

BIO-PATH HOLDINGS INC  
Form 10-Q  
May 16, 2011

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, 2011  
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.)

3293 Harrison Boulevard, Suite 220, Ogden, UT 84403  
(Address of principal executive offices)

Registrant's telephone no., including area code: (801) 580-2326

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

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

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

Large accelerated filer

Accelerated filer

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

Smaller reporting company

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

At May 13, 2011, the Company had 49,400,605 outstanding shares of common stock, no par value.

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## 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,” “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, 2010, 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

	March 31, 2011 (Unaudited)	December 31, 2010
<b>ASSETS</b>		
Current assets		
Cash	\$765,768	\$ 238,565
Grants receivable	-	244,479
Prepaid drug product for testing	-	88,400
Other current assets	51,005	72,993
<b>Total current assets</b>	<b>816,773</b>	<b>644,437</b>
Other assets		
Technology licenses - related party	3,076,253	3,043,821
Less Accumulated Amortization	(631,510 )	(579,754 )
	2,444,743	2,464,067
<b>TOTAL ASSETS</b>	<b>\$3,261,516</b>	<b>\$ 3,108,504</b>
<b>LIABILITIES &amp; SHAREHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable	25,688	88,400
Accrued expense	87,221	84,141
Accrued license payments - related party	75,000	74,217
<b>Total current liabilities</b>	<b>187,909</b>	<b>246,758</b>
Long term debt	-	-
<b>TOTAL LIABILITIES</b>	<b>187,909</b>	<b>246,758</b>
Shareholders' Equity		
Preferred Stock, \$.001 par value 10,000,000 shares authorized, no shares issued and outstanding	-	-
Common Stock, \$.001 par value, 200,000,000 shares authorized 49,400,605 shares issued and outstanding as of 3/31/11 and 12/31/10, respectively	49,401	49,401
Additional paid in capital	9,760,433	9,719,147
Additional paid in capital for shares to be issued a/ b/	1,041,902 a/	278,600 b/

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Accumulated deficit during development stage	(7,778,129)	(7,185,402 )
Total shareholders' equity	3,073,607	2,861,746
<b>TOTAL LIABILITIES &amp; SHAREHOLDERS' EQUITY</b>	<b>\$3,261,516</b>	<b>\$ 3,108,504</b>

a/ Represents 3,473,008 shares of common stock

a/ Represents 928,667 shares of common stock

SEE ACCOMPANYING NOTES TO FINANCIAL STATEMENTS

BIO-PATH HOLDINGS, INC.  
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF OPERATIONS  
Unaudited

	First Quarter January 1 to March 31		From inception 05/10/07 to 3/31/11
	2011	2010	
Revenue	\$-	\$-	\$ -
Operating expense			
Research and development (including stock option expense of \$15,205 and \$36,176 for quarters ending 3/31/2011 and 3/31/2010, respectively, and \$318,466 for the period from inception through 3/31/2011)	192,499	220,955	2,782,387
Research and development - related party	50,000	-	111,950
General & administrative (including stock, stock option and warrant expense of \$104,776 and \$107,770 for quarters ending 3/31/2011 and 3/31/2010, respectively, and \$2,668,966 for the period from inception through 3/31/2011)	350,238	270,588	5,198,786
Total operating expense	592,737	491,543	8,093,123
Net operating loss	\$(592,737 )	\$(491,543 )	\$ (8,093,123 )
Other income (expense)			
Interest income	191	602	73,595
Other income		-	244,479
Other expense	(180 )	-	(3,080 )
Total Other Income (Expense)	11	602	314,994
Net Loss	\$(592,726 )	\$(490,941 )	\$ (7,778,129 )
Loss per share			
Net loss per share, basic and diluted	\$(0.01 )	\$(0.01 )	\$ (0.19 )
Basic and diluted weighted average number of common shares outstanding	49,400,605	46,609,602	40,879,289

SEE ACCOMPANYING NOTES TO FINANCIAL STATEMENTS





BIO-PATH HOLDINGS, INC.  
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF CASH FLOWS  
Unaudited

	January 1 to March 31 2011	March 31 2010	From inception 05/10/2007 to 3/31/2011
<b>CASH FLOW FROM OPERATING ACTIVITIES</b>			
Net loss	\$(592,726 )	\$(490,941 )	\$ (7,778,129 )
Adjustments to reconcile net loss to net cash used in operating activities			
Amortization	51,756	47,697	631,510
Common stock issued for services	-	-	300,000
Stock options and warrants	119,981	143,946	2,687,432
(Increase) decrease in assets			
Grants receivable	244,479	-	-
Drug product for testing	88,400	-	-
Other current assets	21,988	(58,186 )	(51,005 )
Increase (decrease) in liabilities			
Accounts payable and accrued expenses	(58,849 )	70,982	187,909
Net cash used in operating activities	(124,971 )	(286,502 )	(4,022,283 )
<b>CASH FLOW FROM INVESTING ACTIVITIES</b>			
Purchase of exclusive license - related party	(32,432 )	(25,000 )	(722,086 )
Net cash used in investing activities	(32,432 )	(25,000 )	(722,086 )
<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	684,606	198,827	5,090,137
Net cash from financing activities	684,606	198,827	5,510,137
<b>NET INCREASE/(DECREASE) IN CASH</b>	<b>527,203</b>	<b>(112,675 )</b>	<b>765,768</b>
Cash, beginning of period	238,565	567,249	-
Cash, end of period	\$765,768	\$454,574	\$ 765,768

