BIO-PATH HOLDINGS INC
Form 10-Q
August 16, 2010
UNITED STATES

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2010

Or

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

For the transition period from _____

Commission file number: 000-53404

Bio-Path Holdings, Inc.
(Exact name of registrant as specified in its charter)

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ¨ No ¨

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

Large accelerated filer ¨ Accelerated filer ¨

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ x No

At August 12, 2010, the Company had 48,617,832 outstanding shares of common stock, no par value.

Forward-Looking Statements

Statements in this quarterly report on Form 10-Q that are not strictly historical in nature are forward-looking statements. These statements may include, but are not limited to, statements about: the timing of the commencement, enrollment, and completion of our anticipated clinical trials for our product candidates; the progress or success of our product development programs; the status of regulatory approvals for our product candidates; the timing of product launches; our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others; and our estimates for future performance, anticipated operating losses, future revenues, capital requirements, and our needs for additional financing. In some cases, you can identify forward-looking statements by terms such as “anticipates,” “believes,” “could,” “estimates,” “expects,” “intends,” “may,” “potential,” “predicts,” “projects,” “should,” “will,” “would,” “goal,” and similar expressions intended to identify forward-l statements. These statements are only predictions based on current information and expectations and involve a number of risks and uncertainties. The underlying information and expectations are likely to change over time. Actual events or results may differ materially from those projected in the forward-looking statements due to various factors, including, but not limited to, those set forth under the caption “Risk Factors” in “ITEM 1. BUSINESS” of our Annual Report on Form 10-K as of and for the fiscal year ended December 31, 2009, and those set forth in our other filings with the Securities and Exchange Commission. Except as required by law, we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

TABLE OF CONTENTS

		Page
PART I - FINANCIAL INFORMATION		
Item 1.	Financial Statements	1
	Consolidated Balance Sheets	1
	Consolidated Statements of Operations	2
	Consolidated Statement of Cash Flows	3
	Notes to Unaudited Consolidated Financial Statements Ending June 30, 2010	4
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	9
Item 3.	Quantitative and Qualitative Disclosures about Market Risk	17
Item 4T.	Controls and Procedures	17
PART II - OTHER INFORMATION		
Item 1.	Legal Proceedings	18
Item 1A.	Risk Factors	18
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	18
Item 3.	Defaults Upon Senior Securities	18
Item 4.	(Removed and Reserved)	18
Item 5.	Other Information	18
Item 6.	Exhibits	18

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	June 30, 2010 (Unaudited)	December 31, 2009
ASSETS		
Current assets		
Cash	$ 602,424	$ 567,249
Drug product for testing	608,440	608,440
Other current assets	102,564	74,297
Total current assets	1,313,428	1,249,986
Other assets		
Technology licenses	2,906,355	2,814,166
Less Accumulated Amortization	(478,495)	(382,486)
	2,427,860	2,431,680
TOTAL ASSETS	$ 3,741,288	$ 3,681,666
LIABILITIES & SHAREHOLDERS' EQUITY		
Current liabilities		
Accounts payable	124,209	6,453
Accrued expense	188,637	133,450
Accrued license payments	100,000	125,000
Total current liabilities	412,846	264,903
Long term debt	-	-
TOTAL LIABILITIES	412,846	264,903
Shareholders' Equity		
Preferred Stock, $.001 par value 10,000,000 shares authorized, no shares issued and outstanding	-	-
Common Stock, $.001 par value, 200,000,000 shares authorized 48,617,832 and 42,649,602 shares issued and outstanding as of 6/30/10 and 12/31/09, respectively	48,617	42,649
Additional paid in capital	9,301,482	7,803,016
Additional paid in capital for shares to be issued a/	-	675,000
Accumulated deficit during development stage	(6,021,657)	(5,103,902)
Total shareholders' equity	3,328,442	3,416,763
TOTAL LIABILITIES & SHAREHOLDERS' EQUITY	$ 3,741,288	$ 3,681,666

