BIO-PATH HOLDINGS INC
Form 424B3
July 29, 2010

This filing is made pursuant to Rule 424(b)(3)
under the Securities Act of 1933, as amended, in connection
with Registration No. 333-167600

PROSPECTUS

Bio-Path Holdings, Inc.

7,000,000 SHARES OF COMMON STOCK

This prospectus relates to the offer and sale, from time to time, of up to 7,000,000 shares of common stock, no par value, of Bio-Path Holdings, Inc., a Utah corporation, held by or issuable to Lincoln Park Capital Fund, LLC, or LPC or the selling stockholder. The common shares being offered by the selling stockholder are outstanding or issuable pursuant to the LPC Purchase Agreement. See “The LPC Transaction” for a description of the LPC Purchase Agreement. The prices at which the selling stockholder may sell the shares will be determined by the prevailing market price for the shares or in negotiated transactions. We do not know when or in what amount the selling stockholder may offer the shares for sale. See "Plan of Distribution" on page 43 for a description of how the selling stockholder may dispose of the shares covered by this prospectus. We will not receive proceeds from the sale of our shares by the selling stockholder; however, we may receive proceeds of up to $7 million under the LPC Purchase Agreement. We have agreed to pay certain expenses related to the registration of the shares of common stock pursuant to the registration statement of which this prospectus forms a part.

Our common stock is registered under Section 12(g) of the Securities Exchange Act of 1934, as amended, and quoted on the Over-The-Counter Bulletin Board, or OTCBB, under the symbol "BPTH.OB." On July 23, 2010, the last reported sale price for our common stock as reported on the OTCBB was $0.40 per share.

Lincoln Park Capital Fund, LLC is an "underwriter" within the meaning of the Securities Act of 1933, as amended.

For information regarding sales of securities covered by this prospectus in certain states, see the back cover page of this prospectus. Brokers or dealers effecting transactions in these shares should confirm that the shares are registered under the applicable state law or that an exemption from registration is available.

INVESTING IN OUR COMMON STOCK INVOLVES SUBSTANTIAL RISKS. SEE THE SECTION TITLED "RISK FACTORS" BEGINNING ON PAGE 3 OF THIS PROSPECTUS TO READ ABOUT FACTORS YOU SHOULD CONSIDER BEFORE BUYING SHARES OF OUR COMMON STOCK.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR PASSED UPON THE ADEQUACY OR ACCURACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this prospectus is July 29, 2010.

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You should rely only on the information contained in this prospectus or any related prospectus supplement, including the content of all documents incorporated by reference into the registration statement of which this prospectus forms a part. We have not authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. The information contained in this prospectus or incorporated by reference herein is accurate only on the date of this prospectus. Our business, financial condition, results of operations and prospects may have changed since such date. Other than as required under the federal securities laws, we undertake no obligation to publicly update or revise such information, whether as a result of new information, future events or any other reason.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary does not contain all of the information that you should consider before making an investment decision with respect to our securities. You should read this entire prospectus, including all documents incorporated by reference, carefully, especially the "Risk Factors" section beginning on page 3 of this prospectus and our financial statements and related notes contained in this prospectus before making an investment decision with respect to our securities. Please see the section titled, "Where You Can Find More Information," beginning on page 48 of this prospectus. Unless the context indicates otherwise, references to "Bio-Path," "the Company," "we," "us," or "our," refers to Bio-Path Holdings, Inc. and our wholly-owned subsidiary, Bio-Path, Inc. Our wholly-owned subsidiary, Bio-Path, Inc., is sometime hereafter referred to as "Bio-Path Subsidiary."

Some of the industry data contained in this prospectus is derived from data from various third-party sources. We have not independently verified any of this information and cannot assure you of its accuracy or completeness. While we are not aware of any misstatements regarding any industry data presented herein, such data is subject to change based on various factors, including those discussed under the "Risk Factors" section beginning on page 3 of this prospectus.

We have provided definitions for some of the industry terms used in this prospectus in the "Glossary of Terms" on page A-1 of this prospectus.

Overview

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

We believe that our core technology, if successful, will enable us to be at the center of emerging genetic and molecular target-based therapeutics that require systemic delivery of DNA and RNA-like material. Our two lead drug candidates treat acute myeloid leukemia, chronic myelogenous leukemia, acute lymphoblastic leukemia and follicular lymphoma, and if successful, could potentially be used in treating many other indications of cancer. We have received written notification from the U. S. Food and Drug Administration, or the FDA, that our application for Investigational New Drug, or IND, status for the first of our lead drug candidates has been granted. This will allow us to begin a Phase I clinical trial in this drug candidate. We expect to start the Phase I clinical trial in 2010.

The Company was founded in May of 2007 as a Utah corporation. In February of 2008, we completed a reverse merger with Ogden Golf Co. Corporation, a public company traded over the counter that had no current operations. The name of Ogden Golf was changed to Bio-Path Holdings, Inc. and the directors and officers of Bio-Path, Inc. became the directors and officers of Bio-Path Holdings, Inc. Bio-Path has become a publicly traded company (symbol OTCBB: BPTH.OB) as a result of this merger. Our operations to date have been limited to organizing and staffing the Company, acquiring, developing and securing its technology and undertaking product development for a limited number of product candidates including readying its lead drug product candidate BP-100-1.01 for a Phase I clinical trial.

Our principal executive offices are located at 3293 Harrison Boulevard, Suite 220, Ogden, UT 84403 and our telephone number is (801) 399-5500.

THE OFFERING

On June 2, 2010, we executed a purchase agreement, or the LPC Purchase Agreement, and a registration rights agreement, or the LPC Registration Rights Agreement, with Lincoln Park Capital Fund, LLC, or LPC, pursuant to which LPC has purchased 571,429 shares of our common stock together with warrants to purchase an equivalent number of shares at an exercise price of $1.50 per share, for total consideration of $200,000. The warrants have a term of two years. Under the LPC Purchase Agreement, we also have the right to sell to LPC up to an additional $6,800,000 of our common stock at our option as described below. The resale of the 571,429 shares of our common stock and the shares of common stock issuable upon exercise of the warrants purchased by LPC have not been registered and are not a part of this offering.

Pursuant to the LPC Purchase Agreement and the LPC Registration Rights Agreement, we filed a registration statement that included a preliminary prospectus with the U.S. Securities and Exchange Commission, or the SEC, that covered 566,801 shares that have been issued and up to 6,433,199 of the shares that may be issued to LPC under the LPC Purchase Agreement as of such date. Except for the initial 571,429 shares of common stock purchased by LPC, we did not have the right to commence any sales of our shares to LPC until the SEC had declared effective the registration statement of which that prospectus was a part. The SEC declared effective the registration statement on July 12, 2010. On July 16, 2010, LPC purchased 375,000 shares at a purchase price of $.40 per share for total consideration of $150,000. Over approximately the next 24 months, we generally have the right to direct LPC to purchase up to an additional $6,650,000 of our common stock in amounts up to $50,000 as often as every three business days under certain conditions. We can also accelerate the amount of our common stock to be purchased under certain circumstances. No sales of shares may occur at a purchase price below $0.20 per share. The purchase price of the shares will be based on the market prices of our shares at the time of sale as computed under the LPC Purchase Agreement without any fixed discount. We may at any time in our sole discretion terminate the LPC Purchase Agreement without fee, penalty or cost upon one business days notice. We issued 566,801 shares of our common stock to LPC as a commitment fee for entering into the LPC Purchase Agreement, and we may issue up to 283,401 shares pro rata as LPC purchases up to an additional $6,800,000 of our common stock as directed by us.

7,000,000 shares are offered hereby by LPC consisting of 5,774,798 shares of our common stock that we may sell to LPC in the future, 375,000 we issued on July 16, 2010, 573,052 shares we have issued as a commitment fee, and 277,150 shares that we are obligated to issue to LPC as a commitment fee pro rata as up to an additional $6,650,000 of our stock is purchased by LPC. If all of the 7,000,000 shares offered by LPC hereby were issued and outstanding as of June 30, 2010, such shares would represent 12.7% of the total common stock outstanding or 21.2% of the non-affiliates shares outstanding. The number of shares ultimately offered for sale by LPC hereunder is dependent upon the number of shares that we sell to LPC under the LPC Purchase Agreement. See also the section titled "The LPC Transaction" on page 45.

