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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2015

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)

Delaware	87-0652870
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

4710 Bellaire Boulevard, Suite 210, Bellaire, Texas 77401
(Address of principal executive offices)

Registrant's telephone no., including area code: (832) 742-1357

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

Indicate by check mark 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 ☐

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

At October 28, 2015, the Company had 89,762,872 outstanding shares of common stock, par value $0.001 per share.

Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to "we," "our," "us," "the Company" and "Bio-Path" refer to Bio-Path Holdings, Inc. and its subsidiary. Bio-Path Holdings, Inc.'s wholly-owned subsidiary, Bio-Path, Inc., is sometimes referred to herein as "Bio-Path Subsidiary."

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements can be identified by words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," "project," "goal," "strategy," "future," "likely," "may," "should," "will" and variations of these words and similar references to future periods, although not all forward-looking statements contain these identifying words. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent risks, uncertainties, and changes in circumstances, including those discussed in "Item 1A. Risk Factors" to Part I of our Annual Report on Form 10-K as of and for the fiscal year ended December 31, 2014, in "Item 1A. Risk Factors" to Part II of this Quarterly Report on Form 10-Q and in other reports or documents we file with the U.S. Securities and Exchange Commission ("SEC") . As a result, our actual results may differ materially from those expressed or forecasted in the forward-looking statements, and you should not rely on such forward-looking statements. Please refer to "Item 1A. Risk Factors" to Part I of our Annual Report on Form 10-K as of and for the fiscal year ended December 31, 2014, "Item 1A. Risk Factors" to Part II of this Quarterly Report on Form 10-Q and other reports or documents we file with the SEC for a discussion of risks and factors that could cause our actual results and financial condition to differ materially from those expressed or forecasted in this Quarterly Report on Form 10-Q.

Any forward-looking statement made by us in this Quarterly Report on Form 10-Q is based only on information currently available to us and speaks only as of the date on which it is made. We undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future developments or otherwise. However, you should carefully review the risk factors set forth in "Item 1A. Risk Factors" to Part II of this Quarterly Report on Form 10-Q and in other reports or documents we file from time to time with the SEC.

TABLE OF CONTENTS

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

BIO-PATH HOLDINGS, INC.

CONSOLIDATED BALANCE SHEETS
(Unaudited)

	As of September 30, 2015	As of December 31, 2014
ASSETS		
Current assets		
Cash	$ 9,854,816	$ 13,858,798
Prepaid drug product for testing	404,378	154,667
Other current assets	200,773	100,494
Total current assets	10,459,967	14,113,959
Fixed assets		
Furniture, fixtures & equipment	123,410	123,410
Less Accumulated Depreciation	(41,137)	(10,284)
	82,273	113,126
Other assets		
Technology licenses	2,500,374	2,500,374
Less Accumulated Amortization	(1,369,949)	(1,249,481)
	1,130,425	1,250,893
TOTAL ASSETS	$ 11,672,665	$ 15,477,978
LIABILITIES & SHAREHOLDERS' EQUITY		
Current liabilities		
Accounts payable	127,120	41,026
Accounts payable - related party	-	100,450
Accrued expense	354,109	253,445
Accrued expense - related party	-	67,050
Accrued license payments - related party	-	100,000
Total current liabilities	481,229	561,971
Long term debt	-	-
TOTAL LIABILITIES	481,229	561,971
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 89,762,872 and 89,762,872 shares issued and outstanding as of 9/30/15 and 12/31/14, respectively	89,763	89,763
Additional paid in capital	35,026,695	34,743,489
Accumulated deficit	(23,925,022)	(19,917,245)
Total shareholders' equity	11,191,436	14,916,007
TOTAL LIABILITIES & SHAREHOLDERS' EQUITY	$ 11,672,665	$ 15,477,978

SEE ACCOMPANYING NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

BIO-PATH HOLDINGS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenue	$ -	$ -	$ -	$ -
Operating expenses				
Research and development	992,446	424,521	2,149,277	1,048,716
Research and development - related party	-	16,235	-	41,654
General and administrative	519,944	713,352	1,872,944	1,848,751
Total operating expenses	1,512,390	1,154,108	4,022,221	2,939,121
Net operating loss	$ (1,512,390)	$ (1,154,108)	$ (4,022,221)	$ (2,939,121)
Other income (expense)				
Interest income	4,789	5,713	14,444	17,353
Other expense	-	(14)	-	(295)
Total other income (expense)	4,789	5,699	14,444	17,058
Net loss	$ (1,507,601)	$ (1,148,409)	$ (4,007,777)	$ (2,922,063)
Net loss per share, basic and diluted	$ (0.02)	$ (0.01)	$ (0.04)	$ (0.03)
Basic and diluted weighted average number of common shares outstanding	89,762,872	89,237,872	89,762,872	89,237,872

SEE ACCOMPANYING NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

BIO-PATH HOLDINGS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Nine Months Ended September 30,	
	2015	**2014**
CASH FLOW FROM OPERATING ACTIVITIES		
Net loss	$ (4,007,777)	$ (2,922,063)
Adjustments to reconcile net loss to net cash used in operating activities		
Amortization	120,469	120,469
Depreciation	30,853	-
Stock-based compensation and warrants	283,205	327,118
(Increase) decrease in assets		
Prepaid drug product for testing	(249,711)	(45,199)
Other current assets	(100,279)	(130,064)
Increase (decrease) in liabilities		
Accounts payable and accrued expenses	(80,742)	(11,740)
Net cash used in operating activities	(4,003,982)	(2,661,479)
CASH FLOW FROM INVESTING ACTIVITIES		
Purchase furniture, fixtures & equipment	-	(66,124)
Net cash used in investing activities	-	(66,124)
CASH FLOW FROM FINANCING ACTIVITIES		
Net proceeds from sale of common stock	-	13,812,373
Net cash from financing activities	-	13,812,373
`		
NET INCREASE (DECREASE) IN CASH	**(4,003,982)**	**11,084,770**
Cash, beginning of period	13,858,798	3,551,832
Cash, end of period	$ 9,854,816	$ 14,636,602

SEE ACCOMPANYING NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

BIO-PATH HOLDINGS, INC.

Notes to the Unaudited Consolidated Financial Statements Ended September 30, 2015

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 ("SEC") and, therefore, do not include all information and footnotes necessary for a complete presentation of the Company's 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. 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, "Bio-Path" or the "Company") as of and for the fiscal year ended December 31, 2014. The results of operations for the period ended September 30, 2015, are not necessarily indicative of the results for a full-year period.

