BIO-PATH HOLDINGS INC
Form 10-Q
May 15, 2013

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2013

Or

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

For the transition period from _____

Commission file number: 000-53404

Bio-Path Holdings, Inc.

(Exact name of registrant as specified in its charter)

Utah	87-0652870
(State or other jurisdiction of incorporation or organization)	(I.R.S. employer 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 x No ¨

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

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

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

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

At May 8, 2013, the Company had 63,729,050 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-look statements. These statements are only predictions based on current information and expectations and involve a number of risks and uncertainties. The underlying information and expectations are likely to change over time. Actual events or results may differ materially from those projected in the forward-looking statements due to various factors, including, but not limited to, those set forth under the caption “Risk Factors” in “ITEM 1. BUSINESS” of our Annual Report on Form 10-K as of and for the fiscal year ended December 31, 2012, and those set forth in our other filings with the Securities and Exchange Commission. Except as required by law, we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

BIO-PATH HOLDINGS, INC.

(A Development Stage Company)

CONSOLIDATED BALANCE SHEETS

Unaudited

	March 31, 2013	December 31, 2012
ASSETS		
Current assets		
Cash	$288,707	$534,046
Prepaid drug product for testing	96,000	195,000
Other current assets	53,924	42,575
Total current assets	438,631	771,621
Other assets		
Technology licenses - related party	2,500,374	2,500,374
Less Accumulated Amortization	(968,387)	(928,231)
	1,531,987	1,572,143
TOTAL ASSETS	$1,970,618	$2,343,764
LIABILITIES & SHAREHOLDERS' EQUITY		
Current liabilities		
Accounts payable	71,875	57,000
Accounts payable - related party	-	8,582
Accrued expense	153,541	137,662
Accrued expense - related party	15,000	26,000
Accrued license payments - related party	50,000	100,000
Total current liabilities	290,416	329,244

Long term debt	-	-
TOTAL LIABILITIES	290,416	329,244
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 62,219,050 shares issued and outstanding as of 3/31/13 and 12/31/12	62,218	62,218
Additional paid in capital	13,296,560	13,321,075
Additional paid in capital for shares to be issued a/ & b/	1,108,711 a/	762,510 b/
Accumulated deficit during development stage	(12,787,287)	(12,131,283)
Total shareholders' equity	1,680,202	2,014,520
TOTAL LIABILITIES & SHAREHOLDERS' EQUITY	$1,970,618	$2,343,764

a/ Represents 3,695,702 shares of common stock

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

SEE ACCOMPANYING NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

BIO-PATH HOLDINGS, INC.

(A Development Stage Company)

CONSOLIDATED STATEMENTS OF OPERATIONS

Unaudited

	January 1 to March 31		From inception 05/10/07 to
	2013	2012	3/31/13
Revenue	$ -	$ -	$ -
Operating expense			
Research and development a/	401,099	279,613	4,726,696
Research and development - related party b/	15,000	11,700	1,078,620
General & administrative c/	239,811	231,314	7,299,273
Total operating expense	655,910	522,627	13,104,589
Net operating loss	$ (655,910)	$ (522,627)	$ (13,104,589)
Other income (expense)			
Interest income	124	529	77,213
Other income	-	-	244,479
Other expense	(216)	(129)	(4,390)
Total Other Income (Expense)	(92)	400	317,302
Net Loss	$ (656,002)	$ (522,227)	$ (12,787,287)
Loss per share			
Net loss per share, basic and diluted	$ (0.01)	$ (0.01)	$ (0.27)
Basic and diluted weighted average number of common shares outstanding	62,219,050	58,381,419	46,728,530

a/ Research and development expense includes stock option expense of $11,414 and $17,406 for the quarters ending 3/31/2013 and 3/31/2012, respectively; and $434,412 for the period from inception through 3/31/2013. Research

and development expense also includes amortization expense of $40,156 and $48,109 for the quarters ending 3/31/2013 and 3/31/2012, respectively; and $1,016,891 for the period from inception through 3/31/2013.

b/ Includes $690,000 technology impairment charge for the period from inception through 3/31/2013.

c/ General & administrative expense includes stock option expense of $4,605 and $1,950 for the quarters ending 3/31/2013 and 3/31/2012, respectively; and for the period from inception through 3/31/2013, $2,595,361 for stock option and warrant expense and $318,500 in stock for services.

SEE ACCOMPANYING NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

BIO-PATH HOLDINGS, INC.

