

BIO-PATH HOLDINGS INC  
Form 10-Q  
November 14, 2013

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

**(Mark One)**

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

For the quarterly period ended September 30, 2013

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)

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

2626 South Loop, Suite 180, Houston, TX 77054

(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 ☒ No ☐

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

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

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

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

At November 12, 2013, the Company had 84,237,872 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-looking 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, 2012, 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, 2013	December 31, 2012
<b>ASSETS</b>		
Current assets		
Cash	\$ 4,100,841	\$ 534,046
Prepaid drug product for testing	148,301	195,000
Other current assets	49,713	42,575
Total current assets	4,298,855	771,621
Other assets		
Technology licenses - related party	2,500,374	2,500,374
Less Accumulated Amortization	(1,048,700 )	(928,231 )
	1,451,674	1,572,143
<b>TOTAL ASSETS</b>	<b>\$ 5,750,529</b>	<b>\$ 2,343,764</b>

#### LIABILITIES & SHAREHOLDERS' EQUITY

Current liabilities		
Accounts payable	43,578	57,000
Accounts payable - related party	-	8,582
Accrued expense	28,125	137,662
Accrued expense - related party	52,050	26,000
Accrued license payments - related party	50,000	100,000

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Total current liabilities	173,753	329,244
Long term debt	-	-
<b>TOTAL LIABILITIES</b>	<b>173,753</b>	<b>329,244</b>
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 75,380,214 and 62,219,050 shares issued and outstanding as of 9/30/13 and 12/31/12, respectively	75,380	62,218
Additional paid in capital	16,888,167	13,321,075
Additional paid in capital for shares to be issued a/ & b/	3,220,967 a/	762,510 b/
Accumulated deficit during development stage	(14,607,738 )	(12,131,283 )
Total shareholders' equity	5,576,776	2,014,520
<b>TOTAL LIABILITIES &amp; SHAREHOLDERS' EQUITY</b>	<b>\$ 5,750,529</b>	<b>\$ 2,343,764</b>

a/ Represents 8,052,416 shares of common stock

b/ Represents 2,541,700 shares of common stock

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		From inception 05/10/07 to 9/30/13
	2013	2012	2013	2012	
Revenue	\$-	\$-	\$-	\$-	\$ -
Operating expense					
Research and development a/	568,576	546,821	1,125,711	994,459	5,451,308
Research and development - related party b/	15,000	47,582	62,067	426,870	1,125,687
General & administrative c/	810,152	246,086	1,290,506	729,569	8,349,969
Total operating expense	1,393,728	840,489	2,478,284	2,150,898	14,926,964
Net operating loss	\$(1,393,728 ) \$(840,489 ) \$(2,478,284 ) \$(2,150,898 ) \$(14,926,964 )				
Other income (expense)					
Interest income	837	26	2,492	768	79,581
Other income	-	-	-	-	244,479
Other expense	(316 )	(89 )	(661 )	(487 )	(4,834 )
Total Other Income (Expense)	521	(63 )	1,831	281	319,226
Net Loss	\$(1,393,207 ) \$(840,552 ) \$(2,476,453 ) \$(2,150,617 ) \$(14,607,738 )				
Loss per share					
Net loss per share, basic and diluted	\$(0.02 ) \$(0.01 ) \$(0.04 ) \$(0.04 ) \$(0.30 )				
Basic and diluted weighted average number of common shares outstanding	75,380,214	58,902,046	68,068,456	58,717,393	48,619,280

a/ Research and development expense includes stock option expenses of \$6,623 and \$11,414 for the quarters ending 9/30/2013 and 9/30/2012, respectively; \$26,256 and \$42,231 for the nine month periods ending 9/30/2013 and 9/30/2012, respectively; and \$449,255 for the period from inception through 9/30/2013.

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Research and development expense also includes amortization expenses of \$40,156 and \$48,503 for the quarters ending 9/30/2013 and 9/30/2012, respectively; \$120,469 and \$145,115 for the nine month periods ending 9/30/2013 and 9/30/2012, respectively; and \$1,097,203 for the period from inception through 9/30/2013.

b/ Includes \$345,000 technology impairment charge for the nine month period ending 9/30/2012; and \$690,000 for the period from inception through 9/30/2013

c/ General & administrative expense includes stock for services, stock option and warrant expenses of \$599,424 for the quarter ending 9/30/2013; \$609,347 and \$3,250 for the nine month periods ending 9/30/2013 and 9/30/2012, respectively; and for the period from inception through 9/30/2013 \$3,200,103 for stock option and warrant expense and \$318,500 in stock for services.