1. Organization and Business

Bio-Path is a biotechnology company with a lead cancer drug candidate, Liposomal Grb2 ("L-Grb2"), which is currently in clinical trials, and a second liposome delivered antisense drug candidate, Liposomal Bcl2 ("L-Bcl2"), which has completed preclinical development. The planned principal operations are described in the following paragraphs. The Company was founded with technology from The University of Texas, MD Anderson Cancer Center ("MD Anderson") and is dedicated to developing novel cancer drugs under an exclusive license arrangement (the "License Agreement"). The Company has drug delivery platform technology with composition of matter intellectual property for systemic delivery of its proprietary antisense. Bio-Path also plans to investigate developing liposome tumor targeting technology, which has the potential to be developed to augment the Company's current delivery technology to improve further the effectiveness of its antisense. In addition to its existing technology under license, the Company expects to maintain a close working relationship with key members of the MD Anderson staff, which has the potential to provide Bio-Path with additional drug candidates in the future. Bio-Path also expects to broaden its technology to include cancer drugs other than antisense, including drug candidates licensed from institutions other than MD Anderson.

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 liposomal antisense drug candidates are targeted to treat Acute Myeloid Leukemia ("AML"), Myelodysplastic Syndrome ("MDS"), Philadelphia Chromosome Positive Chronic Myelogenous Leukemia ("CML"), Acute Lymphoblastic Leukemia ("ALL") and follicular lymphoma, and if successful, could potentially be used in treating many other indications of cancer. For example, previously Bio-Path announced that it was initiating development of its lead cancer drug L-Grb2 to treat triple negative breast cancer (TNBC) and inflammatory breast cancer (IBC), two cancers characterized by formation of aggressive tumors and relatively high mortality rates.

Bio-Path, Inc. was founded in May 2007 as a Utah corporation. In February 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. 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 and now conducting a Phase I clinical trial in its lead drug product candidate L-Grb2.

On November 5, 2013, the Company filed a shelf registration statement on Form S-3 with the SEC, which was declared effective by the SEC on January 13, 2014. The shelf registration statement was filed to register the offering and sale of up to $100.0 million of our common stock, preferred stock, warrants to purchase common stock or preferred stock or any combination thereof, either individually or in units. The foregoing does not constitute an offer to sell or the solicitation of an offer to buy securities, and shall not constitute an offer, solicitation or sale in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of that jurisdiction.

On January 15, 2014, the Company entered into a securities purchase agreement, as amended, with certain investors, pursuant to which the Company agreed to sell an aggregate of 5.0 million shares of its common stock and warrants to purchase a total of 2.5 million shares of its common stock to such certain investors for gross proceeds of approximately $15.0 million. The net proceeds to the Company from the registered direct public offering, after deducting the placement agent's fees and expenses, the Company's estimated offering expenses, and excluding the proceeds from the exercise of the warrants issued in the offering, were approximately $13.8 million. The offering closed on January 21, 2014.

On March 5, 2014, the NASDAQ Stock Market LLC informed the Company that it had approved the listing of the Company's common stock on the NASDAQ Capital Market. The Company's common stock ceased trading on the OTCQX and commenced trading on the NASDAQ Capital Market on March 10, 2014 under the ticker symbol "BPTH."

In April 2014, the Company entered into a lease agreement for a larger office space. The new, expanded size office is required for the core organization the Company has added.

In December 2014, a former director of the Company exercised stock options on 525,000 shares of the Company's common stock for aggregate gross proceeds of $435,500.

At the December 30, 2014 annual stockholder meeting, stockholders approved a change in incorporation to the State of Delaware. This was subsequently completed effective December 31, 2014.

In June 2015, the Company established an "at the market" ("ATM") program through which it may offer and sell up to $25.0 million of common stock from time to time, at Bio-Path's discretion, through an investment banking firm, acting as sales agent. Sales of Bio-Path common stock under the ATM program will be made directly on or through the NASDAQ Capital Market, among other methods. As of September 30, 2015, the Company has not offered or sold any shares of its common stock under the ATM program.

As of September 30, 2015, Bio-Path had $9.9 million in cash on hand.

As the Company has not begun its planned principal operations of commercializing a product candidate, the Company's activities are subject to significant risks and uncertainties, including the potential requirement to secure additional funding, the outcome of the Company's clinical trials, and failing to operationalize the Company's current drug candidates before another company develops similar products.

2. Prepaid Drug Product for Testing

Advance payments, including nonrefundable amounts, for goods or services that will be used or rendered for future research and development ("R&D") activities are deferred and capitalized. Such amounts will be recognized as an expense as the related goods are delivered or the related services are performed. The Company incurred installments to its contract drug manufacturing and raw material suppliers totaling $154,667 in late 2014 pursuant to a drug supply contract for the manufacture and delivery of the Company's lead drug product for testing in a Phase I clinical trial. This amount was carried on the Balance Sheet as of December 31, 2014 at cost as Prepaid Drug Product for Testing. The Company incurred additional installment costs with advanced payments totaling $404,378 that are carried on the Balance Sheet as of September 30, 2015 as Prepaid Drug Product for Testing (See Note 7).

3. Accounts Payable

As of September 30, 2015, Current Liabilities included accounts payable of $127,120, comprised primarily of amounts owed to MD Anderson for clinical trial hospital expenses and to the Company's drug product manufacturers and raw materials suppliers. By the first week of November 2015, the September 30, 2015 amounts included in accounts payable had been substantially paid. As of December 31, 2014, Current Liabilities included accounts payable of $41,026 and accounts payable – related party of $100,450 for MD Anderson clinical trial hospital expense which had been substantially paid by the first week of May 2015. MD Anderson is no longer a greater than 5% stockholder in the Company. As a result, the Company has consolidated accounts payable with accounts payable – related party on the financial statements beginning in 2015.

4. Accrued Expense

As of September 30, 2015, Current Liabilities included accrued expense of $354,109 for advisory fees, legal fees, clinical trial expenses, drug manufacturing and testing expenses, accrued vacation, accrued license payments and management bonus accrual. As of December 31, 2014, Current Liabilities included accrued expense of $253,445, accrued expense - related party of $67,050 for MD Anderson clinical trial hospital expense and accrued license payments – related party of $100,000 for reimbursement of past patent expenses incurred by MD Anderson prior to the Bio-Path license and the annual license maintenance fee. MD Anderson is no longer a greater than 5% stockholder in the Company. As a result, the Company has consolidated accrued expense with accrued expense – related party and accrued license payments – related party on the financial statements beginning in 2015.

