BIO-PATH HOLDINGS INC
Form S-1/A
July 01, 2010

As filed with the Securities and Exchange Commission on July 1, 2010
Registration Statement File No. 333-167600

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

Amendment No. 1
to
FORM S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

BIO-PATH HOLDINGS, INC.
(Exact name of registrant as specified in its charter)

Utah	5940	87-0652870
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

3293 Harrison Boulevard, Suite 220
Ogden, UT 84403
(801) 399-5500
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Douglas P. Morris
3293 Harrison Boulevard, Suite 220
Ogden, UT 84403
(801) 399-5500
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:
Jeffrey R. Harder, Esq.
Winstead PC
24 Waterway Ave, Suite 500
The Woodlands, TX 77380

APPROXIMATE DATE OF COMMENCEMENT OF PROPOSED SALE TO THE PUBLIC: From time to time after the effective date of this registration statement, as determined by the selling stockholder.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

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

Large accelerated filer	¨	Accelerated filer	¨
Non-accelerated filer	¨	Smaller reporting company	x

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered (1)	Proposed Maximum Offering Price Per Unit (2)	Proposed Maximum Aggregate Offering Price (2)	Amount of Registration Fee
Common Stock	7,000,000 Shares	$ 0.45	$ 3,150,000	$ 225
Total	7,000,000 Shares	$ 0.45	$ 3,150,000	$ 225

(1) Includes (i) 566,801 outstanding shares of common stock; (ii) up to 6,149,798 additional shares of common stock to be issued on various dates at various prices pursuant to the terms of that certain Purchase Agreement dated June 2, 2010 between the Company and Lincoln Park Capital Fund, LLC, or the LPC Purchase Agreement; and (iii) up to 283,401 additional shares of common stock to be issued at various dates for no additional consideration pursuant to the terms of the LPC Purchase Agreement. Pursuant to and in accordance with Rule 416 under the Securities Act, there are also registered hereunder such indeterminate number of securities as may be issued to prevent dilution resulting from stock splits, stock dividends, or similar transactions.

(2) Estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rule 457(c) of the Securities Act. The proposed maximum offering price per share and proposed maximum aggregate offering price are based upon the average of the high, or $0.45, and low, or $0.45, sales prices of our common stock on June 14, 2010, as quoted on the OTCBB. It is not known how many shares of our common stock will be sold under this registration statement or at what price or prices such shares will be sold.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale of these securities is not permitted.

Subject to Completion, Dated June 30, 2010

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 June 14, 2010, the last reported sale price for our common stock as reported on the OTCBB was $0.45 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 _____ __, 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 have filed a registration statement that includes this prospectus with the U.S. Securities and Exchange Commission, or the SEC, covering the shares that have been issued or may be issued to LPC under the LPC Purchase Agreement. Except for the initial 571,429 shares of common stock purchased by LPC, we do not have the right to commence any sales of our shares to LPC until the SEC has declared effective the registration statement of which this prospectus is a part. After the registration statement is declared effective, LPC shall purchase 375,000 shares at a purchase price of $.40 per share for total consideration of $150,000. Thereafter, over approximately 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 6,149,798 shares of our common stock that we may sell to LPC in the future, 566,801 shares we have issued as a commitment fee, and 283,401 shares that we are obligated to issue to LPC as a commitment fee pro rata as up to an additional $6,800,000 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 10, 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 June 14, 2010, the last reported sale price of our common stock was $0.45 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 10, 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 10, 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 $6,800,000 worth of shares of our common stock under the LPC Purchase Agreement over a 24 month period 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 $0.45 per share (the closing sale price of the common stock on June 14, 2010) and the purchase by LPC of the full 6,149,798 shares in the future under the LPC Purchase Agreement, proceeds to us would be $2,767,409.

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 a period of up to 24 months from the date of this prospectus. 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 June 10, 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;