SEE ACCOMPANYING NOTES TO CONSOLIDATED FINANCIAL STATEMENTS



**BIO-PATH HOLDINGS, INC.****(A Development Stage Company)****CONSOLIDATED STATEMENT OF CASH FLOWS**

Unaudited

	January 1, to September 30		From inception
	2013	2012	05/10/2007 to 9/30/2013
<b>CASH FLOW FROM OPERATING ACTIVITIES</b>			
Net loss	\$ (2,476,453 )		\$ (2,150,617 ) \$ (14,607,738 )
Adjustments to reconcile net loss to net cash used in operating activities			
Amortization	120,469	145,115	1,097,203
Technology impairment	-	345,000	690,000
Common stock issued for services	-	18,500	318,500
Stock options and warrants	635,603	45,481	3,649,357
(Increase) decrease in assets			
Prepaid drug product for testing	46,699	73,500	(148,301 )
Other current assets	(7,138 )	3,044	(49,713 )
Increase (decrease) in liabilities			
Accounts payable and accrued expenses	(155,491 )	(47,559 )	173,753
Net cash used in operating activities	(1,836,311 )	(1,567,536 )	(8,876,939 )
<b>CASH FLOW FROM INVESTING ACTIVITIES</b>			
Purchase of exclusive license - related party	-	(25,000 )	(884,710 )
Net cash used in investing activities	-	(25,000 )	(884,710 )
<b>CASH FLOW FROM FINANCING ACTIVITIES</b>			
Proceeds from convertible notes	-	-	435,000
Cash repayment of convertible notes	-	-	(15,000 )
Net proceeds from sale of common stock	5,403,106	973,146	13,442,489
Net cash from financing activities	5,403,106	973,146	13,862,490

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NET INCREASE (DECREASE) IN CASH	3,566,795	(619,390 )	4,100,841
Cash, beginning of period	534,046	952,252	-
Cash, end of period	\$4,100,841	\$332,862	\$4,100,841

SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION

Cash paid for			
Interest	\$ -	\$ -	\$ 445
Income taxes	\$ -	\$ -	\$ -
Non-cash financing activities			
Common stock issued upon conversion of convertible notes	\$ -	\$ -	\$ 420,000
Common stock issued to Placement Agent	\$448,950	\$ -	\$ 1,040,516
Common stock issued to M.D. Anderson for technology license	\$ -	\$ -	\$ 2,354,167
Due diligence and commitment shares issued to Lincoln	\$ -	\$ -	\$ 210,755
		\$ -	

SEE ACCOMPANYING NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**BIO-PATH HOLDINGS, INC.**

**(A Development Stage Company)**

**Notes to the Unaudited Consolidated Financial Statements Ending September 30, 2013**

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, 2012. The results of operations for the period ended September 30, 2013, are not necessarily indicative of the results for a full-year period.

**1. Organization and Business**

Bio-Path is a development stage company with its lead cancer drug candidate, Liposomal Grb-2 (L-Grb-2 or BP-100-1.01), currently in clinical trials. The Company was founded with technology from The University of Texas, 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.

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, myelodysplastic syndrome, chronic myelogenous leukemia, acute lymphoblastic leukemia and follicular lymphoma, and if successful, could potentially be used in treating many other indications of cancer. For example, recently 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 will be tested using a new assay developed by the Company to measure down-regulation of the target protein, the critical scientific data that will 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<sup>2</sup>. 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 was proceeding with requesting the FDA to allow higher dosing in patients. The Principal Investigator for the clinical trial, in consultation with Bio-Path's Board of Directors, 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 60 mg/m<sup>2</sup>, which had been increased from 50 mg/m<sup>2</sup> in the revised protocol. The Company has enrolled three patients in Cohort 6 for treatment at a dose of 90 mg/m<sup>2</sup> and currently has two evaluable patients. The Company is currently awaiting drug resupply to complete Cohort 6.

Patients eligible for enrollment into the Phase I clinical trial have refractory or relapsed Acute Myeloid Leukemia (AML), Philadelphia Chromosome Positive Chronic Myelogenous Leukemia (CML) and Acute Lymphoblastic Leukemia (ALL), or Myelodysplastic Syndrome (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 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 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.

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.

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 plans to evaluate patients at the close of Cohort 6 to evaluate whether the Phase I clinical trial should be ended at that time. 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.

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.

At the end of January 2012, the Company's Board of Directors held a strategic planning session. Among several topics was a discussion of 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 Principal Investigator for the Phase I clinical trial, Dr. Jorge Cortes (the "Principal Investigator"), is a leading expert in the treatment of CML, AML, MDS and ALL. In the continuing effort to keep the leukemia oncology community apprised of the development of Liposomal Grb-2, the Principal Investigator submitted an abstract to the American Society of Hematology (ASH) to be considered for presentation at ASH's annual meeting in December of 2013. The abstract was accepted and a poster updating the progress in the Phase I clinical trial will be presented at the ASH annual meeting. A major part of the update on the Liposomal Grb-2 Phase I trial will be the inclusion of the results of testing of patient blood samples, which demonstrates significant inhibition of the disease causing protein Grb-2. This is a significant development which suggests the potential of Liposomal Grb-2 to inhibit AML and MDS in patients.

The Company was founded in May of 2007 as a Utah corporation. In February of 2008, Bio-Path completed a reverse merger with Ogden Golf Co. Corporation, a public company traded over the counter that had no current operations. The name of Ogden Golf was changed to Bio-Path Holdings, Inc. and the directors and officers of Bio-Path, Inc. became the directors and officers of Bio-Path Holdings, Inc. Bio-Path has become a publicly traded company (symbol OTCBB: BPTH) as a result of this merger. The Company's operations to date have been limited to organizing and staffing the Company, acquiring, developing and securing its technology and undertaking product development for a limited number of product candidates including readying and now conducting a Phase I clinical trial in its lead drug product candidate Liposomal Grb-2.