5. Stockholders' Equity

Issuance of Common Stock – In January 2014, the Company issued a total of 5.0 million shares of the Company's common stock and warrants to purchase 2.5 million shares of the Company's common stock for aggregate gross proceeds of $15.0 million. The warrants are exercisable for a period of five years from the date of issuance. The exercise price of the warrants is $4.74 a share.

As of September 30, 2015, there were 89,762,872 shares of common stock issued and outstanding. There are no preferred shares outstanding as of September 30, 2015.

6. Stock-Based Compensation and Warrants

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

Stock-based compensation expense for the three and nine months ended September 30, 2015 was $98,643 and $283,205, respectively. Of these amounts, stock-based compensation for outside directors, officers, management and administrative staff of the Company was $63,227 for the three months ended September 30, 2015 and $186,453 for the nine months ended September 30, 2015. Stock-based compensation for personnel involved in the Company's R&D activities was $35,416 for the three months ended September 30, 2015 and $96,752 for the nine months ended September 30, 2015. Stock-based compensation expense for the three and nine months ended September 30, 2014 was $118,047 and $327,118, respectively. Of these amounts, stock-based compensation for outside directors, officers, management and administrative staff of the Company was $88,812 for the three months ended September 30, 2014 and $270,851 for the nine months ended September 30, 2014. Stock-based compensation for personnel involved in the Company's R&D activities was $29,235 for the three months ended September 30, 2014 and $56,267 for the nine months ended September 30, 2014. The Company utilized the Black-Scholes valuation model for estimating the fair value of the stock options granted, with the following weighted-average assumptions for options granted in the nine months ended September 30, 2015 and 2014:

	2015	2014
Risk-free interest rate	1.65%	2.03%
Expected volatility	138%	165%
Expected term in years	6.1	6.8
Dividend yield	-%	-%

The following summary represents option activity under the Company's stock-based compensation plan for the nine months ended September 30, 2015:

	Options	Weighted-Average Exercise Price
Outstanding at December 31, 2014	5,427,778	$ 1.03
Granted	349,000	1.46
Forfeited	(18,750)	2.71
Outstanding at September 30, 2015	5,758,028	1.05
Exercisable at September 30, 2015	4,997,361	$ 1.00

As of September 30, 2015, the aggregate intrinsic value of outstanding stock options was $1.7 million. The aggregate intrinsic value represents the total pretax intrinsic value (the difference between the Company's closing stock price on September 30, 2015 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on September 30, 2015. This amount changes based on the fair market value of the Company's stock.

Warrants - There were no warrants for services granted during the three months ended September 30, 2015. The Company had 10,000 warrants for services outstanding as of September 30, 2015 with a weighted average exercise price of $0.90. The 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.

7. Commitments and Contingencies

Technology License – The Company has negotiated exclusive licenses from MD Anderson to develop drug delivery technology for antisense and siRNA drug products. These licenses require, among other things, the Company to reimburse MD Anderson for ongoing patent expense. Related party accrued license payments for past patent expenses and the annual license maintenance fee attributable to the License Agreement totaling $100,000 are included in Current Liabilities as of December 31, 2014. Related party accrued expense totaling $67,050 as of December 31, 2014 represents hospital costs for the clinical trial and are not related to the License Agreement. MD Anderson is no longer a greater than 5% stockholder in the Company. As a result, the Company has consolidated accounts payable with accounts payable – related party, and accrued expense with accrued expense – related party and accrued license payments – related party on the financial statements beginning in 2015.

Operating Lease - In April 2014, the Company entered into a lease agreement for a larger office space, which it occupied as of August 2014. The remaining lease payments due under this lease as of September 30, 2015 are approximately $323,000.

Drug Supplier Project Plan – Bio-Path entered into a project plan agreement with a producer of the Company's drug product for the manufacture and delivery of final drug product in the fourth quarter of 2015. The remaining commitment requires the Company to pay approximately $85,000 in various stages as the final product is manufactured and delivered. In addition, the Company entered into an agreement with its drug substance provider for material to be used in the final drug product supplier plan with a remaining commitment totaling approximately $200,000. The amounts paid to date total $404,378 and are carried on the balance sheet as of September 30, 2015 as Prepaid Drug Product for Testing (See Note 2). Commitments to the drug substance and drug product manufacturers for manufacturing development of Bio-Path's second drug product candidate total approximately $83,000. The balance of drug supplier commitments of approximately $61,000 are for assay development and manufacturing development.

8. Subsequent Events

Bio-Path entered into an agreement for drug substance manufacture of additional development batches for testing. The Company also entered into an agreement with a testing firm for an additional new drug substance characterization assay. In total, these projects will require Bio-Path to pay approximately $105,000 over a twelve month period.

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

When you read this Item 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 Quarterly Report on 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, 2014. 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 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 in "Item 1A. Risk Factors" to Part I of our Annual Report on Form 10-K as of and for the fiscal year ended December 31, 2014, and other risks and uncertainties discussed in filings made with the SEC, including in "Item 1A. Risk Factors" to Part III of this Quarterly Report on Form 10-Q. See "Cautionary Note Regarding Forward Looking Statements" in our Annual Report on Form 10-K as of and for the fiscal year ended December 31, 2014 for additional discussion regarding risks associated with forward-looking statements.

Overview

We are a biotechnology company with a lead cancer drug candidate, Liposomal Grb2 ("L-Grb2" or "BP1001"), which is currently in clinical trials, and a second liposome delivered antisense drug candidate, Liposomal Bcl2 ("BP1002"), which has completed preclinical development. We were founded with technology from The University of Texas, MD Anderson Cancer Center ("MD Anderson") and are dedicated to developing novel cancer drugs under an exclusive license arrangement with MD Anderson. We were formed to finance and facilitate the development of novel cancer therapeutics. Our plan is to acquire licenses for drug technologies from MD Anderson and other leading medical research institutions, to fund clinical and other trials for such technologies and to commercialize such technologies. We currently maintain an exclusive license agreement with MD Anderson (the "License Agreement"). The License Agreement specifically provides drug delivery platform technology with composition of matter intellectual property that enables systemic delivery of antisense. We also plan to investigate developing liposome tumor targeting technology, which has the potential to be developed to augment our current delivery technology to improve further the effectiveness of our antisense. 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 MD Anderson, to advance these candidates into initial human efficacy trials (Phase IIa), and out-license and/or market each successful potential drug to a pharmaceutical company.

