

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended 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

(State or other jurisdiction of  
incorporation or organization)

87-0652870

(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  No

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

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

Large accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company)

Accelerated filer

Smaller reporting company

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

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

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PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

BIO-PATH HOLDINGS, INC.  
(A Development Stage Company)  
CONSOLIDATED BALANCE SHEETS  
Unaudited

	<u>March 31,</u> <u>2013</u>	<u>December 31,</u> <u>2012</u>
<b>ASSETS</b>		
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)
	<u>1,531,987</u>	<u>1,572,143</u>
<b>TOTAL ASSETS</b>	<u>\$ 1,970,618</u>	<u>\$ 2,343,764</u>
<b>LIABILITIES &amp; SHAREHOLDERS' EQUITY</b>		
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		
	-	-
<b>TOTAL LIABILITIES</b>	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/	1,108,711a/	762,510b/
Accumulated deficit during development stage	(12,787,287)	(12,131,283)
Total shareholders' equity	<u>1,680,202</u>	<u>2,014,520</u>
<b>TOTAL LIABILITIES &amp; SHAREHOLDERS' EQUITY</b>	<u>\$ 1,970,618</u>	<u>\$ 2,343,764</u>

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

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

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
<b>CASH FLOW FROM OPERATING ACTIVITIES</b>			
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)
<b>CASH FLOW FROM INVESTING ACTIVITIES</b>			
Purchase of exclusive license - related party	-	(25,000)	(884,710)
Net cash used in investing activities	-	(25,000)	(884,710)
<b>CASH FLOW FROM FINANCING ACTIVITIES</b>			
Proceeds from convertible notes	-	-	435,000
Cash repayment of convertible notes	-	-	(15,000)
Net proceeds from sale of common stock	305,665	49,760	8,345,048
Net cash from financing activities	305,665	49,760	8,765,048
<b>NET INCREASE (DECREASE) IN CASH</b>	<b>(245,339)</b>	<b>(375,429)</b>	<b>288,707</b>
Cash, beginning of period	534,046	952,252	-
Cash, end of period	\$ 288,707	\$ 576,823	\$ 288,707
<b>SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION</b>			
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<sup>2</sup>. 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<sup>2</sup>, which is double the dose used in the second cohort. At the end of April, 2012, there were three evaluable patients in Cohort 3. As a result, a meeting of the Company's medical advisory board was being scheduled to close the cohort and proceed to Cohort 4. Significantly, in the third cohort, all three patients completed the treatment cycle and were evaluable and, because of apparent stabilization from treatment with Bio-Path drug candidate Liposomal Grb-2, had received extended treatment cycles or were on hold for additional treatments pending increased supply of drug.

Based on the experience treating patients in Cohort 3, 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](http://www.biopathholdings.com), and all of our filings with the Securities and Exchange Commission are available free of charge on our website.

### Research and Development

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

### Basic Technical Information

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

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

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

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

#### **BP-100-1.01**

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<sup>2</sup>, 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<sup>2</sup>, 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<sup>2</sup>. 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](http://www.mdanderson.org)). Achieving that goal begins with integrated programs in cancer treatment, clinical trials, educational programs and cancer prevention. MD Anderson is one of the largest and most widely recognized cancer centers in the world: U.S. News & World Report's America's "Best Hospitals" survey has ranked MD Anderson as one of the top two best hospitals in the nation since the survey began in 1990. MD Anderson will treat more than 100,000 patients this year, of which approximately 11,000 will participate in therapeutic clinical research exploring novel treatments which is the largest such program in the nation. MD Anderson employs more than 15,000 people including more than 1,000 medical doctors and Ph.D clinicians and researchers, and is routinely conducting more than 700 clinical trials at any one time.

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

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

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

## Relationship with MD Anderson

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

- allow Bio-Path to develop MD Anderson's neutral lipid delivery technology;
- give Bio-Path 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?

## **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.

**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).

- 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

**PATENT AND TECHNOLOGY LICENSE AGREEMENT**

This AGREEMENT ("AGREEMENT") is made on this 2nd day of November, 2007, by and between THE BOARD OF REGENTS ("BOARD") of THE UNIVERSITY OF TEXAS SYSTEM ("SYSTEM"), an agency of the State of Texas, whose address is 201 West 7th Street, Austin, Texas 78701, on behalf of THE UNIVERSITY OF TEXAS M. D. ANDERSON CANCER CENTER ("UTMDACC"), a component institution of SYSTEM, and BIO-PATH, INC. a corporation having a principal place of business located at 3293 Harrison Boulevard, Suite 230, Ogden, Utah 84403 ("LICENSEE").

**RECITALS**

- A. BOARD owns certain PATENT RIGHTS and TECHNOLOGY RIGHTS related to LICENSED SUBJECT MATTER developed at UTMDACC.
- B. BOARD, through UTMDACC, desires to have the LICENSED SUBJECT MATTER developed in the LICENSED FIELD and used for the benefit of LICENSEE, BOARD, SYSTEM, UTMDACC, the inventor(s), and the public as outlined in BOARD's Intellectual Property Policy.
- C. LICENSEE wishes to obtain a license from BOARD to practice LICENSED SUBJECT MATTER.

NOW, THEREFORE, in consideration of the mutual covenants and promises herein contained, the parties agree as follows:

**I. EFFECTIVE DATE**

- 1.1 This AGREEMENT is effective as of the date written above ("EFFECTIVE DATE") which is the date fully executed by all parties.

**II. DEFINITIONS**

As used in this AGREEMENT, the following terms have the meanings indicated:

- 2.1 AFFILIATE means any business entity more than fifty percent (50%) owned by LICENSEE, any business entity which owns more than fifty percent (50%) of LICENSEE, or any business entity that is more than fifty percent (50%) owned by a business entity that owns more than fifty percent (50%) of LICENSEE.
- 2.2 INITIATED A PHASE I TRIAL means the dosing of the first patient on a human clinical trial, the principal purpose of which is to determine toxicity, absorption, metabolism and/or safe dosage range in patients with the disease target being studied as required in 21 C.F.R. §312 or a similar regulatory requirement in any jurisdiction.
- 2.3 LICENSED FIELD means any human or animal use.
- 2.4 LICENSED PRODUCTS means any product or service sold by LICENSEE, or its AFFILIATES comprising LICENSED SUBJECT MATTER pursuant to this AGREEMENT.
- 2.5 LICENSED SUBJECT MATTER means inventions and discoveries covered by PATENT RIGHTS or TECHNOLOGY RIGHTS within LICENSED FIELD.
- 2.6 LICENSED TERRITORY means worldwide.
- 2.7 NDA means a New Drug Application or Biologics License Application filed with the United States Food and Drug Administration, or the equivalent application filed with any equivalent agency or governmental authority outside of the United States.
- 2.8 NET SALES means the gross revenues received by LICENSEE, or its AFFILIATES from a SALE less sales discounts actually granted, sales and/or use taxes actually paid, import and/or export duties actually paid, outbound transportation actually prepaid or allowed, and amounts actually allowed or credited due to returns (not exceeding the original billing or invoice amount), all as recorded by LICENSEE, or its AFFILIATES in their official books and records in accordance with generally accepted accounting practices and consistent with their published financial statements and/or regulatory filings with the United States Securities and Exchange Commission.
- 2.9 PATENT RIGHTS means BOARD's rights in the information or discoveries described in invention disclosures, or claimed in any patents and/or patent applications, whether domestic or foreign, as identified in Exhibit I attached hereto, and all divisionals, continuations, continuations-in-part (to the extent the claims of such continuations-in-part are entitled to claim priority to the aforesaid patents and/or patent applications identified in Exhibit I), reissues, reexaminations or extensions of the patents and/or patent applications identified in Exhibit I, and any letters patent, domestic or foreign that issue thereon.

