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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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	87-0652870
(State or other jurisdiction of incorporation or organization	(I.R.S. employer identification No.)

2626 South Loop, Suite 180, Houston, TX 77054
(Address of principal executive offices)

Registrant's telephone no., including area code: (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 ☒

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

At November 10, 2011, the Company had 58,066,296 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, 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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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 September 30, 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 formulation intellectual property for small interfering RNA ("siRNA"). Bio-Path has also licensed 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 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 also expects to broaden its technology to include cancer drugs other than antisense and siRNA, including drug candidates licensed from institutions other than MD Anderson.

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

Bio-Path is currently treating patients with its lead cancer drug candidate Liposomal Grb-2 (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 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 given to between 18 to 30 evaluable patients. An evaluable patient is a patient who is able to complete the four-week treatment cycle. The clinical trial is being conducted at The University of Texas MD Anderson Cancer Center.

Patients eligible for enrollment into the Phase I clinical trial have refractory or relapsed Acute Myeloid Leukemia (AML), Philadelphia Chromosome Positive Chronic Myelogenous Leukemia (CML) and Acute Lymphoblastic Leukemia (ALL), or Myelodysplastic Syndrome (MDS) and who have failed other approved treatments. These are patients with very advanced stages of the disease, and consequently, not all patients enrolled are able to complete the four-week treatment cycle because of progressive disease, which is unrelated to the treatment with Liposomal-Grb-2. Enrollment continued in the Phase I clinical trial through the end of the third quarter 2011.

At the end of July 2011, the sixth evaluable patient completed the full treatment cycle. This completed requirements for the first cohort. The Company, its medical advisors and the Principal Investigator agreed that the data demonstrated that Liposomal Grb-2 was safe enough to proceed to the next cohort of the trial, which will treat patients in the trial with a dose that is 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. As of the end of September 2011, enrollment continued in the second cohort of the clinical trial.

The Principal Investigator for the Phase I clinical trial, Dr. Jorge Cortes, is a leading expert in the treatment of CML, AML and ALL. Because the results of the first cohort produced unexpected and clinically interesting results in some patients, the Principal Investigator prepared an abstract of the results of the first cohort that was submitted in for review and potential inclusion at the American Hematology Society annual meeting in December. Subsequently, Dr. Cortes was notified that the abstract was accepted for presentation as a poster at the meeting.

The Company expects that the Phase I clinical trial will be completed during 2012. Since, at the Principal Investigator's

recommendation, some patients who are benefiting from the treatment are being placed on continuing therapy beyond the requirements of the clinical trial, additional expenses may be incurred as the Company is required to supply drug at no charge for the continuing treatment. Additional costs to completion of the Phase I clinical trial are estimated to range from $500,000 to $1.0 million. Bio-Path believes it has sufficient resources and access to additional resources if needed to meet its obligations in this regard.

An important outcome for the Phase I clinical trial is the ability to assess for the first time the performance of the Company's delivery technology platform in human patients. The Company has developed two new assays to be able to provide scientific proof of concept of the delivery technology. The first involves a novel detection method for the drug substance in blood samples that will be used to assess the pharmacokinetics of the drug. The second involves a method to measure the amount of down regulation of the target protein in a patient blood sample that was achieved. The latter measurement will provide critical proof that the neutral liposome delivery technology delivered the drug substance to the cell and was able to transport it across the cell membrane into the interior to block cellular production of the Grb-2 protein.

Being platform technology, a successful demonstration of the delivery technology in this study will allow the Company to immediately begin expanding Bio-Path's drug candidates by applying the delivery technology template to multiple new drug product targets. In this manner, Bio-Path believes that it can quickly build an attractive drug product pipeline with multiple drug product candidates for treating cancer as well as treating other important diseases, such as 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 the third quarter 2011, the Company had $983,286 in cash on hand as of September 30, 2011, including $142,000 raised through investors' exercise of warrants. 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 third quarter ending September 30, 2011, MD Anderson received $25,000 in cash from the Company for patent expenses previously accrued and related to the Company's Technology License, plus an additional $50,000 in expense was accrued for R&D related clinical trial expense. As of September 30, 2011, the Company had accrued expenses due to the related party totaling $150,000, comprised of $50,000 in accrued license payments related to the Company's Technology License and $100,000 in accrued R&D related expense for the clinical trial. 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 September 30, 2011, the Company had supplies of drug product on hand for use in the clinical trial estimated to be sufficient for requirements through the end 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 September 30, 2011, Current Liabilities included accrued expense of $111,862. R&D expenses related to MD Anderson treating patients in the Phase I clinical trial comprised $100,000 of this amount. Accrued expenses for corporate communication and travel to suppliers, meetings and conferences represented the balance of accrued expenses.