We believe that our core technology, if successful, will enable us to be at the center of emerging genetic and molecular target-based therapeutics that require systemic delivery of DNA and RNA-like material. Our two liposomal antisense drug candidates are targeted to treat acute myeloid leukemia ("AML"), myelodysplastic syndrome ("MDS"), chronic myelogenous leukemia ("CML"), acute lymphoblastic leukemia ("ALL") and follicular lymphoma, and if successful, could potentially be used in treating many other indications of cancer. We also believe that the opportunity to develop, in conjunction with MD Anderson, our lead cancer drug BP1001 to treat triple negative breast cancer ("TNBC") and inflammatory breast cancer ("IBC") is promising.

We were originally incorporated in May 2000 as a Utah corporation under the name of Ogden Golf Co. Corporation. We terminated our retail golf store operations in December 2006. On February 14, 2008, we acquired Bio-Path, Inc., a Utah corporation, in a reverse merger transaction (the "Merger"). In connection with the Merger, we changed our name to Bio-Path Holdings, Inc., acquired Bio-Path Subsidiary as a wholly-owned subsidiary and appointed the officers and directors of Bio-Path Subsidiary as officers and directors of Bio-Path Holdings, Inc. We also increased our authorized capital stock and adopted a stock incentive plan. The Merger and related matters are further described in a Current Report on Form 8-K filed with the SEC on February 19, 2008. Subsequent to the Merger, we changed our fiscal year end from June 30th to December 31st. On March 10, 2014, our common stock ceased trading on the OTCQX and commenced trading on the NASDAQ Capital Market under the ticker symbol "BPTH." We changed our state of incorporation from Utah to Delaware on December 31, 2014 through a statutory conversion pursuant to the Utah Revised Business Corporation Act and the Delaware General Corporation Law.

As of September 30, 2015, we had an accumulated deficit of $23.9 million. Our net loss was $1.5 million and $1.1 million for the three months ended September 30, 2015 and 2014, respectively. Our net loss was $4.0 million and $2.9 million for the nine months ended September 30, 2015 and 2014, respectively**.** We expect to continue to incur significant operating losses and we anticipate that our losses may increase substantially as we expand our drug development programs and commercialization efforts. To achieve profitability, we must successfully develop and obtain regulatory approval for one or more of our drug candidates and effectively commercialize any drug candidates we develop. In addition, if we obtain regulatory approval of one or more of our drug candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. There can be no assurance that we will be able to raise additional capital when needed or on terms that are favorable to us, if at all. Even if we succeed in developing and commercializing one or more of our drug candidates, we may not be able to generate sufficient revenue and we may never be able to achieve or sustain profitability.

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 block the expression of proteins that cause disease. RNA is essential in the process of creating proteins. We intend to develop drugs and drug delivery systems that are intended to work by delivering short strands of DNA material that are inserted into a cell to block the production of proteins associated with disease.

The historical perspective of cancer treatments has been the use of 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 drug products, specifically antisense, are a promising field of targeted therapy. Development of antisense, 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. Our currently licensed neutral-lipid based liposome technology is designed to accomplish this. Studies conducted at MD Anderson have shown a 10-fold to 30-fold increase in tumor cell uptake with this technology compared to other delivery methods.

BP1001

Indications for Acute Myeloid Leukemia (AML), Chronic Myelogenous Leukemia (CML), Myelodysplastic Syndrome (MDS) and Acute Lymphoblastic Leukemia (ALL)

BP1001 is our lead liposome delivered antisense drug candidate, which has been clinically tested in patients having AML, CML, MDS and ALL.

The Investigational New Drug ("IND") for BP1001 was submitted to the U.S. Food and Drug Administration ("FDA") in February 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 FDA had allowed an IND for our lead cancer drug candidate BP1001 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 preclinical studies, safety, chemistry, manufacturing, 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 preclinical 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.

The Phase I clinical trial was a dose-escalating study to determine the safety and tolerance of escalating doses of L-Grb2. The study determined an optimal biologically active dose for further development. The pharmacokinetics of L-Grb2 in patients from the study are being evaluated. In addition, patient blood samples from the trial were tested using a new assay developed by us to measure down-regulation of the target protein, the critical scientific data that demonstrated the delivery technology does in fact successfully deliver the antisense drug substance to the cell and across the cell membrane into the interior of the cell where expression of the target protein is blocked. The clinical trial was conducted at MD Anderson.

The original IND granted by the FDA in March 2010 allowed us to proceed with a Phase I clinical trial having five cohorts culminating in a maximum dose of 50 mg/m^2. However, in November 2012, we announced that since there had been no evidence of significant toxicity from treatment of patients with L-Grb2, we requested the FDA to allow higher dosing in patients. The principal investigator for the clinical trial, in consultation with our board of directors (the "Board"), advised us that with the absence of any real toxicity barriers, we should continue to evaluate higher doses of L-Grb2. The absence of significant toxicity provided a significant opportunity for us to test higher doses in patients in order to find a dose that provides maximum potential benefit and duration of anti-leukemia effect. These actions were approved and a revised protocol was submitted allowing higher dosing. We announced in October 2014 that we completed Cohort 6, successfully treating three patients at a dose of 90 mg/m^2. There has been no evidence of significant toxicity from treatment of patients with L-Grb2 in our Phase I clinical trial.

An important outcome for the Phase I clinical trial is the ability to assess for the first time the performance of our delivery technology platform in human patients. We have developed two new assays to be able to provide scientific proof of concept of the delivery technology. The first involves a novel detection method for the drug substance in blood samples that will be used to assess the pharmacokinetics of the drug. The second involves a method to measure down-regulation of the target protein in a patient blood sample that was achieved. The latter measurement will provide critical proof that the neutral liposome delivery technology delivered the drug substance to the cell and was able to transport it across the cell membrane into the interior to block cellular production of the Grb2 protein.

In this regard, in August 2013 we announced that our liposomal delivery technology achieved a major milestone in the development of antisense therapeutics based on a scientific assay confirming that treating patients with our drug candidate BP1001 inhibits the Grb2 disease-causing target protein in patients with blood cancers. Inhibition of the disease-causing protein has the effect of down regulating the disease. This will allow for BP1001 to be used potentially in combination with current frontline treatments. This discovery also points to the potential use of a liposomal antisense treatment as a standalone treatment to transform and manage a disease, which has a disease causing protein, as a chronic disorder. This accomplishment is a potentially significant breakthrough for antisense therapeutics, whose development, to date, as a class of therapeutics has been severely limited by a lack of a systemic delivery mechanism that can safely distribute the drug throughout the body and get the antisense drug substance across the cell membrane into the interior of the cell. Further, we expect that scientific proof of principle for our delivery technology may lead to licensing and business development opportunities, furthering our business model.