a/ Represents 2,700,000 shares of common stock

SEE ACCOMPANYING NOTES TO FINANCIAL STATEMENTS

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

CONSOLIDATED STATEMENTS OF OPERATIONS
Unaudited

	Second Quarter April 1 to June 30		Year to Date January 1 to June 30		From inception 05/10/07 to 6/30/10
	2010	2009	2010	2009	
Revenue	$ -	$ -	$ -	$ -	$ -
Operating expense					
Research and development	46,315	112,936	183,397	325,545	1,005,299
General & administrative	189,498	224,706	352,316	418,031	1,932,189
Stock issued for services					300,000
Stock options & warrants	142,710	150,156	286,656	298,883	2,376,751
Amortization	48,312	45,731	96,009	90,996	478,495
Total operating expense	426,835	533,529	918,378	1,133,455	6,092,734
Net operating loss	$ (426,835)	$ (533,529)	$ (918,378)	$ (1,133,455)	$ (6,092,734)
Other income					
Interest income	21	480	623	3,712	71,077
Total Other Income	21	480	623	3,712	71,077
Net Loss	$ (426,814)	$ (533,049)	$ (917,755)	$ (1,129,743)	$ (6,021,657)
Loss per share					
Net loss per share, basic and diluted	$ (0.01)	$ (0.01)	$ (0.02)	$ (0.03)	$ (0.15)
Basic and diluted weighted average number of common shares outstanding	47,565,012	42,165,602	47,087,307	42,044,602	38,889,704

SEE ACCOMPANYING NOTES TO FINANCIAL STATEMENTS

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

CONSOLIDATED STATEMENT OF CASH FLOWS
Unaudited

	Year to Date January 1 to June 30 2010	2009	From inception 05/10/2007 to 6/30/2010
CASH FLOW FROM OPERATING ACTIVITIES			
Net loss	$ (917,755)	$ (1,129,743)	$ (6,021,657)
Adjustments to reconcile net loss to net cash used in operating activities			
Amortization	96,009	90,996	478,495
Common stock issued for services			300,000
Stock options and warrants	286,656	298,883	2,376,751
(Increase) decrease in assets			
Drug product for testing		(298,800)	(608,440)
Other current assets	(28,267)	26,949	(102,564)
Increase (decrease) in liabilities			
Accounts payable and accrued expenses	147,943	(97,198)	412,846
Net cash used in operating activities	(415,414)	(1,108,913)	(3,164,569)
CASH FLOW FROM INVESTING ACTIVITIES			
Purchase of exclusive license	(92,189)	(25,000)	(552,188)
Net cash used in investing activities	(92,189)	(25,000)	(552,188)
CASH FLOW FROM FINANCING ACTIVITIES			
Proceeds from convertible notes			435,000
Cash repayment of convertible notes			(15,000)
Net proceeds from sale of common stock	542,778	142,590	3,899,181
Net cash from financing activities	542,778	142,590	4,319,181
NET INCREASE IN CASH	35,175	(991,323)	602,424
Cash, beginning of period	567,249	1,507,071	-
Cash, end of period	$ 602,424	$ 515,748	$ 602,424
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION			
Cash paid for			
Interest	$ 44	$ 133	$ 445
Income taxes	$ -	$ -	$ -
Non-cash financing activities			
Common stock issued upon conversion of convertible notes			$ 420,000
Common stock issued to Placement Agent	$ 117,300	$ 16,500	$ 412,145

Common stock issued to M.D. Anderson for technology license		$ 2,354,167
Due diligence and commitment shares issued to Lincoln	$ 202,580	$ 202,580

SEE ACCOMPANYING NOTES TO FINANCIAL STATEMENTS

Notes to the Interim Consolidated Financial Statements
Ending June 30, 2010

The accompanying interim financial statements have been prepared with the instructions to Form 10-Q pursuant to the rules and regulations of the Securities and Exchange Commission and, therefore, do not include all information and footnotes necessary for a complete presentation of our financial position, results of operations, cash flows, and stockholders' equity in conformity with generally accepted accounting principals. In the opinion of management, all adjustments considered necessary for a fair presentation of the results of operations and financial position have been included and all such adjustments are of a normal recurring nature. The unaudited quarterly financial statements should be read in conjunction with the audited financial statements and notes thereto included in the Annual Report on Form 10-K of Bio-Path Holdings, Inc. (together with its subsidiary, the "Company") as of and for the fiscal year ended December 31, 2009. The results of operations for the period ended June 30, 2010, are not necessarily indicative of the results for a full-year period.

