008. This amount changes based on the fair market value of the Company's stock.

Edgar Filing: BIO-PATH HOLDINGS INC - Form 10-K

A summary of options outstanding and exercisable as of December 31, 2008:

Range of Exercise Prices	Number Outstanding	Options Outstanding		Options Exercisable	
		Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$0.30	100,000	8.7	\$0.30	-	-
\$0.90	1,165,000	9.3	\$0.90	-	-
\$1.40	2,500,000	9.8	\$1.40	1,250,000	\$ 1.40
	3,765,000	9.6	\$1.22	1,250,000	\$ 1.40

Warrant activity under the Plan for the year ended December 31, 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	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	-	-	-	-

A summary of warrants outstanding and exercisable as of December 31, 2008:

Range of Exercise Prices	Number Outstanding	Options Outstanding		Options Exercisable	
		Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$0.90	85,620	4.9	\$0.90	85,620	\$ 0.90
	85,620	4.9	\$0.90	85,620	\$ .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 1,615,000 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.

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.

10. Commitments and Contingencies

Technology License - The Company has executed an exclusive license from MD Anderson to develop drug delivery technology for antisense and siRNA drug products. This license requires, among other things, the Company to reimburse MD Anderson for ongoing patent expense. The Company estimates these expenses will total approximately \$275,000. The Company estimates that it will be required to pay patent expenses at the minimum 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 by the end of the second quarter 2009. In 2008, the Company paid \$292,800 to this manufacturer under this agreement that is carried at cost as Drug Product for Testing on the balance sheet (see Note 4.) and recorded an additional \$154,000 in R&D expense for unplanned additional manufacturing development. The Company expects to pay an additional \$577,200 to this supplier when it delivers clinical grade drug product for testing in the Company's clinical trial.

Placement Agent Agreement – In the fourth quarter of 2008, 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 commission to the Placement Agent for funds raised. This Agreement will be in effect into the second quarter of 2009.

11. Income Taxes

At December 31, 2008, the Company has a net operating loss carryforward for Federal income tax purposes of \$1,629,057 which expires in varying amounts during the tax years 2027 and 2028. The Company recorded an increase in the valuation allowance of \$509,274 for the year ended December 31, 2008.

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

	December 31,	
	2008	2007
Net Operating Loss (NOL) Carryover	\$ 553,879	\$ 97,373
Share Based Expense	52,767	-
Total Deferred Tax Asset	606,646	97,373
Less: Valuation Allowance	(606,646)	(97,373)
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,	
	2008	2007
Loss Before Income Taxes	\$ (2,852,767)	\$ (281,397)
Tax Benefit @ Statutory Tax Rate	969,941	98,487
Effects of:		
Exclusion of ISO Expense	(457,654)	
(Increase)/Decrease in Valuation Allowance	(509,274)	(97,373)
Other	(3,013)	(1,114)
Provision (Benefit) for Income Taxes	\$ -	\$ -

The Company adopted the provisions of Financial Accounting Standards, or FASB Interpretation No. 48 “Accounting for Uncertainty in Income Taxes — An Interpretation of FASB Statement No. 109,” or FIN 48, on June 1, 2007. As of December 31, 2008 and 2007, 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, 2008 and 2007 is presented in the table below:

	December 31,	
	2008	2007
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, 2008, and 2007.

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.

## 12. Subsequent Events

In July of 2008, Bio-Path initiated discussions with M. D. Anderson for commencement of a Phase I clinical trial for its first cancer drug product. The Company has negotiated an agreement with M. D. Anderson for the conduct of this clinical trial, but is waiting on approval of revisions to the protocol for the clinical trial that have been submitted to M. D. Anderson’s Institutional Review Board for approval. The expected cost of M. D. Anderson’s services to conduct this trial is now expected to be approximately \$240,000. The Company expects the revised protocol to be approved by the end of the first quarter or early second quarter 2009.





