

BIO-PATH HOLDINGS INC  
Form 10-Q  
November 14, 2012

**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, 2012

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 14, 2012, the Company had 62,219,050 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, 2011, 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, 2012	December 31, 2011
<b>ASSETS</b>		
Current assets		
Cash	\$ 332,862	\$ 952,252
Prepaid drug product for testing	79,500	153,000
Other current assets	45,395	48,439
Total current assets	457,757	1,153,691
Other assets		
Technology licenses - related party	2,500,374	2,868,877
Less Accumulated Amortization	(888,075 )	(791,463 )
	1,612,299	2,077,414
<b>TOTAL ASSETS</b>	<b>\$ 2,070,056</b>	<b>\$ 3,231,105</b>
<b>LIABILITIES &amp; SHAREHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable	65,423	121,540
Accounts payable - related party	8,582	67,971
Accrued expense	105,567	46,082
Accrued expense - related party	39,000	41,000
Accrued license payments - related party	50,000	39,538
Total current liabilities	268,572	316,131
Long term debt	-	-
<b>TOTAL LIABILITIES</b>	<b>268,572</b>	<b>316,131</b>

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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 58,918,713 and 58,325,169 shares issued and outstanding as of 9/30/12 and 12/31/11, respectively	58,918	58,325
Additional paid in capital	12,496,929	12,405,395
Additional paid in capital for shares to be issued a/	945,001	-
Accumulated deficit during development stage	(11,699,364 )	(9,548,746 )
Total shareholders' equity	1,801,484	2,914,974
<b>TOTAL LIABILITIES &amp; SHAREHOLDERS' EQUITY</b>	<b>\$2,070,056</b>	<b>\$3,231,105</b>

a/ Represents 3,150,003 shares of common stock

SEE ACCOMPANYING NOTES TO 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 9/30/12
	2012	2011	2012	2011	
Revenue	\$-	\$-	\$-	\$-	\$-
Operating expense					
Research and development a/ Research and development - related party b/	546,821 47,582	127,109 50,000	994,459 426,870	458,803 100,000	4,187,345 1,026,620
General & administrative c/	246,086	327,380	729,569	1,002,191	6,802,934
Total operating expense	840,489	504,489	2,150,898	1,560,994	12,016,899
Net operating loss	\$(840,489 )	\$(504,489 )	\$(2,150,898 )	\$(1,560,994 )	\$(12,016,899 )
Other income					
Interest income	26	870	768	2,171	77,079
Other income	-	-	-	-	244,479
Other expense	(89 )	(200 )	(487 )	(471 )	(4,023 )
Total Other Income	(63 )	670	281	1,700	317,535
Net Loss	\$(840,552 )	\$(503,819 )	\$(2,150,617 )	\$(1,559,294 )	\$(11,699,364 )
Loss per share					
Net loss per share, basic and diluted	\$(0.01 )	\$(0.01 )	\$(0.04 )	\$(0.03 )	\$(0.26 )
Basic and diluted weighted average number of common shares outstanding	58,902,046	56,146,296	58,717,393	52,398,690	45,349,410

a/Research and development expense includes stock option expenses of \$11,414 and \$17,406 for the quarters ending 9/30/2012 and 9/30/2011, respectively; \$42,231 and \$48,693 for the nine month periods ending 9/30/2012 and 9/30/2011, respectively; and \$411,585 for the period from inception through 9/30/2012. Research and development

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expense also includes amortization expenses of \$48,503 and \$53,017 for the quarters ending 9/30/2012 and 9/30/2011, respectively; \$145,115 and \$157,490 for the nine month periods ending 9/30/2012 and 9/30/2011, respectively; and \$936,578 for the period from inception through 9/30/2012.

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 9/30/2012

c/ General & administrative expense includes stock for services, stock option and warrant expenses of \$105,491 for the quarter ending 9/30/2011; \$21,750 and \$314,869 for the nine month periods ending 9/30/2012 and 9/30/2011, respectively; and for the period from inception through 9/30/2012 \$2,584,265 for stock option and warrant expense and \$318,500 in stock for services.

SEE ACCOMPANYING NOTES TO FINANCIAL STATEMENTS



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

Unaudited

	January 1 to September 30 2012	2011	From inception 05/10/2007 to 9/30/2012
<b>CASH FLOW FROM OPERATING ACTIVITIES</b>			
Net loss	\$(2,150,617)	\$(1,559,294)	\$(11,699,364 )
Adjustments to reconcile net loss to net cash used in operating activities			
Amortization	145,115	157,490	936,578
Technology impairment	345,000	-	690,000
Common stock issued for services	18,500	-	318,500
Stock options and warrants	45,481	363,562	2,995,850
(Increase) decrease in assets			
Grants receivable	-	244,479	-
Prepaid drug product for testing	73,500	88,400	(79,500 )
Other current assets	3,044	20,967	(45,395 )
Increase (decrease) in liabilities			
Accounts payable and accrued expenses	(47,559 )	(41,761 )	268,572
Net cash used in operating activities	(1,567,536)	(726,157 )	(6,614,759 )
<b>CASH FLOW FROM INVESTING ACTIVITIES</b>			
Purchase of exclusive license - related party	(25,000 )	(62,547 )	(884,710 )
Net cash used in investing activities	(25,000 )	(62,547 )	(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	973,146	1,533,425	7,412,331
Net cash from financing activities	973,146	1,533,425	7,832,331
NET INCREASE (DECREASE) IN CASH	(619,390 )	744,721	332,862

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Cash, beginning of period	952,252	238,565	-
Cash, end of period	\$332,862	\$983,286	\$ 332,862