1. Organization and Business

Bio-Path Holdings, Inc. ("Bio-Path" or the "Company") is a development stage company with its lead cancer drug candidate, Liposomal Grb-2 (L-Grb-2 or BP-100-1.01), currently in clinical trials. The Company was founded with technology from The University of Texas, M. D. Anderson Cancer Center ("M. D. Anderson") dedicated to developing novel cancer drugs under an exclusive license arrangement. The Company has drug delivery platform technology with composition of matter intellectual property that enables systemic delivery of antisense, small interfering RNA ("siRNA") and small molecules for treatment of cancer. Bio-Path recently licensed new liposome tumor targeting technology, which has the potential to be applied to augment the Company's current delivery technology to improve further the effectiveness of its antisense and siRNA drugs under development as well as future liposome-based delivery technology drugs in the future. In addition to its existing technology under license, the Company expects to have a close working relationship with key members of the M. D. Anderson's staff, which should provide Bio-Path with a strong pipeline of promising drug candidates in the future. Bio-Path expects the working relationship with M. D. Anderson to enable the Company to broaden its technology to include cancer drugs other than antisense and siRNA.

Bio-Path believes that its core technology, if successful, will enable it to be at the center of emerging genetic and molecular target-based therapeutics that require systemic delivery of DNA and RNA-like material. The Company's two lead drug candidates treat acute myeloid leukemia, chronic myelogenous leukemia, acute lymphoblastic leukemia and follicular lymphoma, and if successful, could potentially be used in treating many other indications of cancer.

Bio-Path is currently treating patients with its lead cancer drug candidate Liposomal Grb-2 (L-Grb-2 or BP-100-1.01) in a Phase I clinical trial. In March of 2010, Bio-Path received written notification from the U. S. Food and Drug Administration (the "FDA") that its application for Investigational New Drug ("IND") status for L-Grb-2 had been granted. This enabled the Company to commence its Phase I clinical trial to study L-Grb-2 in human patients, which began shortly after the end of the second Quarter 2010. The Company expects the Phase I clinical trial to last approximately twelve months, primarily depending on the rate of enrollment of patients into the trial. The second of the Company's two lead drug candidates will be ready for a clinical trial after receiving an IND from the FDA.

The Phase I clinical trial is a dose-escalating study to determine the safety and tolerance of escalating doses of L-Grb-2. The study will also determine the optimal biologically active dose for further development. The pharmacokinetics of L-Grb-2 in patients will be studied, making it possible to investigate whether the delivery technology performs as expected based on pre-clinical studies in animals. The trial will evaluate five doses of L-Grb-2 and 18 to 30 patients may be accrued into the study. The clinical trial is being conducted at The University of Texas M. D. Anderson Cancer Center.

An important outcome for the Phase I clinical trial is the ability to assess for the first time the performance of the Company's delivery technology platform in human patients. Being platform technology, a successful demonstration of the delivery technology in this study will allow the Company to immediately begin expanding Bio-Path's drug candidates by simply applying the delivery technology template to multiple new drug product targets. In this manner, Bio-Path can quickly build an attractive drug product pipeline with multiple drug product candidates for treating cancer as well as treating other important diseases including diabetes, cardiovascular conditions and neuromuscular disorders.

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

In the second quarter of 2010, Bio-Path signed an equity purchase agreement for up to $7 million with Lincoln Park Capital Fund, LLC ("LPC"), a Chicago-based institutional investor (see Note 6.). In connection with the signing of the agreement, LPC made an initial purchase of $200,000 of common stock and warrants. The LPC financing structure puts in place a significant amount of equity capital for clinical development of Bio-Path's technology, while allowing the Company to draw on it only as needed, in an effort to minimize shareholder dilution. In addition, the LPC financing represents a maturing of Bio-Path's fund raising efforts, bringing sophisticated institutional investor-involvement to the Company as well as being considerably more cost effective than private placement fund raising previously used by the Company. Private placement fund raising has cost the Company a cash commission and stock commission on funds raised, while the LPC financing required only a significantly lower stock commitment fee and no cash commission. In addition, private placement investors have required 100% warrant coverage, while the LPC financing required warrants only with the initial purchase shares. Management believes that the LPC financing should provide capital necessary to fund operations and its clinical trial at least through the summer of 2011. In addition, prior to signing the LPC agreement, the Company raised $273,000 in funds in the second quarter of 2010 for operations through a private placement sale of shares of the Company's common stock and associated warrants.

