BIO-PATH HOLDINGS INC
Form 10-Q
November 14, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2014

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.)

4710 Bellaire Boulevard, Suite 210, Bellaire, Texas 77401

(Address of principal executive offices)

Registrant's telephone no., including area code: (832) 971-6616

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

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

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

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

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

At November 5, 2014, the Company had 89,237,872 outstanding shares of common stock, no par value.

Forward-Looking Statements

Statements in this Quarterly Report on Form 10-Q that are not strictly historical in nature are forward-looking statements. These statements may include, but are not limited to, statements about: the timing of the commencement, enrollment, and completion of our anticipated clinical trials for our product candidates; the progress or success of our product development programs; the status of regulatory approvals for our product candidates; the timing of product launches; our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others; and our estimates for future performance, anticipated operating losses, future revenues, capital requirements, and our needs for additional financing. In some cases, you can identify forward-looking statements by terms such as “anticipates,” “believes,” “could,” “estimates,” “expects,” “intends,” “may,” “plan “potential,” “predicts,” “projects,” “should,” “will,” “would,” “goal,” and similar expressions intended to identify forward-look statements. These statements are only predictions based on current information and expectations and involve a number of risks and uncertainties. The underlying information and expectations are likely to change over time. Actual events or results may differ materially from those projected in the forward-looking statements due to various factors, including, but not limited to, those set forth under the caption “Risk Factors” in “ITEM 1. BUSINESS” of our Annual Report on Form 10-K as of and for the fiscal year ended December 31, 2013, 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.

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PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

BIO-PATH HOLDINGS, INC.

(A Development Stage Company)

CONSOLIDATED BALANCE SHEETS

Unaudited

	September 30, 2014	December 31, 2013
ASSETS		
Current assets		
Cash	$14,636,602	$3,551,832
Prepaid drug product for testing	96,563	51,364
Other current assets	194,181	64,117
Total current assets	14,927,346	3,667,313
Fixed assets	66,124	-
Other assets		
Technology licenses - related party	2,500,374	2,500,374
Less Accumulated Amortization	(1,209,325)	(1,088,856)
	1,291,049	1,411,518
TOTAL ASSETS	$16,284,519	$5,078,831
LIABILITIES & SHAREHOLDERS' EQUITY		
Current liabilities		
Accounts payable	88,514	76,109
Accrued expense	77,594	66,739

Accrued expense - related party	67,050	52,050
Accrued license payments - related party	50,000	100,000
Total current liabilities	283,158	294,898
Long term debt	-	-
TOTAL LIABILITIES	283,158	294,898
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 89,237,872 and 84,237,872 shares issued and outstanding as of 9/30/14 and 12/31/13, respectively	89,238	84,238
Additional paid in capital	34,231,482	20,096,991
Accumulated deficit	(18,319,359)	(15,397,296)
Total shareholders' equity	16,001,361	4,783,933
TOTAL LIABILITIES & SHAREHOLDERS' EQUITY	$16,284,519	$5,078,831

SEE ACCOMPANYING NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

BIO-PATH HOLDINGS, INC.

(A Development Stage Company)

CONSOLIDATED STATEMENTS OF OPERATIONS

Unaudited

	Third Quarter July 1 to September 30		Year to Date January 1 to September 30	
	2014	2013	2014	2013
Revenue	$-	$-	$-	$-
Operating expense				
Research and development a/	424,521	568,576	1,048,716	1,125,711
Research and development - related party	16,235	15,000	41,654	62,067
General & administrative b/	713,352	810,152	1,848,751	1,290,506
Total operating expense	1,154,108	1,393,728	2,939,121	2,478,284
Net operating loss	$(1,154,108)	$(1,393,728)	$(2,939,121)	$(2,478,284)
Other income (expense)				
Interest income	5,713	837	17,353	2,492
Other expense	(14)	(316)	(295)	(661)
Total Other Income (Expense)	5,699	521	17,058	1,831
Net Loss	$(1,148,409)	$(1,393,207)	$(2,922,063)	$(2,476,453)
Loss per share				
Net loss per share, basic and diluted	$(0.01)	$(0.02)	$(0.03)	$(0.04)
Basic and diluted weighted average number of common shares outstanding	89,237,872	75,380,214	89,237,872	68,068,456

a/ Research and development expense includes stock option expenses of $29,235 and $6,623 for the quarters ending 9/30/2014 and 9/30/2013, respectively; and $56,267 and $26,256 for the nine month periods ending 9/30/2014 and 9/30/2013, respectively. Research and development expense also includes amortization expenses of $40,156 for the quarters ending 9/30/2014 and 9/30/2013; and $120,469 for the nine month periods ending 9/30/2014 and 9/30/2013.

b/ General & administrative expense includes stock for services, stock option and warrant expenses of $88,812 and $599,424 for the quarters ending 9/30/2014 and 9/30/2013; respectively; and $270,851 and $609,347 for the nine month periods ending 9/30/2014 and 9/30/2013, respectively.

SEE ACCOMPANYING NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

BIO-PATH HOLDINGS, INC.

(A Development Stage Company)

CONSOLIDATED STATEMENTS OF CASH FLOWS

Unaudited

	January 1, to September 30	
	2014	2013
CASH FLOW FROM OPERATING ACTIVITIES		
Net loss	$(2,922,063)	$(2,476,453)
Adjustments to reconcile net loss to net cash used in operating activities		
Amortization	120,469	120,469
Stock options and warrants	327,118	635,603
(Increase) decrease in assets		
Prepaid drug product for testing	(45,199)	46,699
Other current assets	(130,064)	(7,138)
Increase (decrease) in liabilities		
Accounts payable and accrued expenses	(11,740)	(155,491)
Net cash used in operating activities	(2,661,479)	(1,836,311)
CASH FLOW FROM INVESTING ACTIVITIES		
Purchase of fixed assets	(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	5,403,106
Net cash from financing activities	13,812,373	5,403,106
NET INCREASE (DECREASE) IN CASH	11,084,770	3,566,795
Cash, beginning of period	3,551,832	534,046

Cash, end of period	$14,636,602	$4,100,841
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash paid for		
Interest	$-	$-
Income taxes	$-	$-
Non-cash financing activities		
Common stock issued to Placement Agent	$-	$448,950

SEE ACCOMPANYING NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

BIO-PATH HOLDINGS, INC.

(A Development Stage Company)

Notes to the Unaudited Consolidated Financial Statements Ended September 30, 2014

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 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. 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, 2013. The results of operations for the period ended September 30, 2014, are not necessarily indicative of the results for a full-year period.

1. Organization and Business

Bio-Path is a biotechnology company with its lead cancer drug candidate, Liposomal Grb-2 ("L-Grb-2" or "BP-100-1.01"), currently in clinical trials. 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 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, in July of 2013 Bio-Path announced that it was initiating development of its lead cancer drug Liposomal Grb-2 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 is currently treating patients with its lead cancer drug candidate Liposomal Grb-2 in a Phase I clinical trial. In March of 2010, Bio-Path received written notification from the U.S. Food and Drug Administration (the "FDA") that its application for Investigational New Drug ("IND") status for L-Grb-2 had been granted. This enabled the Company to commence its Phase I clinical trial to study L-Grb-2 in human patients, which began in the third quarter 2010.

The Phase I clinical trial is a dose-escalating study to determine the safety and tolerance of escalating doses of L-Grb-2. The study will also determine the optimal biologically active dose for further development. The pharmacokinetics of L-Grb-2 in patients will be studied, making it possible to investigate whether the delivery technology performs as expected based on pre-clinical studies in animals. In addition, patient blood samples from the trial are now being tested using a new assay developed by the Company to measure down-regulation of the target protein, the critical scientific data needed to demonstrate that 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 is being conducted at The University of Texas MD Anderson Cancer Center.