- 2.10 SALE or SOLD means the transfer or disposition of a LICENSED PRODUCT for value to a party other than LICENSEE, an AFFILIATE or a ROYALTY-FREE PRACTITIONER. As used herein, "ROYALTY-FREE PRACTITIONER" means UTMDACC and Gabiel Lopez-Berestein, M.D. ("PHYSICIAN INVENTOR"), and any partner or associate who practices medicine with one or more of the PHYSICIAN INVENTOR, but with respect to such partner or associate, only for such time as he/she is engaged in a bona fide medical practice with one or more of the PHYSICIAN INVENTOR.
- 2.11 TECHNOLOGY RIGHTS means BOARD's rights in any technical information, know-how, processes, procedures, compositions, devices, methods, formulae, protocols, techniques, software, designs, drawings or data created by the inventor (s) listed in Exhibit I at UTMDACC before the EFFECTIVE DATE, which are not claimed in PATENT RIGHTS but that are necessary for practicing PATENT RIGHTS.
- 2.12 VALID CLAIM means an issued claim of any unexpired patent or claim of any pending patent application included among the PATENT RIGHTS, which patent has not been held unenforceable, unpatentable or invalid by a decision of a court or governmental body of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, which has not been rendered unenforceable through disclaimer or otherwise, and which has not been lost through an interference proceeding or abandoned.

### III. LICENSE

- 3.1 BOARD, through UTMDACC, hereby grants to LICENSEE a royalty-bearing, exclusive license under LICENSED SUBJECT MATTER to manufacture, have manufactured, use, import, offer to sell and/or sell LICENSED PRODUCTS within LICENSED TERRITORY for use within LICENSED FIELD. This grant is subject to Sections 14.2 and 14.3 hereinbelow, the payment by LICENSEE to UTMDACC of all consideration as provided herein, the timely payment of all amounts due under any related sponsored research agreement between UTMDACC and LICENSEE in effect during this AGREEMENT, and is further subject to the following rights retained by BOARD and UTMDACC to:
- (a) Publish the general scientific findings from research related to LICENSED SUBJECT MATTER, subject to the terms of ARTICLE XI-Confidential Information and Publication; and
  - (b) Use LICENSED SUBJECT MATTER for research, teaching, patient care, and other academically-related purposes; and
  - (c) Transfer LICENSED SUBJECT MATTER to academic or research institutions for non-commercial research use.
- 3.2 LICENSEE may extend the license granted herein to any AFFILIATE provided that the AFFILIATE consents in writing to be bound by this AGREEMENT to the same extent as LICENSEE. LICENSEE agrees to deliver such contract to UTMDACC within thirty (30) calendar days following execution thereof.
- 3.3 LICENSEE may grant sublicenses under LICENSED SUBJECT MATTER consistent with the terms of this AGREEMENT provided that LICENSEE is responsible for its sublicensees relevant to this AGREEMENT, and for diligently collecting all amounts due LICENSEE from sublicensees. If a sublicensee pursuant hereto becomes bankrupt, insolvent or is placed in the hands of a receiver or trustee, LICENSEE, to the extent allowed under applicable law and in a timely manner, agrees to use its best reasonable efforts to collect all consideration owed to LICENSEE and to have the sublicense agreement confirmed or rejected by a court of proper jurisdiction.
- 3.4 LICENSEE must deliver to UTMDACC a true and correct copy of each sublicense granted by LICENSEE, and any modification or termination thereof, within thirty (30) calendar days after execution, modification, or termination.
- 3.5 If this AGREEMENT is terminated pursuant to ARTICLE XIII-Term and Termination, BOARD and UTMDACC agree to accept as successors to LICENSEE, existing sublicensees in good standing at the date of termination provided that each such sublicensee consents in writing to be bound by all of the terms and conditions of this AGREEMENT.

### IV. CONSIDERATION, PAYMENTS AND REPORTS

- 4.1 In consideration of rights granted by BOARD to LICENSEE under this AGREEMENT, LICENSEE agrees to pay UTMDACC the following:
- (a) All out-of-pocket expenses incurred by UTMDACC in filing, prosecuting, enforcing and maintaining PATENT RIGHTS, and all such future expenses incurred by UTMDACC, for so long as, and in such countries as this AGREEMENT remains in effect. UTMDACC will invoice LICENSEE at a rate of Twenty-Five Thousand Dollars (\$25,000) per quarter for expenses incurred before EFFECTIVE DATE and on a quarterly basis thereafter for expenses incurred on or after the EFFECTIVE DATE. The invoiced amounts will be due and payable by LICENSEE within thirty (30) calendar days of invoice; and
  - (b) A nonrefundable license documentation fee in the amount of Sixty Thousand Dollars (\$60,000). This fee will not reduce the amount of any other payment provided for in this ARTICLE IV, and is due and payable within thirty (30) calendar days after the AGREEMENT has been fully executed by all parties and LICENSEE has received an invoice for the amount from UTMDACC; and
  - (c) The following annual maintenance fee ("Annual Maintenance Fees"), which shall be credible against the milestone payments detailed in Section 4.1(f):
    - (i) An annual maintenance fee of Twenty-Five Thousand Dollars (\$25,000) due within thirty (30) calendar days of the first, second, and third anniversaries of the EFFECTIVE DATE until the first SALE.

- (ii) An annual maintenance fee of Fifty Thousand Dollars (\$50,000) due within thirty (30) calendar days of the fourth, fifth, sixth, and seventh anniversaries of the EFFECTIVE DATE until the first SALE.
  - (iii) An annual maintenance fee of One-Hundred Thousand Dollars (\$100,000) due within thirty (30) calendar days of the eighth anniversary of the EFFECTIVE DATE and each anniversary thereafter until the first SALE; and
- (d) A running royalty equal to three percent (3%) of NET SALES will be due with respect to the SALE of LICENSED PRODUCTS during such period that a LICENSED PRODUCT is covered by a VALID CLAIM in the country in which the LICENSED PRODUCT was sold. Notwithstanding anything to the contrary herein contained, in the event LICENSED PRODUCTS are made using TECHNOLOGY RIGHTS and are not covered by a VALID CLAIM in the jurisdiction where the LICENSED PRODUCT is sold, then, LICENSEE agrees to pay UTMDACC a running royalty of one and one-half percent (1.5%) of NET SALES for such LICENSED PRODUCTS. However, if a competitive product (i.e., a product that uses the LICENSED SUBJECT MATTER) is being offered for sale in the same jurisdiction, then LICENSEE, upon written notice to UTMDACC identifying such competitive product, shall not be required to pay a royalty to UTMDACC, the BOARD or any other party pursuant to this Section 4.(d) in that jurisdiction; and
- (e) After the first SALE, minimum annual royalties ("Minimum Annual Royalties") of One Hundred Twenty-Five Thousand Dollars (\$125,000), due and payable (without invoice) within thirty (30) calendar days of the first and subsequent anniversaries of the EFFECTIVE DATE which follows the first SALE; provided, however, that in the event that there is less than a twelve (12) month period between the first SALE, and the first anniversary of the EFFECTIVE DATE which follows the first SALE, then LICENSEE shall pay the following: (1) the Annual Maintenance Fee due for that year multiplied by the fraction, A/C, where A is the number of months between the anniversary of the EFFECTIVE DATE preceding the first SALE, and the first SALE, and C is twelve (12); and (2) the Minimum Annual Royalty multiplied by the fraction, B/C, where B is the number of months between the first SALE, and the first anniversary of the EFFECTIVE DATE which follows the first SALE, C is twelve (12), and A + B = twelve (12). Additionally, running royalties accrued under Section 4.1(d) and paid to UTMDACC during the one year period preceding an anniversary of the EFFECTIVE DATE shall be credited against the Minimum Annual Royalties due on that anniversary date; and
- (f) The following one-time milestone payments, regardless of whether the milestone is achieved by LICENSEE, a sublicensee or AFFILIATE:
- |       |   |              |
|-------|---|--------------|
| (i)   | Submission of first NDA for a LICENSED PRODUCT in the United States:  | \$ 150,000   |
| (ii)  | Submission of first NDA for a LICENSED PRODUCT in Europe:             | \$ 1,000,000 |
| (iii) | Submission of first NDA for a LICENSED PRODUCT in Japan:              | \$ 1,000,000 |
| (iv)  | First regulatory approval of a LICENSED PRODUCT in the United States: | \$ 2,000,000 |
| (v)   | First regulatory approval of a LICENSED PRODUCT in Europe:            | \$ 2,000,000 |
| (vi)  | First regulatory approval of a LICENSED PRODUCT in Japan:             | \$ 2,000,000 |

Each of the foregoing milestone payments shall be made by LICENSEE to UTMDACC (without invoice) within thirty (30) calendar days of achieving the milestone event. Cumulative Annual Maintenance Fees paid by LICENSEE to UTMDACC shall be fully creditable against the milestone payments owed; and