**SUPPLEMENTAL DISCLOSURE OF CASH FLOW  
INFORMATION**

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Cash paid for			
Interest	\$-	\$-	\$ -
Income taxes	\$-	\$-	\$ -
Non-cash financing activities			
Common stock issued upon conversion of convertible notes	\$-	\$-	\$ 420,000
Common stock issued to Placement Agent	\$-	\$90,000	\$ 384,845
Common stock issued to M.D. Anderson for technology license - related party	\$-	\$-	\$ 2,354,167

SEE ACCOMPANYING NOTES TO FINANCIAL STATEMENTS

BIO-PATH HOLDINGS, INC.  
(A Development Stage Company)

Notes to the Unaudited Consolidated Financial Statements Ending March 31, 2011

The accompanying interim financial statements have been prepared with the instructions to Form 10-Q pursuant to the rules and regulations of the Securities and Exchange Commission and, therefore, do not include all information and footnotes necessary for a complete presentation of our financial position, results of operations, cash flows, and stockholders' equity in conformity with generally accepted accounting principals. In the opinion of management, all adjustments considered necessary for a fair presentation of the results of operations and financial position have been included and all such adjustments are of a normal recurring nature. The unaudited quarterly financial statements should be read in conjunction with the audited financial statements and notes thereto included in the Annual Report on Form 10-K of Bio-Path Holdings, Inc. (together with its subsidiary, the "Company") as of and for the fiscal year ended December 31, 2010. The results of operations for the period ended March 31, 2011, are not necessarily indicative of the results for a full-year period.

1. Organization and Business

Bio-Path Holdings, Inc. ("Bio-Path" or the "Company") is a development stage company with its lead cancer drug candidate, Liposomal Grb-2 (L-Grb-2 or BP-100-1.01), currently in clinical trials. The Company was founded with technology from The University of Texas, MD Anderson Cancer Center ("MD Anderson") dedicated to developing novel cancer drugs under an exclusive license arrangement. The Company has drug delivery platform technology with composition of matter intellectual property that enables systemic delivery of antisense and small interfering RNA ("siRNA"). Bio-Path has also licensed liposome tumor targeting technology, which has the potential to be applied to augment the Company's current delivery technology to improve further the effectiveness of its antisense and siRNA drugs under development as well as future liposome-based delivery technology drugs. 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 a strong pipeline of promising drug candidates in the future. Bio-Path expects the working relationship with MD Anderson to provide the opportunity for the Company to broaden its technology to include cancer drugs other than antisense and siRNA.

Bio-Path believes that its core technology, if successful, will enable it to be at the center of emerging genetic and molecular target-based therapeutics that require systemic delivery of DNA and RNA-like material. The Company's two lead liposomal antisense drug candidates treat acute myeloid leukemia, chronic myelogenous leukemia, acute lymphoblastic leukemia and follicular lymphoma, and if successful, could potentially be used in treating many other indications of cancer.

Bio-Path is currently treating patients with its lead cancer drug candidate Liposomal Grb-2 (L-Grb-2 or BP-100-1.01) 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 of 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. The trial will evaluate five doses of L-Grb-2 and 18 to 30 patients may be accrued into the study. The clinical trial is being conducted at The University of Texas MD Anderson Cancer Center.

Enrollment continues in the Phase I clinical trial of its lead cancer drug product Liposomal Grb-2 (also “BP-100-1.01”). Through the end of the first quarter of 2011, seven patients had been enrolled into the study, with another two additional patients in the process of being enrolled at the end of March 2011. Patients eligible for enrollment 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. At the low initial dose levels in the clinical trial, it has taken longer than expected for the Principal Investigator to recruit patients into the trial. In addition, four of the initial patients were unable to stay on the entire four week treatment cycle because of progressive disease, which was unrelated to treatment with Liposomal Grb-2, and consequently, had to be withdrawn from the study before completion of testing.

It is important to note two of the three patients that completed the full four week treatment cycle of the Phase I trial were placed on continuing treatment for additional cycles based on the Principal Investigator’s assessment that they were receiving benefit from the drug. Bio-Path’s FDA-approved protocol for the Phase I clinical trial provides that the Principal Investigator may continue treatment of a patient beyond the initial cycle if, in the Principal Investigator’s opinion the patient is exhibiting stable disease, or else, has improvement of their disease. In the circumstance where a patient is continuing treatment beyond the requirements of the Phase I trial, the Company is required to supply drug at no charge for the continuing treatments but does not incur additional hospital costs. Although it is too early to draw any scientific conclusions about any effect that the Company’s drug candidate Liposomal-Grb-2 has on patients being treated in the trial, the effects of apparent stabilization in some patients is expected to help in recruiting new patients into the clinical trial. In this regard, the Company was very encouraged by the recent new enrollments into the trial.

The Company expects that an additional 12 months could be required to complete the Phase I clinical trial. We are seeking an additional 13-16 patients to complete the trial. Since, at the Principal Investigator's recommendation, some patients who are benefiting from the treatment are being placed on continuing therapy beyond the requirements of the clinical trial, additional expenses may be incurred as the Company is required to supply drug at no charge for the continuing treatment. Additional costs to completion of the Phase I clinical trial are estimated to range from \$750,000 to \$1.2 million. Bio-Path believes it has sufficient resources and access to additional resources if needed to meet its obligations in this regard.