The original IND granted by the FDA in March of 2010 allowed the Company to proceed with a Phase I clinical trial having five (5) cohorts culminating in a maximum dose of 50 mg/m^2. However, in November of 2012, the Company announced that since there had been no evidence of significant toxicity from treatment of patients with L-Grb-2, the Company requested the FDA to allow higher dosing in patients. The Principal Investigator for the clinical trial, Jorge Cortes, M.D. (the "Principal Investigator"), in consultation with Bio-Path's Board of Directors (the "Board"), advised that with the absence of any real toxicity barriers, the Company should continue to evaluate higher doses of Liposomal Grb-2. The absence of significant toxicity provides a significant opportunity for the Company 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 is in place allowing higher dosing. The Company announced in June of 2013 that it completed Cohort 5, successfully treating three patients at a dose of 60 mg/m^2, which had been increased from 50 mg/m^2 in the revised protocol. The Company has enrolled patients in Cohort 6 for treatment at a dose of 90 mg/m^2, has two (2) evaluable patients and is currently treating another patient. Assuming the current patient successfully completes the treatment cycle the Company will be able to close Cohort 6.

Patients eligible for enrollment into the Phase I clinical trial have refractory or relapsed AML, CML and ALL, or MDS and who have failed other approved treatments. These are patients with very advanced stages of the disease, and consequently, not all patients enrolled are able to complete the four-week treatment cycle because of progressive disease, which is unrelated to the treatment with Liposomal-Grb-2.

An important outcome for the Phase I clinical trial is the ability to assess for the first time the performance of the Company's delivery technology platform in human patients. The Company has 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 Grb-2 protein.

In this regard, in August of 2013 Bio-Path made a major announcement that its liposomal delivery technology achieved a major milestone in the development of antisense therapeutics based on a scientific assay confirming that treating patients with its drug candidate BP-100-1.01 inhibits the Grb-2 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 Liposomal Grb-2 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 potentially a 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 principal for our delivery technology may lead to licensing and business development opportunities, furthering our business model.

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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 annual meeting in December of 2011. Results that demonstrated potential anti-leukemia benefits in treated patients were included in the presentation. Subsequently, in the fall of 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 American Society of Hematology annual meeting in December of 2013. Highlights from the presentation prepared by Dr. Cortes for the meeting included:

Data from the Phase I clinical trial

- Among 18 evaluable patients, nine experienced at least a 50 percent 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 marked blast percentage declines, also experienced transient improvement 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 BP-100-1.01 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 Grb-2 Protein

- Grb-2 levels were compared to baseline prior to treatment.
- On day 15, BP-100-1.01 decreased Grb-2 in five of eight samples tested (average reduction 55 percent)
- End of treatment day15, BP-100-1.01 decreased Grb-2 levels in eight out of nine patients (average reduction 45 percent).

Being platform technology, a successful demonstration of the delivery technology in this study will allow the Company to begin expanding Bio-Path's drug candidates by simply applying the delivery technology template to

multiple new drug product targets. In this manner, Bio-Path can quickly build an attractive drug product pipeline with multiple drug product candidates for treating cancer as well as treating other important diseases including diabetes, cardiovascular conditions and neuromuscular disorders. Currently, the Company is researching potential targets for which it can apply its liposomal antisense drug delivery technology and has already identified one new candidate.

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 to date, it is not expected that a MTD will be encountered. As a result, the optimal biological dose will be determined and this dose will be used in the following Phase II clinical trial. Bio-Path is now completing an analysis of the Phase I data to submit to the FDA. Bio-Path has also been working with the Principal Investigator to finalize plans for Phase II clinical trials in Liposomal Grb-2. Significantly, these plans include three Phase II trials, one each for CML, AML and MDS, of the drug candidate Liposomal Grb-2 in salvage therapy for very advanced patients. It expects to begin its Phase II program by the end of 2014. It is anticipated that the first of three Phase II clinical trials will evaluate Liposomal Grb-2 as a combination therapy in AML.

In the process of evaluating patients at the close of Cohort 6, the Company will assess whether the Phase I clinical trial should be ended at this time or continued with a higher dose Cohort 7. It is expected that the down regulation assay will be a factor in the evaluation of whether we have reached optimal inhibition. It is noted, however, that the lack of toxicity is a major advantage for the drug candidate BP-100-1.01 since it allows higher levels of drug to be administered to the patient, increasing the potential therapeutic benefit. In the event that the Company does continue the Phase I clinical trial with a Cohort 7, it would run in parallel with the Phase II program.

Manufacturing scale-up of the drug substance batch size continued. Scale-up of manufacturing batch size previously produced divergence from desired drug substance product parameters, with some product in the fourth quarter of 2013 not being acceptable for use. The most recent manufacturing scale-up drug substance batch appears to have corrected this and a recent drug batch was released for use in the clinical trial by the manufacturer. 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 Bio-Path's 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. The recent success on the part of the Company in raising capital should also improve drug supply by providing the financial resources that will enable the Company to commit to multiple drug batches beyond those required to satisfy near-term requirements. In addition, the Company is currently bringing on a second final drug product manufacturer, which is expected to provide improved scheduling and delivery flexibility.

At the end of January 2012, the Company's Board held a strategic planning session. Among several topics was a discussion of the Company's liposomal siRNA technology. The siRNA discussion covered a broad range of topics including intellectual property, the amount of development that would be needed and the overall impression of diminishing acceptance of siRNA technology by the pharmaceutical industry and equity market investors. The Board compared this to our core liposomal antisense technology, which has a stronger intellectual property position, a method of action blocking expression of disease-causing proteins that is better understood in the scientific community and a much easier path for development than liposomal siRNA technology. Since both antisense and siRNA are means to block expression of disease-causing proteins, the Board concluded that there was no apparent reason to develop a second, higher-risk siRNA method of blocking protein expression when the development of the liposomal antisense method is now much further along and showing promising results. After this discussion the Board decided to discontinue development of the licensed liposomal siRNA technology and the Company commenced discussions regarding this decision with MD Anderson to determine with them whether to modify the license to include other products, postpone the license or simply abandon the license. As an interim step pending final resolution of this matter, the Company took a charge of $345,000 at the end of the fiscal year ending December 31, 2011 to reduce the carrying value of the siRNA license by fifty percent (50%). This amount represented one half of the value of the common stock given to MD Anderson when the original siRNA license was finalized. In June 2012, the Company decided to write-off the balance of the carrying value of the siRNA license, representing $345,000, and cancel the license.

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 became a publicly traded company 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 and now conducting a Phase I clinical trial in its lead drug product candidate Liposomal Grb-2.

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 was filed to register the offering and sale of up to $100 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, we entered into a securities purchase agreement, as amended, with two dedicated healthcare funds (collectively, the "Sabby Investors") that are managed by Sabby Management, pursuant to which the Company agreed to sell an aggregate of 5,000,000 shares of its common stock and warrants to purchase a total of 2,500,000 shares of its common stock to the Sabby Investors for gross proceeds of approximately $15,000,000. 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. We will use the net proceeds from this offering and sale of securities for working capital and general corporate purposes.

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."

On March 11, 2014, the Board of the Company appointed Ulrich W. Mueller, Ph.D., as the Company's Chief Operating Officer. This is the initial hiring step implanting a plan to put in place a core organization that can manage the Company's expanding clinical trials and deliver on the Bio-Path business plan vision of rapidly converting validated protein disease targets into proprietary liposome-antisense drug candidates that enter Phase I clinical trials. In April 2014, the Company progressed further with its organization plan by hiring a director of clinical trials, controller and director of information technology. Subsequent to the close of the second quarter, 2014, the Company has hired additional personnel to add further to the core organization. As of the end of third quarter 2014 the Company has substantially completed its current organization plan.