The principal investigator for the Phase I clinical trial is a leading expert in the treatment of CML, AML, MDS and ALL. Because the results of the first trial produced unexpected and clinically interesting results in some patients, the principal investigator prepared an abstract of the results of the first cohort that was accepted for presentation at the American Society of Hematology ("ASH") annual meeting in December 2011. Results that demonstrated potential anti-leukemia benefits in treated patients were included in the presentation. Subsequently, in fall 2013 the principal investigator prepared an abstract of updated information on the results of the clinical trial through Cohort 5, which was accepted for presentation at the ASH annual meeting in December 2013. Highlights (which have been updated to include patients from Cohort 6) of the presentation prepared by the principal investigator for the meeting included:

Data from the Phase I Clinical Trial

- Among 20 evaluable patients, 15 demonstrated anti-leukemia activity with reduction in peripheral or bone marrow blasts from baseline.
- Five patients demonstrated transient improvement and/or stable disease, three of whom received a total of five cycles each.
- Two patients, in addition to achieving market blast percentage declines, also experienced transient improvements in leukemia cutis lesions.

Disease Stabilization in MDS and AML

- Two patients with MDS, a 53-year-old male and a 72-year-old female, both achieved disease stabilization and continued therapy for five cycles before disease progression.
- A 54-year-old HIV positive male with AML achieved stable disease and marked reduction in peripheral blasts, continuing therapy for five cycles before disease progression.

Experience in CML-Blast Phase

- Patient with myeloid blast crisis of CML.
- Prior therapies consist of: imatinib, dastinib, nilotinib, DCC-2036, Cytarabine + Fludarabine + Dasatinib + Gemtuzumab, PHA-739358, Clofarabine + Dasatinib.
- Upon start of BP1001, patient showed a significant reduction in blasts from 81 percent to 5 percent but due to leptomeningeal disease progression discontinued therapy before full cycle.

Inhibition of Target Grb2 Protein

- Grb2 levels were compared to baseline prior to treatment.
- On day 15, BP1001 decreased Grb2 in seven of eleven samples tested (average reduction 53 percent).
- End of treatment day 15, BP1001 decreased Grb2 levels in ten out of twelve patients (average reduction 50 percent).

Being a platform technology, a successful demonstration of the delivery technology in this study allows us to begin expanding our drug candidates by simply applying the delivery technology template to multiple new drug product targets. In this manner, we 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. Currently, we are researching potential targets for which we can apply our liposomal antisense drug delivery technology and have already identified two new candidates.

The Phase I clinical trial is typically ended when a maximum tolerated dose ("MTD") is encountered. However, due to the lack of toxicity of the drug, a MTD was not observed. As a result, an optimal biological dose was determined and we completed Cohort 6 of our Phase I clinical trial. It is noted, however, that the lack of toxicity is a major advantage for the drug candidate BP1001 since it allows higher levels of drug to be administered to the patient, increasing the potential therapeutic benefit.

On February 9, 2015, we announced that we began enrollment into the safety segment of our Phase II clinical trial on BP1001 in patients with AML. The safety segment of our combination therapy Phase II clinical trial in AML consists of two dosing cohorts (60 mg/m^2 and $90mg/m^2$) to test the safety profile of treating AML patients first with BP1001 and low dose Ara-C. Patients ineligible for intensive induction therapy are currently treated only with low dose Ara-C. This trial will determine if adding BP1001 will yield better response rates in this AML patient population. Following the safety portion, the trial will then be opened in multiple centers to test 40-60 patients with the combination. An interim analysis will be performed after approximately 20 patients have been treated with the combination therapy.

On April 28, 2015, we announced that the FDA granted orphan designation to BP1001 for the treatment of AML. Orphan drug status provides Bio-Path with seven years of exclusivity after receiving formal marketing approval, as well as additional development incentives. The FDA grants this designation to certain drugs that are targeting diseases affecting fewer than 200,000 people in the United States.

On October 9, 2015, we announced that we have completed Cohort 7 of the Phase Ib clinical trial evaluating BP1001 in combination with low dose Ara-C in AML patients. We announced that three patients completed the treatment cycle with no adverse events attributed to the study drug, further confirming that BP1001 is well tolerated. Furthermore, we announced that one patient achieved a complete remission following this treatment and that a second patient had improved and was receiving additional cycles of treatment.

In addition, plans and evaluation of manufacturing scale-up of the drug substance batch size continued. Scale-up of manufacturing output of drug substance product and final drug product is critical to meeting the anticipated potential for high volume requirements of our drug products for patients in multiple diseases. The larger size drug substance and final product batch sizes will also substantially drive down manufacturing cost per drug unit. Further to this, plans are in place and testing is ongoing to increase the amount of drug substance per manufactured vial, which increases even further the effective capacity of our drug manufacturing. We are also currently working to add a second manufacturer for each of the key areas of drug substance, lipids and final drug product. Our recent success in raising capital should also improve drug supply by providing the financial resources that will enable us to commit to multiple drug batches beyond those required to satisfy near-term requirements.

Indications for Triple Negative Breast Cancer (TNBC) and Inflammatory Breast Cancer (IBC)

In July 2013, we announced that we were initiating preclinical testing of BP1001 into two additional indications: TNBC and IBC. TNBC tumors do not express estrogen receptors, progesterone receptors, and low Human Epidermal growth factor Receptor 2 ("HER2"). These negative results mean that the growth of the cancer is not supported by the hormones estrogen and progesterone, or by the presence of too many HER2 receptors. Therefore, TNBC does not respond to hormonal therapy or therapies that target HER2 receptors. In addition, TNBC tumors are very aggressive. Approximately 15 to 20 percent of breast cancers are triple-negative. IBC is a rare and very aggressive disease in which cancer cells block lymph vessels in the skin of the breast. This type of breast cancer is called "inflammatory" because the breast often looks swollen and red, or "inflamed." IBC accounts for two to five percent of all breast cancers. IBC tumors are very aggressive and are frequently hormone receptor negative, which means hormone therapies may not be effective. The five year survival rate for IBC is approximately 40% versus approximately 87% for all breast cancers combined, making IBC a priority area for development of new treatments.

