BIO-PATH HOLDINGS INC
Form 10-Q
November 16, 2009

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2009
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 230, 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 ý 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 ý

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

At November 9, 2009, the Company had 42,649,602 outstanding shares of common stock, $0.001 par value.

DOCUMENTS INCORPORATED BY REFERENCE: NONE

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 Form 10-K for the fiscal year ended December 31, 2008, 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

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

The accompanying unaudited financial statements have been prepared in accordance 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 principles. 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.

Our unaudited balance sheet at September 30, 2009; the related unaudited consolidated statements of operations for the three month and nine month periods ended September 30, 2009 and 2008, and from inception (May 10, 2007) to September 30, 2009; and the related unaudited statement of cash flows for the nine month periods ended September 30, 2009 and 2008, and from inception (May 10, 2007) through September 30, 2009, are attached hereto.

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

CONSOLIDATED BALANCE SHEETS

	September 30 2009 (Unaudited)	December 31 2008
ASSETS		
Current assets		
Cash	$265,963	$1,507,071
Drug product for testing	608,440	292,800
Other current assets	76,527	82,772
Total current assets	950,930	1,882,643
Other assets		
Technology licenses	2,739,167	2,704,167
Less Accumulated Amortization	(335,921)	(199,505)
	2,403,246	2,504,662
TOTAL ASSETS	$3,354,176	$4,387,305
LIABILITIES & SHAREHOLDERS' EQUITY		
Current liabilities		
Accounts payable	4,800	185,843
Accrued expense & other accruals	157,032	16,442
Accrued license payments	85,000	125,000
Total current liabilities	246,832	327,285
Long term debt	-	-
TOTAL LIABILITIES	246,832	327,285
Shareholders' Equity		
Preferred Stock, $.001 par value	-	-
10,000,000 shares authorized, no shares issued and outstanding		
Common Stock, $.001 par value, 200,000,000 shares authorized	42,649	41,923
42,649,602 and 41,923,602 shares issued and outstanding as of 9/30/09 and 12/31/08, respectively		
Additional paid in capital	7,735,803	7,152,261
Accumulated deficit during development stage	(4,671,108)	(3,134,164)
Total shareholders' equity	3,107,344	4,060,020

TOTAL LIABILITIES & SHAREHOLDERS' EQUITY	$3,354,176	$4,387,305

See Accompanying Notes to Financial Statements

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

CONSOLIDATED STATEMENT OF OPERATIONS
Unaudited

	Third Quarter July 1 to September 30		Year to Date January 1 to September 30		From inception 05/10/07 to 9/30/09
	2009	2008	2009	2008	
Revenue	$-	$-	$-	$-	$-
Operating expense					
Research and development	83,565	37,511	409,110	82,679	750,757
General & administrative	130,385	135,430	548,549	419,452	1,406,993
Stock issued for services				260,000	300,000
Stock options & warrants	147,685	30,770	446,569	109,037	1,947,808
Amortization	45,420	43,020	136,416	128,186	335,921
Total operating expense	407,055	246,731	1,540,644	999,354	4,741,479
Net operating loss	$(407,055)	$(246,731)	$(1,540,644)	$(999,354)	$(4,741,479)
Other income					
Interest income		7,682	3,701	37,843	70,371
Other expenses	(145)				
Total Other Income	(145)	7,682	3,701	37,843	70,371
Net Loss	$(407,200)	$(239,049)	$(1,536,943)	$(961,511)	$(4,671,108)
Loss per share					
Net loss per share, basic and diluted	$(0.01)	$(0.01)	$(0.04)	$(0.02)	$(0.13)
Basic and diluted weighted average number of common shares outstanding	42,649,602	41,823,602	42,246,269	40,930,487	36,804,693