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	\$-	\$179,421	\$ 591,566
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 FINANCIAL STATEMENTS

**BIO-PATH HOLDINGS, INC.**

**(A Development Stage Company)**

**Notes to the Unaudited Consolidated Financial Statements Ending September 30, 2012**

The accompanying interim financial statements have been prepared with the instructions to Form 10-Q pursuant to the rules and regulations of the Securities and Exchange Commission and, therefore, do not include all information and footnotes necessary for a complete presentation of our financial position, results of operations, cash flows, and stockholders' equity in conformity with generally accepted accounting principals. In the opinion of management, all adjustments considered necessary for a fair presentation of the results of operations and financial position have been included and all such adjustments are of a normal recurring nature. The unaudited quarterly financial statements should be read in conjunction with the audited financial statements and notes thereto included in the Annual Report on Form 10-K of Bio-Path Holdings, Inc. (together with its subsidiary, the "Company") as of and for the fiscal year ended December 31, 2011. The results of operations for the period ended September 30, 2012, are not necessarily indicative of the results for a full-year period.

**1. Organization and Business**

Bio-Path Holdings, Inc. ("Bio-Path" or the "Company") is a development stage company with its lead cancer drug candidate, Liposomal Grb-2 (L-Grb-2 or BP-100-1.01), currently in clinical trials. The Company was founded with technology from The University of Texas, 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 treat acute myeloid leukemia, chronic myelogenous leukemia, acute lymphoblastic leukemia and follicular lymphoma, and if successful, could potentially be used in treating many other indications of cancer.

Bio-Path is currently treating patients with its lead cancer drug candidate Liposomal Grb-2 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 current protocol for the trial requires evaluation of five doses of L-Grb-2 and enrollment of a sufficient number of patients in the study to achieve 18 to 30 evaluable patients. An evaluable patient is a patient who is able to complete the four-week treatment cycle. The clinical trial is being conducted at The University of Texas MD Anderson Cancer Center.

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.

At the end of July 2011, the Company completed requirements for treating patients in the first cohort. The Company, its medical advisors and the Principal Investigator agreed that the data from the first cohort demonstrated that Liposomal Grb-2 was safe enough to proceed to the next cohort of the trial, which treated patients in the trial with a dose that was double the dose used in the first cohort. As a result of this review, the first cohort was closed and the second cohort was opened for recruiting patients into the clinical trial. In January of 2012, the Company completed requirements for treating patients in the second cohort. The Company, its medical advisors and the Principal Investigator agreed that the data from the second cohort demonstrated that Liposomal Grb-2 was safe enough to proceed to the third cohort of the trial, which is treating patients with a dose of 20 mg/m<sup>2</sup>, which is double the dose used in the second cohort. At the end of April, 2012, there were three evaluable patients in Cohort 3. As a result, a meeting of the Company's medical advisory board was being scheduled to close the cohort and proceed to Cohort 4. Significantly, in the third cohort, all three patients completed the treatment cycle and were evaluable and, because of apparent stabilization from treatment with Bio-Path drug candidate Liposomal Grb-2, had received extended treatment cycles or were on hold for additional treatments pending increased supply of drug.

Based on the experience treating patients in Cohort 3, when all three patients benefited from treatment with Liposomal Grb-2 and were apparently stabilized, the assumption for drug requirements for Cohort 4 and beyond have increased significantly. Specifically, the assumption now is that all patients will benefit from treatment with the drug candidate Liposomal Grb-2 and be eligible to receive up to six months of treatments. In this regard, the Company increased the capacity of its drug supply chain, adding new suppliers for the Grb-2 drug substance and for the final drug product. Substantially increased supplies of the drug candidate Liposomal Grb-2 were delivered in July of 2012.

The Principal Investigator for the Phase I clinical trial, Dr. Jorge Cortes, is a leading expert in the treatment of CML, AML and ALL. Because the results of the first trial produced unexpected and clinically interesting results in some patients, the Principal Investigator prepared an abstract of the results of the first cohort that was accepted for presentation at the American Society of Hematology annual meeting in December of 2011. Results from the second cohort also demonstrated potential anti-leukemia benefits in treated patients. The next opportunity for the Bio-Path to present information at the American Hematology Society annual meeting will be when the Company has completed the Phase I clinical trial.

The Company has completed testing of patients of Cohort 4 patients and expects at any time to receive clearance to formally close the Cohort. There has not to date been any signs of significant toxicity from the treatment of patients with Bio-Path's drug Liposomal Grb-2. This presents an opportunity for testing of Liposomal Grb-2 at even higher doses that could potentially provide even greater and longer duration benefits to patients, thereby increasing chances for an early approval of Bio-Path's drug candidate Liposomal Grb-2. 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. The opportunity for three drug approvals in a relatively moderate timeframe could be very significant for Bio-Path's shareholders. The Company expects to update investors on its development plans in the very near future. An update for timelines and budgets will be given at that time.

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.

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

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. The Company has 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 represents one half of the value of the common stock given to MD Anderson when the original siRNA license was finalized. In June 2012, the Company decided to write-off the balance of the carrying value of the siRNA license, representing \$345,000, and cancel the license.