Please refer to the section titled "Selling Stockholder" beginning on page 41.

The Company is not selling any shares of common stock in this offering and therefore will not receive any proceeds from this offering; however, we may receive proceeds of up to $7,000,000 under the LPC Purchase Agreement. All costs associated with this registration statement will be borne by the Company.

Shares of common stock are being offered for sale by the selling stockholder at prices established on the Over-the-Counter Bulletin Board, or the OTCBB, during the term of this offering. On July 23, 2010, the last reported sale price of our common stock was $0.40 per share. Our common stock is quoted on the OTCBB under the symbol "BPTH.OB". These prices will fluctuate based on the demand for the shares of our common stock.

Common stock offered by the selling stockholder:	7,000,000 shares

Offering price:	Market price
Common stock outstanding (held by non affiliates) as of June 30, 2010:	48,617,832 shares (26,649,362 shares)
Use of proceeds:	The selling stockholder will receive all net proceeds from sale by it of our common stock covered by this prospectus; however, we may receive proceeds of up to $7 million under the LPC Purchase Agreement. See "Use of Proceeds" on page 17.
Risk Factors	See "Risk Factors" beginning on page 3 and other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in the shares.
Ticker Symbol:	BPTH.OB

RISK FACTORS

An investment in our securities involves a high degree of risk. Before you decide to invest in our securities, you should consider carefully all of the information in this registration statement, including the risks described below, as well as other information included in this prospectus, particularly the specific risk factors discussed in the sections titled "Risk Factors" contained in our filings with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended. Any of these risks could have a material adverse effect on our business, prospects, financial condition and results of operations. In any such case, the trading price of our common stock could decline and you could lose all or part of your investment. You should also refer to the other information contained in this prospectus, or incorporated herein by reference, including our financial statements and the notes to those statements, and the information set forth under the caption "Forward Looking Statements." The risks described below and contained in our other periodic reports are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also adversely affect our business operations.

Risks Related to Our Business

We are a development stage company with no revenue.

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 and does not expect any revenues to be generated in the foreseeable future. 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. The drug development process is a lengthy process and no revenues from product sales will be generated for years, if ever. 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.

We require substantial additional capital, which if not obtained could result in a need to curtail or cease operations.

Our business plan calls for us to raise an additional approximately $10,000,000 from the sale of our securities in order to accomplish our near term objectives. As of June 30, 2010, we have raised approximately $5,117,256 in gross funds and $4,626,181 in net funds after the payment of certain commissions. The LPC Purchase Agreement may provide us with up to $7,000,000 in equity financing which should help to fund our operations for the next two (2) years. After such time, we will be required to raise 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 may direct LPC to purchase up to an additional $6,650,000 worth of shares of our common stock under the LPC Purchase Agreement over approximately the next 24 months generally in amounts of up to $50,000 every three business days. However, LPC will not have the right nor the obligation to purchase any shares of our common stock on any business day that the market price of our common stock is less than $0.20. Assuming a purchase price of $0.40 per share (the closing sale price of the common stock on July 23, 2010) and the purchase by LPC of the full 5,774,798 shares in the future under the LPC Purchase Agreement, proceeds to us would be $2,309,919.

The extent we rely on LPC as a source of funding will depend on a number of factors including, the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources.

Specifically, LPC will not have the right nor the obligation to purchase any shares of our common stock on any business days that the market price of our common stock is less than $0.20. If obtaining sufficient funding from LPC were to prove unavailable or prohibitively dilutive and if we are unable to sell enough of our products, we will need to secure another source of funding in order to satisfy our working capital needs. Even if we sell all $7,000,000 under the LPC Purchase Agreement to LPC, we will still need additional capital to fully implement our business, operating and development plans.

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. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, 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. The consequences could have a material adverse effect on our business, operating results, financial condition and prospects.

We have had a history of operating losses and we may never achieve profitability. If we continue to incur operating losses, we may be unable to continue our operations.

From inception on May 10, 2007 through March 31, 2010, we had a cumulative loss of $5,594,844. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. In the absence of substantial revenue from the sale of products or other sources, the amount, timing, nature or source of which cannot be predicted, our losses will continue as we conduct our research and development activities.

Successful development of any of our product candidates is highly uncertain.

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

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is highly uncertain. If any of our drug trials are delayed or yield unfavorable results, we will have to delay or may be unable to obtain regulatory approval for our product candidates.

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

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

We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use.

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

Conflicts with our collaborators could jeopardize the success of our collaborative agreements and harm our product development efforts.

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

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

- disputes may arise in the future with respect to the ownership of rights to technology developed with collaborators;
- disagreements with collaborators could delay or terminate the research, development or commercialization of products, or result in litigation or arbitration;
- we may have difficulty enforcing the contracts if one of our collaborators fails to perform;
- our collaborators may terminate their collaborations with us, which could make it difficult for us to attract new collaborators or adversely affect the perception of us in the business or financial communities;
- collaborators will have considerable discretion in electing whether to pursue the development of any additional drugs and may pursue technologies or products either on their own or in collaboration with our competitors that are similar to or competitive with our technologies or products that are the subject of the collaboration with Bio-Path; and
- our collaborators may change the focus of their development and commercialization efforts. Pharmaceutical and biotechnology companies historically have re-evaluated their priorities following mergers and consolidations, which have been common in recent years in these industries. The ability of our products to reach their potential could be limited if our collaborators decrease or fail to increase spending relating to such products.

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

We rely on third party manufacturers to supply our product candidates, which could delay or prevent the clinical development and commercialization of our product candidates.

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 product candidate BP-100-1.01. Althea is a manufacturer that operates under the FDA's current good manufacturing practices, or 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.

If we do not obtain the support of new, and maintain the support of existing, key scientific collaborators and management staff, it may be difficult to develop and commercialize products using our technologies as a standard of care for various indications, which may limit our revenue growth and profitability and could have a material adverse effect on our business, prospects, financial condition and operating results.

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.

If we are unable to obtain, maintain and enforce our proprietary rights, we may not be able to compete effectively or operate profitably.

We have entered into three license agreements with M.D. Anderson. The patents underlying the licensed intellectual property and positions, and those of other biopharmaceutical companies, are generally uncertain and involve complex legal, scientific and factual questions.

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

- obtain and/or develop broad, protectable intellectual property;
- obtain additional licenses to the proprietary rights of others on commercially reasonable terms;
- operate without infringing upon the proprietary rights of others;
- prevent others from infringing on our proprietary rights; and
- protect trade secrets.

We do not know whether any of the patent applications which we 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 we nor our licensors can be certain that either we or our licensors were the first to make the inventions claimed in issued patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in these patent applications.

The patent positions of pharmaceutical and biopharmaceutical products are complex and uncertain.

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.

If we are unable to maintain and enforce our proprietary rights, we may not be able to compete as effectively and our business and financial prospects may be harmed.

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

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

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

The market for our services is highly competitive and is subject to rapid scientific change, which could have a material adverse affect on our business, results of operations and financial condition.

The pharmaceutical and biotechnology industry is highly competitive and characterized by rapid and significant technological change. We 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.

Our product candidates may never achieve market acceptance even if we obtain regulatory approvals.

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.

M. D. Anderson, our sole licensor, may under certain circumstances terminate our license agreements, which are required for us to conduct our proposed business. In addition, we can provide no assurance that M.D. Anderson will continue to license its intellectual property rights to us.

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, have a commercial sale of a licensed product within an agreed upon period of time or raise certain amounts of capital. If any 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.

We lack sales, marketing and distribution capabilities and will rely on third parties to market and distribute our drug candidates, which may harm or delay our product development and commercialization efforts.

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.

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for a product candidate and may have to limit its commercialization.

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. Although we intend to obtain product liability or clinical trial insurance prior to commencing our planned Phase I clinical trial for our product candidate BP-100-1.01, 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.

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.

Our competitors may develop products that make our products obsolete.

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.

We will incur increased costs as a result of recently enacted and proposed changes in laws and regulations and our management will be required to devote substantial time to comply with such laws and regulations.