It is noted that the difficulty that the Company and the Principal Investigator for the clinical trial have in estimating the rate of progress through the Phase I clinical trial is due to two factors: (1) the rate of patient accrual into the trial, and (2) the ability of a patient who has started treatment to complete a full treatment cycle. It has been noted previously that it has been difficult initially for the Principal Investigator to recruit patients into the trial, primarily because eligibility requires patients who are refractory or relapsed to existing treatments and the very low starting dose (which the FDA determined) offered little prospect of benefit in treating their disease. However, the fact that some patients were benefiting from treatment, even at low starting doses, is expected to improve patient recruitment. The second factor relates to a patient's ability to complete the full treatment cycle (four weeks). The patients in this clinical trial are very advanced in their disease, but while on treatment cycle, they are not allowed to receive any other chemotherapy. As a result, many patients who have started treatment had to withdraw due to progression of the disease, which was unrelated to treatment from Liposomal Grb-2. If a patient does not complete the entire treatment cycle, then that patient is not deemed evaluable for the trial, and a new patient must be recruited and treatment started again. Although the above factors make it more challenging to progress through the early stages of the Company's clinical trial, the positive side is that benefitting these patients could result in faster FDA approvals of Liposomal Grb-2 as standard treatment.

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

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 BP-100-1.01.

At the end of March 2011, Bio-Path had \$765,768 in cash on hand. During the first quarter 2011, the Company continued the sale of shares of its common stock through a Private Placement Memorandum. At the end of April, 2011, the Company concluded its efforts in this Private Placement, having sold, or agreed to sell, approximately \$1.8 million of its common stock for cash. The amount of cash resources in Company accounts is expected to fund Bio-Path's operations into the second half of 2011, when the Company should have sufficient preliminary data from its Phase I clinical trial to start early assessments of the utility of the drug and the delivery technology. The Company 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. In the first quarter ending March 31, 2011, MD Anderson received \$25,000 in cash from the Company for R&D related expense, plus an additional \$25,000 in expense was accrued, and \$32,432 in cash for patent expense related to the Company's Technology License. As of March 31, 2011, the Company had accrued expenses due to the related party totaling \$75,000. See Note 6.

## 3. Prepaid Drug Product for Testing

Advance payments, including nonrefundable amounts, for goods or services that will be used or rendered for future R&D activities are deferred and capitalized. Such amounts will be recognized as an expense as the related goods are delivered or the related services are performed. The Company incurred installments to its contract drug manufacturing and raw material suppliers totaling \$88,400 during 2010 pursuant to a Project Plan and Supply Agreement (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, 2010 at cost as Prepaid Drug Product for Testing and was expensed when the drug product was received by the Company in 2011. As of March 31, 2011, the Company had supplies of drug product on hand for use in the clinical trial estimated to be sufficient for requirements through the summer of 2011.

4. Grants Receivable

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

5. Accrued Expense

As of March 31, 2011, Current Liabilities included accrued expense of \$87,221. R&D expenses for the Phase I clinical trial comprised \$30,000 of this amount. R&D expense for consultants approximated \$3,560 and corporate expenses for communications, filings and expense reports accrued totaled approximately \$7,410. Management bonus pool accrual comprises \$46,250 of accrued expense as of March 31, 2011.

6. Accrued License Payments – Related Party

Accrued license payments – related party totaling \$75,000 were included in Current Liabilities as of March 31, 2011. This amount represents patent expenses and maintenance fees for the licensed technology from the MD Anderson Cancer Center. It is expected that the accrued license payments will be made to MD Anderson in 2011.

7. Additional Paid In Capital For Shares To Be Issued

In November and December of 2010, the Company sold shares of common stock for \$278,600 in cash to investors pursuant to a private placement memorandum. These shares were not issued by the December 31, 2010 year end. In February and March of 2011, the Company sold additional shares of common stock for \$763,302 in cash to investors pursuant to a private placement memorandum. These shares were not issued by March 31, 2011. When issued, investors will receive 3,473,008 shares of common stock. In connection with this private placement, the Company will issue 347,301 shares of common stock to the Placement Agent as commission for the shares of common stock sold to 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"), 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 March 31, 2011 the Company sold shares of common stock for \$1,041,902 in cash to investors pursuant to a private placement memorandum. These shares were not issued by March 31, 2011. When issued, investors will receive 3,473,008 shares of common stock. In connection with this private placement, the Company will issue 347,301 shares of common stock to the Placement Agent as commission for the shares of common stock sold to investors.

As of March 31, 2011, there were 49,400,605 shares of common stock issued and outstanding. There are no preferred shares outstanding as of March 31, 2011.

9. Stock Options and Warrants

Stock Options - There were no stock option awards granted in 2009. Total stock option expense for the year 2009 totaled \$588,857.

There were no stock option awards in 2010. Total stock option expense for the year 2010 totaled \$477,356.

In February of 2011 the Company made a stock option grant for services to purchase in the aggregate 20,000 shares of the Company's common stock. Terms of the stock option grant require, among other things, that the individual continues to provide services over the vesting period of the option, which is four years from the date that the option was granted. The exercise price of the option is \$0.53 a share, which was the closing price of the common stock at the date of grant. The stock option grant was not for current management and officers of the Company. The Company determined the fair value of the stock options granted using the Black Scholes model and expenses this value monthly based upon the vesting schedule of the stock option award. For purposes of determining fair value, the Company used an average annual volatility of one hundred sixty six percent (166%), which was calculated based on the closing price of the Company's stock over the preceding five years. The risk free rate of interest used in the model was taken from a table of the market rate of interest for U. S. Government Securities for the date of the stock option award and the effective term. The total value of the stock option granted was determined using this methodology to be \$10,260, which is being expensed over the four years following the date of grant based on the stock option vesting schedule.

