

BIO-PATH HOLDINGS INC

Form 10-Q

May 15, 2009

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2009

Or

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

For the transition period from \_\_\_\_\_

Commission file number: 000-53404

\_\_\_\_\_  
Bio-Path Holdings, Inc. \_\_\_\_\_  
(Exact name of registrant as specified in its charter)

Utah  
(State or other jurisdiction of  
incorporation or organization)

87-0652870  
(I.R.S. employer  
identification No.)

3293 Harrison Boulevard, Suite 230, Ogden, UT 84403  
(Address of principal executive offices)

Registrant's telephone no., including area code: (801) 399-5500

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 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)  
reporting company

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

At May 14, 2009, the Company had 41,923,602 outstanding shares of common stock, \$0.001 par value.

DOCUMENTS INCORPORATED BY REFERENCE: NONE

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## Forward-Looking Statements

Statements in this quarterly report on Form 10-Q that are not strictly historical in nature are forward-looking statements. These statements may include, but are not limited to, statements about: the timing of the commencement, enrollment, and completion of our anticipated clinical trials for our product candidates; the progress or success of our product development programs; the status of regulatory approvals for our product candidates; the timing of product launches; our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others; and our estimates for future performance, anticipated operating losses, future revenues, capital requirements, and our needs for additional financing. In some cases, you can identify forward-looking statements by terms such as “anticipates,” “believes,” “could,” “estimates,” “expects,” “intends,” “may,” “potential,” “predicts,” “projects,” “should,” “will,” “would,” “goal,” and similar expressions intended to identify forward-looking statements. These statements are only predictions based on current information and expectations and involve a number of risks and uncertainties. The underlying information and expectations are likely to change over time. Actual events or results may differ materially from those projected in the forward-looking statements due to various factors, including, but not limited to, those set forth under the caption “Risk Factors” in “ITEM 1. BUSINESS” of our Form 10-K for the fiscal year ended December 31, 2008, and those set forth in our other filings with the Securities and Exchange Commission. Except as required by law, we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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## PART I - FINANCIAL INFORMATION

### ITEM 1. FINANCIAL STATEMENTS

The accompanying unaudited financial statements have been prepared in accordance with the instructions to Form 10-Q pursuant to the rules and regulations of the Securities and Exchange Commission and, therefore, do not include all information and footnotes necessary for a complete presentation of our financial position, results of operations, cash flows, and stockholders' equity in conformity with generally accepted accounting principles. In the opinion of management, all adjustments considered necessary for a fair presentation of the results of operations and financial position have been included and all such adjustments are of a normal recurring nature.

Our unaudited balance sheet at March 31, 2009; the related unaudited consolidated statements of operations for the three month periods ended March 31, 2009 and 2008, and from inception (May 10, 2007) to March 31, 2009; and the related unaudited statement of cash flows for the three month periods ended March 31, 2009 and 2008, and from inception (May 10, 2007) through March 31, 2009, are attached hereto.

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

CONSOLIDATED BALANCE SHEETS

|                                                                     | March 31<br>2009<br>(Unaudited) | December<br>31<br>2008 |
|---------------------------------------------------------------------|---------------------------------|------------------------|
| <b>ASSETS</b>                                                       |                                 |                        |
| <b>Current assets</b>                                               |                                 |                        |
| Cash                                                                | \$ 783,155                      | \$ 1,507,071           |
| Drug product for testing                                            | 591,600                         | 292,800                |
| Other current assets                                                | 38,414                          | 82,772                 |
| <b>Total current assets</b>                                         | <b>1,413,169</b>                | <b>1,882,643</b>       |
| <b>Other assets</b>                                                 |                                 |                        |
| Technology licenses                                                 | 2,704,167                       | 2,704,167              |
| Less Accumulated Amortization                                       | (244,770)                       | (199,505)              |
|                                                                     | 2,459,397                       | 2,504,662              |
| <b>TOTAL ASSETS</b>                                                 | <b>\$ 3,872,566</b>             | <b>\$ 4,387,305</b>    |
| <b>LIABILITIES &amp; SHAREHOLDERS' EQUITY</b>                       |                                 |                        |
| <b>Current liabilities</b>                                          |                                 |                        |
| Accounts payable                                                    | 2,059                           | 185,843                |
| Accrued expense & other accruals                                    | 187,523                         | 16,442                 |
| Accrued license payments                                            | 75,000                          | 125,000                |
| <b>Total current liabilities</b>                                    | <b>264,582</b>                  | <b>327,285</b>         |
| <b>Long term debt</b>                                               | <b>-</b>                        | <b>-</b>               |
| <b>TOTAL LIABILITIES</b>                                            | <b>264,582</b>                  | <b>327,285</b>         |
| <b>Shareholders' Equity</b>                                         |                                 |                        |
| Preferred Stock, \$.001 par value                                   | -                               | -                      |
| 10,000,000 shares authorized, no shares issued and outstanding      |                                 |                        |
| Common Stock, \$.001 par value, 200,000,000 shares authorized       | 41,923                          | 41,923                 |
| 41,923,602 shares issued and outstanding as of 3/31/09 and 12/31/08 |                                 |                        |
| <b>Additional paid in capital</b>                                   | <b>7,296,920</b>                | <b>7,152,261</b>       |
| <b>Accumulated deficit during development stage</b>                 | <b>(3,730,859)</b>              | <b>(3,134,164)</b>     |
| <b>Total shareholders' equity</b>                                   | <b>3,607,984</b>                | <b>4,060,020</b>       |