6. Accrued License Payments – Related Party

Accrued license payments – related party totaling $50,000 were included in Current Liabilities as of September 30, 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. At the end of the second quarter 2011, the Company closed this offering and issued 928,667 shares of common stock to these investors. At the end of September 2011, the Company raised $142,000 through investors' exercise of warrants to purchase shares of common stock for cash. These shares were not issued by the September 30, 2011 end of the quarter. Subsequently in October of 2011, 473,334 shares of common stock were issued 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"), 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.

As of September 30, 2011, there were 56,146,296 shares of common stock issued and outstanding. There are no preferred shares outstanding as of September 30, 2011.

9. Stock Options and Warrants

Stock Options **-** 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 granted a stock option 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 Company used the simplified method to determine the expected term of the options due to the lack of historical data. 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.

In June of 2011 the Company made two stock option grants to purchase in the aggregate 125,000 shares of the Company's common stock for service as a director of the Company and for consulting services. 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 one year from the date of grant for the director service stock option and four years from the date of grant for the consulting service stock option. The exercise price of

the options is $0.33 a share, which was the closing price of the common stock at the date of grant. The stock option grants were 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 two percent (162%), 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 Company used the simplified method to determine the expected term of the options due to the lack of historical data. The total fair value of the stock option granted was determined using this methodology to be $39,600, which is being expensed following the date of grant based on the stock option vesting schedule.

Total stock option expense for the second quarter of 2011 totaled $120,684. Of this amount, $16,082 related to stock options for personnel involved in R&D activities and $104,602 related to stock options for management involved in general and administrative functions and directors.

There were no stock option grants in the third quarter of 2011. Total stock option expense for the third quarter of 2011 totaled $122,897. Of this amount, $17,406 related to stock options for personnel involved in R&D activities and $105,491 related to stock options for management involved in general and administrative functions and directors.

Warrants **-** 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 year 2011 through the third quarter of 2011 and there was no warrant expense in the year 2011 through the third quarter of 2011. Warrants previously issued in connection with the sale of units of common stock were for cash value received and as such were not grants of compensation-based warrants.

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 $50,000 are included in Current Liabilities as of September 30, 2011. As of September 30, 2011, the Company estimates reimbursable past patent expenses will total approximately $100,000 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 June 30, 2011, there were no further obligations under this drug supplier project plan with the contract manufacturer. Subsequently, in October of 2011, the Company entered into a new project plan agreement with its contract manufacturing supplier for a batch of drug product with expected delivery by year end. The project plan requires the company to pay the supplier $177,440 for this drug product.

11. Subsequent Events

In October of 2011, the Company raised $434,000 through investors' exercise of warrants to purchase common stock for cash. Including the $142,000 exercise of warrants by investors at the end of September of 2011, the Company raised $576,000 through investors exercising warrants to purchase common stock for cash during the end of September through October 2011 timeframe. A total of 1,920,000 shares were issued to these investors. No cash or stock commissions were owed from these equity sales.

In October of 2011, the Company entered into a new project plan agreement with its contract manufacturing supplier for a batch of drug product with expected delivery by year end. The project plan requires the Company to pay the supplier $177,440 for this drug product. See Note 10.

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 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, 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. (together with its subsidiary, "Bio-Path" or the "Company" or "we," "us" or "our") 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.

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.

Our principal executive offices are located at 2626 South Loop, Suite 180, Houston Texas, 77054. Our telephone number is (801) 580-2326. Our Internet website address is www.biopathholdings.com, and all of our filings with the Securities and Exchange Commission are available free of charge on our website.

Research and Development

Our research and development is currently conducted through agreements we have with MD Anderson. 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).

RNA is essential in the process of creating proteins. We intend to develop antisense and siRNA drugs and drug delivery systems that are intended to interfere with the production of proteins associated with disease.

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 it is intended that a sufficient number of 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 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. Enrollment continued in the Phase I clinical trial through the end of the third quarter of 2011, with seventeen patients having been enrolled into the study. At the low initial dose levels in the clinical trial, it initially took longer than expected for the Principal Investigator to recruit patients into the trial.

At the end of July 2011, the sixth evaluable patient completed the full treatment cycle. This completed requirements for the first cohort. The Company, its medical advisors and the Principal Investigator agreed that the data demonstrated that Liposomal Grb-2 was safe enough to proceed to the next cohort of the trial, which will treat patients in the trial with a dose that is 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. As of the end of September 2011, enrollment continued in the second cohort of the clinical trial.

The Principal Investigator for the Phase I clinical trial, Dr. Jorge Cortes, is a leading expert in the treatment of CML, AML and ALL. Because the results of the first trial produced unexpected and clinically interesting results in some patients, the Principal Investigator prepared an abstract of the results of the first cohort that was submitted in for review and potential inclusion at the American Hematology Society annual meeting in December. Subsequently, Dr. Cortes was notified that the abstract was accepted for presentation as a poster at the meeting.