Total stock option expense for the first quarter of 2011 totaled \$119,981. Of this amount, \$15,205 related to stock options for personnel involved in R&D activities and \$104,776 related to stock options for management involved in general and administrative functions.

Warrants - There were no warrants for services granted in 2009 and there was no warrant expense for the year 2009. There were no warrants for services granted in 2010 and there was no warrant expense for the year 2010. There were no warrants for services granted in the first quarter of 2011 and there was no warrant expense for the first quarter 2011. Warrants issued in connection with the sale of units of common stock were for cash value received and as such were not grants of compensation-based warrants.

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 and to develop liposome tumor targeting technology. These licenses require, among other things, the Company to reimburse MD Anderson for ongoing patent expense. Accrued license payments totaling \$75,000 are included in Current Liabilities as of March 31, 2011. As of March 31, 2011, the Company estimates reimbursable patent expenses will total approximately \$150,000 for the antisense license. The Company will be required to pay when invoiced the patent expenses at the rate of \$25,000 per quarter.

Drug Supplier Project Plan - In June of 2008, Bio-Path entered into a Project Plan agreement with a contract drug manufacturing supplier for delivery of drug product to support commencement of the Company's Phase I clinical trial of its first cancer drug product. The Company commenced this trial and was enrolling patients by the end of the second quarter 2010. Previously in 2008 and 2009, the Company paid \$608,440 to this manufacturer and its drug substance raw material supplier. During the first quarter 2011, \$88,400 previously carried on the balance sheet as of December 31, 2010 as prepaid drug product for testing was charged to R&D expense after the manufacturer delivered the final lot of drug product under this contract to the Company. As of March 31, 2011 there were no further obligations under the drug supplier project plan with the contract manufacturer.

11. Subsequent Events

During the fourth quarter of 2010 and the first quarter 2011, the Company sold shares of its common stock through a Private Placement Memorandum. At the end of April, 2011, the Company concluded its efforts in this Private Placement, having sold, or agreed to sell, approximately \$1.8 million of its common stock for cash. When fully issued, investors will receive 3,473,008 shares of common stock. The Placement Agent for this offering received a cash commission of ten percent (10%) and will be issued of one share of the Company's common stock for each 10 shares sold and issued to investors. As a result, in addition to cash commissions paid in connection with this private placement, the Company will issue 347,301 shares of common stock to the Placement Agent as commission for the shares of common stock sold to investors. The Company expects to issue all shares owed to investors and Placement Agent under this private placement no later than May 31, 2011.

12. New Accounting Pronouncements

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



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

When you read this section of this Quarterly Report on Form 10-Q, it is important that you also read the unaudited financial statements and related notes included elsewhere in this Form 10-Q and our audited financial statements and notes thereto included in our Annual Report on Form 10-K as of and for the fiscal year ended December 31, 2010. 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 in our 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, 2010, 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., through our wholly-owned subsidiary Bio-Path, Inc. (“Bio-Path Subsidiary”), is engaged in the business of financing and facilitating the development of novel cancer therapeutics. Our initial plan is and continues to be, the acquisition of licenses for drug technologies from The University of Texas MD Anderson Cancer Center (“MD Anderson”), funding clinical and other trials for such technologies and to commercialize such technologies. We have acquired three exclusive licenses (“License Agreements”) from MD Anderson for three lead products and related nucleic acid drug delivery technology, including tumor targeting technology. These licenses specifically provide drug delivery platform technology with composition of matter intellectual property that enables systemic delivery of antisense, small interfering RNA (“siRNA”) and potentially small molecules for the treatment of cancer.

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

Bio-Path Subsidiary was formed in May 2007. Bio-Path acquired Bio-Path Subsidiary in February 2008 in a reverse merger transaction (the “Merger”).

Our principal executive offices are located at 3293 Harrison Boulevard, Suite 220, Ogden, UT 84403. Our telephone number is (801) 580-2326. 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. A summary of the material terms of the License Agreements are detailed in our Annual Report on Form 10-K as of and for the fiscal year ended December 31, 2010. As the Company looks to expand its pipeline of drugs in the future, it may develop small, leased laboratory space where preparation of new drug product candidates can be controlled. Produced quantities of these new drug candidates would then be sent to contract research laboratories to complete preclinical toxicity and efficacy testing programs in animals needed for the submission of an Investigational New Drug (IND)

application to the U.S. Food and Drug Administration (FDA) for the drug candidate to commence a Phase I clinical trial.

#### 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 modify the genetic material RNA to treat disease. RNA is essential in the process of creating proteins. The “i” in RNAi stands for “interference.” We intend to develop drugs and drug delivery systems that are intended to work by using RNA to interfere with the production of proteins associated with disease. The discovery of RNAi, in 1998, has led not only to its widespread use in the research of biological mechanisms and target validation, but also to its application in down-regulating the expression of certain disease-causing proteins found in a wide spectrum of diseases including inflammation, cancer, and metabolic dysfunction. RNAi-based therapeutics work through a naturally occurring process within cells that has the effect of reducing levels of messenger RNA (mRNA) required for the production of proteins. At this time, several RNAi-based therapeutics are being evaluated in human clinical trials.