- (g) One Million Eight Hundred Eighty-Three Thousand Three Hundred Thirty-Three (1,883,333) shares (the "SHARES") of LICENSEE's common stock, par value of \$0.001 per share (the "COMMON STOCK"); LICENSEE represents and warrants to UTMDACC that the SHARES equal thirteen and forty-one one-hundredths percent (13.41%) of the outstanding shares of COMMON STOCK of the LICENSEE as of the EFFECTIVE DATE; LICENSEE will issue the SHARES within thirty (30) days of the EFFECTIVE DATE pursuant to the Stock Purchase Agreement attached hereto as Exhibit II; and
- (h) The following percentages of all consideration, other than payments to reimburse LICENSEE for past and future research and development money related to the LICENSED SUBJECT MATTER received by LICENSEE from any sublicensee pursuant to Sections 3.3 and 3.4 hereinabove, including but not limited to, up-front payments, royalties, marketing, distribution, franchise, option, license, or documentation fees, bonus and milestone payments (less any amount paid to UTMDACC under Section 4.1(f)) and equity securities:

- (i) Thirty percent (30%) if the sublicense is executed before the second anniversary of the EFFECTIVE DATE; and
  - (ii) Twenty percent (20%) if the sublicense is executed on or after the second anniversary of the EFFECTIVE DATE; and
- provided, however, in no circumstance shall royalties owed to UTMDACC be less than two percent (2%) of the Net Sales of the sublicensee. For the purposes of this Section, "Net Sales" shall have the same definition of NET SALES as applied to a sublicensee; and

- (i) A one-time fee of Two Hundred Fifty Thousand Dollars (\$250,000) upon assignment of the company's assets which includes the LICENSED SUBJECT MATTER to another entity pursuant to Article XII.

4.2 Unless otherwise provided, all such payments are payable within thirty (30) calendar days after March 31, June 30, September 30, and December 31 of each year during the term of this AGREEMENT, at which time LICENSEE will also deliver to UTMDACC a true and accurate report, giving such particulars of the business conducted by LICENSEE, its AFFILIATES and its sublicensees, if any exist, during the preceding three (3) calendar months under this AGREEMENT as necessary for UTMDACC to account for LICENSEE's payments hereunder. This report will include pertinent data, including, but not limited to:

- (a) the accounting methodologies used to account for and calculate the items included in the report and any differences in such accounting methodologies used by LICENSEE since the previous report; and
- (b) a list of LICENSED PRODUCTS produced for the three (3) preceding calendar months categorized by the technology it relates to under PATENT RIGHTS; and
- (c) the total quantities of LICENSED PRODUCTS produced by the category listed in Section 4.2(b); and
- (d) the total SALES by the category listed in Section 4.2(b); and
- (e) the calculation of NET SALES by the category listed in Section 4.2(b); and
- (f) the royalties so computed and due UTMDACC by the category listed in Section 4.2(b) and/or Minimum Annual Royalties; and
- (g) all consideration received from each sublicensee or assignee and payments due UTMDACC; and
- (h) all other amounts due UTMDACC herein.

Simultaneously with the delivery of each such report, LICENSEE agrees to pay UTMDACC the amount due, if any, for the period of such report. These reports are required even if no payments are due.

4.3 During the term of this AGREEMENT and for one (1) year thereafter, LICENSEE agrees to keep complete and accurate records of its, its AFFILIATES' and its sublicensees' SALES and NET SALES in sufficient detail to enable the royalties and other payments due hereunder to be determined. LICENSEE agrees to permit UTMDACC or its representatives, at UTMDACC's expense, to periodically examine LICENSEE's books, ledgers, and records during regular business hours for the purpose of and to the extent necessary to verify any report required under this AGREEMENT. If any amounts due UTMDACC are determined to have been underpaid in an amount equal to or greater than five percent (5%) of the total amount due during the period so examined, then LICENSEE will pay the cost of the examination plus accrued interest at the highest allowable rate.

4.4 Within thirty (30) calendar days following each anniversary of the EFFECTIVE DATE, LICENSEE will deliver to UTMDACC a written progress report as to LICENSEE's (and any sublicensee's) efforts and accomplishments during the preceding year in diligently commercializing LICENSED SUBJECT MATTER in the LICENSED TERRITORY and LICENSEE's (and sublicensees') commercialization plans for the upcoming year.

4.5 All amounts payable hereunder by LICENSEE will be paid in United States funds without deductions for taxes, assessments, fees, or charges of any kind. Checks are to be made payable to The University of Texas M. D. Anderson Cancer Center, and sent by United States mail to Box 297402, Houston, Texas 77297, Attention: Grants and Contracts or by wire transfer to:

JPMorgan Chase Bank, N.A.

910 Travis

Houston, Texas 77002

SWIFT: CHASUS33 (for international wires only)

ABA ROUTING NO:

ACCOUNT NAME: Univ. of Texas M. D. Anderson Cancer Center

ACCOUNT NO.:

REFERENCE: include title and EFFECTIVE DATE of AGREEMENT and type of payment (e.g., license documentation fee, milestone payment, royalty [including applicable patent/application identified by MDA reference number and patent number or application serial number], or maintenance fee, etc.).

- 4.6 No payments due or royalty rates owed under this AGREEMENT will be reduced as the result of co-ownership of LICENSED SUBJECT MATTER by BOARD and another party, including, but not limited to, LICENSEE.
- 4.7 Notwithstanding the other provisions of this AGREEMENT, in the event that the LICENSEE, its AFFILIATES or sublicensees determines that it is necessary to pay royalties or other fees to any third party to obtain a license to practice any third party's rights in order to practice the rights granted hereunder in any jurisdiction, then fifty percent (50%) of the royalties payable to such third party may be deducted from royalties otherwise payable to UTMDACC from the respective LICENSEE, AFFILIATE or sublicensee in that jurisdiction, provided that in no event shall the royalties payable to UTMDACC pursuant to Section 4.1(d) in any quarterly period in such jurisdiction be less than two percent (2%) of NET SALES, as the case may be, of the respective LICENSEE, AFFILIATE or sublicensee as a result of any such deduction.

#### **V. SPONSORED RESEARCH**

- 5.1 If LICENSEE desires to sponsor research for or related to the LICENSED SUBJECT MATTER, and particularly where LICENSEE receives payments for sponsored research pursuant to a sublicense under this AGREEMENT, LICENSEE (a) will notify UTMDACC in writing of all opportunities to conduct this sponsored research (including clinical trials, if applicable), (b) will solicit research and/or clinical proposals from UTMDACC for this purpose, and (c) will give good faith consideration to funding the proposals at UTMDACC.

#### **VI. PATENTS AND INVENTIONS**

- 6.1 If after consultation with LICENSEE both parties agree that a new patent application should be filed for LICENSED SUBJECT MATTER, UTMDACC will prepare and file appropriate patent applications, and LICENSEE will pay the cost of searching, preparing, filing, prosecuting and maintaining same. If LICENSEE notifies UTMDACC that it does not intend to pay the cost of an application, or if LICENSEE does not respond or make an effort to agree with UTMDACC on the disposition of rights of the subject invention, then UTMDACC may file such application at its own expense and LICENSEE's rights to such invention under this AGREEMENT shall terminate in their entirety. UTMDACC will provide LICENSEE with a copy of the application for which LICENSEE has paid the cost of filing, as well as copies of any documents received or filed during prosecution thereof. The parties agree that they share a common legal interest to get valid enforceable patents and that LICENSEE will keep all privileged information received pursuant to this Section confidential.

#### **VII. INFRINGEMENT BY THIRD PARTIES**

- 7.1 LICENSEE, at its expense, is responsible to enforce any patent exclusively licensed hereunder against substantial infringement by third parties and is entitled to retain recovery from such enforcement. After reimbursement of LICENSEE's reasonable legal costs and expenses related to such recovery, LICENSEE agrees to pay UTMDACC either: (a) the royalty detailed in Section 4.1(d) for any monetary recovery that is for sales of LICENSED PRODUCTS lost due to the infringement and twenty percent (20%) of related punitive damages; or (b) twenty percent (20%) of reasonable royalties awarded and twenty percent (20%) of related punitive damages in any monetary recovery in which the award is for reasonable royalties. LICENSEE must notify UTMDACC in writing of any potential infringement within thirty (30) calendar days of knowledge thereof and whether such infringement is deemed a substantial infringement. If LICENSEE does not file suit against a substantial infringer within six (6) months of knowledge thereof, then BOARD or UTMDACC may, at its sole discretion, enforce any patent licensed hereunder on behalf of itself and LICENSEE, with UTMDACC retaining all recoveries from such enforcement, and/or reduce the license granted hereunder to non-exclusive for the technology infringed.
- 7.2 In any suit or dispute involving an infringer, the parties agree to cooperate fully with each other. At the request and expense of the party bringing suit, the other party will permit access during regular business hours, to all relevant personnel, records, papers, information, samples, specimens, and the like in its possession.