The Company was founded in May of 2007 as a Utah corporation. In February of 2008, Bio-Path completed a reverse merger with Ogden Golf Co. Corporation, a public company traded over the counter that had no current operations. The name of Ogden Golf was changed to Bio-Path Holdings, Inc. and the directors and officers of Bio-Path, Inc. became the directors and officers of Bio-Path Holdings, Inc. Bio-Path 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 and Bio-Path is very pleased to have qualified for the OTCQX given its high standards. 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. The OTCQX is a premier platform that distinguishes the best companies traded over-the-counter from the thousands of securities traded on the OTC Bulletin Board who are not required to meet any financial standards or undergo a qualitative review. Bio-Path's commencement of trading on the OTCQX attests to the quality of the Company's financial reporting and its technology. In addition, Roth Capital Partners is a firm with a strong life sciences research and investment banking practice and a focus on small-cap companies.



As of September 30, 2012, Bio-Path had \$332,862 in cash on hand. During the third quarter, 2012 the Company raised \$795,001 through the sale of shares of its common stock to accredited investors through a private placement that the Company initiated at the beginning of the second quarter of 2012. The Company has additional commitments that increase the total amount to \$1.7 million. Based on the positive response from investors, the Company has amended the private placement to extend the timeframe of the private placement through December 31, 2012 and increase the maximum amount to be raised to \$4 million. Bio-Path plans to begin raising significant amounts of additional development capital at anticipated higher share prices once there is demonstration of proof-of-concept of Bio-Path's technology in human patients.

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, 2012 and 2011, MD Anderson related party research and development expense was \$47,582 and \$50,000, respectively. MD Anderson related party research and development expense for the quarter ending September 30, 2012 consisted of \$39,000 for expenses for treating Cohort 4 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. For the quarter ended September 30, 2011, the Company had \$50,000 in R&D related party expense for clinical trial hospital expense, \$100,000 in accrued expense related party for clinical trial hospital expense and \$50,000 for accrued license payments related party for past patent expense for the Company's Technology License.

## **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 \$153,000 during 2011 for the manufacture and delivery of a lot 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, 2011 at cost as Prepaid Drug Product for Testing and was expensed when the drug product was received by the Company in 2012. During the third quarter of 2012, the Company ordered an additional lot of drug substance and an additional lot of drug product and incurred \$79,500 in charges (see Note 9.). This amount is carried on the Balance Sheet as of September 30, 2012 at cost as Prepaid Drug Product for Testing and will be expensed when manufacturing

of the lot has been completed and the drug product has been received by the Company.

#### **4. Grants Receivable**

As of December 31, 2010, Current Assets included grants receivable of \$244,479. This represents a grant award that Bio-Path received in October 2010 for its application to receive grant funding from the U.S. Government's Qualifying Therapeutic Discovery Project Program. The Company received these grant funds during the first week of February 2011.

#### **5. Accrued Expense**

As of September 30, 2012, Current Liabilities included accrued expense of \$105,567. This includes amounts for accrued expenses of \$6,276 for legal fees, consulting fees of \$5,500, and management bonus accrual totaling \$92,500. As of September 30, 2012, Current Liabilities also included accrued expense related party consisting of \$39,000 for clinical trial R&D hospital expenses related to MD Anderson treating patients in the Phase I clinical trial (see Note 2.).

## 6. Accrued License Payments – Related Party

Accrued license payments – related party totaling \$50,000 were included in Current Liabilities as of September 30, 2012. This amount represents payment of past patent expenses incurred by MD Anderson prior to entering into the license with the Company. It is expected that the accrued license payments will be made to MD Anderson in the first half of 2013.

## 7. 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”), 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 recognized \$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.

As of September 30, 2012, there were 58,918,713 shares of common stock issued and outstanding. There are no preferred shares outstanding as of September 30, 2012.

## **8. Stock Options and Warrants**

**Stock Options** - There were no stock option awards granted in the quarter ending September 30, 2012. Total stock option expense for the nine months ending September 30, 2012 was \$45,481.

**Warrants** - There were no warrants for services granted in the quarter ending September 30, 2012 and there was no warrant expense for the quarter ending September 30, 2012. Warrants previously issued in connection with the sale of units of common stock were for cash value received and as such were not grants of compensation-based warrants. All such investor warrants have expired.



## 9. Commitments and Contingencies

**Technology License – Related Party** – The Company has negotiated exclusive licenses from the MD Anderson Cancer Center to develop drug delivery technology for antisense and siRNA drug products. These licenses require, among other things, the Company to reimburse MD Anderson for ongoing patent expense. Related party accrued license payments attributable to the Technology License totaling \$50,000 are included in Current Liabilities as of September 30, 2012. Related party accrued expense totaling \$39,000 as of September 30, 2012 represent hospital costs for the clinical trial and are not related to the Technology License. As of September 30, 2012, the Company estimates reimbursable past patent expenses will total approximately \$75,000 for the antisense 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 has decided to discontinue development of its siRNA technology, and consequently, does not anticipate incurring any significant additional exposure for future siRNA patent expense (See Note 1).

**Drug Supplier Project Plan** - In August of 2012, Bio-Path entered into a project plan agreement with the Company's drug substance manufacturer for delivery of drug substance for a batch of final drug product scheduled to be manufactured in the fourth quarter 2012. In September of 2012, the Company entered into a project plan for the delivery of final drug product incorporating the drug substance for expected delivery in the fourth quarter of 2012. Taken together, these two project plans will require the Company to pay approximately \$340,000 once manufacturing has been completed and drug product delivered to the Company. Of this amount, \$79,500 has been paid for by the Company, which is carried on the Balance Sheet as Prepaid Drug Product for Testing. This amount substantially represents the entire financial commitments to the drug substance and the drug product manufacturers for the new batch of drug material.

## 10. Subsequent Events

In October of 2012, the Company amended its current private placement to extend the period of the offering through December 31, 2012 and increase the maximum amount of the offering from \$2 million to \$4 million.