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

As of September 30, 2014, Bio-Path had $14,636,602 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. Related Party

Based on its stock ownership in the Company, MD Anderson Cancer Center meets the criteria to be deemed a related party of Bio-Path Holdings. For the quarters ending September 30, 2014 and 2013, MD Anderson related party research and development expense was $16,235 and $15,000, respectively. MD Anderson related party research and

development expense for the quarter ending September 30, 2014 was comprised of $1,235 in current patent maintenance fees for the License Agreement and $15,000 for MD Anderson clinical trial hospital expense. Accrued expense related party for MD Anderson was $67,050 for clinical trial hospital costs for the clinical trial and accrued license payments related party of $50,000 for past patent expenses (See Notes 4., 5. and 6.). MD Anderson related party research and development expense for the quarter ending September 30, 2013 was comprised of $15,000 for MD Anderson clinical trial hospital expense. As of December 31, 2013, accrued expense related party consisted of $52,050 for MD Anderson clinical trial hospital costs and $100,000 in accrued license payments payable due to the related party for past patent expenses and for the annual license maintenance fee for the License Agreement. See Notes 5 and 6.

3. Prepaid Drug Product for Testing

Advance payments, including nonrefundable amounts, for goods or services that will be used or rendered for future 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 $51,364 in late 2013 pursuant to a Drug Supply Contract (See Note 9.) 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, 2013 at cost as Prepaid Drug Product for Testing. The Company incurred additional installment costs with the total costs incurred totaling $96,563 being carried on the Balance Sheet as of September 30, 2014 as Prepaid Drug Product for Testing (See Note 9.).

4. Accounts Payable

As of September 30, 2014, Current Liabilities included accounts payable of $88,514 comprised primarily of approximate amounts owed totaling $31,770 to the Company's drug product manufacturer and raw material suppliers, $24,751 to suppliers of services used in the clinical trial, $22,282 for legal services and other miscellaneous items totaling $9,711. By the first week of November 2014, the September 30, 2014 amounts included in accounts payable had been substantially paid. As of December 31, 2013, Current Liabilities included accounts payable of $76,109, which amounts were subsequently paid in 2014.

5. Accrued Expense

As of September 30, 2014, Current Liabilities included accrued expense of $77,594 for travel expense, advisory fees, intellectual property attorney fees, testing services and management bonus accrual. Current Liabilities as of September 30, 2014 also included accrued expense related party of $67,050 for MD Anderson clinical trial hospital expense. (See Note 2.). As of December 31, 2013, Current Liabilities included accrued expense of $66,739 and accrued expense related party of $52,050.

6. Accrued License Payments – Related Party

Accrued license payments related party totaling $50,000 and $100,000 were included in Current Liabilities as of September 30, 2014 and December 31, 2013, respectively. The amount included for September 30, 2014 represents reimbursement of past patent expenses incurred by MD Anderson prior to the Bio-Path license and the amount included for December 31, 2013 included past patent expenses and the annual maintenance fee for the License Agreement.

7. Stockholders' Equity

Issuance of Common Stock – In February and March of 2013, the Company sold $346,202 in shares of its common stock pursuant to a private placement, with shares to be issued.

In April and May of 2013, the Company sold $2,000,198 in shares of its common stock pursuant to a private placement, with shares to be issued, and $489,501 in shares of its common stock pursuant in a direct offering, with shares to be issued.

In June of 2013, the Company issued 11,664,665 shares of common stock to investors in connection with the private placement and direct offering. In June of 2013 the Company issued 1,496,499 shares of common stock to the Placement Agent as commission for the shares of common stock sold to investors. No warrants to purchase additional shares of common stock of the Company were issued to these investors or to the Placement Agent in connection with the sale of the common stock.

In August and September of 2013, the Company sold $3,220,966 in shares of its common stock pursuant to a private placement, with shares to be issued.

In November of 2013, the Company issued 8,052,416 shares of common stock to investors in connection with the private placement. In November of 2013 the Company issued 805,242 shares of common stock to the Placement Agent as commission for the shares of common stock sold to investors. No warrants to purchase additional shares of common stock of the Company were issued to these investors or to the Placement Agent in connection with the sale of the common stock.

In January of 2014, the Company issued a total of 5,000,000 shares of the Company's common stock and warrants to purchase 2,500,000 shares of the Company's common stock for aggregate gross proceeds of $15,000,000. 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, 2014, there were 89,237,872 shares of common stock issued and outstanding. There are no preferred shares outstanding as of September 30, 2014.

8. Stock Options and Warrants

Stock Options

In April of 2014, the Company made a stock option grant to purchase 25,000 shares of the Company's common stock for services rendered by a director of the Company. Terms of the stock option grant require, among other things, that the individual continues to provide services over the vesting period of the option, which is one year from the date of grant for the director service stock option. The exercise price of the option is $2.38 a share, which was the closing price of the common stock at the date of grant being approved. The Company determined the fair value of the stock option granted using the Black Scholes model and expenses this value monthly based upon the vesting schedule of the stock option award. For purposes of determining fair value, the Company used an average annual volatility of one hundred seventy eight percent (178%), which was calculated based on the closing price of the Company's stock over the preceding five years. 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 award and the expected term. The Company used the simplified method to determine the expected term of the options due to the lack of historical data. The total fair value of the stock option granted was determined using this methodology to be $57,425, which is being expensed following the date of grant based on the stock option vesting schedule.

In April of 2014, the Company made two stock option grants each to purchase 25,000 shares of the Company's common stock to two new Company employees. Terms of the stock option grants require, among other things, that the individuals continues to provide services over the vesting period of the option, which is four years from the date of grant for each employee stock option. The exercise price of the options is $2.71 a share, which was the closing price of the common stock at the date of the grant being approved. The Company determined the fair value of the stock option granted using the Black Scholes model and expenses this value monthly based upon the vesting schedule of the stock option award. For purposes of determining fair value, the Company used an average annual volatility of one hundred seventy eight percent (178%), which was calculated based on the closing price of the Company's stock over the preceding five years. 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 award and the expected term. The Company used the simplified method to determine the expected term of the options due to the lack of historical data. The total fair value for both of the stock options granted taken together was determined using this methodology to be $133,200, which is being expensed following the date of grant based on the stock option vesting schedule.

In May of 2014, the Company made a stock option grant to purchase 25,000 shares of the Company's common stock to a new Company employee. Terms of the stock option grant require, among other things, that the individual continues to provide services over the vesting period of the option, which is four years from the date of grant for each employee stock option. The exercise price of the options is $2.40 a share, which was the closing price of the common stock at the date of grant being approved. The Company determined the fair value of the stock option granted using the Black Scholes model and expenses this value monthly based upon the vesting schedule of the stock option award. For purposes of determining fair value, the Company used an average annual volatility of one hundred seventy eight percent (178%), which was calculated based on the closing price of the Company's stock over the preceding five years. 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 award and the expected term. The Company used the simplified method to determine the expected term of the options due to the lack of historical data. The total fair value of the stock option granted was determined using this methodology to be $58,975, which is being expensed following the date of grant based on the stock option vesting schedule.

In May of 2014, the Company made a stock option grant to purchase 125,000 shares of the Company's common stock to a newly hired officer of the Company. Terms of the stock option grant require, among other things, that the individual continues to provide services over the vesting period of the option, which is four years from the date of grant for each employee stock option. The exercise price of the options is $2.40 a share, which was the closing price of the common stock at the date of grant being approved. The Company determined the fair value of the stock option granted using the Black Scholes model and expenses this value monthly based upon the vesting schedule of the stock option award. For purposes of determining fair value, the Company used an average annual volatility of one hundred seventy eight percent (178%), which was calculated based on the closing price of the Company's stock over the preceding five years. 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 award and the expected term. The Company used the simplified method to determine the expected term of the options due to the lack of historical data. The total fair value of the stock option granted was determined using this methodology to be $294,500, which is being expensed following the date of grant based on the stock option vesting schedule.