(A Development Stage Company)

CONSOLIDATED STATEMENTS OF CASH FLOWS

Unaudited

	January 1 to March 31 2013	2012	From inception 05/10/2007 to 3/31/2013
CASH FLOW FROM OPERATING ACTIVITIES			
Net loss	$(656,002)	$(522,227)	$(12,787,287)
Adjustments to reconcile net loss to net cash used in operating activities			
Amortization	40,156	48,109	1,016,891
Technology impairment	-	-	690,000
Common stock issued for services	-	-	318,500
Stock options and warrants	16,019	19,356	3,029,773
(Increase) decrease in assets			
Prepaid drug product for testing	99,000	132,000	(96,000)
Other current assets	(11,349)	(7,891)	(53,924)
Increase (decrease) in liabilities			
Accounts payable and accrued expenses	(38,828)	(69,536)	290,416
Net cash used in operating activities	(551,004)	(400,189)	(7,591,631)
CASH FLOW FROM INVESTING ACTIVITIES			
Purchase of exclusive license - related party	-	(25,000)	(884,710)
Net cash used in investing activities	-	(25,000)	(884,710)
CASH FLOW FROM FINANCING ACTIVITIES			
Proceeds from convertible notes	-	-	435,000
Cash repayment of convertible notes	-	-	(15,000)
Net proceeds from sale of common stock	305,665	49,760	8,345,048
Net cash from financing activities	305,665	49,760	8,765,048
NET INCREASE (DECREASE) IN CASH	(245,339)	(375,429)	288,707
Cash, beginning of period	534,046	952,252	-

Cash, end of period	$288,707	$576,823	$288,707
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	$-	$-	$591,566
Common stock issued to M.D. Anderson for technology license	$-	$-	$2,354,167
Due diligence and commitment shares issued to Lincoln	$-	$625	$210,755

SEE ACCOMPANYING NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

BIO-PATH HOLDINGS, INC.

(A Development Stage Company)

Notes to the Unaudited Consolidated Financial Statements Ending March 31, 2013

The accompanying interim financial statements have been prepared with the instructions to Form 10-Q pursuant to the rules and regulations of the Securities and Exchange Commission and, therefore, do not include all information and footnotes necessary for a complete presentation of our financial position, results of operations, cash flows, and stockholders' equity in conformity with generally accepted accounting principles. In the opinion of management, all adjustments considered necessary for a fair presentation of the results of operations and financial position have been included and all such adjustments are of a normal recurring nature. The unaudited quarterly financial statements should be read in conjunction with the audited financial statements and notes thereto included in the Annual Report on Form 10-K of Bio-Path Holdings, Inc. (together with its subsidiary, "Bio-Path" or the "Company") as of and for the fiscal year ended December 31, 2012. The results of operations for the period ended March 31, 2013, are not necessarily indicative of the results for a full-year period.

1. Organization and Business

Bio-Path is a development stage company with its lead cancer drug candidate, Liposomal Grb-2 (L-Grb-2 or BP-100-1.01), currently in clinical trials. The Company was founded with technology from The University of Texas, MD Anderson Cancer Center ("MD Anderson") and is dedicated to developing novel cancer drugs under an exclusive license arrangement. The Company has drug delivery platform technology with composition of matter intellectual property for systemic delivery of antisense. Bio-Path also plans to investigate developing liposome tumor targeting technology, which has the potential to be developed to augment the Company's current delivery technology to improve further the effectiveness of its antisense. In addition to its existing technology under license, the Company expects to maintain a close working relationship with key members of the MD Anderson staff, which has the potential to provide Bio-Path with additional drug candidates in the future. Bio-Path also expects to broaden its technology to include cancer drugs other than antisense, including drug candidates licensed from institutions other than MD Anderson.

Bio-Path believes that its core technology, if successful, will enable it to be at the center of emerging genetic and molecular target-based therapeutics that require systemic delivery of DNA and RNA-like material. The Company's two lead liposomal antisense drug candidates are targeted to treat acute myeloid leukemia, myelodysplastic syndrome, chronic myelogenous leukemia, acute lymphoblastic leukemia and follicular lymphoma, and if successful, could potentially be used in treating many other indications of cancer. For example, recently in December of 2012 Bio-Path announced that it was initiating development of its lead cancer drug Liposomal Grb-2 to treat triple negative breast cancer (TNBC) and inflammatory breast cancer (IBC), two cancers characterized by formation of aggressive tumors and relatively high mortality rates.

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

The Phase I clinical trial is a dose-escalating study to determine the safety and tolerance of escalating doses of L-Grb-2. The study will also determine the optimal biologically active dose for further development. The pharmacokinetics of L-Grb-2 in patients will be studied, making it possible to investigate whether the delivery technology performs as expected based on pre-clinical studies in animals. In addition, patient blood samples from the trial will be tested using a new assay developed by the Company to measure down-regulation of the target protein, the critical scientific data that will demonstrate that the delivery technology does in fact successfully deliver the antisense drug substance to the cell and across the cell membrane into the interior of the cell where expression of the target protein is blocked. The initial protocol for the trial required 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.