Through mid-November 2012 the Company raised approximately \$1.7 million through its private placement. Approximately \$1 million of this amount has been brought into the Company, while approximately \$700,000 remains in escrow or various stages of completing necessary documentation. It is expected that \$100,000 to \$300,000 of this amount will be brought into the Company as of the time of filing this third quarter 2012 10Q document.

## 11. New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by FASB that are adopted by the Company as of the specified effective date. If not discussed, management believes that the impact of recently issued standards, which are not yet effective, will not have a material impact on the Company's financial statements upon adoption.

## 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, 2011. 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, 2011, and other risks and uncertainties discussed in filings made with the Securities and Exchange Commission. See "Forward Looking Statements" for additional discussion regarding risks associated with forward-looking statements.*

### Overview

Bio-Path Holdings, Inc. (together with its subsidiary, "Bio-Path" or the "Company" or "we," "us" or "our") is engaged in the business of developing novel cancer therapeutics licensed to us from The University of Texas MD Anderson Cancer Center ("MD Anderson") for two lead products and related nucleic acid drug delivery technology, including tumor targeting technology. These licenses specifically provide (i) drug delivery platform technology with composition of matter intellectual property for antisense that enables systemic delivery of antisense, and (ii) potentially small molecules for the treatment of cancer. The Company is currently only developing the liposomal antisense technology.

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 through proof-of-concept into safety study (Phase I), to 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 interfere with 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**

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 this outcome is favorable, we expect there will be opportunities to negotiate non-exclusive license applications involving upfront cash payments with pharmaceutical companies developing antisense drugs that need systemic delivery technology.

The IND for BP-100-1.01 was submitted to the FDA in February of 2008 and included all *in vitro* testing, animal studies and manufacturing and chemistry control studies completed. The FDA requested some changes be made to the application submission. We resubmitted information to the FDA in response to such request. On March 12, 2010, we issued a press release announcing that the US Food and Drug Administration (FDA) had allowed an IND (Investigational New Drug) for Bio-Path's lead cancer drug candidate liposomal BP-100-1.01 to proceed into clinical trials. The IND review process was performed by the FDA's Division of Oncology Products and involved a comprehensive review of data submitted by us covering pre-clinical studies, safety, chemistry, manufacturing, and controls, and the protocol for the Phase I clinical trial. The primary objective of the Phase I clinical trial, as in any Phase I clinical trial, is the safety of the drug for treatment of human patients. Additional key objectives of the trial are to demonstrate the effectiveness of our drug delivery technology similar to that experienced in pre-clinical treatment of animals and to assess whether the drug candidate test article produces a favorable impact on the cancerous condition of the patient at the dose levels of the study.

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 trial will evaluate five doses of L-Grb-2 and patients will be enrolled in the study to achieve 18 to 30 evaluable patients. An evaluable patient is a patient who is able to complete the four-week treatment cycle. The clinical trial is being conducted at MD Anderson.

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.

At the end of July 2011, the Company completed requirements for treating patients in the first cohort. The Company, its medical advisors and the Principal Investigator agreed that the data from the first cohort demonstrated that Liposomal Grb-2 was safe enough to proceed to the next cohort of the trial, which treated patients in the trial with a dose that was double the dose used in the first cohort. As a result of this review, the first cohort was closed and the second cohort was opened for recruiting patients into the clinical trial. In January 2012, the Company completed requirements for treating patients in the second cohort. The Company, its medical advisors and the Principal Investigator agreed that the data from the second cohort demonstrated that Liposomal Grb-2 was safe enough to proceed to the third cohort of the trial, which is treating patients with a dose of  $20 \text{ mg/m}^2$ , which is double the dose used in the second cohort. The Company, its medical advisors and the Principal Investigator agreed that the data from the third cohort demonstrated that Liposomal Grb-2 was safe enough to proceed to the fourth cohort of the trial, which is treating patients with a dose of  $40 \text{ mg/m}^2$ , which is double the dose used in the third cohort. Significantly, in the third cohort, all three patients completed the treatment cycle and were evaluable and, because of apparent stabilization from treatment with Bio-Path drug candidate Liposomal Grb-2, had received or anticipated to receive extended treatment cycles.

Based on the experience treating patients in Cohort 3, when all three patients benefited from treatment with Liposomal Grb-2 and were apparently stabilized, the assumption for drug requirements for Cohort 4 and beyond have increased significantly. Specifically, the assumption now is that all patients will benefit from treatment with the drug candidate Liposomal Grb-2 and be eligible to receive up to six months of treatments. In this regard, the Company increased the capacity of its drug supply chain, adding new suppliers for the Grb-2 drug substance and for the final drug product. Substantially increased supplies of the drug candidate Liposomal Grb-2 were delivered in July 2012.

The Company has completed testing of Cohort 4 patients and expects at any time to receive clearance to formally close the Cohort. There has not to date been any signs of significant toxicity from the treatment of patients with Bio-Path's drug Liposomal Grb-2. This presents an opportunity for testing of Liposomal Grb-2 at even higher doses that could potentially provide even greater and longer duration benefits to patients, thereby increasing chances for an early approval of Bio-Path's drug candidate Liposomal Grb-2. 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. The opportunity for three drug approvals in a relatively moderate timeframe could be very significant for Bio-Path's shareholders. The Company expects to update investors on its development plans in the very near future. An update for timelines and budgets will be given at that time.