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

2. Drug Product for Testing

The Company has paid installments to its contract drug manufacturing and raw material suppliers totaling $292,800 during 2008 and $315,640 during 2009 pursuant to a Project Plan and Supply Agreement (see Note 8.) for the manufacture and delivery of the Company's lead drug product for testing in a Phase I clinical trial. This amount is carried on the Balance Sheet as of June 30, 2010 at cost as Drug Product for Testing. The Drug Product for Testing on hand will commence being expensed in the third quarter of 2010 as the drug product is used during the Phase I clinical trial.

3. Accrued Expense

As of June 30, 2010, Current Liabilities included accrued expense of $188,637. R&D expenses for drug development and the Phase I clinical trial comprised approximately $40,000 of this amount, including $29,000 to the Company's contract drug manufacturer. Bonus pool accrual comprised approximately $139,000 and corporate expense for auditors, legal and insurance comprised an additional $10,000.

4. Accrued License Payments

Accrued license payments totaling $100,000 were included in Current Liabilities as of June 30, 2010. These amounts represent patent expenses for the licensed technology expected to be invoiced from M. D. Anderson. It is expected that the accrued license payments will be made to M. D. Anderson in 2010 and the first quarter of 2011.

5. Additional Paid In Capital For Shares To Be Issued

In November and December of 2009, the Company sold shares of common stock and warrants to purchase shares of common stock for $675,000 in cash to investors pursuant to a private placement memorandum. These shares were not issued as of the December 31, 2009 year end and the $675,000 was carried on the Balance Sheet as Additional Paid In Capital For Shares To Be Issued. Subsequently in January of 2010, the Company issued these investors 2,700,000 shares of common stock and warrants to purchase an additional 2,700,000 shares of common stock. The warrants must be exercised within two years from the date of issuance. The exercise price of the warrants is $1.50 a share.

6. Stockholders' Equity

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

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

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

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

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

As of June 30, 2010, there were 48,617,832 shares of common stock issued and outstanding. There are no preferred shares outstanding as of June 30, 2010.

7. Stock Options and Warrants

Stock Options - There were no stock option awards granted in 2009. Total stock option expense for the year 2009 totaled $588,857.

There were no stock option awards granted in the first or second quarters of 2010. Total stock option expense for the first quarter of 2010 totaled $143,946 and for the current second quarter 2010 being reported on stock option expense totaled $142,710.

Warrants - There were no warrants for services granted in 2009 and there was no warrant expense for the year 2009.

There were no warrants for services granted in the first or second quarters of 2010 and there was no warrant expense in the first quarter of 2010 or the current second quarter of 2010 being reported on. Warrants issued in connection with the sale of units of common stock were for cash value received and as such were not grants of compensation-based warrants.

8. Commitments and Contingencies

Technology License - The Company has negotiated exclusive licenses from M. D. Anderson to develop drug delivery technology for siRNA and antisense drug products and to develop liposome tumor targeting technology. These licenses require, among other things, the Company to reimburse M. D. Anderson for ongoing patent expense. Accrued license payments totaling $100,000 are included in Current Liabilities as of June 30, 2010. As of June 30, 2010, the Company estimates reimbursable patent expenses will total approximately $150,000 for the antisense license and $25,000 for the siRNA license. The Company will be required to pay when invoiced the patent expenses at the rate of $25,000 per quarter.