An important milestone was achieved for the Company in the second quarter, 2012 when Bio-Path's common stock began trading on the quality-controlled OTCQX. OTCQX is the highest tier, premier trading platform for OTC companies. The Company also announced that it had retained Roth Capital Partners to serve as the Company's Designated Advisor for Disclosure ("DAD") on OTCQX, responsible for providing guidance on OTCQX requirements.

As of September 30, 2013, Bio-Path had \$4,100,841 in cash on hand. During the third quarter of 2013, the Company received approximately \$2.8 million in cash net of placement agent commissions from the sale of shares of common stock in a private placement.



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

## **2.**

### **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, 2013 and 2012, MD Anderson related party research and development expense was \$15,000 and \$47,582, respectively. MD Anderson related party research and development expense for the quarter ending September 30, 2013 was comprised of MD Anderson clinical trial hospital expense of \$15,000. As of September 30, 2013 accrued expense related party was \$52,050 for MD Anderson clinical trial hospital expense and accrued license payments related party of \$50,000 for past patent expenses (See Notes 4., 5. and 6.). For the quarter ending September 30, 2012 related party research and development expense consisted of \$39,000 for expenses for treating patients in the Company's clinical trial and \$8,582 for patent expenses. As of September 30, 2012, the Company had accrued expense of \$39,000 for clinical trial expense for the related party, \$8,582 in related party accounts payable and \$50,000 in accrued license payments payable due to the related party for past patent expenses for the Company's Technology License. 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 \$195,000 during 2012 pursuant to a Drug Supply Contract (See Note 10.) 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, 2012 at cost as Prepaid Drug Product for Testing. This product was delivered to the Company in the first quarter of 2013 and costs associated with this drug batch were expensed. Another drug batch was in the process of starting to be produced in the third quarter of 2013 and installment costs totaling \$148,301 are carried on the Balance Sheet as of September 30, 2013 as Prepaid Drug Product for Testing (See Note 10.).

### **4. Accounts Payable**

As of September 30, 2013, Current Liabilities included accounts payable of \$43,578 comprised primarily of approximate amounts owed to the Company's drug substance manufacturer totaling \$9,900, \$8,100 for consultants and advisors to the Company, \$6,900 in services as the Company commenced development of a data management system for clinical trial patient data, \$9,300 for legal fees and \$9,400 for communications, miscellaneous drug development

and clinical trial expense. As of December 31, 2012, Current Liabilities included accounts payable \$57,000 and accounts payable related party of \$8,582, which amounts were subsequently paid in 2013.

## **5. Accrued Expense**

As of September 30, 2013, Current Liabilities included accrued expense of \$28,125 for clinical trial operations management and management bonus accrual. Current Liabilities as of September 30, 2013 also included accrued expense related party of \$52,050 for MD Anderson clinical trial hospital expense. (See Note 2.). As of December 31, 2012, Current Liabilities included accrued expense of \$137,662 and accrued expense related party of \$26,000.

## **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, 2013 and December 31, 2012, respectively. The amount included for September 30, 2013 represents reimbursement of past patent expenses incurred by MD Anderson prior to the Bio-Path license.

## 7. Additional Paid In Capital For Shares To Be Issued

During 2012 the Company sold shares of common stock for cash to investors in a private placement. As of December 31, 2012, there were 2,541,700 shares of common stock remaining to be issued, representing \$762,510 in sales to accredited investors. The Company has closed this offering at the end of the first quarter 2013 and subsequently issued the shares of common stock to these investors in the second quarter of 2013. During the third quarter of 2013 the Company sold shares of common stock for cash to investors in another private placement. As of September 30, 2013, there were 8,052,416 shares of common stock to be issued, representing \$3,220,967 in sales to accredited investors. The Company closed this offering during September of 2013.

## 8. Stockholders' Equity

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

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

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

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

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

In July of 2010, the Company received \$150,000 from LPC in exchange for 375,000 shares of the Company's common stock. LPC was also issued 6,251 shares of the Company's common stock as a commitment fee in connection with the purchase of the 375,000 shares of common stock. No warrants to purchase additional shares of common stock of the Company were issued to Lincoln in connection with the sale of the common stock.

In September of 2010, the Company received \$50,000 from LPC in exchange for 125,000 shares of the Company's common stock. LPC was also issued 2,084 shares of the Company's common stock as a commitment fee in connection with the purchase of the 125,000 shares of common stock. No warrants to purchase additional shares of common stock of the Company were issued to Lincoln in connection with the sale of the common stock.

In October of 2010, the Company received \$50,000 from LPC in exchange for 135,135 shares of the Company's common stock. LPC was also issued 2,084 shares of the Company's common stock as a commitment fee in connection with the purchase of the 135,135 shares of common stock. No warrants to purchase additional shares of common stock of the Company were issued to Lincoln in connection with the sale of the common stock.

In November of 2010, the Company received \$50,000 from LPC in exchange for 135,135 shares of the Company's common stock. LPC was also issued 2,084 shares of the Company's common stock as a commitment fee in connection with the purchase of the 135,135 shares of common stock. No warrants to purchase additional shares of common stock

of the Company were issued to Lincoln in connection with the sale of the common stock.