It is important to note that two patients in the first cohort 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 treatment with the drug Liposomal Grb-2 was benefiting these patients. This was described as a remarkable and unexpected result based on the initial, low dose being given to patients in the first cohort. 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 his or her disease. In the circumstance where a patient is continuing treatment beyond the requirements of the Phase I trial, the Company is required to supply the drug at no charge for the continuing treatments but

it is not required to 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.

The Company expects to complete the Phase I clinical trial during 2012. Since, at the Principal Investigator's recommendation, some patients who are benefiting from the treatment are being placed on continuing therapy beyond the requirements of the clinical trial, additional expenses may be incurred as the Company is required to supply drug at no charge for the continuing treatment. Additional costs to completion of the Phase I clinical trial are estimated to range from $500,000 to $1 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 $300,000 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.

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.

In October of 2011 the Company entered into a new project plan agreement with its contract manufacturing supplier for a batch of drug product with expected delivery by year end. The project plan requires the company to pay the supplier $177,440 for this drug product.

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

As of September of 2011, we anticipate that we need to raise an additional $8,600,000 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 $6,450,000 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. In addition at the end of the third quarter 2011, the Company raised $142,000 through investors' exercise of warrants to purchase common stock for cash. Bio-Path had $983,286 in cash on hand as of September 30, 2011. In October of 2011, the Company raised an additional $434,000 through investors' exercise of warrants to purchase common stock for cash. Including the $142,000 exercise of warrants by investors at the end of September of 2011, in aggregate the company raised $576,000 through investors exercising warrants to purchase common stock for cash during the end of September through October 2011 timeframe. A total of 1,920,000 shares were issued to these investors. No cash or stock commissions were owed from these equity sales.

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

As of the end of October, 2011, this infusion of capital from the exercise of the warrants has produced current cash balances of approximately $1,300,000. The amounts of future funding required, and related existing cash balances, are expected to support clinical develop of our lead products and sustain operations through the end of second quarter of 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 1 clinical trial in Liposomal siRNA FAK or another liposomal nucleic acid drug candidate.

We have currently budgeted approximately $975,000 out of the approximate $8,600,000 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 approximately $8,600,000 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 – as of September 30, 2011 the Company has cash of $983,286 to finance the completion of this trial. The Phase I clinical trial of BP-100.1-02 ($2,000,000), the Phase II clinical trial of BP-100-1.01 ($1,600,000), initiation but not completion of a Phase I clinical trial in Liposomal siRNA FAK or other new drug candidate ($1,100,000), 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 four 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). 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 30 months is focused on achievement of milestones with the intent to demonstrate clinical proof-of concept of our drug delivery technology and lead drug products. Furthermore, subject to adequate capital, we will attempt to validate our business model by in-licensing additional products to broaden our drug product pipeline.

At September 30, 2011, we anticipated that over the next 30 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 $6,450,000 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 $6,358,956 as of September 30, 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 of 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.

In July of 2011, the Company announced that it had relocated its corporate office to Houston, Texas. This location is located on the south side of the Texas Medical Center near the MD Anderson Cancer Center.

Results of Operations for the three and nine months ended September 30, 2011 and 2010.

Revenues. We have no operating revenues since our inception. We had interest income of $870 for the three months ended September 30, 2011 compared to $236 for the three months ended September 30, 2010. We had interest income of $2,171 for the nine months ended September 30, 2011 compared to $1,283 for the nine months ended September 30, 2010. The increase of interest income in the comparable nine month periods results from increases in bank cash balances in the comparable periods due to financing activities in the first nine months of 2011. Our interest income was derived from cash and cash equivalents net of bank fees.

Research and Development Expenses. Our research and development expense was $127,109 for the three months ended September 30, 2011; a decrease of $108,237 over the three months ended September 30, 2010. Our research and development expense was $458,803 for the nine months ended September 30, 2011; a decrease of $128,301 of over the nine months ended September 30, 2010. The year to date decrease in research and development expense results primarily from lower drug development testing and supply expense and stock options expense offset by lesser increases in clinical trial and amortization expense. Research and development expense – related party is higher for the quarter and year to date versus prior year due to greater clinical trial patient expense accrued or paid to MD Anderson.

General and Administrative Expenses. Our general and administrative expenses were $327,380 for the three months ended September 30, 2011; an increase of $61,438 over the three months ended September 30, 2010. Our general and administrative expenses were $1,002,191 for the nine months ended September 30, 2011; an increase of $169,673 over the nine months ended September 30, 2010. The increase in general and administrative expenses in the respective periods results from the increased operating expenses relating to legal and accounting expense, increased participation in industry conferences and general expenses related to being a public company.