We face burdens relating to the recent trend toward stricter corporate governance and financial reporting standards. Legislation or regulations such as Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as other rules implemented by the SEC, follow the trend of imposing stricter corporate governance and financial

reporting standards have led to an increase in the costs of compliance for companies similar to us, including increases in consulting, auditing and legal fees. New rules could make it more difficult or more costly for us to obtain certain types of insurance, including directors' and officers' liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. Failure to comply with these new laws and regulations may impact market perception of our financial condition and could materially harm our business. Additionally, it is unclear what additional laws or regulations may develop, and we cannot predict the ultimate impact of any future changes in law. Our management and other personnel will need to devote a substantial amount of time to these requirements.

In addition, the Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Our compliance with Section 404 will require that we incur substantial accounting and related expense and expend significant management efforts. In the future, we may need to hire additional accounting and financial staff to satisfy the ongoing requirements of Section 404. Moreover, if we are not able to comply with the requirements of Section 404, or we or our independent registered public accounting firm identifies deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations, the SEC or other regulatory authorities.

Risks Related to Our Industry

Any failure or delay in commencing or completing clinical trials for our product candidates could severely harm our business.

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

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

We have limited experience in designing, conducting, and managing the clinical testing necessary to obtain such regulatory approval. Satisfaction of these regulatory requirements, which includes satisfying the FDA and foreign regulatory authorities that the product is both safe and effective for its intended therapeutic uses, typically takes several years depending upon the type, complexity and novelty of the product and requires the expenditure of substantial resources. In addition to our internal resources, we will depend on regulatory consultants and our 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.

If we fail to demonstrate efficacy in our preclinical studies and clinical trials our future business prospects, financial condition and operating results will be materially adversely affected.

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

The results from preclinical testing of a drug candidate that is under development may not be predictive of results that will be obtained in human clinical trials. In addition, the results of early human clinical trials may not be predictive of results that will be obtained in larger scale, advanced stage clinical trials. A failure of one or more of our clinical trials can occur at any stage of testing. Further, there is to date no data on the long-term clinical safety of our lead compounds under conditions of prolonged use in humans, nor on any long-term consequences subsequent to human use. We may experience numerous unforeseen events during, or as a result of, preclinical testing and the clinical trial process that could delay or prevent its ability to receive regulatory approval or commercialize our products, including:

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

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

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

- the availability of alternative treatments.

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

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

If any products we develop become subject to unfavorable pricing regulations, third party reimbursement practices or healthcare reform initiatives, our ability to successfully commercialize our products will be impaired.

Our future revenues, profitability and access to capital will be affected by the continuing efforts of governmental and private third party payors to contain or reduce the costs of health care through various means. We expect a number of federal, state and foreign proposals to control the cost of drugs through government regulation. We are unsure of the impact recent health care reform legislation may have on our business or what actions federal, state, foreign and private payors may take in response to the recent reforms. Therefore, it is difficult to provide the effect of any implemented reform on our business. Our ability to commercialize our products successfully will depend, in part, on the extent to which reimbursement for the cost of such products and related treatments will be available from government health administration authorities, such as Medicare and Medicaid in the United States, private health insurers and other organizations. Significant uncertainty exists as to the reimbursement status of newly approved health care products, particularly for indications for which there is no current effective treatment or for which medical care typically is not sought. Adequate third party coverage may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product research and development. If adequate coverage and reimbursement levels are not provided by government and third party payors for use of our products, our products may fail to achieve market acceptance and our results of operations will be harmed.

Regulatory and legal uncertainties could result in significant costs or otherwise harm our business.

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

Our product candidates are based on new technology and, consequently, are inherently risky. Concerns about the safety and efficacy of our products could limit our future success.

We are subject to the risks of failure inherent in the development of product candidates based on new technologies. These risks include the possibility that the products we create will not be effective, that our product candidates will be unsafe or otherwise fail to receive the necessary regulatory approvals or that our product candidates will be hard to manufacture on a large scale or will be uneconomical to market.

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

Unsuccessful or delayed regulatory approvals required to exploit the commercial potential of our future products could increase our future development costs or impair our future sales.

No Bio-Path technologies have been approved by the FDA for sale in the United States or in foreign countries. To exploit the commercial potential of our technologies, we are conducting and planning to conduct additional pre-clinical studies and clinical trials. This process is expensive and can require a significant amount of time. Failure

can occur at any stage of testing, even if the results are favorable. Failure to adequately demonstrate safety and efficacy in clinical trials would prevent regulatory approval and restrict our ability to commercialize our technologies. Any such failure may severely harm our business. In addition, any approvals obtained may not cover all of the clinical indications for which approval is sought, or may contain significant limitations in the form of narrow indications, warnings, precautions or contraindications with respect to conditions of use, or in the form of onerous risk management plans, restrictions on distribution, or post-approval study requirements.

Federal and State pharmaceutical marketing compliance and reporting requirements may expose us to regulatory and legal action by state governments or other government authorities.

The Food and Drug Administration Modernization Act, or the FDMA, established a public registry of open clinical trials involving drugs intended to treat serious or life-threatening diseases or conditions 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. 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.

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.

Other companies may claim that we infringe their intellectual property or proprietary rights, which could cause us to incur significant expenses or prevent us from selling products.

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

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

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

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

Any inability to protect intellectual property rights in the United States and foreign countries could limit our ability to manufacture or sell products.

We will rely on trade secrets, unpatented proprietary know-how, and continuing technological innovation and, in some cases, patent protection to preserve a competitive position. Our patents and licensed patent rights may be challenged, invalidated, infringed or circumvented, and the rights granted in those patents may not provide proprietary protection or competitive advantages to us. We and our licensors may not be able to develop patentable products. Even if patent claims are allowed, the claims may not issue, or in the event of issuance, may not be sufficient to protect the technology owned by or licensed to us. Third party patents could reduce the coverage of the patent's license, or that may be licensed to or owned by us.

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

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

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

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

Risks Related to Our Common Stock

There are a substantial number of shares of our common stock eligible for future sale in the public market, and the issuance or sale of equity, convertible or exchangeable securities in the market, or the perception of such future sales or issuances, could lead to a decline in the trading price of our common stock.

Our authorized capital consists of 200,000,000 shares of common stock and 10,000,000 shares of preferred stock. Any issuance of equity, convertible or exchangeable securities, including for the purposes of financing acquisitions and the expansion of our business, may have a dilutive effect on our existing stockholders. In addition, the perceived risk associated with the possible issuance of a large number of shares of our common stock or securities convertible or exchangeable into a large number of shares of our common stock could cause some of our stockholders to sell their common stock, thus causing the trading price of our common stock to decline. Subsequent sales of our common stock in the open market or the private placement of our common stock or securities convertible or exchangeable into our common stock could also have an adverse effect on the trading price of our common stock. If our common stock price declines, it may be more difficult for us to or we may be unable to raise additional capital.

In addition, future sales of substantial amounts of our currently outstanding common stock in the public market, or the perception that such sales could occur, could adversely affect prevailing trading prices of our common stock, and could impair our ability to raise capital through future offerings of equity or equity-related securities. We cannot predict what effect, if any, future sales of our common stock, or the availability of shares for future sales, will have on the trading price of our common stock.

We have also issued a significant number of warrants to purchase shares of our common stock. These stock issuances and other future issuances of common stock underlying unexpired and unexercised warrants have and will result in, significant dilution to our stockholders. In connection with other collaborations, joint ventures, license agreements or future financings that we may enter into in the future, we may issue additional shares of common stock or other equity securities, and the value of the securities issued may be substantial and create additional dilution to our existing and future common stockholders.

We can issue shares of preferred stock that may adversely affect the rights of a stockholder of our common stock.

Our articles of incorporation authorize us to issue up to 10,000,000 shares of preferred stock with designations, rights and preferences determined from time-to-time by our board of directors without any action by our stockholders. Accordingly, our board of directors is empowered, without stockholder approval, to issue preferred stock with dividend, liquidation, conversion, voting or other rights superior to those of stockholders of our common stock. 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.

The sale of our common stock to LPC may cause dilution and the sale of the shares of common stock acquired by LPC could cause the price of our common stock to decline.