#### **VIII. PATENT MARKING**

- 8.1 LICENSEE agrees that all packaging containing individual LICENSED PRODUCT(S), documentation therefore, and, when possible, actual LICENSED PRODUCT(S) sold by LICENSEE, AFFILIATES, and/or sublicensees of LICENSEE will be permanently and legibly marked with the number of any applicable patent(s) licensed hereunder in accordance with each country's patent laws, including Title 35, United States Code, to the extent such marking is necessary or required to fully preserve PATENT RIGHTS in each such country.

#### **IX. INDEMNIFICATION AND INSURANCE**

- 9.1 LICENSEE agrees to hold harmless and indemnify BOARD, SYSTEM, UTMDACC, their Regents, officers, employees, students and agents from and against any claims, demands, or causes of action whatsoever, costs of suit and reasonable attorney's fees, including without limitation, those costs arising on account of any injury or death of persons or damage to property caused by, or arising out of, or resulting from, the exercise or practice of the rights granted hereunder by LICENSEE, its officers, its AFFILIATES or their officers, employees, agents or representatives.

- 9.2 In no event shall BOARD, SYSTEM or UTMDACC be liable for any indirect, special, consequential or punitive damages (including, without limitation, damages for loss of profits or expected savings or other economic losses, or for injury to persons or property) arising out of, or in connection with, this AGREEMENT or its subject matter, regardless of whether BOARD, SYSTEM or UTMDACC knows or should know of the possibility of such damages.
- 9.3 Beginning at the time when any LICENSED SUBJECT MATTER is being distributed or sold (including for the purpose of obtaining regulatory approvals) by LICENSEE, an AFFILIATE, or by a sublicensee, LICENSEE shall, at its sole cost and expense, procure and maintain commercial general liability insurance in amounts not less than Two Million Dollars (\$2,000,000) per incident and Two Million Dollars (\$2,000,000) annual aggregate, and LICENSEE shall use reasonable efforts to have the BOARD, SYSTEM, UTMDACC, their Regents, officers, employees, students and agents named as additional insureds. Such commercial general liability insurance shall provide: (i) product liability coverage; (ii) broad form contractual liability coverage for LICENSEE's indemnification under this AGREEMENT; and (iii) coverage for litigation costs. The minimum amounts of insurance coverage required herein shall not be construed to create a limit of LICENSEE's liability with respect to its indemnification under this AGREEMENT.
- 9.4 LICENSEE shall provide UTMDACC with written evidence of such insurance within thirty (30) calendar days of its procurement. Additionally, LICENSEE shall provide UTMDACC with written notice of at least fifteen (15) calendar days prior to the cancellation, non-renewal or material change in such insurance.
- 9.5 LICENSEE shall maintain such commercial general liability insurance beyond the expiration or termination of this AGREEMENT during: (i) the period that any LICENSED SUBJECT MATTER developed pursuant to this AGREEMENT is being commercially distributed or sold by LICENSEE, an AFFILIATE or by a sublicensee or agent of LICENSEE; and (ii) the five (5) year period immediately after such period.

#### **X. USE OF BOARD AND UTMDACC'S NAME**

- 10.1 LICENSEE will not use the name of (or the name of any employee of) UTMDACC, SYSTEM or BOARD in any advertising, promotional or sales literature, on its Web site, or for the purpose of raising capital without the advance express written consent of BOARD secured through:

The University of Texas  
M. D. Anderson Cancer Center  
Legal Services, Unit 0537  
P.O. Box 301439  
Houston, TX 77230-1439  
ATTENTION: Natalie Wright  
Email: [nwright@mdanderson.org](mailto:nwright@mdanderson.org)

Notwithstanding the above, LICENSEE may use the name of (or name of employee of) UTMDACC, SYSTEM or BOARD in routine business correspondence, or as needed in appropriate regulatory submissions without express written consent.

#### **XI. CONFIDENTIAL INFORMATION AND PUBLICATION**

- 11.1 UTMDACC and LICENSEE each agree that all information contained in documents marked "confidential" and forwarded to one by the other (i) are to be received in strict confidence, (ii) are to be used only for the purposes of this AGREEMENT, and (iii) will not be disclosed by the recipient party (except as required by law or court order), its agents or employees without the prior written consent of the disclosing party, except to the extent that the recipient party can establish by competent written proof that such information:
- (a) was in the public domain at the time of disclosure; or
  - (b) later became part of the public domain through no act or omission of the recipient party, its employees, agents, successors or assigns; or
  - (c) was lawfully disclosed to the recipient party by a third party having the right to disclose it; or
  - (d) was already known by the recipient party at the time of disclosure; or
  - (e) was independently developed by the recipient party without use of the disclosing party's confidential information; or
  - (f) is required by law or regulation to be disclosed.
- 11.2 Each party's obligation of confidence hereunder will be fulfilled by using at least the same degree of care with the disclosing party's confidential information as it uses to protect its own confidential information, but always at least a reasonable degree of care. This obligation will exist while this AGREEMENT is in force and for a period of three (3) years thereafter.
- 11.3 UTMDACC reserves the right to publish the general scientific findings from research related to LICENSED SUBJECT MATTER, with due regard to the protection of LICENSEE's confidential information. UTMDACC will submit the manuscript of any proposed publication to LICENSEE at least thirty (30) calendar days before publication, and LICENSEE shall have the right to review and comment upon the publication in order to protect LICENSEE's confidential information. Upon LICENSEE's request, publication may be delayed up to sixty (60) additional calendar days to enable LICENSEE to secure adequate intellectual property protection of LICENSEE's confidential information that would otherwise be affected by the publication.

## **XII. ASSIGNMENT**

- 12.1 Except in connection with the sale of all of LICENSEE's assets to a third party, this AGREEMENT may not be assigned by LICENSEE without the prior written consent of UTMDACC, which will not be unreasonably withheld.

## **XIII. TERM AND TERMINATION**

- 13.1 Subject to Sections 13.3 and 13.4 hereinbelow, the term of this AGREEMENT is from the EFFECTIVE DATE to the full end of the term or terms for which PATENT RIGHTS have not expired, or if only TECHNOLOGY RIGHTS are licensed and no PATENT RIGHTS are applicable, for a term of fifteen (15) years.
- 13.2 Any time after eighteen (18) months from the EFFECTIVE DATE, BOARD or UTMDACC have the right to terminate this license if LICENSEE has not INITIATED A PHASE I TRIAL of at least one LICENSED PRODUCT.
- 13.3 Subject to any rights herein which survive termination, this AGREEMENT will earlier terminate in its entirety:
- (a) automatically, if LICENSEE becomes bankrupt or insolvent and/or if the business of LICENSEE shall be placed in the hands of a receiver, assignee, or trustee, whether by voluntary act of LICENSEE or otherwise; or
  - (b) upon thirty (30) calendar days written notice from UTMDACC, if LICENSEE breaches or defaults on the payment or report obligations of ARTICLE IV, or use of name obligations of ARTICLE X, unless, before the end of the such thirty (30)- calendar day notice period, LICENSEE has cured the default or breach to UTMDACC's satisfaction, and so notifies UTMDACC, stating the manner of the cure; or
  - (c) upon ninety (90) calendar days written notice from UTMDACC if LICENSEE breaches or defaults on any other obligation under this AGREEMENT, unless, before the end of the such ninety (90) calendar-day notice period, LICENSEE has cured the default or breach to UTMDACC's satisfaction and so notifies UTMDACC, stating the manner of the cure; or
  - (d) at any time by mutual written agreement between LICENSEES and UTMDACC upon one hundred eighty (180) calendar days written notice to all parties and subject to any terms herein which survive termination; or
  - (e) if Section 13.2 or 15.9 is invoked; or
  - (f) if LICENSEE has defaulted or been late on its payment obligations pursuant to the terms of this AGREEMENT on any two (2) occasions in a twelve (12) month period.
- 13.4 Upon termination of this AGREEMENT:
- (a) nothing herein will be construed to release either party of any obligation maturing prior to the effective date of the termination; and
  - (b) LICENSEE covenants and agrees to be bound by the provisions of ARTICLES IX (Indemnification and Insurance), X (Use of Board and UTMDACC's Name) and XI (Confidential Information and Publication) of this AGREEMENT; and
  - (c) LICENSEE may, for a period of one year after the effective date of the termination, sell all LICENSED PRODUCTS and parts therefor that it has on hand at the date of termination, if LICENSEE pays the earned royalty thereon and any other amounts due pursuant to ARTICLE IV of this AGREEMENT; and
  - (d) Subject to Section 13.4(c), LICENSEE agrees to cease and desist any use and all SALE of the LICENSED SUBJECT MATTER and LICENSED PRODUCTS upon termination of this AGREEMENT; and
  - (e) LICENSEE grants to BOARD and UTMDACC a nonexclusive royalty bearing license with the right to sublicense others with respect to improvements made by LICENSEE (including improvements licensed by LICENSEE from third parties) in the LICENSED SUBJECT MATTER. LICENSEE and UTMDACC agree to negotiate in good faith the royalty rate for the nonexclusive license. BOARD's and UTMDACC's right to sublicense others hereunder is solely for the purpose of permitting others to develop and commercialize the entire technology package.