In November of 2012, the Company announced that since there had been no evidence of significant toxicity from treatment of patients with L-Grb-2, the Company was proceeding with requesting the FDA to allow higher dosing in patients. The Principal Investigator for the clinical trial, in consultation with Bio-Path's Board of Directors, advised that with the absence of any real toxicity barriers, the Company should continue to evaluate higher doses of Liposomal Grb-2. The absence of significant toxicity provides a significant opportunity for the Company to test higher doses in patients in order to find a dose that provides maximum potential benefit and duration of anti-leukemia effect. These actions were approved and a revised protocol is in place allowing higher dosing. The Company has enrolled and is currently treating three patients in Cohort 5 at a dose of 60 mg/m^2. The Company expects all three patients to have completed their treatment cycle successfully by the end of May of 2013. 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^2, 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, during which all three patients benefited from treatment with Liposomal Grb-2 and were apparently stabilized, the assumption for drug requirements for Cohort 4 and beyond were 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, MDS and ALL. Because the results of the first trial produced unexpected and clinically interesting results in

some patients, the Principal Investigator prepared an abstract of the results of the first cohort that was accepted for presentation at the American Society of Hematology annual meeting in December of 2011. Results from the second cohort also demonstrated potential anti-leukemia benefits in treated patients and were included in the presentation. Bio-Path and the Principal Investigator plan to present information at leading industry scientific conferences in the future as results become available.

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.

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 begin expanding Bio-Path's drug candidates by simply applying the delivery technology template to multiple new drug product targets. In this manner, Bio-Path can quickly build an attractive drug product pipeline with multiple drug product candidates for treating cancer as well as treating other important diseases including diabetes, cardiovascular conditions and neuromuscular disorders. Currently, the Company is researching potential targets for which it can apply its liposomal antisense drug delivery technology.

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

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

product candidate Liposomal Grb-2.

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

As of March 31, 2013, Bio-Path had $288,707 in cash on hand. After March 31, 2013, the Company received an additional $2.26 million in cash from the sale of shares of common stock in a private placement that was subsequently closed. 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 March 31, 2013 and 2012, MD Anderson related party research and development expense was $15,000 and $11,700, respectively. MD Anderson related party research and development expense for the quarter ending March 31, 2013 was comprised of MD Anderson clinical trial hospital expense of $15,000 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, 6 and 7. As of March 31, 2012, the Company had $11,700 in research and development related party expense for the MD Anderson clinical trial hospital expense, related party accounts payable of $8,582 for current patent expenses, $26,000 in accrued expenses related party for MD Anderson clinical trial hospital expense, and $100,000 in accrued license payments payable due to the related party for past patent expenses and the annual maintenance fee 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 $195,000 during 2012 pursuant to a Drug Supply Contract (see Note 11) for the manufacture and delivery of the Company's lead drug product for testing in a Phase I clinical trial. This amount was carried on the Balance Sheet as of December 31, 2012 at cost as Prepaid Drug Product for Testing. This product was delivered to the Company in the first quarter of 2013 and costs associated with this drug batch were expensed. Another drug batch is scheduled for May 2013 and installment costs totaling $96,000 are carried on the Balance Sheet as of March 31, 2013 as Prepaid Drug Product for Testing (see Note 11).

4. Accounts Payable

As of March 31, 2013, Current Liabilities included accounts payable of $71,875 comprised primarily of approximate amounts owed to the Company's drug contract manufacturers totaling $10,600, $15,900 to the company providing clinical operations management for Bio-Path's clinical trial and $45,400 to the Company's attorneys and auditors for work on the Annual 10K report. As of December 31, 2012, Current Liabilities included accounts payable $57,000 and accounts payable related party of $8,582, which amounts were subsequently paid in 2013.

5. Accrued Expense

As of March 31, 2013, Current Liabilities included accrued expense of $153,541 including approximate amounts for research and development expense for clinical trial operations management of $8,000, $5,500 for advisors and consultants and $138,750 for management bonus accrual. Current Liabilities as of March 31, 2013 also included accrued expenses related party of $15,000 for MD Anderson clinical trial hospital expense. As of December 31, 2012, Current Liabilities included accrued expense of $137,662 and accrued expense related party of $26,000.

6. Accrued License Payments – Related Party

Accrued license payments related party totaling $50,000 and $100,000 were included in Current Liabilities as of March 31, 2013 and December 31, 2012, respectively. The amount included for March 31, 2013 represents reimbursement of past patent expenses incurred by MD Anderson prior to the Bio-Path license.

7. Additional Paid In Capital For Shares To Be Issued

During 2012 and the quarter ending March 31, 2013, the Company sold shares of common stock for cash to investors in a private placement. As of March 31, 2013, there were 3,695,702 shares of common stock remaining to be issued, representing $1,108,711 in sales to accredited investors. The Company has closed this offering at the end of the first quarter 2013 and is in the process of issuing the shares of common stock to these investors.

8. Stockholders' Equity

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

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

issued 66,000 shares of common stock to the Placement Agent as commission for the shares of common stock sold to investors. There were no issuances of shares during the fourth quarter of 2009.

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

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

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

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

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

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

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

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

From November 2010 through April of 2011 the Company sold shares of common stock for $1,794,205 in cash to investors pursuant to a private placement memorandum. In June of 2011, the Company issued 5,980,685 shares of common stock to these investors. In connection with this private placement, in June of 2011 the Company issued 598,069 shares of common stock to the Placement Agent as commission for the shares of common stock sold to investors. No warrants to purchase additional shares of common stock of the Company were issued to these investors in connection with the sale of the common stock.

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

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

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

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

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

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

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

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

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

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

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

In February and March of 2013, the Company sold $346,201 in shares of its common stock pursuant to a private placement, with shares to be issued.