In connection with entering into the LPC Purchase Agreement, we authorized the sale to LPC of up to 7,000,000 shares of our common stock. The number of shares ultimately offered for sale by LPC under this prospectus is dependent upon the number of shares purchased by LPC under the LPC Purchase Agreement. The purchase price for the common stock to be sold to LPC pursuant to the LPC Purchase Agreement will fluctuate based on the price of our common stock. All 7,000,000 shares registered in this offering are expected to be freely tradable. It is anticipated that shares registered in this offering will be sold over approximately the next 24 months. Depending upon market liquidity at the time, a sale of shares under this offering at any given time could cause the trading price of our common

stock to decline. We can elect to direct purchases in our sole discretion but no sales may occur if the price of our common stock is below $0.20 and therefore, LPC may ultimately purchase all, some or none of the 7,000,000 shares of common stock not yet issued but registered in this offering. After it has acquired such shares, it may sell all, some or none of such shares. Therefore, sales to LPC by us under the LPC Purchase Agreement may result in substantial dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock under this offering, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. However, we have the right to control the timing and amount of any sales of our shares to LPC and the LPC Purchase Agreement may be terminated by us at any time at our discretion without any cost to us.

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 "Over-The-Counter 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 may be volatile. Factors such as announcements of fluctuations in our or our competitors' operating results or clinical or scientific results, regulatory matters, new or existing products or procedures, concerns about our financial position, operating results, litigation, government regulation, developments or disputes relating to agreements, patents or proprietary rights, 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. 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 July 23, 2010, the closing sales price of our common stock fluctuated from a low of $0.27 per share to a high of $6.00 per share. In addition, potential dilutive effects of future sales of shares of common stock by stockholders and by the Company, including LPC pursuant to this prospectus and subsequent sale of common stock by the holders of warrants and options could have an adverse effect on the market price of our common stock. 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.

Our stock is a penny stock. Trading of our stock may be restricted by the SEC's penny stock regulations and the FINRA's sales practice requirements, which may limit a stockholder's ability to buy and sell our stock.

Our common stock is considered to be a "penny stock." The SEC has adopted rules under Section 15(g) of the Securities Exchange Act of 1934, as amended, which generally defines "penny stock" to be any equity security that meets one or more of the following: (i) has a market price less than $5.00 per share, or an exercise price of less than $5.00 per share, subject to certain exceptions; (ii) is NOT traded on a "recognized" national exchange; (iii) 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. Our securities are covered by the penny stock rules, which impose additional sales practice requirements on broker-dealers who sell to persons other than established customers and institutional accredited investors. The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document in a form prepared by the SEC which provides information about penny stocks and the nature and level of risks in the penny stock market. The broker-dealer also must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and its salesperson in the transaction and monthly account statements showing the market value of each penny stock held in the customer's account. The bid and offer quotations, and the broker- dealer and salesperson compensation information, must be given to the customer orally or in writing prior to effecting the transaction and must be given to the customer in writing before or with the customer's confirmation. In addition, the penny stock rules require that prior to a transaction in a penny stock not otherwise exempt from these rules, the broker-dealer must make a special written determination that the penny stock is a suitable

investment for the purchaser and receive the purchaser's written agreement to the transaction. These disclosure requirements may have the effect of reducing the level of trading activity in the secondary market for the stock that is subject to these penny stock rules. Consequently, these penny stock rules may affect the ability of broker-dealers to trade our securities. We believe that the penny stock rules discourage investor interest in and limit the marketability of our common stock. Potential investors in our common stock are urged to obtain and read such disclosure documents and information carefully before purchasing any securities that are deemed to be "penny stock."

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

Limitation on director liability.

As permitted by Utah law, our Articles of Incorporation limit the liability of directors to the Company or its 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 shareholders may have limited rights to recover against directors for breach of fiduciary duty.

FORWARD-LOOKING STATEMENTS

This prospectus, other filings with the SEC, and press releases and other public statements by our management throughout the year contain forward-looking statements that have been made pursuant to the provisions of the Private Securities Litigation Reform Act of 1995. All such statements, other than statements of historical facts, including our financial condition, future results of operation, projected revenues and expenses, business strategies, operating efficiencies or synergies, competitive positions, growth opportunities for existing intellectual properties, technologies, products, plans, and objectives of management, markets for our securities, and other matters, are about us and our industry that involve substantial risks and uncertainties and constitute forward-looking statements for the purpose of the safe harbor provided by Section 27A of the Securities Act and Section 21E of the Exchange Act. Such forward-looking statements are based on expectations, estimates and projections about our industry, management's beliefs, and certain assumptions made by our management on the date on which they were made, or if no date is stated, as of the date of the filing made with the SEC in which such statements were made, and may include those described in the section titled "Risk Factors," and including, but not limited to, the following:

- the sufficiency of our existing capital resources and projected cash needs;
- our ability to obtain additional financing;
- our clinical trials, commencement dates for new clinical trials, clinical trial results, evaluation of our clinical trial results by regulatory agencies in other countries;
- the potential benefits and commercial potential of our potential products;
- the uncertainties involved in the drug development process and manufacturing;
- the early stage of the products we are developing;
- our dependence on a limited number of therapeutic compounds;
- the acceptance of any of our future products by physicians and patients;
- level of future sales, if any;
- collections, costs, expenses, capital requirements and 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;
- need for additional research and testing;
- dependence on collaborative partners;
- our ability to obtain adequate intellectual property protection and to enforce these rights;

- our ability to avoid infringement of the intellectual property rights of others;
- our future research and development activities;
- assessment of competitors and potential competitors;
- potential costs resulting from product liability or other third-party claims;
- assessment of impact of recent accounting pronouncements;
- government regulation and approvals;

- loss of key management or scientific personnel; and

- the other factors and risks described under the section captioned "Risk Factors" as well as other factors not identified therein.

Words such as "anticipates," "believes," "estimates," "expects," "plans," "may," "might," "will," "could," "seeks," "should," "would," "projects," "predicts," "intends," "continues," "potential," "opportunity" or the negative of these terms or other comparable terminology 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. You should not place undue reliance on these statements, which only reflect information available as of the date that they were made. We cannot give you any assurance that such forward-looking statements will prove to be accurate and such forward-looking events may not occur. In light of the significant uncertainties inherent in such forward-looking statements, you should not regard the inclusion of this information as a representation by us or any other person that the results or conditions described in those statements or our objectives and plans will be achieved. 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 SEC.

All subsequent forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to herein.

USE OF PROCEEDS

This prospectus relates to shares of our common stock that may be offered and sold from time to time by the selling stockholder. We will receive no proceeds from the sale of shares of common stock in this offering; however, we may receive proceeds of up to $7,000,000 under the LPC Purchase Agreement. Any proceeds from LPC that we receive under the LPC Purchase Agreement will be used for working capital and general corporate purposes.

MARKET PRICE AND DIVIDEND INFORMATION

Our common stock is quoted on the OTCBB under the symbol "BPTH.OB." As of June 30, 2010, there were 48,617,832 shares of our common stock issued outstanding and 226 stockholders of record. Of those shares of outstanding common stock, 37,840,376 shares are deemed "restricted securities," within the meaning of Rule 144 promulgated under the Securities Act, and may not be sold in the absence of registration under the Securities Act, unless an exemption from registration is available, including the exemption provided by Rule 144. Subject to the satisfaction of certain conditions, as of June 30, 2010, there were 34,735,146 shares of "restricted" common stock that could be sold pursuant to the limitations provided by Rule 144. As of June 30, 2010, we had 3,765,000 shares of common stock reserved for issuance upon exercise of outstanding options and 5,697,049 reserved for issuance upon exercise of outstanding warrants (inclusive of the common stock underlying the warrants issued to LPC on June 2, 2010). We have agreed to register the resale of the shares of common stock to be issued upon exercise of the outstanding warrants under certain circumstances, except for the warrants held by LPC. We have no shares of preferred stock outstanding.

There has only been limited trading in our common stock. The following table sets forth, for the quarterly period indicated, the range of high and low sales prices for our common stock as reported by the OTCBB during 2010, 2009 and 2008.