In July of 2014, the Company made a stock option grant to purchase 15,000 shares of the Company's common stock to a new Company employee. Terms of the stock option grant require, among other things, that the individual continues to provide services over the vesting period of the option, which is four years from the date of grant for each employee stock option. The exercise price of the options is $2.85 a share, which was the closing price of the common stock at the date of grant being approved. The Company determined the fair value of the stock option granted using the Black Scholes model and expenses this value monthly based upon the vesting schedule of the stock option award. For purposes of determining fair value, the Company used an average annual volatility of one hundred sixty five percent (165%), which was calculated based on the closing price of the Company's stock over the preceding five years. 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 award and the expected term. The Company used the simplified method to determine the expected term of the options due to the lack of historical data. The total fair value of the stock option granted was determined using this methodology to be $41,595, which is being expensed following the date of grant based on the stock option vesting schedule.

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In September of 2014, the Company made stock option grants to three new employees of the Company to purchase in total 35,000 shares of the Company's common stock. Terms of each stock option grant requires, among other things, that the individual continues to provide services over the vesting period of the option, which is four years from the date of grant for each employee stock option. The exercise prices of the options are $2.28, $2.37 and $2.42 a share, which were the closing prices of the common stock at the date of each grant being approved. The Company determined the fair value of the stock option granted using the Black Scholes model and expenses this value monthly based upon the vesting schedule of the stock option award. For purposes of determining fair value, the Company used an average annual volatility of one hundred sixty five percent (165%), which was calculated based on the closing price of the Company's stock over the preceding five years. 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 award and the expected term. The Company used the simplified method to determine the expected term of the options due to the lack of historical data. The total fair value of the three stock options granted was determined using this methodology to be $80,595, which is being expensed following the date of grant based on the stock option vesting schedule.

Stock option expense for the quarter ending September 30, 2014 was $118,047. Of this amount, $29,235 related to stock options for personnel involved in R&D activities and $88,812 related to stock options for outside directors, officers and management of the Company.

Warrant - There were no warrants for services granted during the quarter ending September 30, 2014. 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.

9. Commitments and Contingencies

Technology License – Related Party - The Company has negotiated exclusive licenses from the MD Anderson Cancer Center 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 attributable to the License Agreement totaling $50,000 are included in Current Liabilities as of September 30, 2014. Related party accrued expense totaling $67,050 as of September 30, 2014 represents hospital costs for the clinical trial and are not related to the License Agreement. As of September 30, 2014, the Company estimates reimbursable past patent expenses will total approximately $50,000 for the License Agreement. The Company will be required to pay when invoiced the past patent expenses at the rate of $25,000 per quarter. In addition, the Company decided to discontinue development of its siRNA technology and subsequently canceled its siRNA license in June of 2012 (See Note 1).

Drug Supplier Project Plan – Bio-Path entered into two project plan agreements with the Company's drug substance manufacturer and its final drug product manufacturer for the manufacture and delivery of final drug product for expected manufacture in the third quarter of 2014. The project plans required the Company to pay approximately $370,000 in various stages as the drug substance and final product are manufactured and delivered to the Company.

The drug product was delivered to the Company in the third quarter of 2014 and costs associated with this batch were expensed. An additional $96,563 has been paid for by the Company, which was carried on the Balance Sheet as Prepaid Drug Product for Testing as of September 30, 2014. The balance of drug product is anticipated to be delivered to the Company in the fourth quarter of 2014 and the Balance Sheet item Prepaid Drug Product for Testing totaling $96,563 will be expensed when received.

10. New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by FASB that are adopted by the Company as of the specified effective date. If not discussed, management believes that the impact of recently issued standards, which are not yet effective, will not have a material impact on the Company's consolidated financial statements upon adoption. Recently, the FASB issued ASU 2014-10 to eliminate the concept of a development stage entity (DSE) from U.S. GAAP. This change rescinds certain financial reporting requirements that have historically applied to DSEs. The amendments are effective for annual reporting periods beginning after December 15, 2014 and interim periods therein. Early adoption is permitted for financial statements that have not yet been issued or made available for issuance. The Company has elected to early adopt ASU 2014-10 as of September 30, 2014.

11. Subsequent Events

Bio-Path entered into a project plan with a new final drug product manufacturer for delivery targeted for the fourth quarter of 2014. This will give the Company two final drug product manufacturers to work with, which is expected to provide improved scheduling and delivery flexibility. The project plan requires the Company to pay approximately $150,000 for the final drug product manufactured.

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

When you read this section of this Quarterly Report on Form 10-Q, it is important that you also read the unaudited financial statements and related notes included elsewhere in this 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, 2013. 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 under the caption "Risk Factors" in "Item 1, BUSINESS" in our Annual Report on Form 10-K as of and for the fiscal year ended December 31, 2013, and other risks and uncertainties discussed in filings made with the Securities and Exchange Commission. See "Note Regarding Forward Looking Statements" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2013 for additional discussion regarding risks associated with forward-looking statements.

Overview

Bio-Path Holdings, Inc. (together with its subsidiary, "Bio-Path" or the "Company" or "we," "us" or "our") is a biotechnology company with its lead cancer drug candidate, Liposomal Grb-2 ("L-Grb-2" or "BP-100-1.01"), currently in clinical trials. The Company was founded with technology from The University of Texas, MD Anderson Cancer Center ("MD Anderson") and is dedicated to developing novel cancer drugs under an exclusive license arrangement. The Company has drug delivery platform technology with composition of matter intellectual property for systemic delivery of 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.

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 then out-license each successful potential drug and/or the drug delivery technology to a pharmaceutical company or, if the final steps to commercialization are within the capabilities of the Company, finalize development and commercialization internally.

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 became a publicly traded company as a result of this merger. On March 10, 2014, the Company's common stock ceased trading on the OTCQX and commenced trading on the NASDAQ Capital Market under the ticker symbol "BPTH."

Our principal executive offices are located at 4710 Bellaire Boulevard, Suite 210, Bellaire, Texas 77401. Our telephone number is (832) 742-1357. Our Internet website address is www.biopathholdings.com, and all of our filings with the Securities and Exchange Commission are available free of charge on our website.

Research and Development

Our research and development is currently conducted through agreements we have with MD Anderson. We have added a new research and development relationship for pre-clinical testing and anticipate that new research and development relationships will be added in the future for clinical trials that require multiple sites for patient testing.

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. Bio-Path's currently licensed neutral-lipid based liposome technology is designed to accomplish this. Studies have shown a 10-fold to 30-fold increase in tumor cell uptake with this technology compared to other delivery methods.

BP-100-1.01

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

BP-100-1.01 is our lead liposome delivered antisense drug candidate, which is being clinically tested in patients having Acute Myeloid Leukemia ("AML"), Chronic Myelogenous Leukemia ("CML"), Myelodysplastic Syndrome ("MDS") and Acute Lymphoblastic Leukemia ("ALL"). If the results of the clinical tests are 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 Investigational New Drug ("IND") for BP-100-1.01 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 Bio-Path's lead cancer drug candidate liposomal BP-100-1.01 to proceed into clinical trials. The IND review process was performed by the FDA's Division of Oncology Products and involved a comprehensive review of data submitted by us covering pre-clinical studies, safety, chemistry, manufacturing, and controls, and the protocol for the Phase I clinical trial. The primary objective of the Phase I clinical trial, as in any Phase I clinical trial, is the safety of the drug for treatment of human patients. Additional key objectives of the trial are to demonstrate the effectiveness of our drug delivery technology similar to that experienced in pre-clinical treatment of animals and to assess whether the drug candidate test article produces a favorable impact on the cancerous condition of the patient at the dose levels of the study.