As of March 31, 2013, there were 62,219,050 shares of common stock issued and outstanding. There are no preferred shares outstanding as of March 31, 2013.

9.Stock Options and Warrants

Stock Option - There were no stock option awards during the quarter ending March 31, 2013. Total stock option expense for the quarter ending March 31, 2013 was $16,019.

Warrant - There were no warrants for services granted during the quarter ending March 31, 2013.

10. Commitments and Contingencies

Technology License – Related Party - The Company has negotiated exclusive licenses from the MD Anderson Cancer Center to develop drug delivery technology for antisense and siRNA drug products. These licenses require, among other things, the Company to reimburse MD Anderson for ongoing patent expense. Related party accounts payable and accrued license payments attributable to the Technology License totaling $50,000 are included in Current Liabilities as of March 31, 2013. Related party accrued expense totaling $15,000 as of March 31, 2013 represents hospital costs for the clinical trial and are not related to the Technology License. As of March 31, 2013, the Company estimates reimbursable past patent expenses will total approximately $75,000 for the Technology License. The Company will be required to pay when invoiced the past patent expenses at the rate of $25,000 per quarter. In addition, the Company decided to discontinue development of its siRNA technology and subsequently canceled its siRNA license in June of 2012 (See Note 1).

Drug Supplier Project Plan - In August of 2012, Bio-Path entered into two project plan agreements with the Company's drug substance manufacturer and its final drug product manufacturer for the manufacture and delivery of final drug product incorporating the drug substance for expected delivery in the fourth quarter of 2012, with delivery subsequently revised to the first quarter of 2013. The project plans required the Company to pay approximately $340,000 in various stages as the drug substance and product are manufactured and delivered to the Company. Of this amount, $195,000 was paid for by the Company and was carried on the Balance Sheet as of December 31, 2012 as Prepaid Drug Product for Testing. The drug product was delivered to the Company in the first quarter of 2013 and the Balance Sheet item Prepaid Drug Product for Testing totaling $195,000 was expensed in the first quarter 2013. Amounts owed to the Company's manufacturers for this drug batch have been paid subsequent to year end. In addition, the Company signed another supply agreement in the first quarter of 2013 for a subsequent batch of drug product. Installment payments paid to the Company's drug manufacturer totaling $96,000 are being carried at cost on the Balance Sheet as of March 31, 2013 as Prepaid Drug Product for testing.

11. Subsequent Events

In the second quarter of 2013, the Company received an additional $2.26 million from the closeout of its private placement. Over an approximate twelve month period ending March 31, 2013 the Company sold $4 million in shares of its common stock to accredited investors in a private placement.

Certain accredited investors contemplated participating in such prior offering; however, such investors were unable to participate due to certain technical issues. In an effort to permit such investors the opportunity to complete their investment, in April of 2013 the Company executed agreements to sell an additional $550,000 of shares of its common stock in a private placement to these investors, of which the balance of $102,000 is expected to be received by May 31, 2013.

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

When you read this section of this Quarterly Report on Form 10-Q, it is important that you also read the unaudited financial statements and related notes included elsewhere in this Form 10-Q and our audited financial statements and notes thereto included in our Annual Report on Form 10-K as of and for the fiscal year ended December 31, 2012. This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations, and intentions. We use words such as "anticipate," "estimate," "plan," "project," "continuing," "ongoing," "expect," "believe," "intend," "may," "will," "should," "could," and similar expressions to identify forward-looking statements. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including the matters discussed under the caption "Risk Factors" in "Item 1, BUSINESS" in our Annual Report on Form 10-K as of and for the fiscal year ended December 31, 2012, and other risks and uncertainties discussed in filings made with the Securities and Exchange Commission. See "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 a development stage company with its lead cancer drug candidate, Liposomal Grb-2 ("L-Grb-2" or "BP-100-1.01"), currently in clinical trials. The Company was founded with technology from The University of Texas, MD Anderson Cancer Center ("MD Anderson") and is dedicated to developing novel cancer drugs under an exclusive license arrangement. The Company has drug delivery platform technology with composition of matter intellectual property for systemic delivery of antisense. Bio-Path also plans to investigate developing liposome tumor targeting technology, which has the potential to be developed to augment the Company's current delivery technology to improve further the effectiveness of its antisense. In addition to its existing technology under license, the Company expects to maintain a close working relationship with key members of the MD Anderson staff, which has the potential to provide Bio-Path with additional drug candidates in the future. Bio-Path also expects to broaden its technology to include cancer drugs other than antisense, including drug candidates licensed from institutions other than MD Anderson.

Our business plan is to act efficiently as an intermediary in the process of translating newly discovered drug technologies into authentic therapeutic drug candidates. Our strategy is to selectively license potential drug candidates for certain cancers, and, primarily utilizing the comprehensive drug development capabilities of MD Anderson, to advance these candidates into initial human efficacy trials (Phase IIa), and then out-license each successful potential drug and/or the drug delivery technology to a pharmaceutical company or, if the final steps to commercialization are within the capabilities of the Company, finalize development and commercialization internally.