See Accompanying Notes to Financial Statements

6

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

CONSOLIDATED STATEMENT OF CASH FLOWS
Unaudited

	Year to Date		From inception 05/10/2007 to 9/30/2009
	January 1 to September 30		
	2009	2008	
CASH FLOW FROM OPERATING ACTIVITIES			
Net loss	$(1,536,943)	$(961,511)	$(4,671,108)
Adjustments to reconcile net loss to net cash used in operating activities			
Amortization	136,416	128,186	335,921
Common stock issued for services		260,000	300,000
Stock options and warrants	446,569	109,037	1,947,808
(Increase) decrease in assets			
Restricted escrow cash		208,144	
Drug product for testing	(315,640)	(280,800)	(608,440)
Other current assets	6,245	(33,001)	(76,527)
Increase (decrease) in liabilities			
Accounts payable and accrued expenses	(80,453)	(28,523)	246,832
Escrow cash payable		(208,144)	
Net cash used in operating activities	(1,343,806)	(806,612)	(2,525,514)
CASH FLOW FROM INVESTING ACTIVITIES			
Purchase of exclusive license	(35,000)	(25,000)	(385,000)
Net cash used in investing activities	(35,000)	(25,000)	(385,000)
CASH FLOW FROM FINANCING ACTIVITIES			
Proceeds from convertible notes			435,000
Cash repayment of convertible notes	.		(15,000)
Net proceeds from sale of common stock	137,698	1,387,339	2,756,477
Net cash from financing activities	137,698	1,387,339	3,176,477
NET INCREASE/(DECREASE) IN CASH	(1,241,108)	555,727	265,963
Cash, beginning of period	1,507,071	1,219,358	-
Cash, end of period	$265,963	$1,775,085	$265,963
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION			
Cash paid for			
Interest	$-	$-	$-
Income taxes	$-	$-	$-

Non-cash financing activities			
Common stock issued upon conversion of convertible notes			$420,000
Common stock issued to Placement Agent	$16,500	$78,970	$294,845
Common stock issued to M.D. Anderson for technology license			$2,354,167

See Accompanying Notes to Financial Statements

Notes to the Interim Consolidated Financial Statements
Ending September 30, 2009

The accompanying interim financial statements have been prepared without audit, pursuant to the rules and regulations of the Securities and Exchange Commission. Certain information and disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted. In the opinion of management, the accompanying interim financial statements contain all adjustments, consisting of normal recurring accruals, necessary for a fair presentation. The results of operations for the period ended September 30, 2009, 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 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 is planned to be applied to augment the Company's current delivery technology to improve further the effectiveness of its antisense and siRNA drugs under development as well as future liposome-based delivery technology drugs in the future. In addition to its existing technology under license, the Company expects to have a close working relationship with key members of the M. D. Anderson's staff, which should provide Bio-Path with a strong pipeline of promising drug candidates in the future. Bio-Path expects the program with M. D. Anderson to enable the Company to broaden its technology to include cancer drugs other than antisense and siRNA.

Bio-Path believes that its core technology, if successful, will enable it to be at the center of emerging genetic and molecular target-based therapeutics that require systemic delivery of DNA and RNA-like material. The Company's two lead drug candidates treat acute myeloid leukemia, chronic myelogenous leukemia, acute lymphoblastic leukemia and follicular lymphoma, and if successful, could potentially be used in treating many other indications of cancer. These two lead drug candidates will be ready for clinical trials after receiving an investigational new drug ("IND") status from the FDA. The Company has filed an IND application for its lead drug candidate and currently anticipates receiving an IND by the end of the year to commence a Phase I clinical trial of this drug.

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

Bio-Path is currently in the process of raising additional funds for operations through a $650,000 private placement sale of shares of the Company's common stock and associated warrants. Subsequent to September 30, 2009, the Company has placed $450,000 in escrow from this fund raising and the balance of $200,000 for this round is over-subscribed. Assuming the IND is granted for Bio-Path's drug candidate BP-100-1.01, Management believes there will be sufficient liquidity to commence the Phase I clinical trial in BP-100-1.01 and continue testing into the first quarter of 2010. The Company will need to raise additional capital to continue beyond in 2010 to complete this clinical trial. The Company's strategy has been to minimize the amount of funds raised at the current lower, pre-Phase I trial share prices to avoid excessive dilution and raise larger amounts of new capital with anticipated higher valuation of the Company's common stock after commencement of the Phase I trial when the Company's technology is expected to be further validated.

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

2. Drug Product for Testing

The Company has paid installments to its contract drug manufacturing supplier totaling $591,600 during the third quarter and fourth quarters of 2008 and first quarter of 2009 pursuant to a Project Plan and Supply Agreement (see Note 6. below) for the manufacture and delivery of the Company's lead drug product for testing in a Phase I clinical trial. In addition, during the third quarter of 2009 the Company purchased $16,480 of oligonucleotide drug substance to be used in manufacturing of the clinical drug product. The installment payments paid to the contract drug manufacturer and the amount paid for the oligonucleotide drug substance taken together total $608,440, which amount is carried on the Balance Sheet as of September 30, 2009 at cost as Drug Product for Testing and will be expensed as the drug product is used during the Phase I clinical trial.