From November 2010 through April of 2011 the Company sold shares of common stock for \$1,794,205 in cash to investors pursuant to a private placement memorandum. In June of 2011, the Company issued 5,980,685 shares of common stock to these investors. In connection with this private placement, in June of 2011 the Company issued 598,069 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 in connection with the sale of the common stock.

In June of 2011, the Company received \$50,000 from LPC in exchange for 164,853 shares of the Company's common stock. LPC was also issued 2,084 shares of the Company's common stock as a commitment fee in connection with the purchase of the 164,853 shares of common stock. No warrants to purchase additional shares of common stock of the Company were issued to Lincoln in connection with the sale of the common stock.

In October of 2011, the Company issued 1,920,000 shares of common stock for \$576,000 to investors who exercised warrants from September to October 2011.

In November of 2011, the Company received \$25,000 from LPC in exchange for 83,333 shares of the Company's common stock. LPC was also issued 1,042 shares of the Company's common stock as a commitment fee in connection with the purchase of the 83,333 shares of common stock. No warrants to purchase additional shares of common stock of the Company were issued to Lincoln in connection with the sale of the common stock.

In December of 2011, the Company received \$50,000 from LPC in exchange for 172,414 shares of the Company's common stock. LPC was also issued 2,084 shares of the Company's common stock as a commitment fee in connection with the purchase of the 172,414 shares of common stock. No warrants to purchase additional shares of common stock of the Company were issued to Lincoln in connection with the sale of the common stock.

In March of 2012, the Company received \$50,000 from LPC in exchange for 166,667 shares of the Company's common stock. LPC was also issued 2,084 shares of the Company's common stock as a commitment fee in connection with the purchase of the 166,667 shares of common stock. No warrants to purchase additional shares of common stock of the Company were issued to Lincoln in connection with the sale of the common stock.

In April of 2012, LPC made three separate purchases of the Company's common stock. The Company received \$25,000 from LPC in exchange for 89,286 shares of the Company's common stock. LPC was also issued 1,042 shares of the Company's common stock as a commitment fee in connection with the purchase of the 89,286 shares of common stock. The Company received another \$25,000 from LPC in exchange for 96,154 shares of the Company's common stock. LPC was also issued 1,042 shares of the Company's common stock as a commitment fee in connection with the purchase of the 96,154 shares of common stock. Finally, the Company received \$50,000 from LPC in exchange for 185,185 shares of the Company's common stock. LPC was also issued 2,084 shares of the Company's common stock as a commitment fee in connection with the purchase of the 185,185 shares of common stock. No warrants to purchase additional shares of common stock of the Company were issued to Lincoln in connection with the sale of the common stock.

In June of 2012, the Company sold \$150,000 in shares of its common stock pursuant to a private placement, with shares to be issued, and \$18,500 in shares of its common stock for services with shares to be issued.

In August of 2012, the Company issued 50,000 shares of its common stock for the \$18,500 shares for services previously recognized in June 2012.

In July through September of 2012, the Company sold \$795,001 in shares of its common stock pursuant to a private placement, with shares to be issued.

In October through December of 2012, the Company sold \$708,600 in shares of its common stock pursuant to a private placement, with shares to be issued.

As of December 31, 2012 the Company issued 3,300,337 shares of its common stock to investors who purchased shares of common stock from the period June through September of 2012.

In February and March of 2013, the Company sold \$346,201 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.

As of September 30, 2013, there were 75,380,214 shares of common stock issued and outstanding. There are no preferred shares outstanding as of September 30, 2013.

## **9. Stock Options and Warrants**

**Stock Option** - In August of 2013 the Company made stock option grants to management and officers to purchase in the aggregate 2,500,000 shares of the Company's common stock. The previous grant of stock options to management and officers was made in 2008. Terms of the stock option grants require that the individuals continue employment with the Company over the vesting period of the option, fifty percent (50%) of which vested upon the date of the grant of the stock options and fifty percent (50%) of which will vest over 3 years from the date that the options were granted. The exercise price of the option is \$0.46 per share, which was the closing price of the common stock at the date of the grants 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 eighty nine percent (189%), 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 awards and the effective term. The Company used the simplified method to determine the expected term of the options due to the lack of historical data. The total value of stock options granted to management and officers was determined using this methodology to be \$1,125,000, half of which was expensed at the date of grant and the balance will be expensed over the next three years based on the stock option service period.