The Principal Investigator for the Phase I clinical trial, Dr. Jorge Cortes, is a leading expert in the treatment of CML, AML and ALL. Because the results of the first trial produced unexpected and clinically interesting results in some patients, the Principal Investigator prepared an abstract of the results of the first cohort that was accepted for presentation at the American Hematology Society annual meeting in December 2011. Results from the second cohort also demonstrated potential anti-leukemia benefits in treated patients. The next opportunity for the Bio-Path to present information at the American Hematology Society annual meeting will be when the Company has completed the Phase I clinical trial.

The Company expects that the patient testing requirements of the Phase I clinical trial will be completed during 2012. Since, at the Principal Investigator's recommendation, some patients who are benefiting from the treatment are being placed on continuing therapy beyond the requirements of the clinical trial, additional expenses may be incurred as the Company is required to supply drug at no charge for the continuing treatment. Additional costs to completion of the Phase I clinical trial are estimated to range from \$400,000 to \$550,000. Bio-Path believes it has sufficient resources and access to additional resources to meet its obligations in this regard.

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.

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

### **BP-100-1.02**

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.

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.

### **BP-100-2.01**

BP-100-2.01 is a small interfering RNA ("siRNA") drug. At the end of January 2012, the Board of Directors (the "Board") of the Company held a strategic planning session. Among several topics of discussion was a discussion of the Company's liposomal siRNA technology. The siRNA discussion covered a broad range of topics including intellectual property, the amount of development that would be needed and the overall impression of diminishing acceptance of siRNA technology by the pharmaceutical industry and equity market investors. The Board compared this to our core liposomal antisense technology, which has a stronger intellectual property position, a method of action blocking expression of disease-causing proteins that is better understood in the scientific community and a much easier path for development than liposomal siRNA technology. Since both antisense and siRNA are means to block expression of disease-causing proteins, the Board concluded that there was no apparent reason to develop a second, higher-risk siRNA method of blocking protein expression when the development of the liposomal antisense method is now much further along and showing promising results. After this discussion, the Board decided to discontinue development of the licensed liposomal siRNA technology. The Company has commenced discussions regarding this decision with MD Anderson to determine whether to modify the license to include other products, postpone the license or 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 represents 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, or \$345,000, and cancel the license.





An important milestone was achieved for the Company in the second quarter of 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 and Bio-Path is very pleased to have qualified for the OTCQX given its high standards. The OTCQX is a premier platform that distinguishes the best companies traded over-the-counter from the thousands of securities traded on the OTC Bulletin Board who are not required to meet any financial standards or undergo a qualitative review. Bio-Path's commencement of trading on the OTCQX attests to the quality of the Company's financial reporting and its technology. The Company also announced that it had retained Roth Capital Partners to serve as the Company's Designated Advisor for Disclosure ("DAD") on OTCQX. Roth Capital Partners is a firm with a strong life sciences research and investment banking practice and a focus on small-cap companies and will be responsible for providing guidance on OTCQX requirements.

On October 1, 2012, the Company's Board increased the size of the Board from three to four members and elected Michael J. Garrison as a director of the Company to fill the vacancy created by such increase. In connection with Mr. Garrison's election to the Board, he will be granted an option to purchase 25,000 shares of the Company's common stock at an exercise price equal to the closing price per share for the Company's common stock on the OTCQX on the date of such election. Such option will vest and become exercisable on the first anniversary date of such grant, based on continuing service to the Company.

### **Projected Financing Needs**

As of September 30, 2012, we anticipate that we need to raise approximately an additional \$7,000,000 to enable us to complete all projected clinical trials for our product candidates and conduct certain additional clinical trials in other Bio-Path drug candidates.

In April 2012, the Company entered into a Placement Agent Agreement for the sale of up to \$2 million of common stock through a private placement. In October, 2012, the Board in conjunction with the Placement Agent decided to increase the sale of up to \$2 million to \$4 million of common stock, and extend the expiration date of the private placement through December 31, 2012. There can be no guarantees or assurances that we will be successful in raising all \$4 million. Through mid-November 2012 the Company received commitments for approximately \$1.7 million through its private placement. Approximately \$1 million of this amount has been brought into the Company, while approximately \$700,000 remains at various stages of finalization. It is expected that \$100,000 to \$300,000 of this amount will be brought into the Company as of the time of filing this quarterly report on Form 10-Q. The Company intends to continue selling its common stock through this private placement with a goal of raising \$4 million. This offering capital, plus the cash on hand of \$332,862, will achieve our short term objective of the completion of the Phase I trial and, in addition, provide the necessary capital to fund operations through the end of Fiscal Year 2012.

The Company plans to begin raising significant amounts of additional development capital once there is demonstration of proof-of-concept of Bio-Path's technology in human patients in the Phase I trial. This trial is targeted

to be completed by the end of 2012, however, the opportunity to utilize higher doses may extend the trial an additional one or two quarters.

The remainder of the Phase I clinical trial of BP-100-1.01 is expected to cost between \$400,000 to \$550,000. If the Phase I clinical trial in BP-100-1.01 is successful, we expect to follow with a Phase IIa trial in BP-100-1.01, subject to available capital. Successful Phase I and IIa trials of BP-100-1.01 will demonstrate clinical proof-of-concept that BP-100-1.01 is a viable therapeutic drug product for treatment of AML, MDS and CML. The Phase IIa clinical trial in BP-100-1.01 is expected to cost approximately \$1,600,000.