Net Loss. Our net loss was $503,819 for the three months ended September 30, 2011, compared to a loss of $501,337 for the three months ended September 30, 2010. Net loss per share, both basic and diluted was the same for the respective three month periods. Our net loss was $1,559,294 for the nine months ended September 30, 2011, compared to a loss of $1,419,092 for the nine months ended September 30, 2010. The increase in year to date net loss for 2011 compared to 2010 was due to higher general and administrative and research and development – related party expense offset to a lesser degree by lower research and development expense.

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.

In February 2011, the Company received a grant from the U.S. Government's Qualifying Therapeutic Discovery Project Program in the amount of $244,479.

From November 2010 through April 30, 2011 the Company sold shares of common stock for an aggregate consideration of $1,794,206 in cash. Such shares were sold by the Company pursuant to a private placement memorandum to accredited investors. The investors were issued 5,980,685 shares of common stock. In connection with this private placement, the Company also issued 598,069 shares of common stock to the Placement Agent as commission for the shares of common stock sold to these investors.

In addition to the private placement, the Company received $50,000 from Lincoln Park Capital, LLC from the mutual parties' financing purchase agreement. The proceeds from the sale of such shares are being used to fund working capital to continue and expand the Company's ongoing business.

Over the last two years, the Company issued a series of warrants at the exercise price of $1.50 per share to certain accredited investors,

pursuant to one of the several subscription agreements related to private placement memoranda. A total of 5,040,000 warrants were issued. The Board of Directors of the Company determined it is in the best interest of the Company to raise additional funds by offering warrant holders the option of making certain adjustments to the exercise price and the expiration dates of the warrants previously issued. The Board of Directors approved the certain adjustments that allow warrant holders the option to revise their existing warrant by reducing the exercise price of the warrant to $0.30 per share and set the expiration date for the exercise of such warrants to September 30, 2011. The holders of a total of 4,240,000 warrants elected to choose the adjustment option and adjust their warrants. The Company raised a total of $576,000 through investors exercising warrants to purchase common stock for cash during the end of September through October 2011 timeframe, A total of 1,920,000 shares were issued to these investors. No cash or stock commissions were owed from these equity sales. The remaining 2,320,000 unexercised warrants expired effective September 30, 2011.

At September 30, 2011, we had cash of $983,286 compared to $238,565 at December 31, 2010. The increase in the nine month period is primarily from the sale of common stock through the private placement offering and the exercise of the warrants for cash. We currently have no lines of credit or other arranged access to debt financing.

Net cash used in operations during the nine months ended September 30, 2011 was $726,157 compared to $995,584 for the nine months ended September 30, 2010. 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 $1,533,425 in net cash from financing activities for the nine months ended September 30, 2011. Since inception we have net cash from financing activities of $6,358,956. 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 June 2012. We need to raise additional capital, in order to fund our operations after the end of June 2012. There can be no assurance that we will be able to raise cash when it is needed to fund our operations.

We believe that our available cash will be sufficient to fund our liquidity and capital expenditure requirements up to June 2012. We anticipate that we will need to raise approximately an additional $8,600,000 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 beyond June of 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 a result of the continuing Phase I trial, the Company believed it was in the best interest of the Company to enter into a new agreement with the same contract drug manufacturer. Subsequently, in October of 2011 the Company entered into a new project plan agreement with its contract manufacturing supplier for a batch of drug product with expected delivery by year end. The project plan requires the Company to pay the supplier $177,440 for this drug product, of which a total of $59,500 has been paid to date.

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

Critical Accounting Policies

The preparation of financial statements in conformity with generally accepted accounting principles (“GAAP”) in the United States has required the management of the Company to make assumptions, estimates and judgments that affect the amounts reported in the financial statements, including the notes thereto, and related disclosures of commitments and contingencies, if any. The Company considers its critical accounting policies to be those that require the more significant judgments and estimates in the preparation of financial statements. Our significant accounting policies are discussed in Note 2 to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 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 September 30, 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 September 30, 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

None.

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	Specimen Stock certificate (incorporated by reference to exhibit 3.2 to the registrant's current report on Form 8-A filed on September 10, 2008)
31*	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Section 302 of the Sarbanes Oxley Act of 2002.
32*	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Section 906 of the Sarbanes Oxley Act of 2002.

* Filed herewith.

SIGNATURE

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

Dated: November 10, 2011

BIO-PATH HOLDINGS, INC.

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

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 our 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: November 10, 2011

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

Exhibit 32

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report on Form 10-Q of Bio-Path Holdings, Inc. (the "Company") for the quarter ended September 30, 2011 as filed with the Securities and Exchange Commission (the "Report"), I Peter H. Nielsen, Chief Executive Officer and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 10, 2011

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