Drug Supplier Project Plan - In June of 2008, Bio-Path entered into a Project Plan agreement with a contract drug manufacturing suppler for delivery of drug product to support commencement of the Company's Phase I clinical trial of its first cancer drug product. The Company commenced this trial and was enrolling patients by the end of the second quarter 2010. Previously in 2008 and 2009, the Company paid $608,440 to this manufacturer and its drug substance raw material supplier that is carried at cost as Drug Product for Testing on the balance sheet (see Note 2.). The Company expects to pay no more than $150,000 to its contract drug manufacturing supplier to complete payments under the current contract when the supplier delivers clinical grade drug product for testing in the Company's clinical trial. Future contracts will be required as the Company's requirement for clinical drug product increase.

9. Subsequent Events

In July of 2010, the Company satisfied all conditions precedent under the equity purchase agreement with Lincoln Park Capital Fund, LLC ("LPC"), a Chicago-based institutional investor, to commence sales of common stock to LPC for up to an aggregate of $7 million. One of the significant conditions that Bio-Path was required to satisfy under the equity purchase agreement was to file a registration statement with the SEC covering the resale of certain shares by LPC and for the SEC to declare that registration statement effective. The registration statement was declared effective on July 12, 2010, and as a result, in July of 2010, Bio-Path received an additional $150,000 from LPC in exchange for the sale of 375,000 shares of common stock, which shares are covered by the registration statement on file with the SEC. No warrants to purchase additional shares of Bio-Path's common stock were issued in connection with this sale. Under the terms of the equity purchase agreement, the Company has the right to sell shares of its common stock

to LPC from time to time over a 24-month period in amounts between $50,000 and $1,000,000 up to an aggregate amount of $7 million depending upon certain conditions set forth in the purchase agreement including that a registration statement related to the transaction has been declared effective by the U.S. Securities and Exchange Commission ("SEC"). Upon signing the agreement in June of 2010, the Company received $200,000 from LPC as an initial purchase in exchange for 571,429 shares ("Initial Purchase Shares") of the Company's common stock and warrants to purchase 571,429 shares of the Company's common stock at an exercise price of $1.50 per share (see Note 6.). Subsequent purchases of the Company's common stock by Lincoln Park under the agreement do not include warrants. The proceeds received by the Company under the purchase agreement are expected to be used for the Phase I clinical trial expenses for the Company's lead cancer compound and for general working capital.

In July of 2010, the Company announced in a press release that the first patient had been dosed in a Phase I study of its cancer drug candidate, Liposomal Grb-2 (L-Grb-2 or BP-100-1.01), in patients with Acute Myeloid Leukemia (AML), Chronic Myelogenous Leukemia (CML), Acute Lymphoblastic Leukemia (ALL) or Myelodysplastic Syndrome (MDS). Bio-Path is developing a neutral lipid-based liposome delivery technology for nucleic acid cancer drugs (including antisense and siRNA molecules), a delivery technology that forms microscopic-sized vehicles to safely deliver these drugs to their intended target cancer cells. The Phase I clinical trial is a dose-escalating study to determine the safety and tolerance of escalating doses of L-Grb-2. The study will also determine the optimal biologically active dose for further development. The pharmacokinetics of L-Grb-2 in patients will be studied, making it possible to investigate whether the delivery technology performs as expected based on pre-clinical studies in animals. The trial will evaluate five doses of L-Grb-2 and 18 to 30 patients may be accrued into the study. The clinical trial is being conducted at The University of Texas M. D. Anderson Cancer Center.

10. New Accounting Pronouncements

In October 2009, the FASB issued authoritative guidance on multiple-deliverable revenue arrangements, which is effective for the Company on January 1, 2011 for new revenue arrangements or material modifications to existing agreements. The guidance amends the criteria for separating consideration in multiple-deliverable arrangements. This guidance establishes a selling price hierarchy for determining the selling price of a deliverable, which is based on: (a) vendor-specific objective evidence; (b) third-party evidence; or (c) estimates. This guidance also eliminates the residual method of allocation and requires that arrangement consideration be allocated at the inception of the arrangement to all deliverables using the relative selling price method. In addition, this guidance significantly expands required disclosures related to a vendor's multiple-deliverable revenue arrangements. The Company is currently evaluating the effect the adoption of the guidance will have on its financial position, results of operations, cash flows and related disclosures.