The historical perspective of cancer treatments has been 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 and siRNA, are two of the most promising fields of targeted therapy. Development of antisense and siRNA, 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 RNAi drug, which will be clinically tested for validation in Acute Myeloid Leukemia (AML), Myelodysplastic Syndrome (MDS) and Chronic Myelogenous Leukemia (CML). If this outcome is favorable, we expect there will be opportunities to negotiate non-exclusive license applications involving upfront cash payments with pharmaceutical companies developing antisense drugs that need systemic delivery technology.

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

On July 29, 2010, we announced that we began the dosing of patients at the MD Anderson Cancer Center. The Phase I clinical trial of BP-100-1.01 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. The trial will evaluate five doses of L-Grb-2 and 18 to 30 patients may be accrued into the study. The clinical trial is being conducted at The University of Texas MD Anderson Cancer Center.

At the end of the first quarter 2011, seven patients have been enrolled into the study, with another two additional patients in the process of being enrolled at the end of March 2011. Patients eligible for enrollment 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. At the low initial dose levels in the clinical trial, it has taken longer than expected for the Principal Investigator to recruit patients into the trial. In addition, four of the initial patients were unable to stay on the entire four week treatment cycle because of progressive disease, which was unrelated to treatment with Liposomal Grb-2, and consequently, had to be withdrawn from the study before completion of testing.

It is important to note two of the three patients that completed the full four week treatment cycle of the Phase I trial were placed on continuing treatment for additional cycles based on the Principal Investigator's assessment that they were receiving benefit from the drug. Bio-Path's FDA-approved protocol for the Phase I clinical trial provides that the Principal Investigator may continue treatment of a patient beyond the initial cycle if, in the Principal Investigator's opinion the patient is exhibiting stable disease, or else, have improvement of their disease. In the circumstance where a patient is continuing treatment beyond the requirements of the Phase I trial, the Company is required to supply drug at no charge for the continuing treatments but does not incur additional hospital costs. Although it is too early to draw any scientific conclusions about any effect that the Company's drug candidate Liposomal-Grb-2 has on patients being treated in the trial, the effects of apparent stabilization in some patients is expected to help in recruiting new patients into the clinical trial. In this regard, the Company was very encouraged by the recent new enrollments into the trial.

The Company expects that an additional 12 months could be required to complete the Phase I clinical trial. We are seeking an additional 13-16 patients to complete the trial. Since, at the Principal Investigator's recommendation, some patients who are benefiting from the treatment are being placed on continuing therapy beyond the requirements of the clinical trial, additional expenses may be incurred as the Company is required to supply drug at no charge for the continuing treatment. Additional costs to completion of the Phase I clinical trial are estimated to range from \$750,000 to \$1.2 million. We will reimburse MD Anderson at the rate of approximately \$13,000 per patient for treating patients in the study. We currently expect to reimburse MD Anderson a total of approximately \$200,000 spread out over one year for patient treatment costs. Bio-Path believes it has sufficient resources and access to additional resources if needed to meet its obligations in this regard.



It is noted that the difficulty that the Company and the Principal Investigator for the clinical trial have in estimating the rate of progress through the Phase I clinical trial is due to two factors: (1) the rate of patient accrual into the trial, and (2) the ability of a patient who has started treatment to complete a full treatment cycle. It has been noted previously that it has been difficult initially for the Principal Investigator to recruit patients into the trial, primarily because eligibility requires patients who are refractory or relapsed to existing treatments and the very low starting dose (which the FDA determined) offered little prospect of benefit in treating their disease. However, the fact that some patients were benefiting from treatment, even at low starting doses, is expected to improve patient recruitment. The second factor relates to a patient's ability to complete the full treatment cycle (four weeks). The patients in this clinical trial are very advanced in their disease, but while on treatment cycle, they are not allowed to receive any other chemotherapy. As a result, many patients who have started treatment had to withdraw due to progression of the disease, which was unrelated to treatment from Liposomal Grb-2. If a patient does not complete the entire treatment cycle, then that patient is not deemed evaluable for the trial, and a new patient must be recruited and treatment started again. Although the above factors make it more challenging to progress through the early stages of the Company's clinical trial, the positive side is that benefitting these patients could result in faster FDA approvals of Liposomal Grb-2 as standard treatment.

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

#### BP-100-1.02

BP-100-1.02 is Bio-Path's co-lead compound. The scientific name for BP-100-1.02 is liposomal Bcl-2, a liposome delivered antisense cancer drug that targets the lymphoma and certain solid tumor markets.

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

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

#### BP-100-2.01

BP-100-2.01 is our lead siRNA drug, which will be clinically tested for validation as a novel, targeted ovarian cancer therapeutic agent. The Company prepared a review package of the testing material for this drug product and reviewed the information with the FDA. Based on this review and feedback, performing the remaining pre-clinical development work for BP-100-2.01 expected to be required for an IND is budgeted for \$225,000. The additional pre-clinical work is expected to include two toxicity studies in mice and primates.