	High	Low
Fiscal Year Ended December 31, 2008		
First Fiscal Quarter (beginning March 4, 2008)	$ 0.90	$ 0.52
Second Fiscal Quarter	$ 6.00	$ 0.90
Third Fiscal Quarter	$ 2.60	$ 1.00
Fourth Fiscal Quarter	$ 1.40	$ 0.20
Fiscal Year Ended December 31, 2009		
First Fiscal Quarter	$ 1.01	$ 0.12
Second Fiscal Quarter	$ 0.31	$ 0.15
Third Fiscal Quarter	$ 0.55	$ 0.12
Fourth Fiscal Quarter	$ 0.52	$ 0.26
Fiscal Year Ending December 31, 2010		
First Fiscal Quarter	$ 0.71	$ 0.25
Second Fiscal Quarter	$ 0.47	$ 0.33
Third Fiscal Quarter (Through July 23, 2010)	$ 0.40	$ 0.35

On July 23, 2010, the last reported sale price for our common stock as reported on the OTCBB was $0.40 per share.

Dividends

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

Equity Compensation Plan Information

Plan Category	Number of shares of common stock to be issued upon exercise of outstanding options	Weighted-average exercise price of outstanding options	Weighted-average term to expiration of options outstanding	Number of shares of common stock remaining available for future issuance under equity compensation plans
Equity compensation plans approved by stockholders (1)(2)	3,765,000	$ 1.22	8.1 yrs	3,235,000
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 June 30, 2010.

(2) There are a total of 2,367,204 options that have vested as of June 30, 2010 under the 2007 Stock Incentive Plan. Within sixty days from June 30, 2010 there will be an additional 69,444 vested options bringing the total number of options vested through such period to 2,436,648.

DESCRIPTION OF BUSINESS

Bio-Path Holdings, Inc. through our wholly-owned subsidiary Bio-Path, Inc., or Bio-Path Subsidiary, is engaged in the business of financing and facilitating the development of novel cancer therapeutics. Our initial plan is and continues to be, the acquisition of licenses for drug technologies from The University of Texas M. D. Anderson Cancer Center, or M. D. Anderson, funding clinical and other trials for such technologies and commercializing such technologies. We have acquired three exclusive licenses, or the License Agreements, from M. D. Anderson for three lead products and related nucleic acid drug delivery technology including tumor targeting technology. These licenses specifically provide drug delivery platform technology with composition of matter intellectual property that enables systemic delivery of antisense, small interfering RNA, or siRNA, and potentially small molecules for the 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 drug candidates. 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 through proof of concept into a safety study (Phase I), to human efficacy trials (Phase IIA), and then out-license each successful potential drug to a pharmaceutical company.

Research and Development

Our research and development is currently conducted through agreements we have with M. D. Anderson. Research continues using grant funds at M. D. Anderson, and research in areas within the scope of our current license agreements will continue to benefit the Company.

Recent Updated Information

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

Basic Technical Information

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

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

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

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

BP-100-1.01

BP-100-1.01 is our lead lipid delivery RNAi drug, which will be clinically tested for validation in Acute Myeloid Leukemia (AML), Myelodysplastic Syndrome (MDS) and Chronic Myelogenous Leukemia (CML). If this outcome is favorable, we expect there will be opportunities to negotiate non-exclusive license applications involving upfront cash payments with pharmaceutical companies developing antisense drugs that need systemic delivery technology.

The IND for BP-100-1.01 was submitted to the FDA in February of 2008 and included all in vitro testing, animal studies and manufacturing and chemistry control studies completed. The FDA requested some changes be made to the application submission. We resubmitted information to the FDA in response to such request. On March 12, 2010, we issued a press release announcing that the US Food and Drug Administration (FDA) has allowed an IND (Investigational New Drug) for Bio-Path's lead cancer drug candidate liposomal BP-100-1.01 to proceed into clinical trials. The IND review process was performed by the FDA's Division of Oncology Products and involved a comprehensive review of data submitted by us covering pre-clinical studies, safety, chemistry, manufacturing, and controls, and the protocol for the Phase I clinical trial. We anticipate that patient enrollment and final preparations for the Phase I clinical trial will start sometime during Fiscal Year 2010. We believe the trial will commence by the end of the second quarter, but there can be no assurance or exact time estimates. The primary objective of the Phase I clinical trial, as in any Phase I clinical trial, is the safety of the drug for treatment of human patients. An additional key objective of the trial is to assess that the effectiveness of the delivery technology.

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

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

We are also required to supply M. D. Anderson with the actual drugs to be administered to the patients in the study. We have entered into a drug supply contract with Althea Technologies which will produce sufficient drugs for testing through two rounds. We expect to pay no more than $150,000 to Althea to complete payments under the current contract. Drug costs for the entire study could cost an additional $1 million including requirements for drug candidate test article for additional treatments of the patients if the drug is having a positive effect on the patients' disease. We have sufficient cash resources to fund the trial through the initial two or three rounds of the study. We will need to

raise additional cash resources through the sale of common stock in 2010 or other financing options in order to be able to continue our development efforts. We have the right to terminate the Althea agreement at any time, subject to payment of a termination fee to Althea. The termination fee is not material.

BP-100-2.01

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

Projected Financing Needs

In December of 2009, we anticipated that we needed to raise an additional $10,000,000 to enable us to complete all projected clinical trials for our product candidates and conduct certain additional clinical trials in other Bio-Path drug candidates. The completion LPC Purchase Agreement may provide Bio-Path with up to $7,000,000 in new capital. This amount of funding is expected to support clinical develop of our lead products and sustain operations for an additional two years. We will still need to raise additional capital to complete our funding plan.

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

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

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

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

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

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 complete our planned clinical trials.

Background Information about M. D. Anderson

We anticipate that our initial drug development efforts will be pursuant to three exclusive License Agreements with M. D. Anderson. M. D. Anderson's stated mission is to "make cancer history" (www.mdanderson.org). Achieving that goal begins with integrated programs in cancer treatment, clinical trials, educational programs and cancer prevention. M. D. Anderson is one of the largest and most widely recognized cancer centers in the world: U.S. News & World Report's "America's Best Hospitals" survey has ranked M. D. Anderson as one of 2 best hospitals for 16 consecutive years. M. D. Anderson will treat more than 100,000 patients this year, of which approximately 11,000 will participate in therapeutic clinical research exploring novel treatments the largest such program in the nation. M. D. Anderson employs more than 15,000 people including more than 1,000 M. D. and Ph.D clinicians and researchers, and is routinely conducting more than 700 clinical trials at any one time.

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

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

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

Relationship with M. D. Anderson

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

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

Bio-Path's Chief Executive Officer is experienced working with M. D. Anderson and its personnel. Bio-Path believes that if Bio-Path obtains adequate financing, Bio-Path will be positioned to help develop current and future M. D. Anderson technology into treatments for cancer patients. This in turn is expected to provide a steady flow of cancer drug candidates for out-licensing to pharmaceutical partners.

Licenses

Bio-Path Subsidiary has negotiated and signed three licenses with M. D. Anderson for late stage preclinical molecules, and intends to use our relationship with M. D. Anderson to develop these drug compounds through Phase IIa clinical trials, the point at which we will have demonstrated proof-of-concept of the efficacy and safety for our product candidates in cancer patients. At such time, we may seek a development and marketing partner in the pharmaceutical or biotech industry. In certain cases, we may choose to complete development and market the product ourselves. Our basic guide to a decision to obtain a license for a potential drug candidate is as follows:

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

Does it fit with the Company's expertise: Does Bio-Path possess the technical and clinical assets to significantly reduce the scientific and clinical risk to a point where a pharmaceutical company partner would likely want to license this candidate within 36-40 months from the date of Bio-Path acquiring a license?

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

Intellectual property and competitive sustainability: Is the intellectual property and competitive analysis sufficient to meet Big Pharma criteria assuming successful early clinical human results?

Out-Licenses and Other Sources of Revenue

Subject to adequate capital, we intend to develop a steady series of drug candidates through Phase IIa clinical trials and then to engage in a series of out-licensing transactions to the pharmaceutical and biotechnology companies. These companies would then conduct later-stage clinical development, regulatory approval, and eventual marketing of the drug. We expect that such out-license transactions would include upfront license fees, milestone/success

payments, and royalties. We intend to maximize the quality and frequency of these transactions, while minimizing the time and cost to achieve meaningful candidates for out-licensing.