Our plan is to develop BP1001 as a targeted therapy against TNBC and IBC. Our treatment goals are two-pronged: the first is to develop BP1001 as a tumor reduction agent in combination with other approved drugs in preoperative settings for TNBC and IBC patients, and the second is to develop BP1001 as a drug to treat and control or eliminate cancer metastasis in TNBC and IBC patients. Both of these treatment goals address high need situations for patients. Once the preclinical studies are successfully completed, we believe that the observations that we learned from the original Phase I trial will help us to increase the speed of progress for such Phase I trial in TNBC and IBC, as the toxicity profile of BP1001 is currently well established.

BP1002

BP1002, also known by its scientific name as Liposomal Bcl2, is our second liposome delivered antisense drug candidate. BP1002 is intended to target the lymphoma and certain solid tumor markets. Clinical targets for BP1002 include lymphoma, breast cancer, colon cancer, prostate cancer and leukemia. We believe that BP1002 has the potential to treat 40%-60% of solid tumors.

Bcl2 is a protein that is involved in regulating apoptosis or programmed cell death. Apoptosis is a physiologic mechanism of cell turnover by which cells actively commit suicide in response to aberrant external signals. Over-expression of Bcl2 prevents the induction of apoptosis in response to cellular insults such as treatment with chemotherapeutic agents. Bcl2 is over-expressed in more than 90% of follicular B-cell non-Hodgkins lymphoma due to a chromosomal rearrangement and is the key factor in the initiation of this malignancy. Bcl2 is also overexpressed in a wide variety of solid tumors (it is estimated to be over-expressed in 40% of cancers). For example, Bcl2 over-expression has been associated with the progression of prostate cancer from hormone dependence to hormone independence and may contribute to the relative drug resistant phenotype typically observed in hormone independent prostate cancer.

On December 22, 2014, we announced that we initiated development of BP1002 as a treatment for follicular lymphoma. We intend to file a new IND to begin clinical testing of BP1002 in patients with follicular lymphoma in early 2016.

Other Liposomal Antisense Products

We also intend to apply our drug delivery technology template to new disease-causing protein targets as a means to develop new liposomal antisense drug candidates. A new product identification template was recently approved that defines a process of scientific, preclinical, commercial and intellectual property evaluation of potential new drug candidates for inclusion into our drug product development pipeline. A significant amount of capital will be allocated for in-licensing promising protein targets that can be developed as new liposomal antisense drug candidates.

Definitions

The following definitions are intended to assist you in understanding certain matters discussed in this "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations":

Antisense is a medication containing part of the non-coding strand of messenger RNA (mRNA), a key molecule involved in the translation of DNA into protein. Antisense drugs hybridize with and inactivate mRNA. This stops a particular gene from producing the protein for which it holds the recipe. Antisense drugs have been developed or are "in the pipeline" to treat eye disease in AIDS, lung cancer, diabetes and diseases such as arthritis and asthma with a major inflammatory component.

Acute Myeloid Leukemia (AML) is a cancer of the myeloid line of white blood cells, characterized by the rapid proliferation of abnormal cells that accumulate in the bone marrow and interfere with the production of normal blood cells. AML is the most common acute leukemia affecting adults, and its incidence increases with age. Although AML is a relatively rare disease, accounting for approximately 1.2% of cancer deaths in the United States, its incidence is expected to increase as the population ages. The symptoms of AML are caused by replacement of normal bone marrow with leukemic cells, resulting in a drop in red blood cells, platelets, and normal white blood cells. These symptoms include fatigue, shortness of breath, easy bruising and bleeding, and increased risk of infection. Although several risk factors for AML have been identified, the specific cause of AML remains unclear. As an acute leukemia, AML progresses rapidly and is typically fatal within weeks or months if left untreated. Acute myeloid leukemia is a potentially curable disease, but only a minority of patients are cured with current therapy.

Chronic Myelogenous Leukemia (CML) is a form of leukemia characterized by the increased and unregulated growth of predominantly myeloid cells in the bone marrow and the accumulation of these cells in the blood. CML is a clonal bone marrow stem cell disorder in which proliferation of mature granulocytes (neutrophils, eosinophils, and basophils) and their precursors is the main finding. It is a type of myeloproliferative disease associated with a characteristic chromosomal translocation called the Philadelphia chromosome.

Liposomal Delivery Technology is used for drug delivery due to their unique properties. A liposome encapsulates a region on aqueous solution inside a hydrophobic membrane; dissolved hydrophilic solutes cannot readily pass through the lipids. Hydrophobic chemicals can be dissolved into the membrane, thereby incorporating the materials, and in this way liposome can carry both hydrophobic molecules and hydrophilic molecules. To deliver the molecules to sites of action, the lipid bilayer can fuse with other bilayers such as the cell membrane, thus delivering the liposome contents. By making liposomes in a solution of DNA or drugs (which would normally be unable to diffuse through the membrane) they can be (indiscriminately) delivered past the lipid bilayer.

Myelodysplastic Syndromes (MDS) are a diverse collection of hematological conditions united by ineffective production (or dysplasia) of myeloid blood cells and risk of transformation to acute myelogenous leukemia. Anemia requiring chronic blood transfusion is frequently present. Myelodysplastic syndromes are bone marrow stem cell disorders resulting in disorderly and ineffective hematopoiesis (blood production) manifested by irreversible quantitative and qualitative defects in hematopoietic (blood-forming) cells. In a majority of cases, the course of disease is chronic with gradually worsening cytopenias due to progressive bone marrow failure.

Nucleic Acid Drug Products are nucleic acid base sequences that play a crucial role in the expression of gene. The gene is responsible for the synthesis of proteins and these proteins, which are synthesized, are responsible for the biological process including diseases. If the nucleic acid sequence is altered, it could be possible to block or transfer the message for protein synthesis, thereby preventing the particular protein, which is responsible for the disease. These nucleic acids act as drugs by different mechanisms, they may bind with the synthesized proteins, and they can hybridize to a messenger RNA leading to translation arrest or may induce degradation to target RNA. In this way the nucleic acids can act as drugs for inhibiting gene expression or protein synthesis.

Financial Operations Overview

Revenue

To date, we have not generated any revenues. Our ability to generate revenues from our drug candidates, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our drug candidates.

Research and development expenses

Research and development expenses consist of costs associated with our research activities, including the development of our drug candidates. Our research and development expenses consist of:

- expenses related to research and development personnel, including salaries, benefits, travel and stock-based compensation;

- external research and development expenses incurred under arrangements with third parties, such as contract research organizations, clinical sites, manufacturing organizations and consultants;
- license fees, including maintenance fees and patent expense paid to MD Anderson in connection with the License Agreement; and
- costs of materials used during research and development activities.