|                                          |              |              |
|------------------------------------------|--------------|--------------|
| TOTAL LIABILITIES & SHAREHOLDERS' EQUITY | \$ 3,872,566 | \$ 4,387,305 |
|------------------------------------------|--------------|--------------|

See Accompanying Notes to Financial Statements



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

CONSOLIDATED STATEMENT OF OPERATIONS  
Unaudited

|                                                                        | First Quarter         |              | From                   |
|------------------------------------------------------------------------|-----------------------|--------------|------------------------|
|                                                                        | January 1 to March 31 |              | inception              |
|                                                                        | 2009                  | 2008         | 05/10/07 to<br>3/31/09 |
| Revenue                                                                | \$ -                  | \$ -         | \$ -                   |
| Operating expense                                                      |                       |              |                        |
| Research and development                                               | 212,609               | 17,650       | 554,256                |
| General & administrative                                               | 193,325               | 183,660      | 1,051,769              |
| Stock issued for services                                              | -                     | -            | 300,000                |
| Stock options & warrants                                               | 148,727               | -            | 1,649,966              |
| Amortization                                                           | 45,265                | 42,583       | 244,770                |
| Total operating expense                                                | 599,926               | 243,893      | 3,800,761              |
| Net operating loss                                                     | \$ (599,926)          | \$ (243,893) | \$ (3,800,761)         |
| Other income                                                           |                       |              |                        |
| Interest income                                                        | 3,232                 | 17,687       | 69,902                 |
| Total Other Income                                                     | 3,232                 | 17,687       | 69,902                 |
| Net Loss                                                               | \$ (596,694)          | \$ (226,206) | \$ (3,730,859)         |
| Loss per share                                                         |                       |              |                        |
| Net loss per share, basic and diluted                                  | \$ (0.01)             | \$ (0.01)    | \$ (0.11)              |
| Basic and diluted weighted average number of common shares outstanding | 41,923,602            | 39,144,256   | 35,343,065             |

See Accompanying Notes to Financial Statements

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

CONSOLIDATED STATEMENT OF CASH FLOWS  
Unaudited

|                                                                            | First Quarter         |              | From                          |
|----------------------------------------------------------------------------|-----------------------|--------------|-------------------------------|
|                                                                            | January 1 to March 31 |              | inception                     |
|                                                                            | 2009                  | 2008         | 05/10/2007<br>to<br>3/31/2009 |
| <b>CASH FLOW FROM OPERATING ACTIVITIES</b>                                 |                       |              |                               |
| Net loss                                                                   | \$ (596,694)          | \$ (226,206) | \$ (3,730,859)                |
| Adjustments to reconcile net loss to net cash used in operating activities |                       |              |                               |
| Amortization                                                               | 45,265                | 42,583       | 244,770                       |
| Common stock issued for services                                           |                       | 80,000       | 300,000                       |
| Stock options and warrants                                                 | 148,727               | -            | 1,649,966                     |
| (Increase) decrease in assets                                              |                       |              |                               |
| Restricted escrow cash                                                     |                       | 208,144      |                               |
| Drug product for testing                                                   | (298,800)             | -            | (591,600)                     |
| Other current assets                                                       | 44,358                | (1,133)      | (38,414)                      |
| Increase (decrease) in liabilities                                         |                       |              |                               |
| Accounts payable and accrued expenses                                      | (62,703)              | (15,423)     | 264,582                       |
| Escrow cash payable                                                        |                       | (208,144)    |                               |
| Net cash used in operating activities                                      | (719,847)             | (120,179)    | (1,901,555)                   |
| <b>CASH FLOW FROM INVESTING ACTIVITIES</b>                                 |                       |              |                               |
| Purchase of exclusive license                                              |                       |              | (350,000)                     |
| Net cash used in investing activities                                      | -                     | -            | (350,000)                     |
| <b>CASH FLOW FROM FINANCING ACTIVITIES</b>                                 |                       |              |                               |
| Proceeds from convertible notes                                            |                       |              | 435,000                       |
| Cash repayment of convertible notes                                        | .                     |              | (15,000)                      |
| Net proceeds (costs) from sale of common stock                             | (4,069)               | 1,406,468    | 2,614,710                     |
| Net cash from financing activities                                         | (4,069)               | 1,406,468    | 3,034,710                     |
| <b>NET INCREASE IN CASH</b>                                                |                       |              |                               |
| Cash, beginning of period                                                  | 1,507,071             | 1,219,358    | -                             |
| Cash, end of period                                                        | \$ 783,155            | \$ 2,505,647 | \$ 783,155                    |
| <b>SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION</b>                    |                       |              |                               |
| Cash paid for                                                              |                       |              |                               |
| Interest                                                                   | \$ -                  | \$ -         | \$ -                          |
| Income taxes                                                               | \$ -                  | \$ -         | \$ -                          |