3. Convertible Debt

The Company issued $435,000 in notes convertible into common stock at a rate of $.25 per common share. As of December 31, 2007, $15,000 of the convertible notes had been repaid in cash and $420,000 of the convertible notes had been converted into 1,680,000 shares of Bio-Path common stock and were included in the seed round completed in August of 2007. No interest was recorded because interest was nominal prior to conversion. No beneficial conversion feature existed as of the debt issuance date since the conversion rate was greater than or equal to the fair value of the common stock on the issuance date.

4. 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 one investor in the Company pursuant to a second round of financing. The Company issued 530,833 shares of 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 issued 1,579,400 shares of common stock for $1,579,400 in cash to investors in the Company pursuant to a private placement memorandum. The Company issued 78,970 in common stock to the Placement Agent as commission for the shares of common stock sold to investors.

9

In February, 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. 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. As of September 30, 2009, there were 42,649,602 shares of common stock issued and outstanding. There are no preferred shares outstanding as of September 30, 2009.

5. Stock Options and Warrants

Stock Options - - In April of 2008 the Company made stock option grants for services over the next three years to purchase in the aggregate 1,615,000 shares of the Company’s common stock. Terms of the stock option grants require, among other things, that the individual continues to provide services over the vesting period of the option, which is four or five years from the date that each option granted to the individual becomes effective. The exercise price of the options is $0.90 a share. None of these stock options grants were for current management and officers of the Company. The Company determined the fair value of the stock options granted using the Black Scholes model and expenses this value monthly based upon the vesting schedule for each stock option award. For purposes of determining fair value, the Company used an average annual volatility of seventy two percent (72%), which was calculated based upon an average of volatility of similar biotechnology stocks. The risk free rate of interest used in the model was taken from a table of the market rate of interest for U. S. Government Securities for the date of the stock option awards and interpolated as necessary to match the appropriate effective term for the award. The total value of stock options granted was determined using this methodology to be $761,590, which will be expensed over the next six years based on the stock option service period.

In October of 2008 the Company made stock option grants to management and officers to purchase in the aggregate 2,500,000 shares of the Company’s common stock. Terms of the stock option grants require that the individuals continue employment with the Company over the vesting period of the option, fifty percent (50%) of which vested upon the date of the grant of the stock options and fifty percent (50%) of which will vest over 3 years from the date that the options were granted. The exercise price of the options is $1.40 a share. The Company determined the fair value of the stock options granted using the Black Scholes model and expenses this value monthly based upon the vesting schedule for each stock option award. For purposes of determining fair value, the Company used an average annual volatility of eighty four percent (84%), which was calculated based upon taking a weighted average of the volatility of the Company’s common stock and the volatility of similar biotechnology stocks. The risk free rate of interest used in the model was taken from a table of the market rate of interest for U. S. Government Securities for the date of the stock option awards and interpolated as necessary to match the appropriate effective term for the award.

The total value of stock options granted to management and officers was determined using this methodology to be $2,485,000, half of which was expensed at the date of grant and the balance will be expensed over the next three years based on the stock option service period.

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

There were no new stock option awards made during the first, second and third quarters of 2009. Total stock option expense for the current quarter ending September 30, 2009 being reported on totaled $147,685.

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

There were no new warrants issued for services in the current quarter ending September 30, 2009 being reported on.

6. Drug Project Plan and Supply Agreement

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 currently expects to receive an IND to start this trial by the end of the year 2009. The clinical grade drug batch to be used in the clinical trial was manufactured at the end of July 2009 and has been successfully tested. In the current quarter ending September 30, 2009, the Company paid $47,334 to this manufacturer, all of which was previously accrued as R&D expense. Previously, $591,600 in payments were made to this manufacturer under this agreement that is carried at cost as Drug Product for Testing on the balance sheet (see Note 2.). The Company expects to pay an additional $168,150 for the original Project Plan to this supplier when the project is completed and clinical grade drug is delivered to the Company, of which $24,000 has been accrued as R&D expense and the balance of $144,150 will be carried on the Balance Sheet at cost as Drug Product for Testing.

7. 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 $85,000 are included in Current Liabilities as of September 30, 2009. As of September 30, 2009, the Company estimates reimbursable patent expenses will total approximately $225,000. The Company will be required to pay when invoiced the patent expenses at the rate of $25,000 per quarter per license.