**Warrant** - There were no warrants for services granted during the quarter ending September 30, 2013.

**10.**

**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 Technology License totaling \$50,000 are included in Current Liabilities as of September 30, 2013. Related party accrued expense totaling \$52,050 as of September 30, 2013 represents hospital costs for the clinical trial and are not related to the Technology License. As of September 30, 2013, the Company estimates reimbursable past patent expenses will total approximately \$75,000 for the Technology License. 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*** - In August of 2012, 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 incorporating the drug substance for expected delivery in the fourth quarter of 2012, with delivery subsequently revised to the first quarter of 2013. The project plans required the Company to pay approximately \$340,000 in various stages as the drug substance and product are manufactured and delivered to the Company. Of this amount, \$195,000 was paid for or owed by the Company and was carried on the Balance Sheet as of December 31, 2012 as Prepaid Drug Product for Testing. The drug product was delivered to the Company in the first quarter of 2013 and the Balance Sheet item Prepaid Drug Product for Testing totaling \$195,000 was expensed in the first quarter 2013. Amounts owed to the Company's manufacturers for this drug batch have been paid subsequent to year end. The Company signed a supply agreement in the third quarter of 2013. Installment payments paid or in accounts payable to the Company's drug manufacturers totaling \$148,301 are being carried at cost on the Balance Sheet as of September 30, 2013 as Prepaid Drug Product for testing.

## **11. Subsequent Events**

Subsequent to September 30, 2013, the Company is committed to issue 8,052,416 shares of common stock pursuant to the private placement disclosed in Note 8. In connection with this private placement, the Company is also committed to issue 805,242 shares of common stock to the Placement Agent as commission for the shares of common stock sold to investors.

On November 5, 2013, the Company filed a registration statement on Form S-3 with the SEC, which has not yet been declared effective. The shelf registration statement has been 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. There can be no assurance that the shelf registration statement will be declared effective.

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

*When you read this section of this Quarterly Report on Form 10-Q, it is important that you also read the unaudited financial statements and related notes included elsewhere in this Form 10-Q and our audited financial statements and notes thereto included in our Annual Report on Form 10-K as of and for the fiscal year ended December 31, 2012. 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, 2012, 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, 2012 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 development stage company with its lead cancer drug candidate, Liposomal Grb-2 ("L-Grb-2" or "BP-100-1.01"), currently in clinical trials. The Company was founded with technology from The University of Texas, 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 has become a publicly traded company (symbol OTCQX: BPTH) as a result of this merger.

Our principal executive offices are located at 2626 South Loop, Suite 180, Houston Texas, 77054. Our telephone number is (832) 971-6616. Our Internet website address is [www.biopathholdings.com](http://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 anticipate that new research and development relationships will be added in the future for pre-clinical testing services and future sites 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 drugs, 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 lipid delivery 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 will be tested using a new assay developed by the Company to measure down-regulation of the target protein, the critical scientific data that will 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<sup>2</sup>. 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 was proceeding with requesting the FDA to allow higher dosing in patients. The Principal Investigator for the clinical trial, in consultation with Bio-Path's Board of Directors, 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 60 mg/m<sup>2</sup>, which had been increased from 50 mg/m<sup>2</sup> in the revised protocol. The Company has enrolled three patients in Cohort 6 for treatment at a dose of 90 mg/m<sup>2</sup> and currently has two evaluable patients. The Company is currently awaiting drug resupply to complete Cohort 6.

Patients eligible for enrollment into the Phase I clinical trial have refractory or relapsed Acute Myeloid Leukemia ("AML"), Philadelphia Chromosome Positive Chronic Myelogenous Leukemia ("CML") and Acute Lymphoblastic Leukemia ("ALL"), or Myelodysplastic Syndrome ("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 Liposomal-Grb-2.

The Principal Investigator for the Phase I clinical trial, Dr. Jorge Cortes (the “Principal Investigator”), is a leading expert in the treatment of CML, AML, MDS and ALL. In the continuing effort to keep the leukemia oncology community apprised of the development of Liposomal Grb-2, the Principal Investigator submitted an abstract to the American Society of Hematology (“ASH”) to be considered for presentation at ASH’s annual meeting in December of 2013. The abstract was accepted and a poster updating the progress in the Phase I clinical trial will be presented at the ASH annual meeting. A major part of the update on the Liposomal Grb-2 Phase I trial will be the inclusion of the results of testing of patient blood samples, which demonstrates significant inhibition of the disease causing protein Grb-2. This is a significant development which suggests the potential of Liposomal Grb-2 to inhibit AML and MDS in patients.

Results from the second cohort also demonstrated potential anti-leukemia benefits in treated patients and such results were included in the presentation to the American Society of Hematology. The Principal Investigator is currently preparing an abstract of updated information for presentation at the American Society of Hematology annual meeting in December of 2013.

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 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.

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.



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 plans to evaluate patients at the close of Cohort 6 to evaluate whether the Phase I clinical trial should be ended at that time. 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.

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.

*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 2014. 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 compound. The scientific name for BP-100-1.02 is Liposomal Bcl-2, a liposome delivered antisense cancer drug that targets the lymphoma and certain solid tumor markets. 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 percent 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.

Clinical targets for BP-100-1.02 include lymphoma, breast cancer, colon cancer, prostate cancer and leukemia.

## **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. 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**

As of September 30, 2013, we anticipate that we need to raise approximately an additional \$6,780,000 to complete our core clinical trials for our product candidates. This includes funds to complete the Phase I clinical trial for BP-100-1.01, one Phase II trial in BP-100-1.01, a Phase I clinical trial for BP-100-1.02, license and patent maintenance costs and general and administrative expense. However, including opportunities for two additional Phase II clinical trials for BP-100-1.01 and a Phase I clinical trial for breast cancer would add the requirement to raise an

additional \$5,500,000. Consequently, funding all of our opportunities for clinical trials would require us to raise as much as \$12,280,000.