The Company was founded in May of 2007 as a Utah corporation. In February of 2008, Bio-Path completed a reverse merger with Ogden Golf Co. Corporation, a public company traded over the counter that had no current operations. The name of Ogden Golf was changed to Bio-Path Holdings, Inc. and the directors and officers of Bio-Path, Inc. became the directors and officers of Bio-Path Holdings, Inc. Bio-Path has become a publicly traded company (symbol OTCQX: BPTH) as a result of this merger.

Our principal executive offices are located at 2626 South Loop, Suite 180, Houston Texas, 77054. Our telephone number is (832) 971-6616. Our Internet website address is www.biopathholdings.com, and all of our filings with the Securities and Exchange Commission are available free of charge on our website.

Research and Development

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

Basic Technical Information

Ribonucleic acid (RNA) is a biologically significant type of molecule consisting of a chain of nucleotide units. Each nucleotide consists of a nitrogenous base, a ribose sugar, and a phosphate. Although similar in some ways to DNA, RNA differs from DNA in a few important structural details. RNA is transcribed from DNA by enzymes called RNA polymerases and is generally further processed by other enzymes. RNA is central to protein synthesis. DNA carries the genetic information of a cell and consists of thousands of genes. Each gene serves as a recipe on how to build a protein molecule. Proteins perform important tasks for the cell functions or serve as building blocks. The flow of information from the genes determines the protein composition and thereby the functions of the cell.

The DNA is situated in the nucleus of the cell, organized into chromosomes. Every cell must contain the genetic information and the DNA is therefore duplicated before a cell divides (replication). When proteins are needed, the corresponding genes are transcribed into RNA (transcription). The RNA is first processed so that non-coding parts are removed (processing) and is then transported out of the nucleus (transport). Outside the nucleus, the proteins are built based upon the code in the RNA (translation).

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

The historical perspective of cancer treatments has been the use of drugs that affect the entire body. Advances in the past decade have shifted to treating the tumor tissue itself. One of the main strategies in these developments has been targeted therapy, involving drugs that are targeted to block the expression of specific disease causing proteins while having little or no effect on other healthy tissue. Nucleic acid drugs, specifically antisense, are a promising field of targeted therapy. Development of antisense, however, has been limited by the lack of a suitable method to deliver these drugs to the diseased cells with high uptake into the cell and without causing toxicity. Bio-Path's currently licensed neutral-lipid based liposome technology is designed to accomplish this. Studies have shown a 10-fold to 30-fold increase in tumor cell uptake with this technology compared to other delivery methods.

BP-100-1.01

BP-100-1.01 is our lead lipid delivery antisense drug candidate, which is being clinically tested in patients having Acute Myeloid Leukemia (AML), Chronic Myelogenous Leukemia (CML), Myelodysplastic Syndrome (MDS) and Acute Lymphoblastic Leukemia (ALL). If the results of the clinical tests are favorable, we expect there will be opportunities to negotiate non-exclusive license applications involving upfront cash payments with pharmaceutical companies developing antisense drugs that need systemic delivery technology.

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

The Phase I clinical trial is a dose-escalating study to determine the safety and tolerance of escalating doses of L-Grb-2. The study will also determine the optimal biologically active dose for further development. The pharmacokinetics of L-Grb-2 in patients will be studied, making it possible to investigate whether the delivery

technology performs as expected based on pre-clinical studies in animals. In addition, patient blood samples from the trial will be tested using a new assay developed by the Company to measure down-regulation of the target protein, the critical scientific data that will demonstrate that the delivery technology does in fact successfully deliver the antisense drug substance to the cell and across the cell membrane into the interior of the cell where expression of the target protein is blocked. The 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 treated patients with a dose of 20 mg/m^2, double the dose used in the second cohort. Significantly, in the third cohort, all three patients completed the treatment cycle and were evaluable and, because of apparent stabilization from treatment with Liposomal Grb-2, had received or anticipated to receive extended treatment cycles. 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 treated patients with a dose of 40 mg/m^2, double the dose used in the third cohort.

Based on the experience treating patients in the third cohort, when all three patients benefited from treatment with Liposomal Grb-2 and were apparently stabilized, the assumption for drug requirements for the fourth cohort 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 Liposomal 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.

In November 2012, the Company announced that since there had been no evidence of significant toxicity from treatment of patients with L-Grb-2, the Company was proceeding with requesting the FDA to allow higher dosing in patients. The Principal Investigator for the clinical trial, in consultation with the Board, advised that with the absence of any real toxicity barriers, the Company should continue to evaluate higher doses of Liposomal Grb-2. The absence of significant toxicity provides a significant opportunity for the Company to test higher doses in patients in order to find a dose that provides maximum potential benefit and duration of anti-leukemia effect. These actions were approved and a revised protocol is in place allowing higher dosing. The Company has enrolled and is currently treating three patients in Cohort 5 at a dose of 60 mg/m^2. The Company expects all three patients to have completed their treatment cycle successfully by the end of May of 2013. The clinical trial is being conducted at The University of Texas MD Anderson.