Clinical Trial Agreement – In the third quarter of 2009, the Company executed a Sponsored Research Agreement with the M. D. Anderson Cancer Center for the Phase I Clinical Trial of its lead drug product BP-100-1.01. Upon full execution, the Company paid M. D. Anderson $39,450 comprised of $14,750 for the institution's administrative fee and expensed as R&D expense, and $24,700 for prepayment of the first two patients carried on the Balance Sheet in Other Current Assets as of September 30, 2009. Assuming the trial runs its full course of eighteen patients, the Company would be required to pay an additional $197,600 over the course of the clinical trial.

8. Subsequent Events

In October 2009, the Company made two additional payments totaling $27,000 to its drug manufacturing supplier. One payment of $12,000 was for additional R&D expense for validation testing and was accrued for and included in Current Liabilities as of September 30, 2009. A second payment of $15,000 was for R&D expense for initiation of a twelve-month drug powder stability study which was accrued for and included in Current Liabilities as of September 30, 2009.

In the third quarter of 2009, the Company executed a new exclusive license from M. D. Anderson for tumor targeting of liposomes. In October of 2009 the Company paid M. D. Anderson a license documentation fee of $10,000 after full execution of the license from M. D. Anderson. The obligation to pay the license documentation fee was accrued for and carried on the Balance Sheet in Other Current Liabilities as of September 30, 2009 and the value increase of the Company's technology arising from the payment is carried on the Balance Sheet at cost in Technology Licenses as of September 30, 2009.

In early October of 2009, Bio-Path initiated a $650,000 fund raising round offering the sale of shares of the Company's common stock and associated warrants through a Private Placement. A Memorandum has been prepared, and through the second week of November 2009 $450,000 has been raised and is in an escrow account. Further, the balance of approximately $200,000 for the round is over-subscribed. The Company will complete this round by the end of November, when the Offering expires.

9. New Accounting Prouncements

In October 2009, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU"), 2009-13, Revenue Recognition (Topic 605): Multiple Deliverable Revenue Arrangements — A Consensus of the FASB Emerging Issues Task Force. This update provides application guidance on whether multiple deliverables exist, how the deliverables should be separated and how the consideration should be allocated to one or more units of accounting. This update establishes a selling price hierarchy for determining the selling price of a deliverable. The selling price used for each deliverable will be based on vendor-specific objective evidence, if available, third-party evidence if vendor-specific objective evidence is not available, or estimated selling price if neither vendor-specific or third-party evidence is available.

12

We will be required to apply this guidance prospectively for revenue arrangements entered into or materially modified after January 1, 2011; however, earlier application is permitted. We have not determined the impact that this update may have on our consolidated financial statements.

In June 2009, the FASB Accounting Standards Codification (“ASC”) issued ASC 105-10 Generally Accepted Accounting Principles - Overall (“ASC 105”). ASC 105 establishes the FASB ASC as the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in the preparation of financial statements in conformity with U.S. GAAP. The FASB will not issue new standards in the form of Statements, FASB Staff Positions or Emerging Issues Task Force Abstracts. Instead, it will issue ASUs. This standard reorganizes the thousands of GAAP pronouncements into roughly 90 accounting topics and displays them using a consistent structure. Also included is relevant SEC guidance organized using the same topical structure in separate sections. ASC 105 is effective for interim and annual periods ending after September 15, 2009. We adopted ASC 105 in the third quarter of fiscal 2009. The adoption does not have an effect on our financial position or results of operations. However, because ASC 105 completely replaces existing standards, it will affect the way U.S. GAAP is referenced within the consolidated financial statements and accounting policies.

In June 2009, the FASB issued guidance now codified as FASB ASC 810-10, Consolidation ("ASC 810"). ASC 810 amends tests for variable interest entities to determine whether a variable interest entity must be consolidated. ASC 810 requires an entity to perform an analysis to determine whether an entity's variable interest or interests give it a controlling financial interest in a variable interest entity. This guidance requires ongoing reassessments of whether an entity is the primary beneficiary of a variable interest entity and enhanced disclosures that provide more transparent information about an entity's involvement with a variable interest entity. We will be required to apply this guidance on January 1, 2010. We have not determined the impact that this guidance may have on our consolidated financial statements.

In May 2009, the FASB issued guidance now codified as FASB ASC 855-10, Subsequent Events, which provides guidance on the assessment of subsequent events. This guidance defines the period after the balance sheet date during which we should evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements, and the required disclosures for such events. The guidance is effective for interim or annual reporting periods ending after June 15, 2009. We adopted this guidance in the second quarter of 2009. We have performed an evaluation of subsequent events through November 16, 2009, which is the date our consolidated financial statements for the nine months ended September 30, 2009 were issued.