## **XIV. WARRANTY: SUPERIOR-RIGHTS**

- 14.1 Except for the rights, if any, of the Government of the United States of America as set forth below, BOARD represents and warrants its belief that (a) it is the owner of the entire right, title, and interest in and to LICENSED SUBJECT MATTER, (b) it has the sole right to grant licenses thereunder, and (c) it has not knowingly granted licenses thereunder to any other entity that would restrict rights granted hereunder except as stated herein.
- 14.2 LICENSEE understands that the LICENSED SUBJECT MATTER may have been developed under a funding agreement with the Government of the United States of America ("Government") and, if so, that the Government may have certain rights relative thereto. This AGREEMENT is explicitly made subject to the Government's rights under any such agreement and any applicable law or regulation. To the extent that there is a conflict between any such agreement, applicable law or regulation and this AGREEMENT, the terms of such Government agreement, applicable law or regulation shall prevail. LICENSEE agrees that LICENSED PRODUCTS used or SOLD in the United States will be manufactured substantially in the United States, unless a written waiver is obtained in advance from the GOVERNMENT. LICENSEE will promptly advise UTMDACC if such a written waiver is requested and/or obtained.

- 14.3 LICENSEE understands and agrees that BOARD and UTMDACC, by this AGREEMENT, make no representation as to the operability or fitness for any use, safety, efficacy, approvability by regulatory authorities, time and cost of development, patentability, and/or breadth of the LICENSED SUBJECT MATTER. BOARD and UTMDACC, by this AGREEMENT, also make no representation as to whether any patent covered by PATENT RIGHTS is valid or as to whether there are any patents now held, or which will be held, by others or by BOARD or UTMDACC in the LICENSED FIELD, nor do BOARD and UTMDACC make any representation that the inventions contained in PATENT RIGHTS do not infringe any other patents now held or that will be held by others or by BOARD.
- 14.4 LICENSEE, by execution hereof, acknowledges, covenants and agrees that LICENSEE has not been induced in any way by BOARD, SYSTEM, UTMDACC or employees thereof to enter into this AGREEMENT, and further warrants and represents that (a) LICENSEE is entering into this AGREEMENT voluntarily; (b) LICENSEE has conducted sufficient due diligence with respect to all items and issues pertaining to this AGREEMENT; and (c) LICENSEE has adequate knowledge and expertise, or has used knowledgeable and expert consultants, to adequately conduct such due diligence, and agrees to accept all risks inherent herein.

## XV. GENERAL

- 15.1 This AGREEMENT constitutes the entire and only agreement between the parties for LICENSED SUBJECT MATTER and all other prior negotiations, representations, agreements and understandings are superseded hereby. No agreements altering or supplementing the terms hereof will be made except by a written document signed by both parties.
- 15.2 Any notice required by this AGREEMENT must be given by prepaid, first class, certified mail, return receipt requested, and addressed in the case of UTMDACC to:
- The University of Texas M. D. Anderson Cancer Center  
Office of Technology Commercialization  
7515 S. Main, Suite 490, Unit 0510  
Houston, Texas 77030  
ATTENTION: Christopher C. Capelli, M.D.
- or in the case of LICENSEE to:  
Bio-Path, Inc.  
3293 Harrison Boulevard, Suite 230  
Ogden, Utah 84403  
ATTENTION: Peter H. Nielsen, President & CEO
- or other addresses as may be given from time to time under the terms of this notice provision.
- 15.3 LICENSEE must comply with all applicable federal, state and local laws and regulations in connection with its activities pursuant to this AGREEMENT. LICENSEE acknowledges that the LICENSED SUBJECT MATTER is subject to U.S. export control jurisdiction. LICENSEE agrees to comply with all applicable international and national laws that apply to the LICENSED SUBJECT MATTER, including U.S. Export Administration Regulations, as well as end-user, end-use, and destination restrictions applied by the United States.
- 15.4 This AGREEMENT will be construed and enforced in accordance with the laws of the United States of America and of the State of Texas, without regard to its conflict of law provisions. The Texas State Courts of Harris County, Texas (or, if there is exclusive federal jurisdiction, the United States District Court for the Southern District of Texas) shall have exclusive jurisdiction and venue over any dispute arising out of this AGREEMENT, and LICENSEE consents to the jurisdiction and venue of such courts and hereby explicitly waives the rights to any other venue to which it might be entitled by cause of action, domicile or otherwise. Nothing in this AGREEMENT shall be deemed as a waiver by BOARD, SYSTEM or UTMDACC of its sovereign immunity.
- 15.5 Any dispute or controversy arising out of or relating to this AGREEMENT, its construction or its actual or alleged breach will be decided by mediation. If the mediation does not result in a resolution of such dispute or controversy, it will be finally decided by an appropriate method of alternate dispute resolution, including without limitation, arbitration, conducted in the city of Houston, Harris County, Texas, in accordance with the applicable, then-current procedures of the American Arbitration Association. The arbitration panel will include members knowledgeable in the evaluation of the LICENSED SUBJECT MATTER. Judgment upon the award rendered may be entered in the highest court or forum having jurisdiction, state or federal. The provisions of this Section 15.5 will not apply to decisions on the validity of patent claims or to any dispute or controversy as to which any treaty or law prohibits such arbitration. The decision of the arbitration must be sanctioned by a court of law having jurisdiction to be binding upon and enforceable by the parties.
- 15.6 Failure of BOARD or UTMDACC to enforce a right under this AGREEMENT will not act as a waiver of right or the ability to later assert that right relative to the particular situation involved.
- 15.7 Headings included herein are for convenience only and will not be used to construe this AGREEMENT.
- 15.8 If any part of this AGREEMENT is for any reason found to be unenforceable, all other parts nevertheless will remain enforceable.

- 15.9 In the event that LICENSEE brings an action before any court, agency or tribunal seeking to invalidate or otherwise challenge the enforceability of or BOARD's ownership of any patent included in the PATENT RIGHTS, then UTMDACC may immediately terminate this AGREEMENT upon written notice to LICENSEE. Additionally, LICENSEE will provide written notice to UTMDACC at least three (3) months prior to seeking to invalidate or challenge any patent under the PATENT RIGHTS. LICENSEE will include with such written notice an identification of all prior art it believes invalidates any claim of a patent under the PATENT RIGHTS and will promptly update such disclosure as LICENSEE becomes aware of additional prior art. Any dispute regarding the validity, enforceability or ownership of any patent included in the PATENT RIGHTS shall be litigated in the courts located in Houston, Texas, and LICENSEE agrees not to challenge personal jurisdiction in that forum. To the extent that LICENSEE unsuccessfully challenges the validity or enforceability of any patent included in the PATENT RIGHTS, LICENSEE agrees to reimburse UTMDACC and BOARD for all costs and fees (including attorney's fees) paid by UTMDACC and BOARD in defending against such challenge. LICENSEE understands and agrees that, in the event LICENSEE successfully challenges the validity or enforceability of any patent included in the PATENT RIGHTS, all payments or other consideration made or otherwise provided by LICENSEE to UTMDACC prior to a final, non-appealable adjudication of invalidity and/or unenforceability shall be non-refundable. The obligations of this Section shall survive the expiration or termination of this AGREEMENT.