Non-cash financing activities

|                                                             |    |        |            |
|-------------------------------------------------------------|----|--------|------------|
| Common stock issued upon conversion of convertible notes    |    | \$     | 420,000    |
| Common stock issued to Placement Agent                      | \$ | 78,970 | \$ 278,345 |
| Common stock issued to M.D. Anderson for technology license |    | \$     | 2,354,167  |

See Accompanying Notes to Financial Statements

Notes to the Interim Consolidated Financial Statements Ending March 31, 2009

The accompanying interim financial statements have been prepared without audit, pursuant to the rules and regulations of the Securities and Exchange Commission. Certain information and disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted. In the opinion of management, the accompanying interim financial statements contain all adjustments, consisting of normal recurring accruals, necessary for a fair presentation. The results of operations for the period ended March 31, 2009, 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 founded with technology from The University of Texas, M. D. Anderson Cancer Center ("M. D. 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, small interfering RNA ("siRNA") and small molecules for treatment of cancer. In addition to its existing technology under license, the Company expects to have a close working relationship with key members of the M. D. Anderson's staff, which should provide Bio-Path with a strong pipeline of promising drug candidates in the future. Bio-Path expects the program with M. D. Anderson to enable the Company to broaden its technology to include cancer drugs other than antisense and siRNA.

Bio-Path believes that its core technology, if successful, will enable it to be at the center of emerging genetic and molecular target-based therapeutics that require systemic delivery of DNA and RNA-like material. The Company's two lead 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. These two lead drug candidates will be ready for clinical trials after receiving an investigational new drug ("IND") status from the FDA. The Company has filed an IND application for its lead drug candidate and currently anticipates commencing a Phase I clinical trial of this drug by the end of the year.

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 has 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. 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. Drug Product for Testing

The Company has paid installments to its contract drug manufacturing supplier totaling \$591,600 during the third quarter and fourth quarters of 2008 and first quarter of 2009 pursuant to a Project Plan and Supply Agreement (see Note 6. below) for the manufacture and delivery of the Company's lead drug product for testing in a Phase I clinical trial. This amount is carried on the Balance Sheet as of March 31, 2009 at cost as Drug Product for Testing and will be expensed as the drug product is used during the Phase I clinical trial.

3. Convertible Debt

The Company issued \$435,000 in notes convertible into common stock at a rate of \$.25 per common share. As of December 31, 2007, \$15,000 of the convertible notes had been repaid in cash and \$420,000 of the convertible notes had been converted into 1,680,000 shares of Bio-Path common stock and were included in the seed round completed in August of 2007. No interest was recorded because interest was nominal prior to conversion. No beneficial conversion feature existed as of the debt issuance date since the conversion rate was greater than or equal to the fair value of the common stock on the issuance date.

4. 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 shares of 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 issued 1,579,400 shares of common stock for \$1,579,400 in cash to investors in the Company pursuant to a private placement memorandum. The Company issued 78,970 in common stock to the Placement Agent as commission for the shares of common stock sold to investors. In February, 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. 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. As of March 31, 2009 there were 41,923,602 shares of common stock issued and outstanding. There are no preferred shares outstanding as of March 31, 2009.