The Principal Investigator for the Phase I clinical trial, Dr. Jorge Cortes (the “Principal Investigator”), is a leading expert in the treatment of CML, AML, MDS and ALL. 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 and he presented such results at the annual meeting of the American Society of Hematology in December of 2011. Results from the second cohort also demonstrated potential anti-leukemia benefits in treated patients and such results were included in the presentation to the American Society of Hematology. Bio-Path and the Principal Investigator plan to present information at leading industry scientific conferences in the future as results become available.

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 combination with the respect frontline treatment for each disease in salvage therapy for advanced patients. The opportunity for three drug approvals in a relatively moderate timeframe could be 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 is anticipated to 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 begin expanding Bio-Path's drug candidates by simply applying the delivery technology template to multiple new drug product targets. In this manner, Bio-Path can quickly build an attractive drug product pipeline with multiple drug product candidates for treating cancer as well as treating other important diseases including diabetes, cardiovascular conditions and neuromuscular disorders. Currently, the Company is researching potential targets for which it can apply its liposomal antisense drug delivery technology.

BP-100-1.02

BP-100-1.02 ("Bcl-2" or "BP-100-1.02") is Bio-Path's co-lead compound. The scientific name for BP-100-1.02 is Liposomal Bcl-2, a liposome delivered antisense cancer drug that targets the lymphoma and certain solid tumor markets. Liposomal Bcl-2 has the potential to treat 40%-60% of solid tumors.

Bcl-2 is a protein that is involved in regulating apoptosis or programmed cell death. Apoptosis is a physiologic mechanism of cell turnover by which cells actively commit suicide in response to aberrant external signals. Over-expression of Bcl-2 prevents the induction of apoptosis in response to cellular insults such as treatment with chemotherapeutic agents. Bcl-2 is over-expressed in more than 90% of follicular B-cell non-Hodgkins lymphoma due to a chromosomal rearrangement and is the key factor in the initiation of this malignancy. Bcl-2 is also overexpressed in a wide variety of solid tumors (it is estimated to be over-expressed in 40 percent of cancers). For example, Bcl-2 over-expression has been associated with the progression of prostate cancer from hormone dependence to hormone independence and may contribute to the relative drug resistant phenotype typically observed in hormone independent prostate cancer.

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

Other Liposomal Antisense Products

As noted previously, the Company intends to apply its drug delivery technology template to new disease-causing protein targets as a means to develop new, liposomal antisense drug candidates. A new product identification template was recently approved that defines a process of scientific, pre-clinical, commercial and intellectual property evaluation of potential new drug candidates for inclusion into the Company's drug product development pipeline. A significant amount of capital will be allocated for in-licensing promising protein targets that can be developed as new liposomal antisense drug candidates.

Projected Financing Needs

As of March 31, 2013, we anticipate that we need to raise approximately an additional $12,700,000 to complete our planned clinical trials for our product candidates.

The remaining cost of the Phase I clinical trial of BP-100-1.01 is expected to be approximately $500,000, provided that the trial is completed after the next two dose levels. If the Phase I clinical trial in BP-100-1.01 is successful, we expect to follow with multi-site Phase II trials in BP-100-1.01. Successful Phase I and II trials of BP-100-1.01 is expected to provide clinical evidence to support BP-100-1.01 as a potential therapeutic drug product for treatment of AML, MDS and CML. The Phase II clinical trials in BP-100-1.01 are expected to cost approximately $2,000,000 each, or approximately $6,000,000 for all three.

Development of BP-100-1.01 to treat triple negative and inflammatory breast cancers over the 30 month plan horizon is expected to require approximately $1,500,000. This amount is expected to fund the preclinical program and the Phase I clinical trial. It is anticipated that the Phase I clinical trial will cost less than a typical Phase I trial because the safety profile will have already been established upon conclusion of BP-100-1.01's current clinical trial. This is expected to result in fewer patients being tested and a more efficient progression to an optimal biological dose.

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

Approximately $300,000 has been allocated to identifying other protein targets for development into liposomal antisense drug candidates. The balance of the $12,700,000 in funding needs from our revised plan over 30 months is approximately $2,400,000, which is planned to fund patent expenses, licensing fees, pre-clinical costs to MD Anderson's Pharmaceutical Development Center, consulting fees and management and administration. Of the projected total of $12,700,000 in funding needs, approximately $10,000,000 in project costs is projected to be spent on clinical trials of our drug candidates and developing new drug candidates, and the balance is projected to be spent on period costs for professionals, management and license costs.

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

There can be no assurance of the following:

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

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

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

Background Information about MD Anderson

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

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

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

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

Relationship with MD Anderson

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

- allow Bio-Path to develop MD Anderson's neutral lipid delivery technology;
- give Bio-Path 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 we obtain adequate financing, Bio-Path will be positioned to translate current and future MD Anderson technology into treatments for cancer patients. This in turn is expected to provide a steady flow of cancer drug candidates to commercialize or for out-licensing to pharmaceutical partners.