In April 2009, the FASB staff issued guidance now codified as FASB ASC 825-10, Interim Disclosures about Fair Value of Financial Instruments (“ASC 825”). ASC 825 amends FASB Statement No. 107, Disclosures about Fair Value of Financial Instruments, to require disclosures about fair value of financial instruments in interim financial statements as well as in annual financial statements. ASC 825 also amends APB Opinion No. 28, Interim Financial Reporting, to require these disclosures in all interim financial statements. The adoption of this guidance did not have a material impact on our consolidated financial statements for the nine months ended September 30, 2009.

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

When you read this section of this Quarterly Form 10Q, it is important that you also read the financial statements and related notes included elsewhere in this Form 10Q. This section of this quarterly report 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,” “in “will,” “should,” “could,” and similar expressions to identify 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 for the fiscal year ended December 31, 2008 those additional risks, discussed in ITEM 1A. of Part II of this quarterly report and other risks and uncertainties discussed in filings made with the Securities and Exchange Commission.

Overview

Bio-Path Holdings, Inc., through our 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 nucleic acid drug delivery technology. These licenses specifically provide drug delivery platform technology with composition of matter intellectual property that enables systemic delivery of antisense, small interfering RNA (“siRNA”) and potentially small molecules for treatment of cancer.

Our business plan is to act efficiently as an intermediary in the process of translating newly discovered drug technologies into authentic therapeutic drugs 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 230, 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.

Plan of Operation

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

We anticipate that over the next 30 months, we will need to raise approximately $11,000,000 to completely implement our business plan. We have completed several financings raising net proceeds of $3,176,477. Our short term plan is to achieve three key milestones:

(1) conduct a Phase I clinical trial of our lead drug BP-100-1.01, which if successful, will validate our liposomal delivery technology for nucleic acid drug products including siRNA;

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

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

In June 2008, we entered into a Project Plan Agreement with Althea Technologies, Inc. ("Althea") relating to supply of drug product for our first Phase I clinical trials of our BP-100-1.01 drug. In September 2008 we executed a definitive agreement with Althea.

Results of Operations

Results of Operations for the three months and nine months ended September 30, 2009 and 2008.

Revenues. We have no operating revenues since our inception. We had interest income of $0.00, for the three months ended September 30, 2009 compared to $7,682 for the three months ended September 30, 2008. We had interest income of $3,701, for the nine months ended September 30, 2009 compared to $37,843 for the nine months ended September 30, 2008. Our interest income was derived from cash and cash equivalents net of bank fees. The decrease in interest income in the respective periods results from increased operating expenses related to drug development, as such, there was less cash held in our savings account earning interest.

Research and Development Expenses. Our research and development costs were $83,565 for the three months ended September 30, 2009; an increase of $46,054 over the three months ended September 30, 2008. Our research and development costs were $409,110 for the nine months ended September 30, 2009; an increase of $326,431 over the nine months ended September 30, 2008. This increase is the result of significant drug research and development and manufacturing protocol from year to year. The majority of the expenses related to the lead drug candidate, BP-100-1.01, have been paid. The Company does not expect this increase to continue with this specific drug candidate.

General and Administrative Expenses. Our general and administrative expenses were $130,385 for the three months ended September 30, 2009; a decrease of $5,045 over the three months ended September 30, 2008. Our general and administrative expenses were $548,549 for the nine months ended September 30, 2009; an increase of $129,097 over the nine months ended September 30, 2008. The increase in general and administrative expenses for the nine months ended September 30,2009 results from the increased operating expenses relating to drug development activity.

Net Loss. Our net loss was $407,200 for the three months ended September 30, 2009, compared to a loss of $239,049 for the three months ended September 30, 2008. Net loss per share, both basic and diluted was $0.01 and $0.01 for the respective periods. Our net loss was $1,536,943 for the nine months ended September 30, 2009, compared to a loss of $961,511 for the nine months ended September 30, 2008. Net loss per share, both basic and diluted was $0.04 and $0.02 for the respective periods. The primary reason for the difference in the increase in net loss in the comparable period's results from increases in research and development expenses related to preparing the lead drug candidate 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 cash on hand, cash from operations, public or private equity offerings and debt financings. Additionally, we are seeking collaborations and license arrangements for our three product candidates. We may seek to access the public or private equity markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time. We cannot be certain that additional funding, which will be required in the next term, will be available on acceptable terms, or at all. Our inability to obtain required funding will have a material adverse effect on one or more of our research or development programs or curtail some of our commercialization efforts.

At September 30, 2009, we had cash of $265,963 compared to $1,507,071 at December 31, 2008. We currently have no lines of credit or other arranged access to debt financing.