## 5. Stock Options and Warrants

**Stock Options -** In April of 2008 the Company made stock option grants for services over the next three years to purchase in the aggregate 1,615,000 shares of the Company's common stock. Terms of the stock option grants require, among other things, that the individual continues to provide services over the vesting period of the option, which is four or five years from the date that each option granted to the individual becomes effective. The exercise price of the options is \$0.90 a share. None of these stock options grants were 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 for each stock option award. For purposes of determining fair value, the Company used an average annual volatility of seventy two percent (72%), which was calculated based upon an average of volatility of similar biotechnology stocks. 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 awards and interpolated as necessary to match the appropriate effective term for the award. The total value of stock options granted was determined using this methodology to be \$761,590, which will be expensed over six years based on the stock option service period.

In October of 2008 the Company made stock option grants to management and officers to purchase in the aggregate 2,500,000 shares of the Company's common stock. Terms of the stock option grants require that the individuals continue employment with the Company over the vesting period of the option, fifty percent (50%) of which vested upon the date of the grant of the stock options and fifty percent (50%) of which will vest over 3 years from the date that the options were granted. The exercise price of the options is \$1.40 a share. 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 for each stock option award. For purposes of determining fair value, the Company used an average annual volatility of eighty four percent (84%), which was calculated based upon taking a weighted average of the volatility of the Company's common stock and the volatility of similar biotechnology stocks. 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 awards and interpolated as necessary to match the appropriate effective term for the award. The total value of stock options granted to management and officers was determined using this methodology to be \$2,485,000, half of which was expensed at the date of grant and the balance will be expensed over a three year period based on the stock option service period.

In December of 2008 the Company made stock option grants for services over the next three years to purchase in the aggregate 100,000 shares of the Company's common stock. Terms of the stock option grants require, among other things, that the individual continues to provide services over the vesting period of the option, which is three or four years from the date that each option granted to the individual becomes effective. The exercise price of the options is \$0.30 a share. None of these stock options grants were 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 for each stock option award. For purposes of determining fair value, the Company used an average annual volatility of eighty four percent (84%), which was calculated based upon taking a weighted average of the volatility of the Company's common stock and the volatility of similar biotechnology stocks. 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 awards and interpolated as necessary to match the appropriate effective term for the award. The total value of stock options granted was determined using this methodology to be \$21,450, which will be expensed over the next four years based on the stock option vesting schedule. There were no new stock option awards made during the first quarter 2009. Total stock option expense for the current quarter ending March 31, 2009 being reported on totaled \$148,727.

Warrants - In April of 2008 the Company awarded warrants for services to purchase in the aggregate 85,620 shares of the Company's common stock. The exercise price is \$0.90 a share. The warrants were one hundred percent (100%) vested upon issuance and were expensed upfront as warrants for services. The fair value of the warrants expensed was determined using the same methodology as described above for stock options. The total value of the warrants granted was determined using this methodology to be \$36,050, the total amount of which was expensed in the second quarter 2008.

There were no new warrants issued in the current quarter ending March 31, 2009 being reported on.

#### 6. Drug Project Plan and Supply Agreement

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 currently expects to start this trial by the end of the second or beginning of the third quarter 2009 and the clinical grade drug batch is scheduled to be manufactured in the second quarter 2009. In the current quarter ending March 31, 2009, the Company paid \$298,800 to this manufacturer under this agreement that is carried at cost as Drug Product for Testing on the balance sheet (see Note 2.) and recorded and paid an additional \$48,000 in R&D expense for manufacturing validation. The Company expects to pay an additional \$294,150 to this supplier when the project is completed and the drug manufacturer delivers clinical grade drug product for testing in the Company's clinical trial.



7. Commitments and Contingencies

Technology License - The Company has negotiated exclusive licenses from MD Anderson to develop drug delivery technology for siRNA and antisense drug products. These licenses require, among other things, the Company to reimburse MD Anderson for ongoing patent expense. Accrued license payments totaling \$75,000 were included in Current Liabilities as of March 31, 2009. It is expected that the accrued license payments will be made to M. D. Anderson in the second quarter 2009. As of March 31, 2009, the Company estimates these expenses will total approximately \$250,000. The Company will be required to pay the patent expenses at the rate of \$25,000 per quarter per license.

8. Subsequent Events

In April 2009, the Board of Directors awarded management bonuses totaling \$128,000 for performance from inception through May 2008. These bonuses will be accrued during the second quarter of 2009 and will be paid once Management and the Board determine there is sufficient liquidity in excess of current operational needs.

9. New Accounting Pronouncements

In April 2009, the FASB issued FSP No. FAS 107-1 and APB 28-1, "Interim Disclosures about Fair Value of Financial Instruments." The FSP amends SFAS No. 107, "Disclosures about Fair Value of Financial Instruments" and Accounting Principles Board ("APB") Opinion No. 28, "Interim Financial Reporting," to require disclosures about the fair value of financial instruments during interim reporting periods. The FSP is effective for interim and annual periods ending after June 15, 2009, which is June 30, 2009 for the Company. The Company will include any required disclosures in the Company's Quarterly Report on Form 10-Q for the interim period ending June 30, 2009.