Licenses

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

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

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

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

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

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Out-Licenses and Other Sources of Revenue

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

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

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

License Agreements

We are currently maintaining the License Agreement with MD Anderson. The License Agreement relates to the delivery technology platform for antisense nucleic acids including two single nucleic acid (antisense) drug products. The License Agreement requires, among other things, that we reimburse MD Anderson for ongoing patent expense. Accrued license payments totaling $50,000 for accrued past patent expenses and the license annual maintenance fee are included in Current Liabilities as of March 31, 2013. Past patent expenses represent patent expenses incurred by MD Anderson prior to executing the License Agreement with Bio-Path that is being amortized in quarterly payments. As of March 31, 2013, the Company estimates remaining reimbursable past patent expenses total approximately $75,000 for the antisense license. The Company will be required to pay when invoiced these patent expenses at the rate of $25,000 per quarter when invoiced by MD Anderson. In addition, accrued expense-related party of $15,000 was included in current liabilities as of March 31, 2013 representing accrued hospital expense for MD Anderson services treating patients in Bio-Path’s clinical trial of BP-100-1.01. This expense is unrelated to the License

Agreement.

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

Business Strategy

Previously, we developed a business plan with milestones that we currently anticipate will require us to raise approximately $7,000,000 to completely implement such business plan. The milestones include completion of the Phase I clinical trial of L-Grb-2, a Phase I clinical trial in an additional liposomal antisense drug product in addition to the drug product L-Grb-2 currently in a Phase I clinical trial and a multi-site Phase II clinical trial of L-Grb-2. In addition, our previous plan of operation included funds to in-license up to four new protein targets for development as liposomal antisense drug product candidates to add to our product pipeline for development. However, the results seen to date in the Phase I clinical trial of Liposomal Grb-2 have created the opportunity to conduct multi-site Phase II clinical trials of Liposomal Grb-2 in three separate blood cancers (specifically, AML, MDS and CML), a significant opportunity for the Company. We also believe that the opportunity to develop, in conjunction with MD Anderson, our lead cancer drug Liposomal Grb-2 to treat triple negative breast cancer (TNBC) and inflammatory breast cancer (IBC), two cancers characterized by formation of aggressive tumors and relatively high mortality rates, is promising. As a result of these two developments over the past year, Bio-Path has revised its business plan over the next 30 months to include (i) milestones for the additional two Phase II clinical trials for Liposomal Grb-2 and (ii) development of Liposomal Grb-2 treatments for triple negative and inflammatory breast cancer, including a pre-clinical program and a Phase I clinical trial. The Company believes that the potential to enhance the value of the Company from these two project additions is significant; however, these projects are expected to cause the capital requirements for the Company over the next 30 months to increase to $12,700,000.

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

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

- Manage trials as if they were being 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.

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

- Use our Medical Advisory Board and the Board to supplement our Management Team to critically monitor existing programs and evaluate new technologies and/or compounds discovered or developed at MD Anderson, or elsewhere, for in-licensing.

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

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

Manufacturing

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

Intellectual Property

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

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

Agreement with Acorn CRO

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

Competition

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

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

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

Government Regulation

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

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

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

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

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

Bio-Path's business model relies on developing drug product candidates through Phase II and either entering into out-license agreements with pharmaceutical licensee partners who will be responsible for post-Phase II clinical testing and working with the FDA on necessary regulatory submissions resulting in approval of new drug applications for commercialization, or internally developing a drug product candidate through commercialization. For more detailed discussions on the clinical trial processes involvement with the FDA, please refer to Annual Report on Form 10-K as of and for the fiscal year ended December 31, 2012.

Results of Operations for the three months ended March 31, 2013 and 2012.

Revenues. We have no operating revenues since our inception.

Research and Development Expenses. Our research and development expense was $401,099 for the three month period ended March 31, 2013, an increase of $121,486 over the three month period ended March 31, 2012. The increase in research and development expense for the three months ended March 31, 2013 compared to the comparable period ended March 31, 2012 was primarily due to a $96,110 increase in drug material used in the clinical trial and a $20,842 increase in clinical trial operations expense. Research and development expense-related party was $15,000 for the three month period ended March 31, 2013, an increase of $3,300 compared to the comparable three month period ended March 31, 2012. The increase in research and development expense-related party was due primarily to a marginally higher increase in patient-related hospital costs for the clinical trial.

General and Administrative Expenses. Our general and administrative expenses were $239,811 for the three month period ended March 31, 2013, an increase of $8,497 compared to the three month period ended March 31, 2012. The increase in general and administrative expense for the three months ended March 31, 2013 compared to the three months ended March 31, 2012 was due to higher expenses from being a public company, including increased legal expense, offset to some extent by lower healthcare expense.

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Net Loss. Our net loss was $(656,002) for the three month period ended March 31, 2013 compared to a loss of $(522,227) for the three month period ended March 31, 2012. The increase in the net loss for the three months ended March 31, 2013 compared to the three months ended March 31, 2012 was due to an increase in research and development expense during the same periods. Net loss per share, both basic and diluted, was $(0.01) per share for the respective three month periods.

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 March 31, 2013, we had cash of $288,707 compared to $534,046 at December 31, 2012. The decrease in cash balances during the three month period ended March 31, 2013 results from $551,004 in cash used in operations, offset by $305,665 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 three months ended March 31, 2013 was $551,004 compared to $400,189 for the three months ended March 31, 2012. Inasmuch as we have not yet generated revenues, our entire expenses of operations are funded by proceeds from the sale of the shares of the Company's common stock and other capital raising efforts.