The remaining cost of the Phase I clinical trial of BP-100-1.01 is expected to be approximately \$300,000, provided that the trial is completed after the next dose level. If the Phase I clinical trial in BP-100-1.01 is successful, we expect 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 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 27 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 \$12,280,000 in funding needs from our revised plan over 27 months is approximately \$2,080,000, which is planned to fund patent expenses, licensing fees, pre-clinical costs, consulting fees and management and administration. Of the projected total of \$12,280,000 in funding needs, approximately \$10,000,000 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, management and license costs.

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 potential pharmaceutical company partners seeking systemic antisense drug treatments, which could potentially provide funding from the partner to Bio-Path 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 five 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](http://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 a "big deal" and substantially impacts those companies who have attained it: Genentech's Avastin, Novartis' Gleevec, OSI's Tarceva and Millennium's Velcade are examples of such 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.



## Licenses

We currently maintain an exclusive license agreement with MD Anderson (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 without “cutting corners”?

**Intellectual property and competitive sustainability:** Is the intellectual property and competitive analysis sufficient to meet “Big Pharma” criteria assuming successful early clinical human results?

## Out-Licenses and Other Sources of Revenue

Subject to 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 forty in the US and perhaps two hundred 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.

### **License Agreement**

We are currently maintaining the License Agreement with MD Anderson. 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 accrued past patent expenses are included in Current Liabilities as of September 30, 2013. 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, 2013, the Company estimates remaining reimbursable past patent expenses total approximately \$75,000 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 \$52,050 was included in current liabilities as of September 30, 2013 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.

Bio-Path is currently developing a neutral-lipid based liposome delivery technology of antisense for the treatment of cancer. The liposome targeting technology previously licensed was developed based on testing of tumor targeting of liposomal siRNA FAK drug candidate. Tumor targeting was a technology that was needed much more for liposomal siRNA technology than for liposomal antisense technology. As a result, with the Board’s decision in 2012 not to proceed with developing the siRNA technology at this time, tumor targeting will be developed at a later time with potentially another targeting technology.



## Business Strategy

Previously, we developed a business plan with milestones that we currently anticipate will require us to raise approximately \$6,780,000 to completely implement such business plan. The milestones include completion of the Phase I clinical trial of L-Grb-2, a Phase I clinical trial in an additional liposomal antisense drug product in addition to the drug product L-Grb-2 currently in a Phase I clinical trial and a multi-site Phase II clinical trial of L-Grb-2. In addition, our previous plan of operation included funds to in-license up to four new protein targets for development as liposomal antisense drug product candidates to add to our product pipeline for development. However, the results seen to date in the Phase I clinical trial of Liposomal Grb-2 have created the opportunity to conduct multi-site Phase II clinical trials of Liposomal Grb-2 in three separate blood cancers (specifically, AML, MDS and CML), a significant opportunity for the Company. We also believe that the opportunity to develop, in conjunction with MD Anderson, our lead cancer drug Liposomal Grb-2 to treat TNBC and IBC, two cancers characterized by formation of aggressive tumors and relatively high mortality rates, is promising. As a result of these two developments over the past year, Bio-Path has revised its business plan over the next 27 months to include (i) milestones for the additional two Phase II clinical trials for Liposomal Grb-2 and (ii) development of Liposomal 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 are expected to cause the capital requirements for the Company over the next 27 months to increase to \$12,280,000.

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 Big Pharma: seamless transition; quality systems; documentation; ..and disciplined program management recognized by Big Pharma diligence teams; trials conducted, monitored and data collected consistent with applicable FDA regulations to maximize Bio-Path’s credibility and value to minimize time to gain registration by partner.

- 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, quality or IP contamination.

- Use our Medical Advisory Board 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 the manufacturing function in the near future. The most likely outcome of the out-license 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**

On April 23, 2009, we announced that had we entered into an agreement with ACORN CRO, a full service, oncology-focused clinical research organization (CRO), to provide us with a contract medical officer and potentially other clinical trial support services. Under such agreement, Bradley G. Somer, M. D., 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 Acute Myeloid Leukemia (AML), Chronic Myelogenous Leukemia (CML), Acute Lymphoblastic Leukemia (ALL) and Myelodysplastic Syndrome (MDS).

## **Competition**

We are engaged in fields characterized by extensive research efforts, rapid technological progress, and intense competition. There are many public and private companies, including pharmaceutical companies, chemical companies, and biotechnology companies, engaged in developing products for the same human therapeutic applications that we are targeting. Currently, 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 drugs and drug candidates, Bio-Path is aware of existing treatments and numerous drug candidates in development by our competitors.

## **Government Regulation**

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

In particular, human therapeutic products are subject to rigorous pre-clinical and clinical testing and other approval procedures of the FDA and similar regulatory authorities in other countries. Various federal statutes and regulations also govern or influence testing, manufacturing, safety, labeling, storage, and record-keeping related to such products and their marketing. The process of obtaining these approvals and the subsequent compliance with the appropriate federal statutes and regulations requires substantial time and financial resources. Any failure by us or our collaborators to obtain, or any delay in obtaining, regulatory approval could adversely affect the marketing of any drug product candidates developed by us, our ability to receive product revenues, and our liquidity and capital resources.