Net cash used in operations during the nine months ended September 30, 2009 was $1,343,806 compared to $806,612 for nine months ended September 30, 2008. The significant increase in net cash used results from implementing the business model of drug development working towards the Phase I study of the lead drug – BP-100-1.01. 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 did raise cash from financing activities for the three months ended September 30, 2009. We raised $137,698 of net cash from financing activities for the nine months ended September 30, 2009. Since inception we have net cash from financing activities of $3,176,477. As discussed in our Plan of Operation above, we believe that our available cash will be sufficient to fund our liquidity and capital expenditure requirements through the fiscal year ending December 31, 2009. However, we believe that we will need to raise approximately an additional $11,500,000 in net proceeds to completely implement our business plan. In the fourth quarter, we have raised to date approximately $450,000 in cash from the sale of common stock through a private placement, the cash is in an escrow account. We anticipate raising an additional $200,000 to maximize the offering total of gross cash of $650,000 by the end of November, 2009. We believe this cash will fund operations through March 31, 2010.

Our available cash has been significantly reduced from December 31, 2008 to September 30, 2009 as we have funded operations but have no generated any revenues from operations. We do not anticipate that we will generate revenues for at least nine months and therefore our ability to continue with our operations is dependent upon our ability to raise additional capital from the sale of our securities, of which there can be no assurance.

Projected Financing Needs

We believe that our available cash will be sufficient to fund our liquidity and capital expenditure requirements through the fiscal year ending December 31, 2009. In the second quarter of 2009, we raised $137,698 in net proceeds from the sale of shares of our common stock. The proceeds were allocated to general working capital. In the fourth quarter, we have raised to date approximately $450,000 in cash from the sale of common stock through a private placement, the cash is in an escrow account. We anticipate raising an additional $200,000 to maximize the offering total of gross cash of $650,000 by the end of November, 2009. However, we believe that we will need to raise approximately an additional $11,500,000 in net proceeds to completely implement our business plan. We do need to raise additional capital during 2009, in order to fund our operations in 2010. There can be no assurance that we will be able to raise cash when it is needed to fund our operations.

BP-100-1.01

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

The IND for BP-100-1.01 was submitted to the FDA in February of 2008 and included all in vitro testing, animal studies and manufacturing and chemistry control studies completed. The FDA requested some changes be made to the application submission. The Company has finalized the requested changes. The final package submission to the FDA, which was submitted to the FDA in the last week of October, 2009, included the manufacturing and chemistry control test data from an engineering test batches that incorporated the same manufacturing procedures to be used to manufacture the drug product to be used on human patients in the Phase I clinical trial. The Company anticipates having the IND approved and commencement of patient enrollment for the Phase I clinical trial to start during the fourth quarter of 2009. The primary objective of the Phase I clinical trial, as in any Phase I clinical trial, is the safety of the drug for treatment of human patients. An additional key objective of the trial is to assess that the effectiveness of the delivery technology.

Our suppliers for the BP-100-1.01 drug successfully manufactured the clinical drug batch and all release testing required for this drug has been completed. As a result, in late October we submitted the necessary drug batch manufacturing and testing data to the FDA. If FDA reviewers have no additional request for information, we anticipate that, within thirty (30) days after such determination, the Investigational New Drug (IND) application for the Company's lead drug candidate will be released. In such event, we would then be able to commence its Phase I clinical trial.

The Phase I clinical trial of BP-100-1.01 is budgeted for $1,675,000. A significant portion of this budget is for acquisition of the drug material to be tested, a majority of which has been paid by the Company. Commencement of the Phase I clinical trial depends on the Federal Drug Administration ("FDA") approving the IND for BP-100-1.01.

We have entered into a supply agreement with Althea Technologies, Inc. for the manufacture of BP-100-1.01 for our upcoming Phase I Clinical Trial. Althea is a contract manufacturer who will formulate and lyophilize our BP-100-1.01 product requirements according to current Good Manufacturing Practices (cGMP). As of September 30, 2009 the contract includes estimated remaining payments by Bio-Path of approximately $168,150 for process development and manufacture of cGMP product suitable for use in human patients in the Company's Phase I clinical trial. Bio-Path has the right to terminate the agreement at any time, subject to payment of a termination fee to Althea. The termination fee is not material.

BP-100-2.01

BP-100-2.01 is our lead siRNA drug, which will be clinically tested for validation as a novel, targeted ovarian cancer therapeutic agent. We have prepared a review package of the testing data 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.