The Phase I clinical trial is a dose-escalating study to determine the safety and tolerance of escalating doses of L-Grb-2. The study will also determine the optimal biologically active dose for further development. The pharmacokinetics of L-Grb-2 in patients will be studied, making it possible to investigate whether the delivery technology performs as expected based on pre-clinical studies in animals. In addition, patient blood samples from the trial are now being tested using a new assay developed by the Company to measure down-regulation of the target protein, the critical scientific data needed to demonstrate that 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 is being conducted at MD Anderson.

The original IND granted by the FDA in March of 2010 allowed the Company to proceed with a Phase I clinical trial having five (5) cohorts culminating in a maximum dose of 50 mg/m ^{2}. However, in November of 2012, the Company announced that since there had been no evidence of significant toxicity from treatment of patients with L-Grb-2, the Company requested the FDA to allow higher dosing in patients. The Principal Investigator for the clinical trial, in consultation with Bio-Path's Board of Directors (the "Board"), advised that with the absence of any real toxicity barriers, the Company should continue to evaluate higher doses of L-Grb-2. The absence of significant toxicity provides a significant opportunity for the Company 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 is in place allowing higher dosing. On October 7, 2014, the Company announced that it completed Cohort 6, successfully treating three patients at a dose of 90 mg/m ^{2}, which had been increased from 60 mg/m ^{2} in the revised protocol. To date, there has been no evidence of significant toxicity from treatment of patients with L-Grb-2 in our Phase I clinical trial. The Company is currently in the process of completing an analysis of the Phase I data to submit to the FDA and the Company expects to begin its Phase II program by the end of 2014.

Patients eligible for enrollment into the Phase I clinical trial have refractory or relapsed AML, CML, ALL, or MDS and have failed other approved treatments. These are patients with very advanced stages of the disease, and consequently, not all patients enrolled are able to complete the four-week treatment cycle because of progressive disease, which is unrelated to the treatment with L-Grb-2.

An important outcome for the Phase I clinical trial is the ability to assess for the first time the performance of the Company's delivery technology platform in human patients. The Company has 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 Grb-2 protein.

In this regard, in August of 2013 Bio-Path announced that its liposomal delivery technology achieved a major milestone in the development of antisense therapeutics based on a scientific assay confirming that treating patients with its drug candidate BP-100-1.01 inhibits the Grb-2 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 L-Grb-2 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 potentially a 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 principal 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, Jorge Cortes, M.D. (the "Principal Investigator"), 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 of 2011. Results that demonstrated potential anti-leukemia benefits in treated patients were included in the presentation. Subsequently, in fall of 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 of 2013. Highlights from the presentation prepared by the Principal Investigator for the meeting included:

Data from the Phase I clinical trial

- Among 18 evaluable patients through five completed cohorts, nine experienced at least a 50 percent 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 BP-100-1.01 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 Grb-2 Protein

- Grb-2 levels were compared to baseline prior to treatment.
- On day 15, BP-100-1.01 decreased Grb-2 in five of eight samples tested (average reduction 55 percent).
- End of treatment day15, BP-100-1.01 decreased Grb-2 levels in eight out of nine patients (average reduction 45 percent).

Being platform technology, a successful demonstration of the delivery technology in this study will allow the Company to begin expanding Bio-Path's drug candidates by simply applying the delivery technology template to multiple new drug product targets. In this manner, Bio-Path can quickly build an attractive drug product pipeline with multiple drug product candidates for treating cancer as well as treating other important diseases including diabetes, cardiovascular conditions and neuromuscular disorders. Currently, the Company is researching potential targets for which it can apply its liposomal antisense drug delivery technology and has already identified one new candidate.

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 to date, it is not expected that a MTD will be encountered. As a result, the optimal biological dose will be determined and this dose will be used in the following Phase II clinical trial. The Company is now completing an analysis of the Phase I data to submit to the FDA. The Company has also been working with the Principal Investigator to finalize plans for Phase II clinical trials in Liposomal Grb-2. Significantly, these plans include three Phase II trials, one each for CML, AML and MDS, of the drug candidate Liposomal Grb-2 in salvage therapy for very advanced patients. We expect to begin the Phase II program by the end of 2014. It is anticipated that the first of three Phase II clinical trials will evaluate Liposomal Grb-2 as a combination therapy in AML.

In the process of evaluating patients at the close of Cohort 6, the Company will assess whether the Phase I clinical trial should be ended at this time or continued with a higher dose Cohort 7. It is expected that the down regulation assay will be a factor in the evaluation of whether we have reached optimal inhibition. It is noted, however, that the lack of toxicity is a major advantage for the drug candidate BP-100-1.01 since it allows higher levels of drug to be administered to the patient, increasing the potential therapeutic benefit. In the event that the Company does continue the Phase I clinical trial with a Cohort 7, it would run in parallel with the Phase II program.

Manufacturing scale-up of the drug substance batch size continued. Scale-up of manufacturing batch size previously produced divergence from desired drug substance product parameters, with some product in the fourth quarter of 2013 not being acceptable for use. The most recent manufacturing scale-up drug substance batch appears to have corrected this and a recent drug batch was released for use in the clinical trial by the manufacturer. 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 Bio-Path's 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. The recent success on the part of the Company in raising capital should also improve drug supply by providing the financial resources that will enable the Company to commit to multiple drug batches beyond those required to satisfy near-term requirements. In addition, the Company is currently bringing on a second final drug product manufacturer, which is expected to provide improved scheduling and delivery flexibility.

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

On July 22, 2013, we announced that we were initiating preclinical testing of BP-100-1.01 into two additional indications: Triple Negative Breast Cancer ("TNBC") and Inflammatory Breast Cancer ("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. 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 BP-100-1.01 as a targeted therapy against TNBC and IBC. Treatment goals are two-pronged: the first being to develop BP-100-1.01 as a tumor reduction agent in combination with other approved drugs in pre-operative settings, and the second is to develop BP-100-1.01 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. Following successful completion of the preclinical studies, we expect to start a Phase I clinical trial in TNBC and IBC in 2015. We believe that the observations that we learn from the on-going Phase I trial will allow us to progress relatively quickly in such Phase I trial in TNBC and IBC, as the toxicity profile of BP-100-1.01 is currently being established.

BP-100-1.02

BP-100-1.02 (“Bcl-2” or “BP-100-1.02”) is Bio-Path's co-lead liposome delivered antisense drug candidate. The scientific name for BP-100-1.02 is Liposomal Bcl-2, a liposome delivered antisense cancer drug. BP-100-1.2 is ready for clinic and is intended to target the lymphoma and certain solid tumor markets. Clinical targets for BP-100-1.02 include lymphoma, breast cancer, colon cancer, prostate cancer and leukemia. Liposomal Bcl-2 has the potential to treat 40%-60% of solid tumors.

Bcl-2 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 Bcl-2 prevents the induction of apoptosis in response to cellular insults such as treatment with chemotherapeutic agents. Bcl-2 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. Bcl-2 is also overexpressed in a wide variety of solid tumors (it is estimated to be over-expressed in 40% of cancers). For example, Bcl-2 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.

Other Liposomal Antisense Products

As noted previously, the Company intends to apply its 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, pre-clinical, commercial and intellectual property evaluation of potential new drug candidates for inclusion into the Company's drug product development pipeline. The Company has one promising new candidate that is in the final stages of patentability review, which could potentially become our first new product candidate using our drug delivery technology template. A significant amount of capital will be allocated for in-licensing promising protein targets that can be developed as new liposomal antisense drug candidates.