In addition to this source of revenue and value, we may forward integrate one or more of our own drug candidates. For example, there are certain cancers that are primarily treated only in a comprehensive cancer center; of which there are approximately forty in the US and perhaps two hundred throughout the world. Hence, "marketing and distribution" becomes a realistic possibility for select products. These candidates may be eligible for Orphan Drug Status which provides additional incentives in terms of market exclusivities and non-dilutive grant funding for clinical trials.

Finally, there are technologies for which we anticipate acquiring licenses whose application goes well beyond cancer treatment. The ability to provide a unique and greatly needed solution to the delivery of small molecules, DNA and siRNA and their efficient uptake by targeted physiological tissues is a very important technological asset that may be commercialized in other areas of medicine.

License Agreements

We have entered into three Patent and Technology License Agreements (the "License Agreements") with M. D. Anderson relating to its technology.

These License Agreements relate to the following technologies: 1) a lead siRNA drug product; 2) two single nucleic acid (antisense) drug products; and 3) delivery technology platform for nucleic acids. These licenses require, among other things, that we reimburse M. D. Anderson for ongoing patent expense. One license requires us to raise at least $2.5 million in funding and, based on the aggregate amount raised, we have agreed to sponsor additional research at M. D. Anderson's laboratories. To maintain our rights to the licensed technology, we must meet certain development and funding milestones.

August 2009 License

The most recent of such License Agreements was entered into effective August 27, 2009. Such License Agreement relates to the development of liposome tumor targeting technology. Bio-Path is currently developing a neutral-lipid based liposome delivery technology for nucleic acid cancer drugs (including antisense and siRNA molecules). The new technology, being licensed in the field of neutral lipid-based liposome delivery of antisense technologies and FAK siRNA, is projected to enhance our liposome delivery technology by adding vectors to the liposomes targeted to a receptor that is specifically over-expressed on a majority of solid and hematological tumors and on 80 percent of metastatic epithelial tumors. We believe this liposome tumor-targeting technology for antisense and FAK siRNA delivery is a highly promising strategy for treating primary and metastatic cancers.

The historical perspective of cancer treatments has been drugs that affect the entire body. Advances in the past decade have shifted to treating the tumor tissue itself. One of the main strategies in these developments has been targeted therapy, involving drugs that are targeted to block the expression of specific disease causing proteins while having little or no effect on other healthy tissue. Nucleic acid drugs, specifically antisense and siRNA, are two of the most promising fields of targeted therapy. Development of antisense and siRNA, however, has been limited by the lack of a suitable method to deliver these drugs to the diseased cells with high uptake into the cell and without causing toxicity. Bio-Path's currently licensed neutral-lipid based liposome technology is designed to accomplish this. Studies have shown a tenfold to thirtyfold increase in tumor cell uptake with this technology compared to other delivery methods. Our first drug with this delivery technology is scheduled to commence a Phase I clinical trial in 2011.

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

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

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

Business Strategy

Our plan of operation over the next 36 months is focused on achievement of milestones with the intent to demonstrate clinical proof-of concept of our drug delivery technology and lead drug products. Furthermore, subject to adequate capital, we will attempt to validate our business model by in-licensing additional products to broaden our drug product pipeline.

At December 31, 2009, we anticipated that over the next 36 months we would need to raise approximately $10,000,000 to completely implement our current business plan. Completion of the LPC Purchase Agreement may provide up to $7,000,000 in new funding. Over the next three years we expected to raise additional capital to complete our funding plan. We have previously completed several financings for use in our Bio-Path operations and have received total net proceeds of $4,626,181 as of June 30, 2010. Our short term plan is to achieve the following 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. As described above we recently received FDA clearance to commence Phase I clinical trials of our BP-100-1.01 drug. In this Phase I trial, we will 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;

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.

We plan to pursue and achieve the above short term milestones by utilizing the following tactics:

1) 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;

2) 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;

3) Hire a small team of employees or consultants: business development, regulatory management, and project management; and

4) 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.

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.

- Leverage M. D. Anderson's pre-clinical and clinical development capabilities, including using the PDC for pre-clinical studies as well as clinical pharmacokinetics and pharmacodynamics and the institution's world-renowned clinics, particularly for early clinical trials. This should allow us to develop our drug candidates with experienced professional staff at a reduced cost compared to using external contract laboratories. This should also allow us to operate in an essentially virtual fashion, thereby avoiding the expense of setting up and operating laboratory facilities, without losing control over timing or quality or IP contamination.

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

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

- Outsource manufacturing and regulatory capabilities. Bio-Path will not need to invest its resources in building functions where it does not add substantial value or differentiation. Instead, it will leverage an executive team with expertise in the selection and management of high quality contract manufacturing and regulatory firms.

Manufacturing

We have no manufacturing capabilities and intend to outsource our manufacturing function. The most likely outcome of the out-license of a Bio-Path drug to a pharmaceutical partner will be that the pharmaceutical partner will be responsible for manufacturing drug product requirements. However, in the event Bio-Path is required to supply a drug product to a distributor or pharmaceutical partner for commercial sale, Bio-Path will need to develop, contract for, or otherwise arrange for the necessary manufacturing capabilities. There are a limited number of manufacturers that operate under the FDA's current good manufacturing practices (cGMP) regulations capable of manufacturing our future products. In September 2008, we executed a Supply Agreement with Althea Technologies, Inc., a cGMP manufacturer of pharmaceutical products, for the supply of drug product needed for Bio-Path's upcoming clinical trials.

Intellectual Property

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

We will actively seek patent protection in the U.S. and, as appropriate, abroad and closely monitor patent activities related to our business.

In addition to patents, we will rely on trade secrets and proprietary know-how, which we seek to protect, in part, through confidentiality and proprietary information agreements.

Agreement with Acorn CRO

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

Employees

We currently employ two (2) full time employees. We also have contractual relationships with 4 additional professionals who perform medical officer, regulatory and drug development duties. We expect to hire additional employees once additional funding has been secured that will enable additional clinical programs to be undertaken.

Scientific Advisory Board

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

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

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

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

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

Competition

We are engaged in fields characterized by extensive research efforts, rapid technological progress, and intense competition. There are many public and private companies, including pharmaceutical companies, chemical companies, and biotechnology companies, engaged in developing products for the same human therapeutic applications that we are targeting. Currently, substantially all of our competitors have substantially greater financial, technical and human resources than Bio-Path and are more experienced in the development of new drugs than Bio-Path. In order for us to compete successfully, we may need to demonstrate improved safety, efficacy, ease of manufacturing, and market acceptance of our products over the products of our competitors.

We will face competition based on the safety and efficacy of our drug candidates, the timing and scope of regulatory approvals, the availability and cost of supply, marketing and sales capabilities, reimbursement coverage, price, patent position and other factors. Our competitors may develop or commercialize more effective, safer or more affordable products than we are able to develop or commercialize or obtain more effective patent protection. As a result, our competitors may commercialize products more rapidly or effectively than we may be able to, which would adversely affect our competitive position, the likelihood that our drug candidates, if approved, will achieve initial market acceptance and our ability to generate meaningful revenues from those drugs. Even if our drug candidates are approved and achieve initial market acceptance, competitive products may render such drugs obsolete or noncompetitive.

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

Government Regulation

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

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

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

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

Bio-path's business model relies on entering into out-license agreements with pharmaceutical licensee partners who will be responsible for post-Phase IIA clinical testing and working with the FDA on necessary regulatory submissions resulting in approval of new drug applications for commercialization.

Non-clinical tests include laboratory evaluation of drug product candidate chemistry, formulation and toxicity, as well as animal studies. The results of pre-clinical testing are submitted to the FDA as part of an investigational new drug application. A 30-day waiting period after the filing of each investigational new drug application is required prior to

commencement of clinical testing in humans. At any time during the 30-day period or at any time thereafter, the FDA may halt proposed or ongoing clinical trials until the FDA authorizes trials under specified terms. The investigational new drug application process may be extremely costly and substantially delay the development of our drug product candidates. Moreover, positive results of non-clinical tests will not necessarily indicate positive results in subsequent clinical trials in humans. The FDA may require additional animal testing after an initial investigational new drug application is approved and prior to Phase III trials.