**AMENDMENT NO. 1 TO THE  
PATENT AND TECHNOLOGY LICENSE AGREEMENT**

This AMENDMENT NO. 1 effective this 11th day of May, 2009 ("AMENDMENT NO. 1 EFFECTIVE DATE"), to the Patent and Technology License Agreement between the Parties dated November 2, 2007 (for MDA 94-036 and MDA 97-004) ("ORIGINAL LICENSE"), is made by and between the BOARD OF REGENTS ("BOARD") of THE UNIVERSITY OF TEXAS SYSTEM ("SYSTEM"), an agency of the State of Texas, whose address is 201 West 7th Street, Austin, Texas 78701, on behalf of THE UNIVERSITY OF TEXAS M. D. ANDERSON CANCER CENTER (hereinafter "UTMDACC"), a component institution of SYSTEM, and BIO-PATH, INC. a Utah corporation having a principal place of business located at 2939 Harrison Boulevard, Suite 230, Ogden, Utah, 84403 ("LICENSEE") BOARD and LICENSEE may be referred to hereafter collectively as the "PARTIES."

**RECITALS**

A. BOARD and LICENSEE desire to amend the ORIGINAL LICENSE to add a new technology and reflect the PARTIES' Original intent with respect to the originally licensed technologies

NOW, THEREFORE, in consideration of the mutual covenants contained herein, the sufficiency of which is hereby acknowledged, the PARTIES hereby agree to the following:

**AMENDED TERMS**

1. Exhibit I of the ORIGINAL LICENSE (which included MDA 94-036 and MDA 97-004) shall be deleted in its entirety and replaced with the new Exhibit I attached hereto.
2. It is understood and agreed by LICENSEE that as a result of this AMENDMENT NO. 1, BIO-PATH's obligation to pay out-of-pocket expenses under Section 4.1(a) of the ORIGINAL LICENSE includes, but is not limited to, those expenses incurred in connection with MDA 96-020 and MDA99-033
3. The PARTIES acknowledge and agree that, except as set forth in this AMENDMENT NO. 1 the terms and conditions of the ORIGINAL LICENSE shall remain in full force and effect.

IN WITNESS WHEREOF, the PARTIES hereto have caused their duly authorized representatives to execute this AMENDMENT NO 1.

BOARD OF REGENTS OF THE UNIVERSITY OF TEXAS SYSTEM

BIO-PATH, INC.

By: /s/ John Mendelsohn, M.D.  
John Mendelsohn, M.D.  
President  
The University of Texas  
M. D. Anderson Cancer Center

By: /s/ Peter H. Nielsen  
Peter H. Nielsen  
President and CEO

Date: May 11, 2009

Date: April 30, 2009

THE UNIVERSITY OF TEXAS M. D. ANDERSON CANCER CENTER

By: /s/ Leon Leach  
Leon Leach  
Executive Vice President  
The University of Texas  
M. D. Anderson Cancer Center

Date: May 11, 2009

Approved as to Content:

By: /s/ Christopher C. Capelli, M.D.  
Christopher C. Capelli, M.D.  
Vice President, Technology Based Ventures  
Office of Technology Commercialization  
M. D. Anderson Cancer Center

Date: May 5, 2009

EXHIBIT I

<u>MDA NO.</u>	<u>Inventors</u>	<u>Title</u>	<u>U.S. and foreign patent application / patent numbers</u>
MDA94-036	Gabiel Lopez-Berestein, M.D.; Ana Maria Tari, Ph.D	Liposomal Phosphodiester, Phosphorothioate, and p-Ethoxy Oligonucleotides	U.S. Patent Nos 5,855,911; 6,042,846; 7,176,302 and Ser # 11/674,563; PCI/US 1996/14146 nationalized Canadian Ser No. 2,228,944; Japanese Ser No. 9-510642; European # 0847272 nationalized 0847272GB 0847272DE 0847272FR
MDA96-009	Gabriel Lopez-Berestein, M.D.; Ana M. Tari, Ph.D; and Ralph Arlinghaus, Ph.D	Inhibition of chronic myelogenous leukemic cell growth by liposomal-antisense oligodeoxynucleotides targeting to Grb2 or Crk1	U S. Patent Nos. 7,309,692 and 7,220,853; Serial No 11/696,015 PCI/US1997/10101 Nationalized Canadian Ser No. 2,259,144 European 0912729 Nationalized European Divisional 1234876 Nationalized 1234876FR 1234876DE 1234876IT 1234876ES
MDA96-020	Mar Tormo, M.D.; Ana Tari, Ph.D; Gabriel Lopez-Berestein, M.D.; Timothy McDonnell, M.D., Ph.D	Inhibition of Bcl-2 protein expression by liposomal antisense oligos	U S. Patent Nos 6,977,244 and 7,285,288; PCT/US/1997/18348 Nationalized Canadian Serial No 2,266,584 Japanese Serial No 10-516985 Japanese Divisional 2007- 248267 European 0939621 Nationalized 0939621DE 0939621ES 0939621FR 0939621IE 0939621GB 0939621IT
MDA99-033	Ana Tari, Ph.D; Gabriel Lopez-Berestein, MD; and Yolanda Gutierrez-Puente	Small oligonucleotide with anti-tumor activity	09506797 PCI/US2001/40159

**SECURITIES PURCHASE AGREEMENT**

This Securities Purchase Agreement (this “Agreement”) is dated as of April 19, 2013, between Bio-Path Holdings, Inc., a Utah corporation (the “Company”), and the purchaser identified on the signature page hereto (the “Purchaser”).

WHEREAS, subject to the terms and conditions set forth in this Agreement, the Company desires to issue and sell to the Purchaser, and the Purchaser desires to purchase from the Company, securities of the Company as more fully described in this Agreement.

NOW, THEREFORE, IN CONSIDERATION of the mutual covenants contained in this Agreement, and for other good and valuable consideration the receipt and adequacy of which are hereby acknowledged, the Company and the Purchaser agree as follows:

**ARTICLE I  
DEFINITIONS**

Definitions. In addition to the terms defined elsewhere in this Agreement, for all purposes of this Agreement, the following terms have the meanings set forth in this Article I:

“Board of Directors” means the board of directors of the Company.

“Business Day” means any day except any Saturday, any Sunday, any day which is a federal legal holiday in the United States or any day on which banking institutions in the State of Texas are authorized or required by law or other governmental action to close.

“Closing” means the closing of the purchase and sale of the Shares pursuant to Section 2.1.

“Closing Date” means the Business Day on which all of the Transaction Documents have been executed and delivered by the applicable parties thereto, and all conditions precedent to (i) the Purchaser’s obligations to pay the Subscription Amount and (ii) the Company’s obligations to deliver the Shares, in each case, have been satisfied or waived.

“Commission” means the United States Securities and Exchange Commission.

“Common Stock” means the common stock of the Company, no par value, and any other class of securities into which such securities may hereafter be reclassified or changed.

“Liens” means a lien, charge, security interest, encumbrance, right of first refusal, preemptive right or other restriction, other than restrictions imposed by securities laws.

“Per Share Purchase Price” equals \$0.30, subject to adjustment for reverse or forward stock splits, stock dividends, stock combinations and other similar transactions of the Common Stock that occur after the date of this Agreement but prior to the Closing.

“Person” means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

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“Proceeding” means an action, claim, suit, investigation or proceeding (including, without limitation, an informal investigation or partial proceeding, such as a deposition), whether commenced or threatened.

“Rule 144” means Rule 144 promulgated by the Commission pursuant to the Securities Act, as such rule may be amended from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same effect as such rule.

“Securities Act” means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

“Shares” means the number of shares of Common Stock as specified below the Purchaser’s name on the signature page of this Agreement next to the heading “Shares.”

“Subscription Amount” means the number of Shares multiplied by the Per Share Purchase Price.

“Transaction Documents” means this Agreement and any other documents or agreements executed in connection with the transactions contemplated hereunder.

“Transfer Agent” means Fidelity Transfer Company, the current transfer agent of the Company, with a mailing address of 8915 S. 700 E. Suite 102, Sandy, Utah 84070 and a facsimile number of (801) 233-0589, and any successor transfer agent of the Company.