Projected Financing Needs

The cost to complete our current business plan over the next 18 months was previously estimated to be approximately $12,800,000. We have added a core organization that will provide increased capabilities to execute our business plan. We continue to conduct a review of our strategy that was started in the third quarter now that the new organization has been completed and we anticipate the updated strategy will incorporate new project(s) currently being finalized for development. However, we currently believe that the previously estimated funding needs of $12,800,000 and expected timelines for current project candidates are approximately correct.

In January 2014, we sold shares of common stock and warrants to an institutional investor in a registered direct offering that provided us with approximately $13,750,000 in net proceeds. As a result, in part, the Company had cash balances on hand in excess of $14,600,000 on September 30, 2014. Accordingly, we believe that our current level of resources should be sufficient to complete our current plan described below.

The remaining cost of the Phase I clinical trial of BP-100-1.01, now that we have completed Cohort 6, is expected to be approximately $100,000, including amounts needed to complete end-of-trial analysis performed on patient data and a formal report. Based on the anticipated success of the Phase I clinical trial in BP-100-1.01, we are preparing to follow with multi-site Phase II trials in BP-100-1.01. Successful Phase I and II trials of BP-100-1.01 are expected to provide clinical evidence to support BP-100-1.01 as a potential therapeutic drug product for treatment of AML, MDS and CML. The Phase I clinical trial for Bp-100-1.01 has already provided important clinical proof of concept that the Company's core liposomal delivery technology appears to in fact work. The Phase II clinical trials in BP-100-1.01 are expected to cost approximately $2,000,000 each, or approximately $6,000,000 for all three to complete the basic treatment for the estimated number of patients.

Development of BP-100-1.01 to treat TNBC and IBC over the 18 month plan horizon is expected to require approximately $1,500,000. This amount is expected to fund the preclinical program and the Phase I clinical trial. It is

anticipated that the Phase I clinical trial will cost less than a typical Phase I trial because the safety profile will have already been established upon conclusion of BP-100-1.01's current clinical trial. This is expected to result in fewer patients being tested and a more efficient progression to an optimal biological dose.

The Phase I clinical trial of BP-100-1.02 (L-Bcl-2) is expected to cost approximately $2,000,000. Commencement of the Phase I clinical trial depends on the FDA approving the IND for BP-100-1.02. Success in the Phase I clinical trial will be based on the demonstration that the drug is well tolerated and other key outcomes. The Phase I clinical trial will likely be a dose-escalating study to determine the safety and tolerance of escalating doses of BP-100-1.02. The study will also likely determine the optimal biologically active dose for further development. The pharmacokinetics of BP-100-1.02 in patients will be studied, as well as down-regulation of the target protein to corroborate any positive anti-cancer effects in addition to confirming effectiveness of the delivery technology.

Approximately $200,000 has been allocated to identifying other protein targets for development into liposomal antisense drug candidates. The balance of the $12,800,000 in funding needs from our revised plan over 18 months is approximately $3,030,000, which is planned to fund patent expenses, licensing fees, pre-clinical costs, consulting fees and management and administration. Of the total of $12,800,000 in projected expenses, approximately $9,750,000 in project costs is projected to be spent on clinical trials of our drug candidates and developing new drug candidates, and the balance is projected to be spent on period costs for professionals, organization and license costs. Actual spending of these funds is expected to be spread over the next 27 months.

The scientific evidence 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 its drug candidate BP-100-1.01 inhibits the Grb-2 disease-causing target protein in patients with blood cancers could potentially be very significant in helping to meet future funding needs. The Company envisions that it might be able to enter into licensing/development agreements with pharmaceutical company partners seeking systemic antisense drug treatments, which could provide funding from the partner to develop their liposomal antisense drug candidate, with residual milestone payments and potential back-end royalty payments if the drug candidate became an FDA approved drug. There are many potential licensing/development structures, which would vary in terms of favorability to the Company.

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

There can be no assurance of the following:

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

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

(3) That we will be able to raise the sufficient funds to allow us to complete our planned clinical trials.

Background Information about MD Anderson

We anticipate that our initial drug development efforts will be pursuant to our exclusive license agreement with MD Anderson. MD Anderson's stated vision is to “make cancer history” (www.mdanderson.org). Achieving that goal begins with integrated programs in cancer treatment, clinical trials, educational programs and cancer prevention. MD Anderson is one of the largest and most widely recognized cancer centers in the world: U.S. News & World Report's America's "Best Hospitals" survey has ranked MD Anderson as one of the top two best hospitals in the nation since the survey began in 1990. MD Anderson will treat more than 100,000 patients this year, of which approximately 11,000 will participate in therapeutic clinical research exploring novel treatments which is the largest such program in the nation. MD Anderson employs more than 15,000 people including more than 1,000 medical doctors and Ph.D. clinicians and researchers, and is routinely conducting more than 700 clinical trials at any one time.

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

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

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

Relationship with MD Anderson

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

- allow Bio-Path to develop MD Anderson's neutral lipid delivery technology;
- give Bio-Path access if needed to MD Anderson's Pharmaceutical Development Center for drug development;
- provide rapid communication to Bio-Path of new drug candidate disclosures in the Technology Transfer Office;
- standardize clinical trial programs sponsored by Bio-Path; and
- standardize sponsored research under a master agreement addressing intellectual property sharing.

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

License Agreement

We currently maintain an exclusive license agreement with MD Anderson (the “License Agreement”). The License Agreement relates to the delivery technology platform for antisense nucleic acids including two single nucleic acid (antisense) drug products. The License Agreement requires, among other things, that we reimburse MD Anderson for ongoing patent expense. Accrued license payments totaling $50,000 for past patent expenses are included in Current Liabilities as of September 30, 2014. Past patent expenses represent patent expenses incurred by MD Anderson prior to executing the License Agreement with Bio-Path that are being amortized in quarterly payments. As of September 30, 2014, the Company estimates remaining reimbursable past patent expenses total approximately $50,000 for the antisense license. The Company will be required to pay these patent expenses at the rate of $25,000 per quarter when invoiced by MD Anderson. In addition, accrued expense-related party of $67,050 was included in current liabilities as of September 30, 2014 representing accrued hospital expense for MD Anderson services treating patients in Bio-Path’s clinical trial of BP-100-1.01. This expense is unrelated to the License Agreement.

We intend to use our relationship with MD Anderson to develop drug compounds covered by such License Agreement through Phase IIa clinical trials, the point at which we will have demonstrated proof-of-concept of the efficacy and safety for our product candidates in cancer patients. At such time, we may seek a development and marketing partner in the pharmaceutical or biotechnology industry. In certain cases, we may choose to complete development and market the products ourselves. Our basic guide to a decision of whether or not to obtain a license for a potential drug candidate is as follows:

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

- **Does it fit with the Company's expertise:** Does Bio-Path possess the technical and clinical assets to significantly reduce the scientific and clinical risk to a point where a pharmaceutical company partner would likely want to license this candidate within 36-48 months from the date of Bio-Path acquiring a license?

- **Affordability and potential for partnering:** Can the clinical trial endpoints be designed in a manner that is unambiguous, persuasive, and can be professionally conducted in a manner consistent with that expected by the pharmaceutical industry at a cost of less than $5-7 million dollars?

- **Intellectual property and competitive sustainability:** Is the intellectual property and competitive analysis sufficient to meet criteria established by major pharmaceutical companies assuming successful early clinical human results?