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

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

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

If the FDA evaluations of the application and the manufacturing facilities are favorable, the FDA may issue an approval letter or an "approvable" letter. An approvable letter will usually contain a number of conditions that must be met in order to secure final approval of the new drug application and authorization of commercial marketing of the drug for certain indications. The FDA may also refuse to approve the new drug application or issue a "not approvable" letter outlining the deficiencies in the submission and often requiring additional testing or information.

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

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

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

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. 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.

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.

Facilities

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

Legal Proceedings

We are not a party to any legal proceedings.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

In addition to historical information, this "Management's Discussion and Analysis of Financial Condition and Results of Operations" section 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 titled "Risk Factors" and the "Note Regarding Forward-Looking Statements" included in the beginning of this prospectus. 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 prospectus.

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 SEC on February 19, 2008. Subsequent to the Merger, we changed our fiscal year end from June 30th to December 31st.

Bio-Path Subsidiary was formed to finance and facilitate the development of novel cancer therapeutics. Our initial plan was to acquire licenses for drug technologies from The University of Texas M. D. Anderson Cancer Center, or M. D. Anderson, to fund clinical and other trials for such technologies and to commercialize such technologies. Bio-Path has negotiated and executed three exclusive licenses, or the 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, or 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.

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 three months ended March 31, 2010 and March 31, 2009.

Revenues. We have no operating revenues since our inception. We had interest income of $602 for the three months ended March 31, 2010 compared to $3,232 for the three months ended March 31, 2009. Our interest income was derived from cash and cash equivalents net of bank fees.

Research and Development Expenses. Our research and development costs were $137,082 for the three months ended March 31, 2010; a decrease of $75,527 from the three months ended March 31, 2009. This decrease results

from the majority of the manufacturing and drug research expenses for BP-100-1.01 being paid in Fiscal Year 2009.

General and Administrative Expenses. Our general and administrative expenses were $162,818 for the three months ended March 31, 2010; a decrease of $30,507 from the three months ended March 31, 2009.

Net Loss. Our net loss was $490,941 for the three months ended March 31, 2010, compared to a loss of $596,694 for the three months ended March 31, 2009. Net loss per share, both basic and diluted was $0.01 and $0.01 for the respective periods. The primary reason for the difference in the decrease in net loss in the comparable periods results from decreases in research and development expenses related to preparing the lead drug candidate, BP-100-1.01 for the upcoming clinical trial.

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

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

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

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

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

Liquidity and Capital Resources

Since our inception, we have funded our operations primarily through private placements of our capital stock. We expect to finance our foreseeable cash requirements through cash on hand, cash from operations, public or private equity offerings and debt financings. Additionally, we are seeking collaborations and license arrangements for our three product candidates. We may seek to access the public or private equity markets whenever conditions are favorable. There can be no assurance that the Company can raise additional capital to fund its operations as necessary.

On June 2, 2010, we entered into the LPC Purchase Agreement, whereby we may sell up to $7,000,000 of our common stock to LPC. See “The LPC Transaction” below.

On May 20, 2010, we entered into subscription agreements with certain investors, pursuant to which we issued an aggregate of 780,000 shares of our common stock and warrants to purchase 780,000 shares of our common stock at an exercise price of $1.50. We received aggregate proceeds from such sales of $273,000.

At March 31, 2010, we had cash of $454,574 compared to $567,249 at December 31, 2009. We currently have no lines of credit or other arranged access to debt financing.

Net cash used in operations during the three months ended March 31, 2010 was $286,502 compared to $719,847 for the three months ended March 31, 2009. The significant decrease in net cash used in the first quarter of 2010 results from the majority of the manufacturing and drug research expenses for BP-100-1.01 being paid in Fiscal Year 2009. Net cash used during the year ended December 31, 2009 was $939,822 compared to a surplus of $287,713 for the year ended December 31, 2008. Inasmuch as we have not yet generated revenues, our entire expenses of operations are funded by our cash assets.

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

Currently all of our cash is, and has been, generated from financing activities. We raised a total of $198,827 cash from financing activities for the three months ended March 31, 2010 and $473,000 since such date through June 30, 2010. Net cash provided by financing activities in 2009 was $737,624 compared to $1,368,313 for 2008. Since inception through June 30, 2010, we have net cash from financing activities of $4,626,181. As discussed in Projected Financing Need above, we believe that our available cash will be sufficient to fund our liquidity and capital expenditure requirements for the next two (2) years. We will need to raise additional capital after such time in order to continue to fund our operations thereafter. There can be no assurance that we will be able to raise cash when it is needed to fund our operations.

We believe that our available cash will not be sufficient to fund our liquidity and capital expenditure requirements through the fiscal year ending December 31, 2012. There is no assurance or guarantee that we will raise any additional capital at such time.

Future capital needs

We anticipate that the total cost of additional needed funds for Phase I Clinical trials of our BP-100-1.01 will range from $1,500,000 to $2,000,000. Inasmuch as we have received no income from operations, we are required to depend upon the sale of our securities as our principal sources of cash for the foreseeable future. We intend to use proceeds from the sale of our common stock to LPC under the LPC Purchase Agreement for such use. There can be no assurance that we will be able to continue to raise cash through the sale of our securities in the future. The amount and pace of research and development work that we can do or sponsor, and our ability to commence and complete the clinical trials that are required in order for us to obtain FDA and foreign regulatory approval of products, depend upon the amount of money we have. We have attempted to reduce overhead expenses due to the limited amount of funds available. Future research and clinical study costs are not presently determinable due to many factors, including the inherent uncertainty of these costs and the uncertainty as to timing, source, and amount of capital that will become available for these projects.

Other Events

In April of 2008 we granted stock options for services to be performed over the next three years, to purchase in the aggregate 1,165,000 shares of our common stock. Terms of the stock option grants require, among other things, that the individual continues to provide services over the vesting period of the option, which is four or five years from the date that each option granted to the individual becomes effective. The exercise price of the options is $0.90 a share. In April of 2008 we awarded warrants for services to purchase in the aggregate 85,620 shares of our common stock. The exercise price is $0.90 a share. In April of 2008, we issued 200,000 shares of our common stock to a firm in connection with introducing Bio-Path, Inc. to its merger partner Ogden Golf. In October, 2008 we granted a total of 2,500,000 employee stock options to our two corporate officers, Peter Nielsen and Douglas Morris.

As of June 30, 2010, a total of 2,367,204 of these options are now vested, and the remaining 1,397,796 vest over an average of an eight year period with a weighted average price of $1.22.

Contractual Obligations and Commitments

Bio-Path has entered into three Patent and Technology License Agreements with M. D. Anderson relating to its technology. A summary of certain material terms of each of such licenses is detailed in the section titled “License Agreements” on page 24.

In September 2008, we 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 estimated remaining payments by Bio-Path of approximately $300,000 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.

In April 2009, we entered into an agreement with ACORN CRO, a full service, oncology-focused clinical research organization, to provide Bio-Path with a contract medical officer and potentially other clinical trial support services. Concurrent with signing the agreement, Bradley G. Somer, M.D., will serve as Bio-Path's Medical Officer and medical liaison for the conduct of the Company's upcoming Phase I clinical study of liposomal BP-100-1.01 in refractory or relapsed Acute Myeloid Leukemia (AML), Chronic Myelogenous Leukemia (CML), Acute Lymphoblastic Leukemia (ALL) and Myelodysplastic Syndrome (MDS).

Inflation

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

Critical Accounting Policies

The preparation of financial statements in conformity with generally accepted accounting principles ("GAAP") in the United States has required the management of the Company to make assumptions, estimates and judgments that affect the amounts reported in the financial statements, including the notes thereto, and related disclosures of commitments and contingencies, if any. The Company considers its critical accounting policies to be those that require the more significant judgments and estimates in the preparation of financial statements, including the following:

Concentration of Credit Risk — Financial instruments that potentially subject the Company to a significant concentration of credit risk consist of cash. The Company maintains its cash balances with one major commercial

bank, J. P. Morgan Chase Bank. The balances are insured by the Federal Deposit Insurance Corporation up to $250,000. As a result, $317,249 of the Company's cash balances as of December 31, 2009 is not covered by the FDIC.