## **ARTICLE II PURCHASE AND SALE**

2.1 Closing. Upon the terms and subject to the conditions set forth herein, substantially concurrent with the execution and delivery of this Agreement by the parties hereto, the Company agrees to sell, and the Purchaser agrees to purchase the Shares. Upon satisfaction of the covenants and conditions set forth in Sections 2.2 and 2.3, the Closing shall occur at the offices of the Company or such other location as the parties shall mutually agree.

### 2.2 Deliveries.

(a) On or prior to the Closing Date, the Company shall deliver or cause to be delivered to the Purchaser or such other Person, as the case may be, the following:

- (i) this Agreement duly executed by the Company; and
- (ii) instructions to the Transfer Agent instructing the Transfer Agent to issue the Shares to the Purchaser in accordance herewith.

(b) On or prior to the Closing Date, the Purchaser shall deliver or cause to be delivered to the Company the following:

- (i) this Agreement duly executed by the Purchaser; and
- (ii) the Subscription Amount by check or wire transfer to the account as specified in writing by the Company.

2.3 Closing Conditions.

- (a) The obligations of the Company hereunder in connection with the Closing are subject to the following conditions being met:
- (i) the accuracy in all material respects when made and on the Closing Date of the representations and warranties of the Purchaser contained herein (unless as of a specific date therein);
  - (ii) all obligations, covenants and agreements of the Purchaser required to be performed at or prior to the Closing Date shall have been performed in all material respects; and
  - (iii) the delivery by the Purchaser of the items set forth in Section 2.2(b).
- (b) The obligations of the Purchaser hereunder in connection with the Closing are subject to the following conditions being met:
- (i) the accuracy in all material respects when made and on the Closing Date of the representations and warranties of the Company contained herein (unless as of a specific date therein);
  - (ii) all obligations, covenants and agreements of the Company required to be performed at or prior to the Closing Date shall have been performed in all material respects; and
  - (iii) the delivery by the Company of the items set forth in Section 2.2(a).

**ARTICLE III  
REPRESENTATIONS AND WARRANTIES**

3.1 Representations and Warranties of the Company. The Company hereby makes the following representations and warranties to the Purchaser:

- (a) Organization. The Company is an entity duly incorporated, validly existing and in good standing under the laws of the jurisdiction of its incorporation, with the requisite power and authority to own and use its properties and assets and to carry on its business as currently conducted.
- (b) Authorization; Enforcement. The Company has the requisite corporate power and authority to enter into and to consummate the transactions contemplated by each of the Transaction Documents and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of each of the Transaction Documents by the Company and the consummation by it of the transactions contemplated hereby and thereby have been duly authorized by all necessary corporate action on the part of the Company and no further corporate action is required by the Company, the Board of Directors or the Company's stockholders in connection therewith. Each Transaction Document to which it is a party has been (or upon delivery will have been) duly executed by the Company and, when delivered in accordance with the terms hereof and thereof, will constitute the valid and binding obligation of the Company enforceable against the Company in accordance with its terms, except (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium, fraudulent transfer, fraudulent conveyance and other laws of general application affecting enforcement of creditors' rights generally, (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

(c) Issuance of the Shares. The Shares are duly authorized and, when issued and paid for in accordance with the Transaction Documents, will be duly and validly issued, fully paid and nonassessable, free and clear of all Liens imposed by the Company.

(d) Brokers and Finders. Except for certain fees or commissions agreed upon and negotiated by the Company, no other Person will have, as a result of the transactions contemplated by the Transaction Documents, any valid right, interest or claim against or upon the Company for any commission, fee or other compensation pursuant to any agreement, arrangement or understanding entered into by or on behalf of the Company.

The Purchaser acknowledges and agrees that the Company does not make and has not made any representations or warranties with respect to the transactions contemplated hereby other than those specifically set forth in this Section 3.1.

3.2 Representations and Warranties of the Purchaser. The Purchaser hereby makes the following representations and warranties to the Company:

(a) Organization; Authority. The Purchaser is either an individual or an entity duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization with full right, corporate or partnership power and authority to enter into and to consummate the transactions contemplated by this Agreement and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of this Agreement and performance by the Purchaser of the transactions contemplated by this Agreement have been duly authorized by all necessary corporate, partnership, limited liability company or similar action, as applicable, on the part of the Purchaser. Each Transaction Document to which it is a party has been duly executed by the Purchaser, and when delivered by the Purchaser in accordance with the terms hereof, will constitute the valid and legally binding obligation of the Purchaser, enforceable against it in accordance with its terms, except: (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally, (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

(b) No Conflicts. The execution, delivery and performance by the Purchaser of the Agreement and the consummation by it of the transactions contemplated hereby do not and will not (i) conflict with or violate any provision of the Purchaser's certificate or articles of incorporation, bylaws or other organizational or charter documents, as applicable, or (ii) conflict with or result in a violation of any law, rule, regulation, order, judgment, injunction, decree or other restriction of any court or governmental authority to which the Purchaser is subject (including federal and state securities laws and regulations), or by which any property or asset of the Purchaser is bound or affected.

(c) Own Account. The Purchaser is acquiring the Shares as principal for its own account and not with a present view toward the public sale or distribution thereof.

(d) Purchaser Status. At the time the Purchaser was offered the Shares, it was, and as of the date hereof it is an “accredited investor” as defined in Rule 501(a) of Regulation D under the Securities Act.

(e) Experience of the Purchaser. The Purchaser, either alone or together with its representatives, has such knowledge, sophistication and experience in business and financial matters so as to be capable of evaluating the merits and risks of the prospective investment in the Shares, and has so evaluated the merits and risks of such investment. The Purchaser is able to bear the economic risk of an investment in the Shares and, at the present time, is able to afford a complete loss of such investment.

(f) Disclosure of Information. The Purchaser has had an opportunity to receive all information related to the Company requested by it and to ask questions of and receive answers from the Company regarding the Company, its business and the terms and conditions of the offering of the Shares. The Purchaser has had access to and reviewed the Company’s Form 10-K, filed with the Commission on April 1, 2013, together with all filed Form 10-Q, Form 8-K and other filings made by the Company with the Commission as available on the Commission’s EDGAR website (collectively, the “SEC Documents”). The Purchaser has reviewed the risk factors contained in the SEC Documents. The Purchaser has considered the risk factors and all other factors therein.

(g) No Registration. The Purchaser understands that the Shares have not been, and will not be, registered under the Securities Act by reason of a specific exemption from the registration provisions of the Securities Act, the availability of which depends upon, among other things, the bona fide nature of the investment intent and the accuracy of such Investor’s representations as expressed herein or otherwise made pursuant hereto.

(h) Rule 144. The Purchaser acknowledges that the Shares must be held indefinitely unless subsequently registered under the Securities Act or an exemption from such registration is available. The Purchaser is aware of the provisions of Rule 144 promulgated under the Securities Act which permit limited resale of shares purchased in a private placement subject to the satisfaction of certain conditions. The Purchaser acknowledges and understands that the Company may not be satisfying the current public information requirement of Rule 144 at the time the Purchaser wishes to sell the Shares, and that, in such event, the Purchaser may be precluded from selling such securities under Rule 144, even if the other requirements of Rule 144 have been satisfied. The Purchaser acknowledges that, in the event all of the requirements of Rule 144 are not met, registration under the Securities Act or an exemption from registration will be required for any disposition of the Shares. The Purchaser understands that, although Rule 144 is not exclusive, the Commission has expressed its opinion that persons proposing to sell restricted securities received in a private offering other than in a registered offering or pursuant to Rule 144 will have a substantial burden of proof in establishing that an exemption from registration is available for such offers or sales and that such persons and the brokers who participate in the transactions do so at their own risk.

(i) Legends. It is understood that certificates evidencing the Shares may bear the following or any similar legend:

**(i) “The securities represented hereby may not be transferred unless (i) such securities have been registered for sale pursuant to the Securities Act of 1933, as amended, (ii) such securities may be sold pursuant to Rule 144, or (iii) the Company has received an opinion of counsel reasonably satisfactory to it that such transfer may lawfully be made without registration under the Securities Act of 1933, as amended, or qualification under applicable state securities laws.”**

(ii) If required by the authorities of any state in connection with the issuance of sale of the Shares, the legend required by such state authority.

(j) No General Advertisement. The Purchaser did not learn of the investment in the Shares as a result of any public advertisement, article, notice or other communication regarding the Shares published in any newspaper, magazine or similar media or broadcast over television, radio or internet or presented at any seminar or other general advertisement.