## Projected Financing Needs

In December of 2010, we anticipated that we needed to raise an additional \$10,000,000 to enable us to complete all projected clinical trials for our product candidates and conduct certain additional clinical trials in other Bio-Path drug candidates. The completion of the LPC Purchase Agreement may provide us with up to \$6,500,000 in new capital. A summary of the material terms of the LPC Purchase Agreement are detailed in our Annual Report on Form 10-K as of the fiscal year ended December 31, 2010. In addition to the LPC Purchase Agreement, in February 2011, we received grant funds from the U. S. Government in the amount of \$244,479, and we have through April 30, 2011 raised a total of \$1,794,206 in gross proceeds through a Private Placement Offering. This infusion of capital has produced current cash balances of approximately \$1,400,000 (including the balance of \$300,000 in escrow from the sale of common stock through a private placement memorandum), thereby reducing the additional \$10,000,000 requirement to approximately \$8,600,000. These amounts of funding and related existing cash balances, are expected to support clinical develop of our lead products and sustain operations through the end of second quarter Fiscal Year 2014. The remainder of the Phase I clinical trial of BP-100-1.01 is expected to cost between \$750,000 and \$1,200,000 with a mid-point of \$1,000,000. If the Phase I clinical trial in BP-100-1.01 is successful, we will follow with a Phase IIa trial in BP-100-1.01, subject to available capital. Successful Phase I and IIa trials of BP-100-1.01 will demonstrate clinical proof-of-concept that BP-100-1.01 is a viable therapeutic drug product for treatment of AML, MDS and CML. The Phase IIa clinical trial in BP-100-1.01 is expected to cost approximately \$1,600,000.

The Phase I clinical trial of BP-100-1.02 is expected to cost \$2,000,000. Commencement of the Phase I clinical trial depends on the FDA approving the IND for BP-100-1.02 and is subject to available capital. However, the Company does not expect any concerns with FDA approval of the IND for this drug since the safety profile of this class of liposomal antisense drug products will have been well-established by the Phase I clinical trial of BP-100-1.01. Success in the Phase I clinical trial will be based on the demonstration that the delivery technology for BP-100-1.02 has the same delivery characteristics seen in the on-going Phase I clinical trial of BP-100-1.01. As such, if the on-going Phase I clinical trial for BP-100-1.01 proves successful, a significant pathway is established laying the foundation for BP-100-1.02. Finally, \$1,100,000 is budgeted to commence a Phase I clinical trial in Liposomal siRNA FAK or another liposomal nucleic acid drug candidate.

We have currently budgeted approximately \$975,000 out of the approximate \$10,000,000 in net proceeds to be raised for additional drug development opportunities. The balance of the funding is planned to fund patent expenses, licensing fees, pre-clinical costs to MD Anderson's Pharmaceutical Development Center, consulting fees and management and administration.

In the aggregate, the additional capital requirements of \$10,000,000 are expected to fund operations through the second quarter of 2014 including the completion of the Phase I clinical trial of BP-100.1.01 (\$1,000,000), the Phase I clinical trial of BP-100.1.02 (\$2,000,000), the Phase II clinical trial of BP-100-1.01 (\$1,600,000), initiation but not completion of a Phase I clinical trial in Liposomal siRNA FAK or other new drug candidate (\$1,400,000), license-related payments to MD Anderson (\$365,000), provision to in-license new targets and compounds for development (\$975,000) and general and administrative costs for the organization for operations through the second quarter 2014 (\$2,660,000). Costs for personnel directly related to the clinical trial are included in those program estimates. Timing and costs for this plan are best estimates at this point in time and could vary depending on the availability of capital, the rate of enrollments in clinical trials and other factors not controlled by the Company.

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

There can be no assurance of the following:

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

#### Background Information about MD Anderson

We anticipate that our initial drug development efforts will be pursuant to three exclusive License Agreements with MD Anderson. MD Anderson's stated mission is to "make cancer history" ([www.mdanderson.org](http://www.mdanderson.org)). Achieving that goal begins with integrated programs in cancer treatment, clinical trials, educational programs and cancer prevention. MD Anderson is one of the largest and most widely recognized cancer centers in the world: U.S. News & World Report's "America's Best Hospitals" survey has ranked MD Anderson as one of 2 best hospitals for 16 consecutive years. MD Anderson will treat more than 100,000 patients this year, of which approximately 11,000 will participate in therapeutic clinical research exploring novel treatments

which is the largest such program in the nation. MD Anderson employs more than 15,000 people including more than 1,000 Medical Doctors and Ph.D clinicians and researchers, and is routinely conducting more than 700 clinical trials at any one time.

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

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

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

#### Relationship with MD Anderson

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

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

Bio-Path's Chief Executive Officer is experienced in working with MD Anderson and its personnel. Bio-Path believes that if Bio-Path obtains adequate financing, Bio-Path will be positioned to help develop 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 for out-licensing to pharmaceutical partners.

#### Licenses

Bio-Path Subsidiary has negotiated and signed three licenses with MD Anderson for late stage preclinical molecules, and intends to use our relationship with MD Anderson to develop these drug compounds 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 biotech industry. In certain cases, we may choose to complete development and market the product ourselves. Our basic guide to a decision to obtain a license for a potential drug candidate is as follows:

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

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

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

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

#### Out-Licenses and Other Sources of Revenue

Subject to adequate capital, we intend to develop a steady series of drug candidates through Phase IIa clinical trials and then to engage in a series of out-licensing transactions to the pharmaceutical and biotechnology companies. These 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.

In addition to this source of revenue and value, we may forward integrate one or more of our own drug candidates. For example, there are certain cancers that are primarily treated only in a comprehensive cancer center; of which there are approximately forty in the US and perhaps two hundred throughout the world. Hence, "marketing and distribution"

becomes a realistic possibility for select products. These candidates may be eligible for Orphan Drug Status which provides additional incentives in terms of market exclusivities and non-dilutive grant funding for clinical trials.