In April 2009, the FASB issued FSP No. FAS 115-2 and FAS 124-2, "Recognition and Presentation of Other-Than-Temporary Impairments." The FSP amends the other-than-temporary impairment guidance for debt securities to make the guidance more operational and to improve the presentation and disclosure of other-than-temporary impairments on debt and equity securities. The FSP is effective for interim and annual periods ending after June 15, 2009, which is June 30, 2009 for the Company. The FSP is not anticipated to have a material impact on the Company's consolidated financial statements.

In April 2009, the FASB issued FSP No. FAS 157-4, "Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly." The FSP provides additional guidance for estimating fair value when the market activity for an asset or liability has declined significantly. The FSP is effective for interim and annual periods ending after June 15, 2009, which is June 30, 2009 for the Company. The FSP is not anticipated to have a material impact on the Company's consolidated financial statements.

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

When you read this section of this Quarterly Form 10Q, it is important that you also read the financial statements and related notes included elsewhere in this Form 10Q. This section of this quarterly report 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,” “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 for the fiscal year ended December 31, 2008 those additional risks, discussed in ITEM 1A. of Part II of this quarterly report and other risks and uncertainties discussed in filings made with the Securities and Exchange Commission.

### Overview

Bio-Path Holdings, Inc., through our subsidiary Bio-Path, Inc. (“Bio-Path Subsidiary”) is engaged in the business of financing and facilitating the development of novel cancer therapeutics. Our initial plan is and continues to be, the acquisition of licenses for drug technologies from The University of Texas M. D. Anderson Cancer Center (“M. D. Anderson”), funding clinical and other trials for such technologies and to commercialize such technologies. We have acquired two exclusive licenses (“License Agreements”) from M.D. Anderson for three lead products and nucleic acid drug delivery 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 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 drugs candidates. Our strategy is to selectively license potential drug candidates for certain cancers, and, primarily utilizing the comprehensive drug development capabilities of M. D. Anderson, to advance these candidates through proof of concept into a safety study (Phase I), to human efficacy trials (Phase IIA), and then out-license each successful potential drug to a pharmaceutical company.

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

Our principal executive offices are located at, 3293 Harrison Boulevard, Suite 230, Ogden, UT 84403. Our telephone number at that address is (801) 399-5500. Our Internet website address is [www.biopathholdings.com](http://www.biopathholdings.com), and all of our filings with the Securities and Exchange Commission are available free of charge on our website.

### Plan of Operation

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

We anticipate that over the next 36 months, we will need to raise approximately \$11,500,000 to completely implement our business plan. Since its inception, Bio-Path Subsidiary completed several financings raising net proceeds of \$3,034,710. Our short term plan is to achieve three key milestones:

- (1) conduct a 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;
- (2) perform necessary pre-clinical studies in our lead liposomal siRNA drug candidate, BP-100-2.01 to enable the filing of an Investigational New Drug ("IND") for a Phase I clinical trial; and
- (3) out-license (non-exclusively) our delivery technology for either antisense or siRNA to a pharmaceutical partner to speed development applications of our technology.

In June 2008, we entered into a Project Plan Agreement with Althea Technologies, Inc. ("Althea") relating to supply of drug product for our first Phase I clinical trials of our BP-100-1.01 drug. In September 2008 we executed a definitive agreement with Althea.

### Results of Operations

Results of Operations for the three months ended March 31, 2009 and 2008.

**Revenues.** We have no operating revenues since our inception. We had interest income of \$3,232, for the three months ended March 31, 2009 compared to \$17,687 for the three months ended March 31, 2008. Our interest income was derived from cash and cash equivalents net of bank fees.

**Research and Development Expenses.** Our research and development costs were \$212,609 for the three months ended March 31, 2009; an increase of \$194,959 over the three months ended March 31, 2008. This increase is the result of significant drug research and development and manufacturing protocol from year to year. The majority of the expenses related to the lead drug candidate, BP-100-1.01, have been paid. The Company does not expect this increase to continue with this specific drug candidate.

**General and Administrative Expenses.** Our general and administrative expenses were \$193,325 for the three months ended March 31, 2009; an increase of \$9,665 over the three months ended March 31, 2008.