(k) Brokers and Finders. Except for certain fees or commissions agreed upon and negotiated by the Company, no other Person will have, as a result of the transactions contemplated by the Transaction Documents, any valid right, interest or claim against or upon the Company or the Purchaser for any commission, fee or other compensation pursuant to any agreement, arrangement or understanding entered into by or on behalf of the Purchaser.

#### **ARTICLE IV MISCELLANEOUS**

4.1 Termination. This Agreement may be terminated by the Purchaser or the Company by written notice to the other party if the Closing has not been consummated on or before 2013; provided, however, that no such termination will affect the right of any party to sue for any breach by the other party (or parties).

4.2 Fees and Expenses. Except as expressly set forth in the Transaction Documents to the contrary, each party shall pay the fees and expenses of its advisers, counsel, accountants and other experts, if any, and all other expenses incurred by such party incident to the negotiation, preparation, execution, delivery and performance of this Agreement.

4.3 Entire Agreement. The Transaction Documents, together with the exhibits and schedules thereto, contain the entire understanding of the parties with respect to the subject matter hereof and supersede all prior agreements and understandings, oral or written, with respect to such matters, which the parties acknowledge have been merged into such documents, exhibits and schedules.

4.4 Notices. Any and all notices or other communications or deliveries required or permitted to be provided hereunder shall be in writing and shall be deemed given and effective on the earliest of: (a) the date of transmission, if such notice or communication is delivered via facsimile at the facsimile number set forth on the signature pages attached hereto prior to 5:00 p.m. (Houston, Texas time) on a Business Day, (b) the next Business Day after the date of transmission, if such notice or communication is delivered via facsimile at the facsimile number set forth on the signature pages attached hereto on a day that is not a Business Day or later than 5:00 p.m. (Houston, Texas time) on any Business Day, (c) the second (2<sup>nd</sup>) Business Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service or (d) upon actual receipt by the party to whom such notice is required to be given. The address for such notices and communications shall be as set forth on the signature pages attached hereto.

4.5 Amendments; Waivers. No provision of this Agreement may be waived, modified, supplemented or amended except in a written instrument signed, in the case of an amendment, by the Company and the Purchaser or, in the case of a waiver, by the party against whom enforcement of any such waived provision is sought. No waiver of any default with respect to any provision, condition or requirement of this Agreement shall be deemed to be a continuing waiver in the future or a waiver of any subsequent default or a waiver of any other provision, condition or requirement hereof, nor shall any delay or omission of any party to exercise any right hereunder in any manner impair the exercise of any such right.

4.6 Headings. The headings herein are for convenience only, do not constitute a part of this Agreement and shall not be deemed to limit or affect any of the provisions hereof.

4.7 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties and their successors and permitted assigns. Neither party may assign this Agreement or any rights or obligations hereunder without the prior written consent of the other party.

4.8 No Third-Party Beneficiaries. This Agreement is intended for the benefit of the parties hereto and their respective successors and permitted assigns and is not for the benefit of, nor may any provision hereof be enforced by, any other Person.

4.9 Governing Law. All questions concerning the construction, validity, enforcement and interpretation of the Transaction Documents shall be governed by and construed and enforced in accordance with the internal laws of the State of Texas, without regard to the principles of conflicts of law thereof. Each party agrees that all Proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Agreement and any other Transaction Documents (whether brought against a party hereto or its respective affiliates, directors, officers, shareholders, employees or agents) shall be commenced exclusively in the state and federal courts sitting in Houston, Texas. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in Houston, Texas for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein (including with respect to the enforcement of any of the Transaction Documents), and hereby irrevocably waives, and agrees not to assert in any Proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such Proceeding is improper or is an inconvenient venue for such Proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such Proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If either party shall commence a Proceeding to enforce any provisions of the Transaction Documents, then the prevailing party in such Proceeding shall be reimbursed by the other party for its reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such Proceeding.

4.10 Survival. The representations and warranties contained herein shall survive the Closing and the delivery of the Shares.

4.11 Execution. This Agreement may be executed in two or more counterparts, all of which when taken together shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party and delivered to the other party, it being understood that both parties need not sign the same counterpart. In the event that any signature is delivered by facsimile transmission or by e-mail delivery of a ".pdf" format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or ".pdf" signature page were an original thereof.

4.12 Severability. If any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction to be invalid, illegal, void or unenforceable, the remainder of the terms, provisions, covenants and restrictions set forth herein shall remain in full force and effect and shall in no way be affected, impaired or invalidated, and the parties hereto shall use their commercially reasonable efforts to find and employ an alternative means to achieve the same or substantially the same result as that contemplated by such term, provision, covenant or restriction. It is hereby stipulated and declared to be the intention of the parties that they would have executed the remaining terms, provisions, covenants and restrictions without including any of such that may be hereafter declared invalid, illegal, void or unenforceable.

4.13 Remedies. In addition to being entitled to exercise all rights provided herein or granted by law, including recovery of damages, the Purchaser and the Company will be entitled to specific performance under the Transaction Documents. The parties agree that monetary damages may not be adequate compensation for any loss incurred by reason of any breach of obligations contained in the Transaction Documents and hereby agree to waive and not to assert in any action for specific performance of any such obligation the defense that a remedy at law would be adequate.

4.14 Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then such action may be taken or such right may be exercised on the next succeeding Business Day.

4.15 Construction. The parties agree that each of them and/or their respective counsel has reviewed and had an opportunity to revise the Transaction Documents and, therefore, the normal rule of construction to the effect that any ambiguities are to be resolved against the drafting party shall not be employed in the interpretation of the Transaction Documents or any amendments hereto. In addition, each and every reference to share prices and shares of Common Stock in any Transaction Document shall be subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the Common Stock that occur after the date of this Agreement.

4.16 **WAIVER OF JURY TRIAL. IN ANY ACTION, SUIT, OR PROCEEDING IN ANY JURISDICTION BROUGHT BY ANY PARTY AGAINST ANY OTHER PARTY, THE PARTIES EACH KNOWINGLY AND INTENTIONALLY, TO THE GREATEST EXTENT PERMITTED BY APPLICABLE LAW, HEREBY ABSOLUTELY, UNCONDITIONALLY, IRREVOCABLY AND EXPRESSLY WAIVES FOREVER TRIAL BY JURY.**

[Signature Page Follows]

IN WITNESS WHEREOF, the parties hereto have caused this Securities Purchase Agreement to be duly executed by their respective authorized signatories as of the date first indicated above.

**Bio-Path Holdings, Inc.**

Address for Notice:

By: \_\_\_\_\_  
Name: Douglas P. Morris  
Title: VP of Corporate Development

2626 South Loop  
Suite 180  
Houston, TX 77054

With a copy to (which shall not constitute notice):

Winstead PC  
Attn: William R. Rohrlich, II  
24 Waterway Avenue, Suite 500  
The Woodlands, Texas 77380  
Fax: (281) 681-5901

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK  
SIGNATURE PAGE FOR PURCHASER FOLLOWS]

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[PURCHASER SIGNATURE PAGE TO BPTH SECURITIES PURCHASE AGREEMENT]

**IN WITNESS WHEREOF**, the undersigned has caused this Securities Purchase Agreement to be duly executed by its respective authorized signatories as of the date first indicated above.

Name of Purchaser: \_\_\_\_\_

*Signature of Authorized Signatory of Purchaser:* \_\_\_\_\_

Name of Authorized Signatory: \_\_\_\_\_

Title of Authorized Signatory: \_\_\_\_\_

Email Address of Authorized Signatory: \_\_\_\_\_

Facsimile Number of Authorized Signatory: \_\_\_\_\_

Address for Notice of Purchaser:

Address for Delivery of certificated Securities for the Purchaser (if not same as address for notice):

Information for Delivery of uncertificated Securities by DWAC:

Account Number: \_\_\_\_\_

Account Name: \_\_\_\_\_

DTC Number: \_\_\_\_\_

Subscription Amount: \$ \_\_\_\_\_

Shares: \_\_\_\_\_

EIN Number: **[PROVIDE THIS UNDER SEPARATE COVER]**

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**CERTIFICATION OF  
PRINCIPAL EXECUTIVE OFFICER AND  
PRINCIPAL FINANCIAL OFFICER**

I, Peter H. Nielsen, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Bio-Path Holdings, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this report is being prepared; and
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 15, 2013

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

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