Net cash provided by financing activities in during the three month period ended March 31, 2013 was $305,665 compared to $49,760 for the three month period ended March 31, 2012. Since inception through March 31, 2013, we have net cash provided from financing activities of $8,765,048. We believe that our available cash and our ongoing capital raising efforts will be sufficient to fund our liquidity and capital expenditure requirements through the third quarter of 2013. In this regard, in April and early May of 2013, we received in excess of $2 million from the closeout of our latest private placement fund raising program (see Item 2 of Part II of this quarterly report). We believe that we will need to raise approximately $12,700,000 in net proceeds to completely implement our current business plan over the next 30 months.

Contractual Obligations and Commitments

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

In the first quarter of 2013, Bio-Path entered into a supply agreement with its drug product manufacturer for the manufacture of the Company's drug product for delivery in May 2013. The agreement calls for the Company to pay approximately $150,000 in various stages until the final drug product is manufactured, successfully tested and delivered to the Company.

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

Critical Accounting Policies

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Information not required for smaller reporting companies.

ITEM 4. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures. We maintain a system of disclosure controls and procedures that is designed to ensure that information required to be disclosed in our Securities Exchange Act of 1934, as amended (the "Exchange Act") reports is recorded, processed, summarized and reported within the time periods specified in rules and forms of the SEC, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosures. As of March 31, 2013, our management, including our principal executive officer and principal financial officer, had evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) pursuant to Rule 13a-15(b) under the Exchange Act. Based upon and as of the date of the evaluation, our principal executive officer and principal financial officer concluded that information required to be disclosed is recorded, processed, summarized and reported within the specified periods and is accumulated and communicated to management, including our principal executive officer and principal financial officer, to allow for timely decisions regarding required disclosure of material information required to be included in our periodic SEC reports. Based on the foregoing, our management determined that our disclosure controls and procedures were effective as of March 31, 2013.

(b) Changes in Internal Control over Financial Reporting. There were no changes in our internal control over financial reporting that occurred during the period of this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 1A. RISK FACTORS

Information not required for smaller reporting companies.

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

As of March 31, 2013, the Company completed its private offering of up to $4 million of the Company's common stock (the "Prior Offering"). From January 1, 2013 through March 31, 2013, the Company agreed to issue and sell, at a price of $0.30 per share, an aggregate of 6,667,327 shares (the "Prior Offering Shares") of the Company's common stock to certain "accredited investors" (as such term is defined in Rule 501(a) of Regulation D promulgated under the Securities Act of 1933, as amended (the "Securities Act")). The Company agreed to pay cash commissions to its placement agent equal to ten percent of the aggregate purchase price of the Prior Offering Shares. In addition, the Company agreed to issue to its placement agent one share of the Company's common stock for every ten Prior Offering Shares sold as additional compensation.

Certain accredited investors contemplated participating in the Prior Offering; however, such accredited investors were unable to participate due to certain technical issues. In an effort to permit such accredited investors the opportunity to complete their investment, on April 19, 2013, the Company, agreed to issue and sell, at a price of $0.30 per share, an aggregate of 1,850,000 shares (the "Direct Shares") of the Company's common stock to such accredited investors, pursuant to the terms and conditions of a securities purchase agreement with each such accredited investor (the "Purchase Agreements"). The Company has closed the sale of 1,510,000 Direct Shares and the Company anticipates closing the sale of the remaining 340,000 Direct Shares by May 31, 2013. The Company agreed to pay cash commissions to its commission agent equal to ten percent of the aggregate purchase price of the Direct Shares. In addition, the Company agreed to issue to its commission agent one share of the Company's common stock for every ten Direct Shares sold as additional compensation. The foregoing description of the Purchase Agreements does not purport to be complete and is qualified in its entirety by reference to the complete text of the form of Purchase Agreement, a copy of which is attached hereto as Exhibit 10.3 and incorporated herein by reference.

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

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

None.

ITEM 5. OTHER INFORMATION

See Item 2 of Part II of this quarterly report.

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).

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3.4	Amendment No. 1 to Bylaws (incorporated by reference to exhibit 3.2 to the registrant's current report on Form 8-K filed on June 21, 2010).
4.1	Specimen Stock certificate (incorporated by reference to exhibit 3.2 to the registrant's current report on Form 8-A filed on September 10, 2008).
10.1*	Patent and Technology License Agreement, dated as of November 2, 2007, by and between the Company and the Board of Regents of The University of Texas System on behalf of The University of Texas M.D. Anderson Cancer Center.
10.2*	Amendment No. 1 to the Patent and Technology Agreement, dated as of May 11, 2009, by and between the Company and the Board of Regents of the University of Texas System on behalf of The University of Texas M.D. Anderson Cancer Center.
10.3*	Form of Purchase Agreement by and between the Company and certain investors party thereto.
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: May 15, 2013 BIO-PATH HOLDINGS, INC.

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