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

#### License Agreements

We have entered into the License Agreements with MD Anderson relating to its technology. These License Agreements relate to the following technologies: 1) a lead siRNA drug product; 2) two single nucleic acid (antisense) drug products; and 3) delivery technology platform for nucleic acids. These licenses require, among other things, the Company to reimburse MD Anderson for ongoing patent expense. One license requires the Company to raise at least \$2.5 million in funding and, based on the aggregate amount raised, the Company has agreed to sponsor additional research at MD Anderson's laboratories. To maintain our rights to the licensed technology, we must meet certain development and funding milestones. A summary of the material terms of the licenses are detailed in our Annual Report on Form 10-K as of and for the fiscal year ended December 31, 2010.

## Business Strategy

Our plan of operation over the next 36 months is focused on achievement of milestones with the intent to demonstrate clinical proof-of concept of our drug delivery technology and lead drug products. Furthermore, subject to adequate capital, we will attempt to validate our business model by in-licensing additional products to broaden our drug product pipeline.

At March 31, 2011, we anticipated that over the next 36 months we would need to raise approximately \$8,600,000 to completely implement our current business plan. Completion of the LPC Purchase Agreement may provide up to \$6,500,000 in new funding. Over the next three years we expected to raise additional capital to complete our funding plan. We have previously completed several financings for use in our Bio-Path operations and have received total net proceeds of \$5,510,137 as of March 31, 2011. Our short term plan is to achieve the following key milestones:

- 1) Complete the Phase I clinical trial of our lead drug BP-100-1.01, which if successful, will validate our liposomal delivery technology for nucleic acid drug products including siRNA. In this Phase I trial, we will leverage MD Anderson's pre-clinical and clinical development capabilities, including using the PDC for pre-clinical studies as well as clinical pharmacokinetics and pharmacodynamics and the institution's world-renowned clinics, particularly for early clinical trials. This should allow us to develop our drug candidates with experienced professional staff at a reduced cost compared to using external contract laboratories. This should also allow us to operate in an essentially virtual fashion, thereby avoiding the expense of setting up and operating laboratory facilities, without losing control over timing or quality or IP contamination. Effective July 29, 2010, we began dosing of patients of this lead drug – BP-100-1.01 at MD Anderson;
- 2) Perform necessary pre-clinical studies in our second liposomal antisense drug candidate, BP-100-1.02 to enable the filing of an Investigational New Drug (“IND”) for a Phase I clinical trial; and
- 3) Out-license (non-exclusively) our delivery technology for either antisense or siRNA to a pharmaceutical partner to speed development applications of our technology.

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

- 1) 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;
- 2) Use our Scientific Advisory Board to supplement our management team to critically monitor existing programs and evaluate new technologies and/or compounds discovered or developed at MD Anderson, or elsewhere, for in-licensing;
- 3) Hire a small team of employees or consultants: business development, regulatory management, and project management; and
- 4) Outsource manufacturing and regulatory capabilities. Bio-Path will not need to invest its resources in building functions where it does not add substantial value or differentiation. Instead, it will leverage an executive team with expertise in the selection and management of high quality contract manufacturing and regulatory firms.

## Manufacturing

We have no manufacturing capabilities and have developed relationships with third party contract manufacturers and suppliers to supply our drug product requirements. In September of 2008, we executed a Supply Agreement with Althea Technologies, Inc., a cGMP manufacturer of pharmaceutical products, for the supply of drug product needed for Bio-Path's clinical trial in Liposomal Grb-2 (BP-100-1.01). Althea has supplied clinical grade Liposomal Grb-2 under this agreement that is currently being used in a Phase I clinical trial. The Company will continue to evaluate its manufacturing strategy as its product portfolio is developed and demand for future Bio-Path drug products increases.



## Intellectual Property

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

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

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

## Agreement with Acorn CRO

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

## Competition

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

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

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

## Government Regulation

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

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

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

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

adequate and well-controlled clinical trials to establish the safety and efficacy of the drug;

the submission of a new drug application or biologic license application to the FDA; and

FDA review and approval of the new drug application or biologics license application.

Bio-path's business model relies on entering into out-license agreements with pharmaceutical licensee partners who will be responsible for post-Phase IIA clinical testing and working with the FDA on necessary regulatory submissions resulting in approval of new drug applications for commercialization. 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, 2010.

Results of Operations for the three months ended March 31, 2011 and 2010.

Revenues. We have no operating revenues since our inception. We had interest income of \$191 for the three months ended March 31, 2011 compared to \$602 for the three months ended March 31, 2010. Our interest income was derived from cash and cash equivalents net of bank fees.

Research and Development Expenses. Our research and development costs were \$192,499 for the three months ended March 31, 2011; a decrease of \$28,456 from the three months ended March 31, 2010. These expenses included non-cash stock option expense of \$15,205 and \$36,176 for the quarters ending on March 31, 2011 and 2010, respectively. In addition the company expensed a total of \$50,000. to a related party; MD Anderson received \$25,000 in cash from the Company for R&D related expense, plus an additional \$25,000 in expense was accrued, and \$32,432 in cash for patent expense related to the Company's Technology License.