In July 2010, the FASB issued authoritative guidance on disclosures about the credit quality of financing receivables and the allowance for credit losses, which is effective for the Company on December 31, 2010. The guidance requires additional disclosures that facilitate financial statement users' evaluation of: (a) the nature of credit risk inherent in the entity's portfolio of financing receivables; (b) how that risk is analyzed and assessed in arriving at the allowance for credit losses; and (c) the changes and reasons for those changes in the allowance for credit losses. In addition, the guidance amends current requirements to include additional disclosures about financing receivables, including: (a) credit quality indicators of financing receivables at the end of the reporting period by class of financing receivables; (b) the aging of past due financing receivables at the end of the reporting period by class of financing receivables; and (c) the nature and extent of troubled debt restructurings that occurred during the period by class of financing receivables and their effect on the allowance for credit losses. The Company is currently evaluating the effect the adoption of the guidance will have on its financial position, results of operations, cash flows and related disclosures.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

When you read this section of this Quarterly Report on Form 10-Q, it is important that you also read the unaudited financial statements and related notes included elsewhere in this Form 10-Q and our audited financial statements and notes thereto included in our Annual Report on Form 10-K as of and for the fiscal year ended December 31, 2009. This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations, and intentions. We use words such as "anticipate," "estimate," "plan," "project," "continuing," "ongoing," "expect," "believe," "intend," "may," "will," "should," "could," and similar expressio forward-looking statements. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including the matters discussed under the caption "Risk Factors" in "Item 1, BUSINESS" in our Annual Report on Form 10-K as of and for the fiscal year ended December 31, 2009 and other risks and uncertainties discussed in filings made with the Securities and Exchange Commission. See "Forward Looking Statements" for additional discussion regarding risks associated with forward-looking statements.

Overview

Bio-Path Holdings, Inc., through our wholly-owned subsidiary Bio-Path, Inc. ("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 ("M. D. Anderson"), funding clinical and other trials for such technologies and to commercialize such technologies. We have acquired three exclusive licenses ("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 ("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.

Bio-Path Subsidiary was formed in May 2007. Bio-Path acquired Bio-Path Subsidiary in February 2008 in a reverse merger transaction (the "Merger").

Our principal executive offices are located at 3293 Harrison Boulevard, Suite 220, Ogden, UT 84403. Our telephone number at that address is (801) 399-5500. Our Internet website address is www.biopathholdings.com, and all of our filings with the Securities and Exchange Commission are available free of charge on our website.

Research and Development

Our research and development is currently conducted through agreements we have with M. D. Anderson. A summary of the material terms of the License Agreements are detailed in our Annual Report on Form 10-K as of and for the fiscal year ended December 31, 2009.

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. The primary objective of the Phase I clinical trial, as in any Phase I clinical trial, is the safety of the drug for treatment of human patients. Additional key objectives of the trial are to demonstrate the effectiveness of our drug delivery technology similar to that experienced in pre-clinical treatment of animals and to assess whether the drug candidate test article produces a favorable impact on the cancerous condition of the patient at the dose levels of the study.

On July 29, 2010, we announced that we began the dosing of patients at the M. D. Anderson Cancer Center. The Phase I clinical trial of BP-100-1.01 is a dose-escalating study to determine the safety and tolerance of escalating doses of L-Grb-2. The study will also determine the optimal biologically active dose for further development. The pharmacokinetics of L-Grb-2 in patients will be studied, making it possible to investigate whether the delivery technology performs as expected based on pre-clinical studies in animals. The trial will evaluate five doses of L-Grb-2 and 18 to 30 patients may be accrued into the study. The clinical trial is being conducted at The University of Texas M. D. Anderson Cancer Center.

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 or other financing options in order to be able to complete 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 of the LPC Purchase Agreement (as defined below) may provide us 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 through the second quarter of 2011. 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 shareholders.

There can be no assurance of the following:

1) That the actual costs of a particular trial will come within our budgeted amount.

2) That any trials will be successful or will result in drug commercialization opportunities.