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

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

Bio-Path's business model relies on 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, 2012.

***Results of Operations for the three and nine months ended September 30, 2013 and 2012.***

***Revenues.*** We have no operating revenues since our inception.

***Research and Development Expenses.*** Our research and development expense was \$568,576 for the three month period ended September 30, 2013, an increase of \$21,755 from the three month period ended September 30, 2012. The increase in research and development expense for the three months ended September 30, 2013 compared to the comparable period ended September 30, 2012 was primarily due to an approximate \$37,000 increase from development costs for a clinical trial data management system, offset to some extent by lower expense for drug material used and drug testing services. Research and development expense-related party was \$15,000 for the three month period ended September 30, 2013, a decrease of \$32,582 compared to the comparable three month period ended September 30, 2012. The decrease in research and development expense-related party was due primarily to lower clinical trial hospital expense in the three month period ended September 30, 2013.

Our research and development expense was \$1,125,711 for the nine months ended September 30, 2013, an increase of \$131,252 from the nine months ended September 30, 2012. This increase in the nine month period ended September 30, 2013 was primarily the result of higher costs for data management system development, drug material used and drug testing services, offset to some extent by lower expense for advisory services. Research and development expense - related party was \$62,067 for the nine months ended September 30, 2013, a decrease of \$364,803 from the nine months ended September 30, 2012. This decrease was a result of technology impairment expense that was recognized in the nine month period ended September 30, 2012.

***General and Administrative Expenses.*** Our general and administrative expenses were \$810,152 for the three month period ended September 30, 2013, an increase of \$564,066 compared to the three month period ended September 30, 2012. The increase in general and administrative expense for the three months ended September 30, 2013 compared to the three months ended September 30, 2012 was due to an approximate \$595,000 stock option expense resulting from a stock option grant made during the three month period ending September 30, 2013 to officers and management. The amount of expense from the stock options granted to officers and management does not represent an expenditure of cash but instead represents the imputed value of the stock options granted determined using the Black Scholes model, half of which was expensed at the date of grant during the three month period ending September 30, 2013. See Note 9. of the Notes to the Unaudited Consolidated Financial Statements included elsewhere in this Form 10-Q. The last grant of stock options to officers and management was in 2008. Excluding the expense from the stock option grant to officers and directors, administrative expense for the three month period ending September 30, 2013 was lower by approximately \$31,000 than the comparable three month period in 2012.

Our general and administrative expenses were \$1,290,506 for the nine month period ended September 30, 2013, an increase of \$560,937 from the nine months ended September 30, 2012. The increase in general and administrative expense for the nine months ended September 30, 2013 compared to the nine months ended September 30, 2012 was

due to stock option expense of approximately \$595,000 non-cash expense resulting from a stock option grant made to officers and directors in the nine month period ended September 30, 2013. Excluding the stock option expense attributable to the grant of stock options to officers and directors, general and administrative expense for the nine months ending September 30, 2013 was lower by approximately \$34,000 than the comparable nine month period in 2012.

**Net Loss.** Our net loss was \$1,393,207 for the three month period ended September 30, 2013 compared to a net loss of \$840,552 for the three month period ended September 30, 2012. The increase in the net loss for the three months ended September 30, 2013 compared to the three months ended September 30, 2012 was due to general and administrative expense being higher in the quarter ended September 30, 2013 due to non-cash expense of approximately \$595,000 resulting from a stock option grant made to officers and management. Excluding the non-cash stock option expense during the three month period ending September 30, 2013, net loss for the three month period ending September 30, 2013 was approximately \$42,000 lower than from the comparable three month period ending September 30, 2012. Net loss per share, both basic and diluted, was \$0.02 per share for the three month period ending September 30, 2013 and \$0.01 for the three month period ending September 30, 2012.

Our net loss was \$2,476,453 for the nine months ended September 30, 2013, compared to a loss of \$2,150,617 for the nine months ended September 30, 2012. Net loss per share, both basic and diluted, was \$0.04 for the respective periods. The primary reason for the increase in net loss for the nine month period ended September 30, 2013 compared to the nine month period ended September 30, 2012 was due to general and administrative expense being higher in the nine months ended September 30, 2012 due to non-cash expense of approximately \$595,000 resulting from a stock option grant made to officers and management. Excluding the non-cash stock option expense during the nine month period ending September 30, 2013, net loss for the nine month period ending September 30, 2013 was approximately \$269,164 lower than for the comparable nine month period ending September 30, 2012.

### **Liquidity and Capital Resources**

Since our inception, we have funded our operations primarily through private placements and direct 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 three product candidates. We may seek to access the public or private equity markets whenever conditions are favorable.

At September 30, 2013, we had cash of \$4,100,841 compared to \$534,046 at December 31, 2012. The increase in cash balances during the nine month period ended September 30, 2013 results from \$1,836,311 in cash used in operations, offset by \$5,403,106 in net proceeds received from the sale of shares of the Company's common stock. 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, 2013 was \$1,836,311 compared to \$1,567,536 for the nine months ended September 30, 2012. Inasmuch as we have not yet generated revenues, our entire expenses of operations are funded by proceeds from the sale of the shares of the Company's common stock and other capital raising efforts.