Out-Licenses and Other Sources of Revenue

Subject to demonstrating proof of concept for our delivery technology and obtaining adequate capital, we intend to develop a steady series of drug candidates through Phase II clinical trials and then to engage in a series of out-licensing transactions to pharmaceutical and biotechnology companies. Such companies would then conduct later-stage clinical development, regulatory approval, and eventual marketing of the drug. We expect that such out-license transactions would include upfront license fees, milestone/success payments, and royalties. We intend to maximize the quality and frequency of these transactions, while minimizing the time and cost to achieve meaningful candidates for out-licensing. Our near-term strategy for these licensing transactions is to develop sufficient revenue to cover our burn rate and provide development capital for clinical testing of drug candidates through Phase II for out-licensing, and for some candidates, potentially through full development and commercialization. Longer term, out-licensing transactions will be viewed in terms of creating maximum shareholder value to add to the economic value of drug candidates fully developed and marketed by the Company, as noted below.

In addition to out-licensing revenue and value creation, we may fully develop one or more of our own drug candidates. For example, there are certain cancers that are primarily treated only in a comprehensive cancer center; of which there are approximately 40 in the US and perhaps 200 throughout the world. As a result, “marketing and distribution” can become a realistic possibility for select products. These candidates may be eligible for orphan drug designation by the FDA which provides additional incentives in terms of market exclusivities and non-dilutive grant funding for clinical trials.

Finally, there are technologies for which we anticipate acquiring licenses whose application goes well beyond cancer treatment. The ability to provide the delivery of antisense and small molecules, and their efficient uptake into cells is a very important technological asset that is expected to be commercialized in other areas of medicine.

Business Strategy

The results seen to date in the Phase I clinical trial of L-Grb-2 have created the opportunity to conduct multi-site Phase II clinical trials of L-Grb-2 in three separate blood cancers (specifically, AML, MDS and CML), a significant opportunity for the Company. Additionally, we have the opportunity to develop, in conjunction with MD Anderson, our lead cancer drug L-Grb-2 to treat TNBC and IBC, two cancers characterized by formation of aggressive tumors and relatively high mortality rates. As a result of these opportunities, our business plan over the next 18 months includes: (i) milestones for the additional two Phase II clinical trials for L-Grb-2 and (ii) development of L-Grb-2 treatments for TNBC and IBC, including a pre-clinical program and a Phase I clinical trial. The Company believes that the potential to enhance the value of the Company from these two project additions is significant; however, these projects were expected to cause the capital requirements to be raised by the Company over the next 18 months to increase to $12,800,000. Since then, in January 2014, we sold shares of common stock and warrants to an institutional investor in a registered direct offering that provided us with approximately $13,750,000 in net proceeds. Actual spending of these funds is expected to be spread over the next 27 months. We are currently adding a core organization that will provide increased capabilities to execute our business plan. We are conducting a review of our strategy commenced in the third quarter now that the new organization has been completed. However, we currently believe that the previously estimated funding needs for current projects of $12,800,000 and expected timelines are approximately correct.

In order to capitalize on the growing need for new drug candidates by the pharmaceutical industry, and recognizing the value of clinical data, we have developed our commercialization strategy based on the following concepts:

- Develop in-licensed compounds to proof-of-concept in patients through Phase II.

- Manage trials as if they were being conducted by a major pharmaceutical company: seamless transition; quality systems; documentation; and disciplined program management recognized by diligence teams of major pharmaceutical companies; trials conducted, monitored and data collected consistent with applicable FDA regulations to maximize Bio-Path's credibility and value to minimize time to gain registration by partner.

- Leverage outside testing firms for pre-clinical capabilities and MD Anderson for clinical development capabilities. Outside testing firms perform pre-clinical studies as well as clinical pharmacokinetics and pharmacodynamics while MD Anderson's world-renowned clinics will be used for clinical trials, particularly for early clinical trials. This should allow us to develop our drug candidates with experienced professional staff at a reduced cost compared to using external contract research organizations to run clinical trials. This should also allow us to operate in an essentially virtual fashion, thereby avoiding the expense of setting up and operating laboratory facilities, and without losing control over timing or quality or IP contamination.

- Use our scientific advisors and the Board to supplement our management team to critically monitor existing programs and evaluate new technologies and/or compounds discovered or developed at MD Anderson, or elsewhere, for in-licensing.

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

- Outsource manufacturing and regulatory capabilities. Bio-Path will not need to invest its resources in building functions where it does not add substantial value or differentiation. Instead, it will leverage an executive team with expertise in the selection and management of high quality contract manufacturing and regulatory firms. Future manufacturing capabilities may be developed at a later date as a means to control the technology and ensure adequate supplies of our future internally developed drug products and for out-licensed drug products.

Manufacturing

We have no manufacturing capabilities and intend to outsource our manufacturing function in the near future. The most likely outcome of the out-licensing of a Bio-Path drug to a pharmaceutical partner will be that the pharmaceutical partner will be responsible for manufacturing drug product requirements. However, in the event Bio-Path is required to supply a drug product to a distributor or pharmaceutical partner for commercial sale, Bio-Path will need to develop, contract for, or otherwise arrange for the necessary manufacturing capabilities. There are a limited number of manufacturers that operate under the FDA's current good manufacturing practices (cGMP) regulations capable of manufacturing our future products. As noted previously, future manufacturing capabilities may be developed at a later date as a means to control the technology and ensure adequate supplies of our future internally developed drug products and for out-licensed drug products.

Intellectual Property

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

We will actively seek patent protection in the U.S. and, as appropriate, abroad and closely monitor patent activities related to our business. In addition to patents, we will rely on trade secrets and proprietary know-how, which we seek to protect, in part, through confidentiality and proprietary information agreements.

Agreement with ACORN CRO

We entered into an agreement with ACORN CRO, a full service, oncology-focused clinical research organization, to provide us with a contract medical officer and potentially other clinical trial support services. Under such agreement, Bradley G. Somer, M.D., commenced serving as our medical advisor and medical liaison for the conduct of our Phase I clinical study of liposomal BP-100-1.01 in refractory or relapsed AML, CML, ALL and MDS.

Competition

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

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

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

Government Regulation

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

In particular, human therapeutic products are subject to rigorous pre-clinical and clinical testing and other approval procedures of the FDA and similar regulatory authorities in other countries. Various federal statutes and regulations also govern or influence testing, manufacturing, safety, labeling, storage, and record-keeping related to such products and their marketing. The process of obtaining these approvals and the subsequent compliance with the appropriate

federal statutes and regulations requires substantial time and financial resources. Any failure by us or our collaborators to obtain, or any delay in obtaining, regulatory approval could adversely affect the marketing of any drug product candidates developed by us, our ability to receive product revenues, and our liquidity and capital resources.

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

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

Bio-Path's business model relies on developing drug product candidates through Phase II and either entering into out-license agreements with pharmaceutical licensee partners who will be responsible for post-Phase II clinical testing and working with the FDA on necessary regulatory submissions resulting in approval of new drug applications for commercialization, or internally developing a drug product candidate through commercialization. For more detailed discussions on the clinical trial processes involvement with the FDA, please refer to “Part I, Item 1. Description of Business - Government Regulation” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2013.

Results of Operations for the three and nine months ended September 30, 2014 and 2013.

Revenues. We have no operating revenues since our inception.