Costs and expenses that can be clearly identified as research and development are charged to expense as incurred in accordance with generally accepted accounting policies ("GAAP"). Advance payments, including nonrefundable amounts, for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts will be recognized as an expense as the related goods are delivered or the related services are performed. If the goods will not be delivered, or services will not be rendered, then the capitalized advance payment is charged to expense.

We expect research and development expenses associated with the completion of the associated clinical trials to be substantial and to increase over time. The successful development of our drug candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete development of our drug candidates or the period, if any, in which material net cash inflows from our drug candidates may commence. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the rate of progress, results and costs of completion of ongoing clinical trials of our drug candidates;
- the size, scope, rate of progress, results and costs of completion of any potential future clinical trials and preclinical trials of our drug candidates that we may initiate;
- competing technological and market developments;
- the performance of third-party manufacturers and suppliers;
- the ability of our drug candidates, if they receive regulatory approval, to achieve market success; and
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our drug candidates.

A change in the outcome of any of these variables with respect to the development of a drug candidate could mean a significant change in the costs and timing associated with the development of that drug candidate. For example, if the FDA or other regulatory authority were to require us to conduct clinical trials beyond those which we currently anticipate will be required for the completion of clinical development of a drug candidate or if we experience significant delays in enrollment in any clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

General and administrative expenses

Our general and administrative expenses consist primarily of salaries and benefits for management and administrative personnel, professional fees for legal, accounting and other services, travel costs and facility-related costs such as rent, utilities and other general office expenses.

Results of Operations

Comparisons of the Three Months Ended September 30, 2015 to the Three Months Ended September 30, 2014

Research and Development Expense. Our research and development expense for the three months ended September 30, 2015 was $1.0 million, an increase of $0.6 million compared to the three months ended September 30, 2014. The increase in research and development expense was primarily due to increased drug material manufacturing and testing, an increase in drug material used as well as increased clinical trial expenses. Research and development - related party expense has been consolidated with research and development expense on our financial statements in 2015 as MD Anderson is no longer a greater than 5% stockholder in the Company.

	Three Months Ended September 30,	
	2015	2014
Research and development expense	$ 957,030	$ 395,286
Research and development - related party expense	-	16,235
Non-cash stock-based compensation expense	35,416	29,235
Total research and development expense	$ 992,446	$ 440,756

General and Administrative Expense. Our general and administrative expense for the three months ended September 30, 2015 was $0.5 million, a decrease of $0.2 million compared to the three months ended September 30, 2014. The decrease in general and administrative expense was primarily due to decreased management and administrative personnel costs.

	Three Months Ended September 30,	
	2015	2014
General and administrative expense	$ 456,717	$ 624,540
Non-cash stock-based compensation expense	63,227	88,812
Total general and administrative expense	$ 519,944	$ 713,352

Net Loss. Our net loss for the three months ended September 30, 2015 was $1.5 million, an increase of $0.4 million compared to the three months ended September 30, 2014. Net loss per share, both basic and diluted, was $0.02 per share for the three months ended September 30, 2015 compared to $0.01 per share for the three months ended September 30, 2014.

Comparisons of the Nine Months Ended September 30, 2015 to the Nine Months Ended September 30, 2014

Research and Development Expense. Our research and development expense for the nine months ended September 30, 2015 was $2.1 million, an increase of $1.1 million compared to the nine months ended September 30, 2014. The increase in research and development expense was primarily due to increased manufacturing development, preclinical studies, clinical trial expenses and personnel costs associated with the addition of our support staff hired in the second half of 2014. Research and development - related party expense has been consolidated with research and development expense on our financial statements in 2015 as MD Anderson is no longer a greater than 5% stockholder in the Company.

	Nine Months Ended September 30,	
	2015	2014
Research and development expense	$ 2,052,525	$ 992,449
Research and development - related party expense	-	41,654
Non-cash stock-based compensation expense	96,752	56,267
Total research and development expense	$ 2,149,277	$ 1,090,370

General and Administrative Expense. Our general and administrative expense for the nine months ended September 30, 2015 was $1.9 million, an increase of $24,000 compared to the nine months ended September 30, 2014. The increase in general and administrative expense was primarily due to increased professional fees.

	Nine Months Ended September 30,	
	2015	2014
General and administrative expense	$ 1,686,491	$ 1,577,900
Non-cash stock-based compensation expense	186,453	270,851
Total general and administrative expense	$ 1,872,944	$ 1,848,751

Net Loss. Our net loss for the nine months ended September 30, 2015 was $4.0 million, an increase of $1.1 million compared to the nine months ended September 30, 2014. Net loss per share, both basic and diluted, increased to $0.04 per share for the nine months ended September 30, 2015 compared to $0.03 per share for the nine months ended September 30, 2014.

Liquidity and Capital Resources

Overview

To date, we have not generated any revenues. Since our inception, we have funded our operations primarily through public and private offerings of our capital stock and other securities. We expect to finance our foreseeable cash requirements through cash on hand, cash from operations and public or private equity offerings. Additionally, we may seek collaborations and license arrangements for our drug candidates. We may seek to access the public or private equity markets whenever conditions are favorable. We currently have no lines of credit or other arranged access to debt financing.

We had a cash balance of $9.9 million as of September 30, 2015 compared to a cash balance of $13.9 million as of December 31, 2014. We believe that our available cash at September 30, 2015 will be sufficient to fund our liquidity and capital expenditure requirements for at least the next 12 months.

Cash Flows

Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2015 was $4.0 million. Net cash used in operating activities for the nine months ended September 30, 2015 consisted primarily of the net loss for the period of $4.0 million, an increase in prepaid drug product for testing of $0.2 million, an increase in other current assets of $0.1 million and a net decrease in current liabilities of $0.1 million. These are partially offset by non-cash stock-based compensation expense of $0.3 million and technology license amortization expense of $0.1 million.

2014 Shelf Registration

On November 5, 2013, we filed a shelf registration statement on Form S-3 with the SEC, which was declared effective by the SEC on January 13, 2014 (the "Shelf Registration Statement"). The Shelf Registration Statement was filed to register the offering and sale of up to $100.0 million of our common stock, preferred stock, warrants to purchase common stock or preferred stock or any combination thereof, either individually or in units. The foregoing does not constitute an offer to sell or the solicitation of an offer to buy securities, and shall not constitute an offer, solicitation or sale in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of that jurisdiction.