General and Administrative Expenses. Our general and administrative expenses were \$350,238 for the three months ended March 31, 2011; an increase of \$79,650 from the three months ended March 31, 2010 primarily due to increased accounting, legal and insurance expenses, increased expenses related to being a public company, increased personnel expenses and higher travel expenses. These expenses included non-cash stock option expense of \$104,776 and \$107,770 for the quarters ending March 31, 2011 and 2010, respectively.

Net Loss. Our net loss was \$592,726 for the three months ended March 31, 2011, compared to a loss of \$490,941 for the three months ended March 31, 2010. Net loss per share, both basic and diluted was \$0.01 and \$0.01 for the respective 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.

From November 2010 through March 31, 2011 the Company sold shares of common stock for \$1,041,902 in cash to investors pursuant to a private placement memorandum. These shares were not issued by March 31, 2011. When issued, investors will receive 3,473,008 shares of common stock. In connection with this private placement, the Company will issue 347,301 shares of common stock to the Placement Agent as commission for the shares of common stock sold to investors.

At March 31, 2011, we had cash of \$765,768 compared to \$238,565 at December 31, 2010. The increase in the quarter is primarily from the sale of common stock in this first quarter through a Private Placement Offering. 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, 2011 was \$124,971 compared to \$286,502 for the three months ended March 31, 2010. The significant decrease in net cash used results from the receipt of the grant award of \$244,479 during the three months ended March 31, 2011. Inasmuch as we have not yet generated revenues, our entire expenses of operations are funded by our cash assets.

Currently all of our cash is, and has been, generated from financing activities. We raised a total of \$684,606 cash from financing activities for the three months ended March 31, 2011. Since inception we have net cash from financing activities of \$5,510,137. As discussed in Projected Financing Needs above, we believe that our available cash will be sufficient to fund our liquidity and capital expenditure requirements through December 2011. We need to raise additional capital, in order to fund our operations after the end of December 2011. There can be no assurance that we will be able to raise cash when it is needed to fund our operations.

We believe that our available cash will be sufficient to fund our liquidity and capital expenditure requirements through the fiscal year ending December 31, 2011. We anticipate that we will need to raise approximately an additional \$8,000,000 in net proceeds to completely implement our business plan. However, we have several discussions underway with potential investors at this time which could result in us receiving sufficient capital to extend our operations into 2012 and possibly even 2013. There is no assurance or guarantee that we will raise any additional capital.

## Contractual Obligations and Commitments

Bio-Path has recently entered into two Patent and Technology License Agreements (the “Licenses”) with MD Anderson relating to its technology. A summary of certain material terms of each of the Licenses is detailed in our Annual Report on Form 10-K as of and for the fiscal year ended December 31, 2010.

In June of 2008, Bio-Path entered into a Project Plan agreement with a contract drug manufacturing supplier for delivery of drug product to support commencement of the Company’s Phase I clinical trial of its first cancer drug product. The Company commenced this trial and was enrolling patients by the end of the second quarter 2010. Previously in 2008 and 2009, the Company paid \$608,440 to this manufacturer and its drug substance raw material supplier. During the first quarter 2011, \$88,400 previously carried on the balance sheet as of December 31, 2010 as prepaid drug product for testing was charged to R&D expense after the manufacturer delivered the final lot of drug product under this contract to the Company. As of March 31, 2011 there were no further obligations under the drug supplier project plan with the contract manufacturer.

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

## Critical Accounting Policies

The preparation of financial statements in conformity with generally accepted accounting principles (“GAAP”) in the United States has required the management of the Company to make assumptions, estimates and judgments that affect the amounts reported in the financial statements, including the notes thereto, and related disclosures of commitments and contingencies, if any. The Company considers its critical accounting policies to be those that require the more significant judgments and estimates in the preparation of financial statements. Our significant accounting policies are discussed in Note 2 to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2010.

## 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, 2011, 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, 2011.

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

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 1A. RISK FACTORS

Information not required for smaller reporting companies.

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

From November 2010 through March 31, 2011, the Company has issued or has agreed to issue, 3,473,008 shares of its common stock (exclusive of shares of its common stock issued or to be issued to the Placement Agent as described below), pursuant to subscription agreements with certain accredited investors in exchange for aggregate consideration of \$1,041,902. The Company engaged ACAP Financial, Inc. (the “Placement Agent”) as placement agent in connection with the sale of such shares. As consideration for its services, the Company has agreed to pay to the Placement Agent 10% of the gross proceeds from the sale of the shares of its common stock sold pursuant to such subscription agreements and to issue to the Placement Agent one share of its common stock for each ten shares of common stock sold by the Placement Agent. The Company’s efforts in this private placement continued until April 30, 2011. The total gross proceeds the Company raised pursuant to such sale of securities was \$1,794,205, representing total shares to be issued of 5,980,684, of which 598,068 are to be issued to the Placement Agent. None of such shares have yet been issued. Such shares were sold by the Company pursuant to Section 4(2) and/or Rule 506 of Regulation D promulgated under the Securities Act of 1933, as amended. The proceeds from the sale of such shares are to be used to fund working capital to continue and expand the Company’s ongoing business.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. (Removed and Reserved)

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit No.	Description of Exhibit
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	

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Specimen Stock certificate (incorporated by reference to exhibit 3.2 to the registrant's current report on Form 8-A filed on September 10, 2008)

31\* Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Section 302 of the Sarbanes Oxley Act of 2002.

32\* Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Section 906 of the Sarbanes Oxley Act of 2002.

\* Filed herewith.

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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 16, 2011

BIO-PATH HOLDINGS, INC.

By

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