Research and Development Expenses. Our research and development expense was $424,521 for the three months ended September 30, 2014, a decrease of $144,055 from the three months ended September 30, 2013. The decrease in research and development expense for the three months ended September 30, 2014, compared to the three months ended September 30, 2013, was primarily due to approximately $182,000 in lower costs of drug material used in our clinical trial offset to some extent by increased manufacturing development expenses of approximately $30,000 and approximately $8,000 in other increased miscellaneous research and development expenses. Research and development expense-related party was $16,235 for the three months ended September 30, 2014, an increase of $1,235 compared to the three months ended September 30, 2013. The increase in research and development expense-related party was primarily due to patent maintenance fees related to the Company's Technology License. Our research and development expense was $1,048,716 for the nine months ended September 30, 2014, a decrease of $76,995 from the nine months ended September 30, 2013. The decrease in research and development expense for the nine months ended September 30, 2014, compared to the nine months ended September 30, 2013, was primarily due to approximately $181,000 in lower costs of drug material used on our clinical trial, offset to some extent by increased manufacturing development expense of $82,000, and higher expenses for preclinical programs for drug candidates, and other miscellaneous expenses. Research and development expense-related party was $41,654 for the nine months ended September 30, 2014, a decrease of $20,413 compared to the nine months ended September 30, 2013. The decrease in research and development expense-related party was primarily due to approximately $37,000 in lower MD Anderson clinical trial hospital costs, offset to some extent by $17,000 in higher license maintenance fees related to the Company's Technology License.

General and Administrative Expenses. Our general and administrative expenses were $713,352 for the three months ended September 30, 2014, a decrease of $96,800 compared to the three months ended September 30, 2013. The decrease in general and administrative expense for the three months ended September 30, 2014, compared to the three months ended September 30, 2013, was due to lower stock option expense of approximately $510,000, offset by increases of $264,000 in compensation expense for the new organization compared to the organization in place in the third quarter of 2013, increased expenses totaling $102,000 for legal, insurance, and communications associated with being a NASDAQ listed company; higher employee expenses of $35,000 including healthcare expenses; and higher travel expenses of $12,000.

Our general and administrative expenses were $1,848,751 for the nine months ended September 30, 2014, an increase of $558,245 compared to the nine months ended September 30, 2013. The increase in general and administrative expense for the nine months ended September 30, 2014, compared to the nine months ended September 30, 2013, was primarily due to an increase of $451,000 in compensation expense for the new organization compared to the organization in place for the nine months ended September 30, 2013; increased expenses totaling $310,000 for legal, insurance, and communications associated with being a NASDAQ listed company, including the NASDAQ listing fee, higher employee costs of $62,000 including healthcare expense; and higher costs for office expense ($22,000), travel ($22,000) and all other items ($29,000). The increased expenses for the nine months ended September 30, 2014 compared to the nine months ended September 30, 2013 were offset to some extent by lower stock option expense of approximately $338,000.

Net Loss. Our net loss was $1,148,409 for the three months ended September 30, 2014 compared to a net loss of $1,393,207 for the three months ended September 30, 2013. The decrease in the net loss for the three months ended

September 30, 2014, compared to the three months ended September 30, 2013, was primarily due to a decrease in research and development expense of $144,055 and a decrease in general and administrative expense of $96,800. Net loss per share, both basic and diluted, was $0.01 per share for the three months ended September 30, 2014 and $0.02 per share for the three months ended September 30, 2013.

Our net loss was $2,922,063 for the nine months ended September 30, 2014 compared to a loss of $2,476,453 for the nine months ended September 30, 2013. The increase in the net loss for the nine months ended September 30, 2014, compared to the nine months ended September 30, 2013, was primarily due to an increase in general and administrative expense of $558,245 offset to some extent by a decrease in research and development expense of $76,995. Net loss per share, both basic and diluted, was $0.03 for the nine months ended September 30, 2014 and $0.04 for the nine months ended September 30, 2013.

Liquidity and Capital Resources

Since our inception, we have funded our operations primarily through private placements and direct public and private sales 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 will be seeking collaborations and license arrangements for our product candidates. We may seek to access the public or private equity markets whenever conditions are favorable.

At September 30, 2014, we had cash of $14,636,602 compared to $3,551,832 at December 31, 2013. The increase in cash balances during the nine months ended September 30, 2014 primarily resulted from the sale of an aggregate of 5,000,000 shares of our common stock and warrants to purchase a total of 2,500,000 shares of our common stock to the Sabby Investors for gross proceeds of approximately $15,000,000. 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, 2014 was $2,661,479 compared to $1,836,311 for the nine months ended September 30, 2013. Inasmuch as we have not yet generated revenues, our entire expenses of operations are funded by proceeds from the sale of the Company’s securities and other capital raising efforts.

Net cash provided by financing activities during the nine months ended September 30, 2014 was $13,812,373 compared to $5,403,106 for the nine months ended September 30, 2013. Since inception through September 30, 2014, we have net cash provided from financing activities of $27,602,704. We believe that our available cash and our ongoing capital raising efforts will be sufficient to fund our liquidity and capital expenditure requirements through the first quarter of 2016.

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 was filed to register the offering and sale of up to $100 million of our common stock, preferred stock or 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, we entered into a securities purchase agreement, as amended, with two dedicated healthcare funds (collectively, the “Sabby Investors”) that are managed by Sabby Management, pursuant to which the Company agreed to sell an aggregate of 5,000,000 shares of its common stock and warrants to purchase a total of 2,500,000 shares of its common stock to the Sabby Investors for gross proceeds of approximately $15,000,000. 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 potential proceeds from the exercise of the warrants issued in the offering, were approximately $13,750,000. The offering closed on January 21, 2014. We will use the net proceeds from this offering and sale of securities for working capital and general corporate purposes.

Critical Accounting Policies

The preparation of financial statements in conformity with generally accepted accounting principles in the United States has required the management of the Company to make assumptions, estimates and judgments that affect the amounts reported in the financial statements, including the notes thereto, and related disclosures of commitments and contingencies, if any. The Company considers its critical accounting policies to be those that require the more significant judgments and estimates in the preparation of financial statements. Our significant accounting policies are discussed in Note 2 to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2013.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Information not required for smaller reporting companies.

ITEM 4. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures. We maintain a system of disclosure controls and procedures that is designed to ensure that information required to be disclosed in our Securities Exchange Act of 1934, as amended (the "Exchange Act") reports is recorded, processed, summarized and reported within the time periods specified in rules and forms of the SEC, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosures. As of September 30, 2014, our management, including our principal executive officer and principal financial officer, had evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) pursuant to Rule 13a-15(b) under the Exchange Act. Based upon and as of the date of the evaluation, our principal executive officer and principal financial officer concluded that information required to be disclosed is recorded, processed, summarized and reported within the specified periods and is accumulated and communicated to management, including our principal executive officer and principal financial officer, to allow for timely decisions regarding required disclosure of material information required to be included in our periodic SEC reports. Based on the foregoing, our management determined that our disclosure controls and procedures were effective as of September 30, 2014.

(b) Changes in Internal Control over Financial Reporting. There were no changes in our internal control over financial reporting that occurred during the period of this report 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

Information not required for smaller reporting companies.

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 Company, 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	Restated Articles of Incorporation (incorporated by reference to exhibit 3.1 to the Company's registration statement on Form 8-A filed on September 10, 2008).
3.2	Restated Bylaws (incorporated by reference to exhibit 3.1 to the Company's current report on Form 8-K filed on February 13, 2014).
3.3	Articles of Merger relating to the merger of Biopath Acquisition Corp. with and into Bio-Path, Inc. (incorporated by reference to exhibit 3.2 to the Company's current report on Form 8-K filed on February 19, 2008).
4.1	Specimen Stock certificate (incorporated by reference to exhibit 3.2 to the Company's registration statement on Form 8-A filed on September 10, 2008).
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 10.2 to the registrant's current report on Form 8-K filed on January 21, 2014).
31*	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Section 302 of the Sarbanes Oxley Act of 2002.
32*	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Section 906 of the Sarbanes Oxley Act of 2002.
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 report to be signed on its behalf by the undersigned thereunto duly authorized.

Dated: November 14, 2014 BIO-PATH HOLDINGS, INC.

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