**Net Loss.** Our net loss was \$596,694 for the three months ended March 31, 2009, compared to a loss of \$226,206 for the three months ended March 31, 2008. Net loss per share, both basic and diluted was \$0.01 and \$0.01 for the respective periods. The two primary reasons for the difference in the increase in net loss in the comparable periods results from increases in research and development expenses related to preparing the lead drug candidate for the upcoming clinical trial. The other reason is the Company recognized as a non-cash item, the stock option and warrants expense in the three months ended March 31, 2009 compared to zero stock option and warrants expense in the prior period.

### 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, even if we do not have an immediate need for additional capital at that time. We cannot be certain that additional funding, which will be required in the next term, will be available on acceptable terms, or at all. Our inability to obtain required funding will have a material adverse effect on one or more of our research or development programs or curtail some of our commercialization efforts.



At March 31, 2009, we had cash of \$783,155 compared to \$1,507,071 at December 31, 2008. We currently have no lines of credit or other arranged access to debt financing.

Net cash used in operations during the three months ended March 31, 2009 was \$719,847 compared to \$120,179 for the three months ended March 31, 2008. The significant increase in net cash used results from implementing the business model of drug development working towards the Phase I study of the lead drug – BP-100-1.01. 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 no cash from financing activities for the three months ended March 31, 2009. Since inception we have net cash from financing activities of \$3,034,710. As discussed in our Plan of Operation above, we believe that our available cash will be sufficient to fund our liquidity and capital expenditure requirements through the fiscal year ending December 31, 2009. However, we believe that we will need to raise approximately an additional \$11,500,000 in net proceeds to completely implement our business plan. We do need to raise additional capital during 2009, in order to fund our operations in 2010. There can be no assurance that we will be able to raise cash when it is needed to fund our operations.

#### Projected Financing Needs

We believe that our available cash will be sufficient to fund our liquidity and capital expenditure requirements through the fiscal year ending December 31, 2009. However, we believe that we will need to raise approximately an additional \$11,500,000 in net proceeds to completely implement our business plan. We do need to raise additional capital during 2009, in order to fund our operations in 2010. There can be no assurance that we will be able to raise cash when it is needed to fund our operations.

#### 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. The Company is currently finalizing the requested changes. The final package submission to the FDA must include the manufacturing and chemistry control test data from an engineering test batches that incorporated the same manufacturing procedures to be used to manufacture the drug product to be used on human patients in the Phase I clinical trial. The clinical batch of drug product is currently scheduled to be manufactured in mid May, 2009 and the Company expects to have the final data submitted to the FDA during the second quarter of 2009. Based on this timetable, the Company anticipates having the IND approved and commencement of patient enrollment for the Phase I clinical trial to start during the end of the second or beginning of the third quarter of 2009. 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. An additional key objective of the trial is to assess that the effectiveness of the delivery technology.

The Phase I clinical trial of BP-100-1.01 is budgeted for \$1,675,000. A significant portion of this budget is for acquisition of the drug material to be tested, a majority of which has been paid by the Company. Commencement of the Phase I clinical trial depends on the Federal Drug Administration (“FDA”) approving the IND for BP-100-1.01.

We have entered into a supply agreement with Althea Technologies, Inc. for the manufacture of BP-100-1.01 for our upcoming Phase I Clinical Trial. Althea is a contract manufacturer who will formulate and lyophilize our BP-100-1.01 product requirements according to current Good Manufacturing Practices (cGMP). The contract includes estimated remaining payments by Bio-Path of approximately \$300,000 for process development and manufacture of cGMP product suitable for use in human patients in the Company’s Phase I clinical trial. Bio-Path has the right to terminate the agreement at any time, subject to payment of a termination fee to Althea. The termination fee is not material.

#### 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 data 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.

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, or (3) That we will be able to raise the sufficient funds to allow us to operate for three years or to complete our trials.

#### Other Events

None.

#### Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

#### Contractual Obligations and Commitments

Bio-Path has recently entered into two Patent and Technology License Agreements (the “Licenses”) with M. D. Anderson relating to its technology. A summary of certain material terms of each of the Licenses is as follows:

|           |                                                                                                                          |
|-----------|--------------------------------------------------------------------------------------------------------------------------|
| Licensor: | The Board of Regents of the University of Texas System on behalf of The University of Texas M. D. Anderson Cancer Center |
| Licensee: | Bio-Path, Inc.                                                                                                           |
| License:  | A royalty bearing, exclusive license to manufacture, use and sell the Licensed Products                                  |