The Phase I clinical trial of BP-100-1.02 is expected to cost \$2,000,000. Commencement of the Phase I clinical trial depends on the FDA approving the IND for BP-100-1.02 and is subject to available capital. However, the Company does not expect any concerns with FDA approval of the IND for this drug since the safety profile of this class of liposomal antisense drug products will have been well-established by the Phase I clinical trial of BP-100-1.01. Success in the Phase I clinical trial will be based on the demonstration that the delivery technology for BP-100-1.02 has the same delivery characteristics seen in the on-going Phase I clinical trial of BP-100-1.01. As such, if the on-going Phase I clinical trial for BP-100-1.01 proves successful, a significant pathway is established laying the foundation for BP-100-1.02.

We have currently budgeted approximately \$975,000 out of the approximate \$7,000,000 in net proceeds to be raised for additional drug development opportunities. The balance of the funding is planned to fund patent expenses, licensing fees, laboratory testing services including potentially to MD Anderson's Pharmaceutical Development Center, consulting fees and management and administration.

In the aggregate, the additional capital requirements of approximately \$7,000,000 are expected to fund operations through the second quarter of 2014 including the completion of the Phase I clinical trial of BP-100.1.01 (\$500,000). As of September 30, 2012, the Company has cash of \$332,862, plus the additional cash expected from the ongoing private placement described herein, to finance the completion of this trial. The Phase I clinical trial of BP-100.1-02 (\$2,000,000), the Phase II clinical trial of BP-100-1.01 (\$1,600,000), license-related payments to MD Anderson (\$365,000), provision to in-license new targets and compounds for development (\$975,000) and general and administrative costs for the organization are anticipated for operations through the second quarter of 2014 (\$2,660,000). Costs for personnel directly related to the clinical trial are included in those program estimates. Timing and costs for this plan are best estimates at this point in time and could vary depending on the availability of capital, the rate of enrollments in clinical trials and other factors not controlled by the Company. Expanding the Phase II clinical trial of BP-100-1.01 into Phase II trials for three separate diseases has not been factored into the current budget plan. However, the three-disease Phase II plan would add an estimated \$3 million to our budget.

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 report will be successful or that we can continue to receive additional financing. Our business is subject to risks inherent in growing an enterprise, including limited capital resources and possible rejection of our new products and/or clinical development methods. If financing is not available on satisfactory terms, we may be unable to continue expanding our operations. Equity financing will result in a dilution to existing shareholders.

There can be no assurance of the following:

- (1) That the actual costs of a particular trial will come within our budgeted amount.
- (2) That any trials will be successful or will result in drug commercialization opportunities.
- (3) That we will be able to raise the sufficient funds to allow us to complete our planned clinical trials.

### **Background Information about MD Anderson**

We anticipate that our initial drug development efforts will be pursuant to two exclusive License Agreements with MD Anderson. MD Anderson's stated mission 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 2 best hospitals for 16 consecutive years. 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.

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 ("pK"), 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 ongoing access 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 Bio-Path obtains 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

Bio-Path Subsidiary has two licenses with MD Anderson for late stage preclinical molecules, and we intend to use our relationship with MD Anderson to develop these drug compounds through Phase IIa clinical trials, the point at which we believe 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 product ourselves. Our basic guide to a decision to obtain a license for a potential drug candidate is as follows:

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

**Does it fit with the Company's expertise:** Does Bio-Path possess the technical and clinical assets to significantly reduce the scientific and clinical risk to a point where a pharmaceutical company partner would likely want to license this candidate within 36-40 months from the date of Bio-Path acquiring a license?

**Affordability and potential for partnering:** Can the clinical trial endpoints be designed in a manner that is unambiguous, persuasive, and can be professionally conducted consistent with that expected by the pharmaceutical industry at a cost of less than \$5-\$7 million dollars without cutting corners?

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

## Out-Licenses and Other Sources of Revenue

Subject to demonstrating proof-of-concept for our delivery technology and obtaining adequate capital, we intend to develop a steady series of drug candidates through Phase IIa clinical trials and then to engage in a series of out-licensing transactions to the pharmaceutical and biotechnology companies for the purpose of conducting later-stage clinical development, regulatory approval, and eventual marketing of the drug. We expect that such out-license transactions would include upfront license fees, milestone/success payments, and royalties. We intend to maximize the quality and frequency of these transactions, while minimizing the time and cost to achieve meaningful candidates for out-licensing.

In addition to this source of revenue and value, we may forward integrate one or more of our own drug candidates. For example, there are certain cancers that are primarily treated only in a comprehensive cancer center; of which there are approximately forty in the US and perhaps two hundred throughout the world. Hence, "marketing and distribution" becomes a realistic possibility for select products. These candidates may be eligible for Orphan Drug Status which provides additional incentives in terms of market exclusivities and non-dilutive grant funding for clinical trials.

Finally, there are technologies for which we anticipate acquiring licenses whose application goes well beyond cancer treatment. The ability to provide a unique and greatly needed solution to the delivery of small molecules, DNA and their efficient uptake by targeted physiological tissues is a very important technological asset that may be commercialized in other areas of medicine.

### **License Agreements**

We have entered into two Patent and Technology License Agreements (the "License Agreements") with MD Anderson relating to its technology. These License Agreements relate to the following technologies: (1) two single nucleic acid (antisense) drug products; and (2) delivery technology platform for nucleic acids. These licenses require, among other things, the Company to reimburse MD Anderson for ongoing patent expense. A summary of the material terms of the licenses are detailed in our Annual Report on Form 10-K as of and for the fiscal year ended December 31, 2011. During the second quarter of 2012, the Company and MD Anderson agreed to terminate the license agreement relating to siRNA technology.