Intangible Assets/Impairment of Long-Lived Assets. As of December 31, 2009, Other Assets totals $2,431,680 for the Company's three technology licenses, comprised of $2,814,166 in value acquiring the Company's technology licenses and its intellectual property, less accumulated amortization of $382,486. The technology value consists of $460,000 in cash paid or accrued to be paid to M. D. Anderson, plus 3,138,889 shares of common stock granted to M. D. Anderson valued at $2,354,166. This value is being amortized over a fifteen year (15 year) period from November 7, 2007, the date that the technology licenses became effective. As of December 31, 2009 accrued payments to be made to M. D. Anderson totaled $125,000, and such payments are expected to be made in 2010. The Company accounts for the impairment and disposition of its long-lived assets in accordance with generally accepted accounting principles (GAAP). Long-lived assets are reviewed for events of changes in circumstances which indicate that their carrying value may not be recoverable. The Company estimates that approximately $190,000 will be amortized per year for each future year for the current value of the technology licenses acquired until approximately 2022.

Research and Development. Costs and expenses that can be clearly identified as research and development are charged to expense as incurred in accordance with GAAP. For the year 2009, the Company had $480,255 of costs classified as research and development expense. Of this amount, approximately $280,000 is comprised of raw materials and costs for the Company's raw material suppliers and contract drug manufacturer to perform unplanned additional engineering test runs of the Company's lead drug product in advance of manufacturing a current Good Manufacturing Practice (cGMP) clinical batch of this drug for use in an upcoming Phase I Clinical Trial.

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

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

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

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

Net Loss Per Share. In accordance with GAAP, and SEC Staff Accounting Bulletin ("SAB") No. 98, basic net loss per common share is computed by dividing net loss for the period by the weighted average number of common shares outstanding during the period. Although there were warrants and stock options outstanding during 2008, no potential

common shares shall be included in the computation of any diluted per-share amount when a loss from continuing operations exists. Consequently, diluted net loss per share is not presented in the financial statements for the year 2009. The calculation of Basic and Diluted earnings per share for 2009 did not include 1,985,937 shares and 745,620 shares issuable pursuant to the exercise of vested common stock and vested warrants, respectively, as of December 31, 2009 as the effect would be anti-dilutive. The calculation of Basic and Diluted earnings per share for 2008 did not include 1,250,000 shares and 85,620 shares issuable pursuant to the exercise of vested common stock and vested warrants, respectively, as of December 31, 2008 as the effect would be anti-dilutive.

Comprehensive Income — Comprehensive income (loss) is defined as all changes in a company's net assets, except changes resulting from transactions with stockholders. At December 31, 2009, the Company has no reportable differences between net loss and comprehensive loss.

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

Recent Accounting Pronouncements:

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

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

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

MANAGEMENT

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 stockholders or until their successors are elected or appointed and qualified, are set forth below:

Name	Age	Position - Committee
Peter Nielsen	60	Chief Executive Officer/President/Chief Financial Officer/Treasurer/ Chairman of the Board of Directors
Douglas P. Morris	55	Vice President of Corporate Development/ Secretary/Director
Dr. Thomas Garrison	51	Director
Gillian Ivers-Read	56	Director

Background Information

Peter Nielsen, CEO is a co-founder of Bio-Path, serving as its Chief Executive Officer, President and Chief Financial Officer/Treasurer and Chairman of the Board of Directors. Mr. Nielsen has developed a close working relationship over the last five years with key individuals at M. D. Anderson and suppliers. Mr. Nielsen has a broad management background in senior management, leading turnarounds of several large companies. He also has experience in finance, product development, cost and investment analysis, manufacturing and planning. He has also worked with several other biotech companies developing and executing on strategies for growth and is currently a Director of Synthecon, Inc., a manufacturer of 3D bioreactors. Prior to joining Bio-Path, Mr. Nielsen served as Chief Financial Officer of Omni Energy Services Corp., a NASDAQ traded energy services company. Mr. Nielsen was a Lieutenant in the U.S. Naval Nuclear Power program where he was director of the physics department. and was employed at Ford Motor Company in product development. He holds engineering and M.B.A. finance degrees from the University of California-Berkeley.

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 has also owned and operated Hyacinth Resources, LLC ("Hyacinth"). Hyacinth is a privately held business consulting firm. Hyacinth consults with privately held and publicly held corporations relating to management, merger and acquisitions, debt and equity financing, capital market access, and market support for publicly traded securities. Hyacinth also holds investments purchased by Mr. Morris. In 2007, Mr. Morris formed Sycamore Ventures, LLC, a privately-held consulting firm. Mr. Morris has a B.A. from Brigham Young University and a Masters in Public Administration from the University of Southern California.

Dr. Thomas Garrison is a practicing medical doctor with over twenty years experience in the clinical medical field with extensive administration responsibilities. He is residency trained and board certified in emergency medicine. He has extensive experience in high-acuity, high-volume emergency departments with large trauma referral bases. He has co-authored several textbooks on emergency medicine. In addition to his professional medical career, he has been involved in a number of successful entrepreneurial pursuits. He is currently involved as the Medical Director of Sono

Bello Body Contour Centers and has ownership in several of the centers. Sono Bello is a nationally growing Company, specializing in minimally invasive liposuction and non-invasive body contouring. He is responsible for medical oversight, written policies, regulatory input, equipment selection, pharmaceuticals, training and other medically relevant issues.

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

Gillian Ivers-Read. Ms. Ivers-Read is currently head of Techinical Operations at Clovis Oncology, a recently formed bio-technology company. From April 2002 until April 2009, Ms. Ivers-Read had been Executive Vice President, Development Operations of Pharmion Corp., a publicly held biotech company. From 1996 to 2001, Ms. Ivers-Read held various regulatory positions with Hoechst Marion Roussel and its successor Aventis Pharmaceuticals, Inc., where she most recently held the position of Vice President, Global Regulatory Affairs. From 1994 to 1996, Ms. Ivers-Read was Vice President, Development and Regulatory Affairs for Argus Pharmaceuticals and from 1984 to 1994 she served as a regulatory affairs director for Marion Merrell Dow.

Board of Directors

Our operations are managed under the broad supervision of the board of directors, which has ultimate responsibility for the establishment and implementation of our general operating philosophy, objectives, goals and policies. Our board of directors is currently comprised of two independent directors and two non-independent directors. The board of directors has determined that current directors, Dr. Thomas Garrison and Gillian Ivers-Read are "independent" as independence is defined under the listing standards for The Nasdaq Stock Market. The board based these determinations primarily on a review of the responses our directors provided to questions regarding employment and compensation history, affiliations and family and other relationships.

Committees of the Board of Directors

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

Key Consultants

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

Thomas A. Walker, Ph.D. Dr. Walker was appointed as Bio-Path's Chemistry, Manufacturing and Controls CMC Development Specialist. Dr. Walker 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 Associate Professor at the University of Washington. Dr. MacKenzie provides consulting services to the Company in the area of manufacturing development, as it pertains to lyophilization of the Company's drug products in the drug manufacturing process.

Ana Tari, Ph.D. Dr. Tari is an Associate Professor at the University of Florida at Gainsville. Dr. Tari was the lead researcher who has developed Bio-Path's lead cancer drug BP-100-1.01. Dr. Tari provides consulting services in the areas of manufacturing development of the drug BP-100-1.01, methods and assays for the drug product and the pre-clinical testing program performed on the drug product.

Communications with Board Members

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

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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 principal elements of executive compensation are salary, bonus and will, from time to time, 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 ($)(1)	Total ($)
Peter Nielsen, CEO, President,	2009	$ 250,000	-0-	-0-	$ 250,000
Chairman	2008	$ 250,000	-0-	$ 1,491,000	$ 1,741,000
	2007	$ 133,333	$ 20,000	-0-	$ 153,333
Douglas P. Morris, VP Corporate Development/Director	2009	$ 120,000	-0-	-0-	$ 120,000

Corporate Development Director	2008	$ 120,000	-0-	$ 994,000	$	1,114,000
	2007	$ 80,000	-0-	-0-	$	80,000

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

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

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

GRANTS OF PLAN-BASED AWARDS

			All Other Options Awards: Number of	Exercise or Base