Registered Direct Offering

On January 15, 2014, we entered into a securities purchase agreement, as amended, with certain investors, pursuant to which we agreed to sell an aggregate of 5.0 million shares of our common stock and warrants to purchase a total of 2.5 million shares of our common stock to such certain investors for gross proceeds of approximately $15.0 million. The net proceeds from the registered direct public offering, after deducting the placement agent's fees and expenses, our estimated offering expenses, and excluding the proceeds from the exercise of the warrants issued in the offering, were approximately $13.8 million. The offering closed on January 21, 2014.

"At the Market" Offering

On June 24, 2015, we entered into a Controlled Equity Offering^{SM} Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor Fitzgerald"), as sales agent, pursuant to which we may offer and sell, from time to time, through Cantor Fitzgerald shares of our common stock. Sales of shares of common stock under the Sales Agreement will be made pursuant to the Shelf Registration Statement and a related prospectus supplement filed with the SEC on June 25, 2015, for an aggregate offering price of up to $25.0 million. Under the Sales Agreement, Cantor Fitzgerald may sell shares by any method deemed to be an "at the market" offering as defined in Rule 415 under the Securities Act or any other method permitted by law, including in privately negotiated transactions. We will pay Cantor Fitzgerald a commission of 3.4% of the aggregate gross proceeds from each sale of shares under the Sales Agreement and have agreed to provide Cantor Fitzgerald with customary indemnification and contribution rights. We have also agreed to reimburse Cantor Fitzgerald for certain specified expenses. As of September 30, 2015, we have not offered or sold any shares of common stock under the Sales Agreement.

Future Capital Requirements

We expect to continue to incur significant operating expenses in connection with our ongoing activities, including conducting clinical trials, manufacturing and seeking regulatory approval of our drug candidates, BP1001 and BP1002. Accordingly, we will continue to require substantial additional capital to fund our projected operating requirements. Such additional capital may not be available when needed or on terms favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current and future operating plan. There can be no assurance that we will be able to continue to raise additional capital through the sale of our securities in the future. Our future capital requirements may change and will depend on numerous factors, which are discussed in detail in "Item 1A. Risk Factors" to Part I of our Annual Report on Form 10-K as of and for the fiscal year ended December 31, 2014, in "Item 1A. Risk Factors" to Part II of this Quarterly Report on Form 10-Q and in other reports or documents we file from time to time with the SEC.

Off-Balance Sheet Arrangements

As of September 30, 2015, we did not have any material off-balance sheet arrangements.

Critical Accounting Policies

The preparation of financial statements in conformity with 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. We consider our 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 as of and for the year ended December 31, 2014.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Interest Rate Risk. We had cash and cash equivalents of approximately $9.9 million as of September 30, 2015. Although this cash account is subject to fluctuations in interest rates and market conditions, no significant gain or loss on this account is expected to be recognized in earnings. We do not invest in derivative securities.

Capital Market Risk. We currently have no product revenues and depend on funds raised through other sources. Potential sources of funding include future debt or equity offerings. Our ability to raise funds in this manner depends upon capital market forces affecting our stock price.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, including our Chief Executive Officer and our Chief Financial Officer, have reviewed and evaluated the effectiveness of our disclosure controls and procedures, as defined in Section 240.13a-15(e) or Section 240.15d-15(e) of the Exchange Act, as of the end of the period covered by this Quarterly Report on Form 10-Q. Following this review and evaluation, management collectively determined that our disclosure controls and procedures are effective and that they ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act (i) is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and (ii) is accumulated and communicated to management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 1A. RISK FACTORS

There were no material changes from the risk factors previously disclosed under "Item 1A. Risk Factors" to Part I of our Annual Report on Form 10-K as of and for the fiscal year ended December 31, 2014, other than the additional disclosure of the risk factors listed below.

Certain patents under the License Agreement are set to expire over the next few years.

Under the License Agreement, we license rights to certain patents that are necessary or useful for our business. Some of these material patents are set to expire as early as 2017. We are actively reviewing and preparing patent applications to expand our patent portfolio, but there can be no assurances that patents related to these applications will be issued or that any issued patents will provide meaningful protection for our drug candidates, which could materially adversely affect our competitive business position, business prospects and financial condition.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

None.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit No.	Description of Exhibit
2.1	Agreement and Plan of Merger and Reorganization dated September 27, 2007, by and among the Company, Biopath Acquisition Corp., a Utah corporation and wholly owned subsidiary of the registrant, and Bio-Path, Inc., a Utah corporation (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed on September 27, 2007).
3.1	Certificate of Incorporation (incorporated by reference to Exhibit 3.3 to the Company's Current Report on Form 8-K filed on January 6, 2015).
3.2	Bylaws (incorporated by reference to Exhibit 3.4 to the Company's Current Report on Form 8-K filed on January 6, 2015).
3.3	Articles of Merger relating to the merger of Biopath Acquisition Corp. with and into Bio-Path, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on February 19, 2008).
3.4	Certificate of Conversion (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed on January 6, 2015).

3.5	Articles of Transfer (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on January 6, 2015).
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Company's Annual Report on Form 10-K filed on March 16, 2015).
4.2	Warrant Agreement, dated April 25, 2008, by and between the Company and Randeep Suneja, M.D. (incorporated by reference to Exhibit 4.2 to the Company's Annual Report on Form 10-K filed on March 31, 2014).
4.3	Form of Warrant issued to Maxim Group LLC, Sabby Healthcare Volatility Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd. (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on January 21, 2014).
31*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 Sarbanes Oxley Act of 2002.
32*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

SIGNATURE

In accordance with the requirements of the Exchange Act, the Company has caused this Quarterly Report on Form 10-Q to be signed on its behalf by the undersigned thereunto duly authorized.

Dated: November 9, 2015

BIO-PATH HOLDINGS, INC.

By: /s/ Peter H. Nielsen
Peter H. Nielsen
President
Chief Executive Officer
(Principal Executive Officer)
Chief Financial Officer
(Principal Financial Officer)

CERTIFICATION OF
PRINCIPAL EXECUTIVE OFFICER AND
PRINCIPAL FINANCIAL OFFICER

I, Peter H. Nielsen, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Bio-Path Holdings, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this report is being prepared; and

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant’s board of directors:

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2015

By: /s/ Peter H. Nielsen
Peter H. Nielsen
Chief Executive Officer
(Principal Executive Officer)
Chief Financial Officer
(Principal Financial Officer)

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Bio-Path Holdings, Inc. (the "Company") for the quarter ended September 30, 2015 as filed with the Securities and Exchange Commission (the "Report"), I, Peter H. Nielsen, Chief Executive Officer and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 9, 2015

By: /s/ Peter H. Nielsen
Peter H. Nielsen
Chief Executive Officer
Chief Financial Officer