3) That we will be able to raise the sufficient funds to allow us to 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 which is 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 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, the Company to reimburse M. D. Anderson for ongoing patent expense. One license requires the Company to raise at least $2.5 million in funding and, based on the aggregate amount raised, the Company has 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. A summary of the material terms of the licenses are detailed in our Annual Report on Form 10-K as of and for the fiscal year ended December 31, 2009.

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 $4,319,181 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. Effective July 29, 2010, we began dosing of patients of this lead drug – BP-100-1.01 at M. D. Anderson;

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.

Manufacturing

We have no manufacturing capabilities and have developed third party contract manufacturers and suppliers to supply our drug product requirements. In September of 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 clinical trial in Liposomal Grb-2 (BP-100-1.01). Althea has supplied clinical grade Liposomal Grb-2 under this agreement that is currently being used in a Phase I clinical trial. The Company will continue to evaluate its manufacturing strategy as its product portfolio is developed and demand for future Bio-Path drug products increases.

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).

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. For more detailed discussions on the clinical trial processes involvement with the FDA, please refer to Annual Report on Form 10-K as of and for the fiscal year ended December 31, 2009.

Results of Operations for the three and six months ended June 30, 2010 and 2009.

Revenues. We have no operating revenues since our inception. We had interest income of $21 for the three months ended June 30, 2010 compared to $480 for the three months ended June 30, 2009, We had interest income of $623 for the six months ended June 30, 2010 compared to $3,712 for the six months ended June 30, 2009. The decrease in interest income results from decreases in bank cash balances in the comparable periods. Our interest income was derived from cash and cash equivalents net of bank fees.

Research and Development Expenses. Our research and development costs were $46,315 for the three months ended June 30, 2010; a decrease of $66,621 over the three months ended June 30, 2009. Our research and development costs were $183,397 for the six months ended June 30, 2010; a decrease of $142,148 over the six months ended June 30, 2009. This decrease results from the majority of the manufacturing and drug research expenses for BP-100-1.01 being paid in 2009.

General and Administrative Expenses. Our general and administrative expenses were $189,498 for the three months ended June 30, 2010; a decrease of $35,208 over the three months ended June 30, 2009. Our general and administrative expenses were $352,316 for the six months ended June 30, 2010; a decrease of $65,715 over the six months ended June 30, 2009. The decrease in general and administrative expenses in the respective periods results from the decreased operating expenses relating to drug development activity compared to 2009.

Net Loss. Our net loss was $426,814 for the three months ended June 30, 2010, compared to a loss of $533,049 for the three months ended June 30, 2009. Net loss per share, both basic and diluted was the same for the respective three month periods. Our net loss was $917,755 for the six months ended June 30, 2010, compared to a loss of $1,129,743 for the six months ended June 30, 2009. The primary reason for the difference in the decrease in net loss in the comparable six month 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.

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 the Lincoln Capital financing arrangement described below, and from cash on hand. However, we will require additional capital to complete our currently anticipated drug

development efforts, and will likely pursue other public or private equity offerings and debt financings. Additionally, we are seeking collaborations and license arrangements for our three product candidates. In May of 2010, the Company completed a private placement through the sale of common stock and warrants to purchase shares of common stock with a Placement Agent. The total net proceeds received through this private placement was $245,700. In addition, in June, 2010 the Company received net proceeds of $200,000 from the sale of common stock and warrants to purchase shares of common stock from another private placement.

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 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. 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.

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. 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 additional commitment fee 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 can be offered by LPC under the registration statement 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.

At June 30, 2010, we had cash of $602,424 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 six months ended June 30, 2010 was $415,414 compared to $1,108,913 for the six months ended June 30, 2009. The significant decrease in net cash used results from the majority of the manufacturing and drug research expenses for BP-100-1.01 being paid in 2009. Inasmuch as we have not yet generated revenues, our entire expenses of operations are funded by our cash assets.

Currently all of our cash is, and has been, generated from financing activities. We raised a total of $445,700 net cash from financing activities for the three months ended June 30, 2010. Since inception we have net cash from financing activities of $4,319,181. We believe that our available cash and future cash proceeds to be received from the sale of shares of our common stock under the LPC Purchase Agreement will be sufficient to fund our liquidity and capital expenditure requirements through the second quarter 2011. We need to raise additional capital to completely implement our business model. There can be no assurance that we will be able to raise cash when it is needed to fund our operations.