|                      |                                                                                                                                                                                                                                        |
|----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Territory:           | Worldwide                                                                                                                                                                                                                              |
| Retained Rights      | Certain research and academic rights are retained by Licensor                                                                                                                                                                          |
| License Fees:        | Documentation Fee - \$40,000 for the first license and \$60,000 for the second license; annual maintenance fee - \$25,000 for years 1, 2 & 3 increasing to \$100,000 in the eighth year. After the first sale, increasing to \$125,000 |
| Royalties:           | Three percent of net sales                                                                                                                                                                                                             |
| Milestone Payments:  | One-time payments range from \$150,000 to \$2,000,000. Total up to \$8,150,000                                                                                                                                                         |
| Securities Issuance: | 1,883,333 shares of Bio-Path for the first License and 1,255,556 shares for the second License. These shares were converted into shares of the Company's common stock in the Merger.                                                   |
| Expense:             | Bio-Path will reimburse M. D. Anderson for expenses                                                                                                                                                                                    |
| Term:                | Full term of patents                                                                                                                                                                                                                   |

In September 2008, we entered into a supply agreement with Althea Technologies, Inc. for the manufacture of BP-100-1.01 for our upcoming Phase I Clinical Trial. Althea is a contract manufacturer who will formulate and lyophilize our BP-100-1.01 product requirements according to current Good Manufacturing Practices (cGMP). The contract includes estimated remaining payments by Bio-Path of approximately \$300,000 for process development and manufacture of cGMP product suitable for use in human patients in the Company's Phase I clinical trial. Bio-Path has the right to terminate the agreement at any time, subject to payment of a termination fee to Althea. The termination fee is not material.

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 officer 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).

#### Inflation

The Company does not believe that inflation will negatively impact its business plans.



## 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, including the following:

**Concentration of Credit Risk** -- Financial instruments that potentially subject the Company to a significant concentration of credit risk consist of cash. The Company maintains its cash balances with one major commercial bank, JPMorgan Chase Bank. The balances are insured by the Federal Deposit Insurance Corporation up to \$250,000. As a result, \$533,155 of the Company's cash balances is not covered by the FDIC.

**Intangible Assets/Impairment of Long-Lived Assets** -- As of March 31, 2009, Other Assets totals \$2,459,397 for the Company's two technology licenses, comprised of \$2,704,167 in value acquiring the Company's technology licenses and its intellectual property, less accumulated amortization of \$244,770. The technology value consists of \$350,000 in cash paid or accrued to be paid to M.D. Anderson, plus 3,138,889 shares of common stock granted to M.D. Anderson valued at \$2,354,167. This value is being amortized over a fifteen year (15 year) period from November 7, 2007, the date that the technology licenses became effective. As of December 31, 2008 accrued payments to be made to M. D. Anderson totaled \$125,000, and such payments are expected to be made in 2009. The Company accounts for the impairment and disposition of its long-lived assets in accordance with Statement of Financial Accounting Standards ("SFAS") No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets. In accordance with SFAS No. 144, long-lived assets are reviewed for events of changes in circumstances which indicate that their carrying value may not be recoverable. The Company estimates that approximately \$175,000 will be amortized per year for each future year for the current value of the technology licenses acquired until approximately 2022.

**Research and Development Costs** -- Costs and expenses that can be clearly identified as research and development are charged to expense as incurred in accordance with SFAS No. 2, "Accounting for Research and Development Costs." From inception through the period ending March 31, 2009, the Company had \$554,256 of costs classified as research and development expense. Of this amount, approximately \$225,000 is comprised of raw materials and costs for the Company's raw material suppliers and contract drug manufacturer to perform unplanned additional engineering test runs of the Company's lead drug product in advance of manufacturing a current Good Manufacturing Practice (cGMP) clinical batch of this drug for use in an upcoming Phase I Clinical Trial.

**Stock-Based Compensation** -- The Company has accounted for stock-based compensation under the provisions of Statement of Financial Accounting Standards No. 123(R), "Share-Based Payment." This statement requires us to record an expense associated with the fair value of stock-based compensation. We currently use the Black-Scholes option valuation model to calculate stock based compensation at the date of grant. Option pricing models require the input of highly subjective assumptions, including the expected price volatility. Changes in these assumptions can materially affect the fair value estimate.

Stock Option Grants - In April of 2008 the Company made stock option grants for services over the next three years to purchase in the aggregate 1,615,000 shares of the Company's common stock. Terms of the stock option grants require, among other things, that the individual continues to provide services over the vesting period of the option, which is four or five years from the date that each option granted to the individual becomes effective. The exercise price of the options is \$0.90 a share. None of these stock options grants were 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 service period schedule for each stock option award. For purposes of determining fair value, the Company used an average annual volatility of seventy two percent (72%), which was calculated based upon an average of volatility of similar biotechnology stocks. 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 awards and interpolated as necessary to match the appropriate effective term for the award. The total value of stock options granted was determined using this methodology to be \$761,590, which will be expensed over the next six years based on the service period.