### **Business Strategy**

Our plan of operation over the next 30 months is focused on achievement of milestones with the intent to demonstrate clinical proof-of concept of our drug delivery technology and lead drug products. Furthermore, subject to adequate capital, we will attempt to validate our business model by in-licensing additional products to broaden our drug product pipeline.

At September 30, 2012, we anticipated that over the next 24 months we will need to raise approximately \$7,000,000 to completely implement our current business plan. We have previously completed several financings for use in our operations and have received total net proceeds of \$7,832,331 as of September 30, 2012. Our short term plan is to achieve the following key milestones:

Complete the Phase I clinical trial of our lead drug BP-100-1.01, which if successful, will validate our liposomal delivery technology for nucleic acid drug products. In this Phase I trial, we will leverage MD Anderson's pre-clinical and clinical development capabilities, including using the PDC for pre-clinical studies as well as clinical pharmacokinetics and pharmacodynamics and the institution's world-renowned clinics, particularly for early clinical trials. This should allow us to develop our drug candidates with experienced professional staff at a reduced cost compared to using external contract laboratories. This should also allow us to operate in an essentially virtual fashion, thereby avoiding the expense of setting up and operating laboratory facilities, without losing control over timing or quality or IP contamination. Effective July 29, 2010, we began dosing of patients of this lead drug - BP-100-1.01 at MD Anderson and we have since completed the fourth cohort and shortly will begin enrolling patients in the fifth cohort thereunder;

- (1) Prepare a master protocol to conduct three Phase II trials of BP-101-1.01 for diseases CML, AML and MDS.
- (2) Recruit three additional cancer centers in addition to MD Anderson to enable four site Phase II clinical trials to be conducted and prepare necessary documentation to receive approval of the Phase II protocol and FDA approval to proceed with the trials.
- (3) Perform necessary pre-clinical studies in our second liposomal antisense drug candidate, BP-100-1.02 to enable the filing of an IND for a Phase I clinical trial; and
- (4) Out-license (non-exclusively) our delivery technology to a pharmaceutical partner to speed development of applications of our technology.

We plan to pursue and achieve the above short term milestones by utilizing the following tactics:

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

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

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

Outsource manufacturing and regulatory capabilities. Bio-Path will not need to invest its resources in building functions where it does not add substantial value or differentiation. Instead, it will leverage an executive team with expertise in the selection and management of high quality contract manufacturing and regulatory firms.



## **Manufacturing**

We have no manufacturing capabilities and have developed relationships with third party contract manufacturers and suppliers to supply our drug product requirements. In August 2012, Bio-Path entered into a project plan agreement with the Company's drug substance manufacturer for delivery of a drug substance for a batch of final drug product scheduled to be manufactured in the fourth quarter of 2012. In September 2012, the Company entered into a project plan for the delivery of final drug product incorporating the drug substance for expected delivery in the fourth quarter of 2012. Taken together, these two project plans will require the Company to pay approximately \$340,000 once manufacturing has been completed and the drug product has been delivered to the Company. Of this amount, \$79,500 has been paid for by the Company, which is carried on the Balance Sheet as Prepaid Drug Product for Testing. This amount substantially represents the entire financial commitments to the drug substance and the drug product manufacturers for the new batch of drug material.

## **Intellectual Property**

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

We will actively seek patent protection in the U.S. and, as appropriate, abroad and closely monitor patent activities related to our business.

In addition to patents, we will rely on trade secrets and proprietary know-how, which we seek to protect, in part, through confidentiality and proprietary information agreements.

## **Agreement with Acorn CRO**

On April 23, 2009, we announced that had we entered into an agreement with ACORN CRO, a full service, oncology-focused clinical research organization (CRO), to provide us with a contract medical officer and potentially other clinical trial support services. Under such agreement, Bradley G. Somer, M.D., started serving as our Medical Advisor and medical liaison for the conduct of the Phase I clinical study of liposomal BP-100-1.01 in refractory or relapsed Acute Myeloid Leukemia (AML), Chronic Myelogenous Leukemia (CML), Acute Lymphoblastic Leukemia (ALL) and Myelodysplastic Syndrome (MDS).

## **Competition**

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

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

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

## **Government Regulation**

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

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

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

pre-clinical laboratory tests, pre-clinical studies in animals, formulation studies and the submission to the FDA of an investigational new drug application;

- adequate and well-controlled clinical trials to establish the safety and efficacy of the drug;
- the submission of a new drug application or biologic license application to the FDA; and
- FDA review and approval of the new drug application or biologics license application.

Bio-Path's business model relies on 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 IIA 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 Annual Report on Form 10-K as of and for the fiscal year ended December 31, 2011.

***Results of Operations for the three and nine months ended September 30, 2012 and 2011.***

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

**Research and Development Expenses.** Our research and development expense was \$546,821 for the three months ended September 30, 2012; an increase of \$419,712 over the three months ended September 30, 2011. The increase in research and development expense for three months ending September 30, 2012 compared to the comparable period ending September 30, 2011 was primarily due to \$410,055 expense for drug product material to be used in our clinical trial. The Company incurred installments from its contract drug manufacturing and raw material suppliers for a lot of the Company's drug product for testing in its Phase I clinical trial, which amounts were carried on the Balance Sheet as Prepaid Drug Product for Testing and expensed during the quarter upon delivery of the drug product to the company. See Note 3. Our research and development expense was \$994,459 for the nine months ended September 30, 2012; an increase of \$535,656 of over the nine month period ended September 30, 2011. The increase in research and development expense for the nine month period ending September 30, 2012 was primarily due to increased drug product expense used in the Company's Phase I clinical trial. Research and development expense – related party for the three months ending September 30, 2012 was essentially flat with the comparable period ending September 30, 2011. Research and development expense – related party for the nine month period ending September 30, 2012 was \$426,870, an increase of \$326,870 from the comparable nine month period ending September 30, 2011. The increase in research and development expense – related party for the nine month period ending September 30, 2012 versus the comparable period in 2011 was primarily due to expense related to the Company's decision to halt development of liposomal siRNA technology.