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, or (3) That we will be able to raise the sufficient funds to allow us to operate for three years or to complete our trials.

Other Events

None.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

Contractual Obligations and Commitments

Bio-Path has entered into three Patent and Technology License Agreements (the "Licenses") with M. D. Anderson relating to its technology. A summary of certain material terms of the two core delivery technology Licenses is as follows:

Licensor:	The Board of Regents of the University of Texas System on behalf of The University of Texas M. D. Anderson Cancer Center
Licensee:	Bio-Path, Inc.
License:	A royalty bearing, exclusive license to manufacture, use and sell the Licensed Products
Territory:	Worldwide
Retained Rights	Certain research and academic rights are retained by Licensor

18

License Fees:	Documentation Fee - $40,000 for the first license and $60,000 for the second license; annual maintenance fee - $25,000 for years 1, 2 & 3 increasing to $100,000 in the eighth year. After the first sale, increasing to $125,000
Royalties:	Three percent of net sales
Milestone Payments:	One-time payments range from $150,000 to $2,000,000. Total up to $8,150,000
Securities Issuance:	1,883,333 shares of Bio-Path for the first License and 1,255,556 shares for the second License. These shares were converted into shares of the Company's common stock in the Merger.
Expense:	Bio-Path will reimburse M. D. Anderson for expenses
Term:	Full term of patents

The terms and structure of the third License for tumor targeting of liposomes parallels the two primary Licenses with the exception that there is not stock consideration in lieu of milestone payments.

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 as of September 30, 2009 of approximately $168,150 for process development and manufacture of cGMP product suitable for use in human patients in the Company's Phase I clinical trial. Bio-Path has the right to terminate the agreement at any time, subject to payment of a termination fee to Althea. The termination fee is not material.

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

August 27, 2009 License Agreement

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

19

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

Pursuant to the License Agreement, the Registrant is obligated to various one time and recurring expenses and royalties. As of September 30, 2009 we accrued $10,000 for the license documentation fee related to this new license agreement

Inflation

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

Critical Accounting Policies

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

Concentration of Credit Risk -- Financial instruments that potentially subject the Company to a significant concentration of credit risk consist of cash. The Company maintains its cash balances with one major commercial bank, JPMorgan Chase Bank. The balances are insured by the Federal Deposit Insurance Corporation up to $250,000. As a result, $15,963 of the Company’s cash balances is not covered by the FDIC.

Intangible Assets/Impairment of Long-Lived Assets -- As of September 30, 2009, other Assets totaled $2,403,246 for the Company’s our technology licenses, comprised of $2,739,167 in value acquiring the Company’s technology licenses and its intellectual property, less accumulated amortization of $335,921. The technology value consists of $350,000 in cash paid or accrued to be paid to M.D. Anderson, plus 3,138,889 shares of common stock granted to M.D. Anderson valued at $2,354,167. This value is being amortized over a fifteen year (15 year) period from November 7, 2007, the date that the technology licenses became effective. As of December 31, 2008 accrued payments to be made to M. D. Anderson totaled $125,000, and such payments are expected to be made in 2009. The Company accounts for the impairment and disposition of its long-lived assets by reviewing for events of changes in circumstances which indicate that their carrying value may not be recoverable. The Company estimates that approximately $175,000 will be amortized per year for each future year for the current value of the technology licenses acquired until approximately 2022.

Research and Development Costs -- Costs and expenses that can be clearly identified as research and development are charged to expense as incurred. From inception through the period ending September 30, 2009, the Company had $750,757 of costs classified as research and development expense. Of this amount, approximately $475,000 is comprised of raw materials and costs for the Company's raw material suppliers and contract drug manufacturer to perform unplanned additional engineering test runs of the Company's lead drug product in advance of manufacturing a current Good Manufacturing Practice (cGMP) clinical batch of this drug for use in an upcoming Phase I Clinical Trial.

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

Stock Option Grants - In April of 2008 the Company made stock option grants for services over the next three years to purchase in the aggregate 1,615,000 shares of the Company's common stock. Terms of the stock option grants require, among other things, that the individual continues to provide services over the vesting period of the option, which is four or five years from the date that each option granted to the individual becomes effective. The exercise price of the options is $0.90 a share. None of these stock options grants were for current management and officers of the Company. The Company determined the fair value of the stock options granted using the Black Scholes model and expenses this value monthly based upon the service period schedule for each stock option award. For purposes of determining fair value, the Company used an average annual volatility of seventy two percent (72%), which was calculated based upon an average of volatility of similar biotechnology stocks. The risk free rate of interest used in the model was taken from a table of the market rate of interest for U. S. Government Securities for the date of the stock option awards and interpolated as necessary to match the appropriate effective term for the award. The total value of stock options granted was determined using this methodology to be $761,590, which will be expensed over the next six years based on the service period.