Contractual Obligations and Commitments

Bio-Path has entered into the License Agreements with M. D. Anderson relating to its technology. A summary of certain material terms of each of the License Agreements is detailed in our Annual Report on Form 10-K as of and for the fiscal year ended December 31, 2009.

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 ongoing 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).

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. Our significant accounting policies are discussed in Note 2 to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2009.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Information not required for smaller reporting companies.

ITEM 4T. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures. Our management, with the participation of our principal executive officer and principal financial officer, have evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of the end of the period covered by this quarterly report (the "Evaluation Date"). Based on such evaluation, our principal financial officer and principal executive officer have concluded that, as of the Evaluation Date, our disclosure controls and procedures are effective and designed to ensure that the information relating to our company (including our consolidated subsidiaries) required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the requisite time periods.

(b) Changes in Internal Controls. There was no change in our internal control over financial reporting (as defined in Rules 13a–15(f) and 15d-15(f) under the Exchange Act) that occurred during the quarter covered by this report that has materially affected, or is reasonably likely to materially affect, such controls.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 1A. RISK FACTORS

Information not required for smaller reporting companies.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

In May, 2010, the Company sold to individual accredited investors through a registered broker/dealer 780,000 units of the Company's securities for an aggregate purchase price of $273,000. Each unit is comprised of two shares of common stock ($0.35 per share) and two warrants to purchase one share of common stock at an exercise price of $1.50. The warrants have a term of two years. After sales commissions, the Company received net proceeds of $245,700.

In June, 2010, the Company sold to LPC 571,429 shares also at $0.35 per share and 571,429 warrants in a private placement. The Company received net proceeds of $200,000. There was no commission paid. The warrants have the same terms as described above.

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

ITEM 3. DEFAULTS BY THE COMPANY ON ITS SENIOR SECURITIES

None.

ITEM 4. (Removed and Reserved)

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit No.	Description of Exhibit
3.1	Restated Articles of Incorporation (incorporated by reference to exhibit 3.2 to the registrant's current report on Form 8-A filed on September 10, 2008)
3.2	Bylaws (incorporated by reference to exhibit 3.2 to the registrant's current report on Form 8-A filed on September 10, 2008)
3.3	Articles of Merger relating to the merger of Biopath Acquisition Corp. with and into Bio-Path, Inc. (incorporated by reference to exhibit 3.2 to the registrant's current report on Form 8-K filed on February 19, 2008)
3.4	Amendment No. 1 to Bylaws (incorporated by reference to exhibit 3.2 to the registrant's current report on Form 8-K filed on June 21, 2010)

4.1	Specimen Stock certificate (incorporated by reference to exhibit 3.2 to the registrant's current report on Form 8-A filed on September 10, 2008)
4.2	Form of Warrant issued to Lincoln Park Capital Fund, LLC (incorporated by reference to exhibit 4.1 to the registrant's current report on Form 8-K filed on June 4, 2010)
10.1	Purchase Agreement, dated as of June 2, 2010, by and between the Company and Lincoln Park Capital Fund, LLC (incorporated by reference to exhibit 10.1 to the registrant's current report on Form 8-K filed on June 4, 2010)
10.2	Registration Rights Agreement, dated as of June 2, 2010, by and between the Company and Lincoln Park Capital Fund, LLC (incorporated by reference to exhibit 10.2 to the registrant's current report on Form 8-K filed on June 4, 2010)
31*	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Section 302 of the Sarbanes Oxley Act of 2002
32*	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Section 906 of the Sarbanes Oxley Act of 2002

* Filed herewith.

SIGNATURE

In accordance with the requirements of the Exchange Act, the Company has caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

BIO-PATH HOLDINGS, INC.

Dated: August 16, 2010	By	/s/ Peter H. Nielsen, Chief Executive Officer, President/Principal Executive Officer, Chief Financial Officer, Principal Financial Officer