In October of 2008 the Company made stock option grants to management and officers to purchase in the aggregate 2,500,000 shares of the Company's common stock. Terms of the stock option grants require that the individuals continue employment with the Company over the vesting period of the option, fifty percent (50%) of which vested upon the date of the grant of the stock options and fifty percent (50%) of which will vest over 3 years from the date that the options were granted. The exercise price of the options is \$1.40 a share. The Company determined the fair value of the stock options granted using the Black Scholes model and expenses this value monthly based upon the service period for each stock option award. For purposes of determining fair value, the Company used an average annual volatility of eighty four percent (84%), which was calculated based upon taking a weighted average of the volatility of the Company's common stock and the volatility of similar biotechnology stocks. 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 awards and interpolated as necessary to match the appropriate effective term for the award.

The total value of stock options granted to management and officers was determined using this methodology to be \$2,485,000, half of which was expensed at the date of grant and the balance will be expensed over the next three years based on the stock option vesting schedule.

In December of 2008 the Company made stock option grants for services over the next three years to purchase in the aggregate 100,000 shares of the Company's common stock. Terms of the stock option grants require, among other things, that the individual continues to provide services over the vesting period of the option, which is three or four years from the date that each option granted to the individual becomes effective. The exercise price of the options is \$0.30 a share. None of these stock options grants were 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 for each stock option award. For purposes of determining fair value, the Company used an average annual volatility of eighty four percent (84%), which was calculated based upon taking a weighted average of the volatility of the Company's common stock and the volatility of similar biotechnology stocks.

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 awards and interpolated as necessary to match the appropriate effective term for the award. The total value of stock options granted was determined using this methodology to be \$21,450, which will be expensed over the next four years based on the stock option vesting schedule.

Total stock option expense being reported for the period ending March 31, 2009 is \$148,727 and from inception May 10, 2007 to March 31, 2009 is \$1,649,966.

**Warrant Grants** - In April of 2008 the Company awarded warrants for services to purchase in the aggregate 85,620 shares of the Company's common stock. The exercise price is \$0.90 a share. The warrants were one hundred percent (100%) vested upon issuance and were expensed upfront as warrants for services. The fair value of the warrants expensed was determined using the same methodology as described above for stock options. The total value of the warrants granted was determined using this methodology to be \$36,050, the total amount of which was expensed in the second quarter 2008.

**Net Loss Per Share** – In accordance with SFAS No. 128, Earnings Per Share, and SEC Staff Accounting Bulletin ("SAB") No. 98, basic net loss per common share is computed by dividing net loss for the period by the weighted average number of common shares outstanding during the period. Under SFAS No. 128, diluted net income (loss) per share is computed by dividing the net income (loss) for the period by the weighted average number of common and common equivalent shares, such as stock options and warrants, outstanding during the period.

**Comprehensive Income** -- Comprehensive income (loss) is defined as all changes in a company's net assets, except changes resulting from transactions with shareholders. At March 31, 2009, the Company has no reportable differences between net loss and comprehensive loss.

**Use of Estimates** -- The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the Company's consolidated financial statements and accompanying notes. On an ongoing basis, the Company evaluates its estimates and judgments, which are based on historical and anticipated results and trends and on various other assumptions that the Company believes to be reasonable under the circumstances. By their nature, estimates are subject to an inherent degree of uncertainty and, as such, actual results may differ from the Company's estimates.

### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Information not required for smaller reporting companies.

### ITEM 4(T). CONTROLS AND PROCEDURES

(a) **Evaluation of Disclosure Controls and Procedures.** Our management, with the participation of our principal executive officer and principal financial officer, have evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of the end of the period covered by this quarterly report (the "Evaluation Date"). Based on such evaluation, our principal financial officer and principal executive officer have concluded that, as of the Evaluation Date, our disclosure controls and procedures are effective and designed to ensure that the information relating to our company (including our consolidated subsidiaries) required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the requisite time periods.

(b) **Changes in Internal Controls.** There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the quarter covered by this report that has materially affected, or is reasonably likely to materially affect, such controls.



PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

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

None.

ITEM 3. DEFAULTS BY THE COMPANY ON ITS SENIOR SECURITIES

None.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matter was submitted to our shareholders for a vote or consent during the quarter ended March 31, 2009. Our 2009 Annual Meeting of Shareholders is scheduled for July 15, 2009.

ITEM 5. OTHER INFORMATION

None

ITEM 6. EXHIBITS

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

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

SIGNATURE

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

Dated: May 14, 2009

BIO-PATH HOLDINGS, INC.

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