**General and Administrative Expenses.** Our general and administrative expenses were \$246,086 for the three months ended September 30, 2012; a decrease of \$81,294 compared to the three month period ended September 30, 2011. The decrease in general and administrative expense for the quarter ending September 30, 2012 compared to the quarter ending September 30, 2011 was due to lower stock option expense. General and administrative expenses were \$729,569 for the nine months ended September 30, 2012; a decrease of \$272,622 compared to the nine month period ended September 30, 2011. The decrease in general and administrative expenses for the nine month period ending September 30, 2012 compared to the nine month period ending September 30, 2011 was the result of a \$314,869 decrease in stock option expense, which decrease was more significant than the offsetting results of increased expenses of being a public company, insurance and corporate communications.

**Net Loss.** Our net loss was \$840,552 for the three months ended September 30, 2012, compared to a loss of \$503,819 for the three months ended September 30, 2011. The increase in the net loss for the quarter ending September 30, 2012 compared to the quarter ending September 30, 2011 was due to an increase in research and development expense more than offsetting a decrease in general administrative expense during the same periods. Net loss per share, both basic and diluted was \$0.01 per share, was the same for the respective three month periods. Our net loss was \$2,150,617 for the nine months ended September 30, 2012, compared to a loss of \$1,559,294 for the nine month period ended September 30, 2011. The increase in net loss for the nine month period ending September 30, 2012 compared to the comparable period ending September 30, 2011 was due to increases in research and development and research and development-related party expenses more than offsetting lower general and administrative expense. Net loss per share, both basic and diluted, was \$0.04 per share for the nine month period ending September 30, 2012 and \$0.03 per share for the comparable nine month period ending September 30, 2011.

## Liquidity and Capital Resources

Since our inception, we have funded our operations primarily through private placements of our capital stock. We expect to finance our foreseeable cash requirements through cash on hand, cash from operations, public or private equity offerings and debt financings. Additionally, we are seeking collaborations and license arrangements for our three product candidates. We may seek to access the public or private equity markets whenever conditions are favorable.

At September 30, 2012, we had cash of \$332,862 compared to \$952,252 at December 31, 2011. The decrease in cash balances during the nine month period ending September 30, 2012 results from \$1,567,536 in cash used in operations and a \$25,000 purchase related to the Company's exclusive license with the related party, offset by \$973,146 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, 2012 was \$1,567,536 compared to \$726,157 for the nine months ended September 30, 2011. Inasmuch as we have not yet generated revenues, our entire expenses of operations are funded by our cash assets.

With the exception of a \$244,479 grant received from the United States Government, currently all of our cash is, and has been, generated from financing activities. We raised a total of \$973,146 in net cash from financing activities for the nine months ended September 30, 2012. Since inception we have net cash from financing activities of \$7,832,331. As discussed in Projected Financing Needs above, we believe that our available cash will be sufficient to fund our liquidity and capital expenditure requirements through March 2013. We will need to raise additional capital in order to fund our operations subsequent to March 2013. There can be no assurance that we will be able to raise cash when it is needed to fund our operations.

We believe that our available cash will be sufficient to fund our liquidity and capital expenditure requirements up to March 2013. We anticipate that we will need to raise approximately an additional \$7 million in net proceeds to completely implement our business plan. We believe the Company will be successful in raising a total of \$4 million in the current private placement offering. However, there can be no assurances that we will be successful in raising this total amount. We also have several discussions underway with potential investors at this time which could result in us receiving sufficient capital to extend our operations beyond 2013 and possibly even 2014. There is no assurance or guarantee that we will raise any additional capital.

### **Contractual Obligations and Commitments**

Bio-Path has entered into two patent and technology license agreements (the "Licenses") with MD Anderson relating to its technology. A summary of certain material terms of each of the Licenses is detailed in our Annual Report on Form 10-K as of and for the fiscal year ended December 31, 2011.



As a result of the continuing Phase I trial, the Company believed it was in the best interest of the Company to enter into a new agreement with a larger capacity manufacturer. Consequently, in August 2012 the Company entered into a new project plan agreement with its contract manufacturing supplier for a batch of drug product with expected delivery by year end. The project plan requires the Company to pay the supplier \$340,000 for this drug product, of which a total of \$79,500 has been paid to date.

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., will serve as Bio-Path's Medical Officer and medical liaison for the conduct of the Company's upcoming Phase I clinical study of liposomal BP-100-1.01 in refractory or relapsed Acute Myeloid Leukemia (AML), Chronic Myelogenous Leukemia (CML), Acute Lymphoblastic Leukemia (ALL) and Myelodysplastic Syndrome (MDS).

### **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, 2011.

### **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, 2012, 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, 2012.

**(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 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, 2012 through September 30, 2012, the Company sold to accredited investors a total of 2,650,003 shares of common stock. The Company received net proceeds from these sales of \$795,001.

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

### **ITEM 3. DEFAULTS 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)
31*	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Section 302 of the Sarbanes Oxley Act of 2002.
32*	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Section 906 of the Sarbanes Oxley Act of 2002.

\*

Filed herewith.

**SIGNATURE**

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

Dated: November 14, 2012 BIO-PATH HOLDINGS, INC.

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