Net cash provided by financing activities during the nine month period ended September 30, 2013 was \$5,403,106 compared to \$973,146 for the nine month period ended September 30, 2012. Since inception through September 30, 2013, we have net cash provided from financing activities of \$13,862,490. 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 second quarter of 2014. We believe that we will need to raise approximately \$12,280,000 in net proceeds to completely implement our current business plan over the next 27 months.

On November 5, 2013, we filed a shelf registration statement on Form S-3 with the SEC, which has not yet been declared effective. The shelf registration statement has been 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. There can be no assurance that the shelf registration statement will be declared effective. If the shelf registration statement is declared effective, we may use proceeds from an offering and sale of such securities for working capital and general corporate purposes unless otherwise indicated.

### **Contractual Obligations and Commitments**

Bio-Path has entered into the License Agreement with MD Anderson. A summary of certain material terms of the License Agreement is detailed in our Annual Report on Form 10-K as of and for the fiscal year ended December 31, 2012.

In the first quarter of 2013, Bio-Path entered into a supply agreement with its drug product manufacturer for the manufacture of the Company's drug product for delivery in May 2013. In addition, the Company signed a supply agreement with the drug substance supplier in the second quarter of 2013. Installment payments paid or in accounts

payable to the Company's drug manufacturers totaling \$148,301 are being carried at cost on the Balance Sheet as of September 30, 2013 as Prepaid Drug Product for Testing. The manufactured drug batch was subsequently completed and delivered to the Company after the end of the second quarter. Amounts owed for this batch have been substantially paid. Another drug batch was in the process of starting to be produced in the third quarter of 2013 and installment costs totaling \$148,301 are carried on the Balance Sheet as of September 30, 2013 as Prepaid Drug Product for Testing.

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

### **Critical Accounting Policies**

The preparation of financial statements in conformity with generally accepted accounting principles ("GAAP") in the United States has required the management of the Company to make assumptions, estimates and judgments that affect the amounts reported in the financial statements, including the notes thereto, and related disclosures of commitments and contingencies, if any. The Company considers its critical accounting policies to be those that require the more significant judgments and estimates in the preparation of financial statements. Our significant accounting policies are discussed in Note 2 to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2012.

### **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, 2013, 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, 2013.

**(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**

From July 1, 2013 through September 30, 2013, the Company agreed to issue, at a price of \$0.40 per share, an aggregate of 8,052,416 shares (the “Shares”) of the Company’s common stock to certain “accredited investors” (as such term is defined in Rule 501(a) of Regulation D promulgated under the Securities Act of 1933, as amended (the “Securities Act”)) resulting in gross proceeds from the sale thereof of approximately \$3.22 million. The Company agreed to pay cash commissions to its placement agent equal to ten percent of the aggregate purchase price of the Shares. In addition, the Company agreed to issue to its placement agent one share of the Company’s common stock for every ten Shares sold as additional compensation.

The Shares will not be or have not been registered under the Securities Act and may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements. Such Shares were issued pursuant to an exemption from registration provided by Section 4(2) of the Securities Act and/or Rule 506 of Regulation D promulgated under the Securities Act.

### **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 Ogden Golf Co. Corporation, a Utah corporation (the registrant), Biopath Acquisition Corp., a Utah corporation and wholly owned subsidiary of the registrant, and Bio-Path, Inc., a Utah corporation (incorporated by reference to exhibit 2.1 to the registrant's current report on Form 8-K filed on September 27, 2007).
3.1	Restated Articles of Incorporation (incorporated by reference to exhibit 3.2 to the registrant's current report on Form 8-A filed on September 10, 2008).
3.2	Bylaws (incorporated by reference to exhibit 3.2 to the registrant's current report on Form 8-A filed on September 10, 2008).
3.3	Articles of Merger relating to the merger of Biopath Acquisition Corp. with and into Bio-Path, Inc. (incorporated by reference to exhibit 3.2 to the registrant's current report on Form 8-K filed on February 19, 2008).
3.4	Amendment No. 1 to Bylaws (incorporated by reference to exhibit 3.2 to the registrant's current report on Form 8-K filed on June 21, 2010).
4.1	Specimen Stock certificate (incorporated by reference to exhibit 3.2 to the registrant's current report on Form 8-A filed on September 10, 2008).
10.1	First Amendment to First Amended 2007 Stock Incentive Plan (incorporated by reference to exhibit 10.1 to the registrant's quarterly report on Form 10-Q filed on August 14, 2013).
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.
99.1*	Temporary Hardship Exemption.
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Schema Document
101.CAL**	XBRL Taxonomy Calculation Linkbase Document
101.DEF**	XBRL Taxonomy Definition Linkbase Document
101.LAB**	XBRL Taxonomy Label Linkbase Document
101.PRE**	XBRL Taxonomy Presentation Linkbase Document
*	Filed herewith.
**	

To be furnished by amendment pursuant to the Temporary Hardship Exemption provided by Rule 201 of Regulation S-T.

**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, 2013 BIO-PATH HOLDINGS, INC.

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