In October of 2008 the Company made stock option grants to management and officers to purchase in the aggregate 2,500,000 shares of the Company's common stock. Terms of the stock option grants require that the individuals continue employment with the Company over the vesting period of the option, fifty percent (50%) of which vested upon the date of the grant of the stock options and fifty percent (50%) of which will vest over 3 years from the date that the options were granted. The exercise price of the options is $1.40 a share. The Company determined the fair value of the stock options granted using the Black Scholes model and expenses this value monthly based upon the service period for each stock option award. For purposes of determining fair value, the Company used an average annual volatility of eighty four percent (84%), which was calculated based upon taking a weighted average of the volatility of the Company's common stock and the volatility of similar biotechnology stocks. The risk free rate of interest used in the model was taken from a table of the market rate of interest for U. S. Government Securities for the date of the stock option awards and interpolated as necessary to match the appropriate effective term for the award.

The total value of stock options granted to management and officers was determined using this methodology to be $2,485,000, half of which was expensed at the date of grant and the balance will be expensed over the next three years based on the stock option vesting schedule.

In December of 2008 the Company made stock option grants for services over the next three years to purchase in the aggregate 100,000 shares of the Company's common stock. Terms of the stock option grants require, among other things, that the individual continues to provide services over the vesting period of the option, which is three or four years from the date that each option granted to the individual becomes effective.

21

The exercise price of the options is $0.30 a share. None of these stock options grants were for current management and officers of the Company. The Company determined the fair value of the stock options granted using the Black Scholes model and expenses this value monthly based upon the vesting schedule for each stock option award. For purposes of determining fair value, the Company used an average annual volatility of eighty four percent (84%), which was calculated based upon taking a weighted average of the volatility of the Company's common stock and the volatility of similar biotechnology stocks.

The risk free rate of interest used in the model was taken from a table of the market rate of interest for U. S. Government Securities for the date of the stock option awards and interpolated as necessary to match the appropriate effective term for the award. The total value of stock options granted was determined using this methodology to be $21,450, which will be expensed over the next four years based on the stock option vesting schedule.

Total stock option expense being reported for the period ending September 30, 2009 is $147,685 and from inception May 10, 2007 to September 30, 2009 is $1,947,808.

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

In the second quarter of 2009, we issued 660,000 shares of our common stock and warrants to purchase an additional 660,000 shares of common stock for gross cash proceeds of $165,000 to investors 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.

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

Comprehensive Income -- Comprehensive income (loss) is defined as all changes in a company's net assets, except changes resulting from transactions with shareholders. At September 30, 2009, the Company has no reportable differences between net loss and comprehensive loss.

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Information not required for smaller reporting companies.

22

ITEM 4(T). 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

There have been no material changes to the risk factors described in the Company's Form 10-K filed with the Securities and Exchange Commission on April 3, 2009

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

None.

ITEM 3. DEFAULTS BY THE COMPANY ON ITS SENIOR SECURITIES

None.

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

We held our annual meeting of stockholders on July 15, 2009. The following is a brief description of each matter voted upon at the annual meeting and the number of votes cast for, withheld, or against, the number of abstentions and the number of broker non-votes with respect to each matter:

1. To elect four directors to our board of directors to hold office until our 2010 annual meeting of stockholders.

Name	Number of Shares	
	For	Withheld
Peter H. Nielsen	22,000,334	3,008
Douglas P. Morris	22,000,334	3,008
Thomas Garrison	22,000,334	3,008
Gillian Ivers-Read	22,000,334	3,008

2. To ratify the appointment of Mantyla & Mc Reynolds as our independent registered public accounting firm for the fiscal year ending December 31, 2009.

For	21,867,500
Against	3,008
Abstain	129,826
Broker Non-Vote	0

ITEM 5. OTHER INFORMATION

None

ITEM 6. EXHIBITS

Exhibit 31 Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Section 302 of the Sarbanes Oxley Act of 2002.

Exhibit 32 Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Section 906 of the Sarbanes Oxley Act of 2002.

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.

Dated: November 16, 2009

BIO-PATH HOLDINGS, INC.

By /s/ Peter H. Nielsen,
Chief Executive Officer, President/Principal Executive Officer, Chief Financial Officer, Principal Financial Officer