

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549

FORM 8-K

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

Date of report (Date of earliest event reported): March 29, 2012

**BIO-PATH HOLDINGS, INC.**  
(Exact name of registrant as specified in its charter)

**Utah**

**000-53404**

**87-0652870**

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(State or other jurisdiction  
of incorporation)

(Commission File Number)

(IRS Employer Identification No.)

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**2626 South Loop, Suite 180, Houston, Texas**

**77054**

(Address of principal executive offices)

(Zip Code)

(832) 971-6616

(Registrant's Telephone Number, Including Area Code)

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

## **Item 2.02 Results of Operations and Financial Condition.**

The information in this Current Report is being furnished pursuant to Item 2.02 of Form 8-K and, according to general instruction B.2. thereunder, the information in this Current Report shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that Section. The information in this Current Report shall not be incorporated by reference into any registration statement pursuant to the Securities Act of 1933, as amended.

On April 3, 2012, Bio-Path Holdings, Inc. (the “Company”) announced financial results for the year ended December 31, 2011. Additional information is included in the Company’s earnings release dated April 3, 2012.

A copy of the Company’s earnings release is attached hereto as Exhibit 99.1. The foregoing description of the earnings release is qualified in its entirety by reference to the attached exhibit.

## **Item 8.01 Other Events.**

On March 29, 2012, the Company issued a press release titled “Bio-Path Holdings Engages PondelWilkinson for Retail Investor Relations Program.”

A copy of such press release is attached hereto as Exhibit 99.2 and is incorporated herein by reference.

## **Item 9.01 Financial Statements and Exhibits.**

### (d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Earnings Release dated April 3, 2012
99.2	Press Release dated March 29, 2012

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**BIO-PATH HOLDINGS, INC.**

Dated: April 3, 2012

By: /s/ Peter H. Nielsen  
Peter H. Nielsen  
President and Chief Executive Officer

## EXHIBIT INDEX

Exhibit Number -----	Description -----
99.1	Earnings Release dated April 3, 2012
99.2	Press Release dated March 29, 2012



## Bio-Path Holdings Reports Fiscal Year 2011 Operational and Financial Results

**April 3, 2012; HOUSTON, TX** – Bio-Path Holdings, Inc., (OTC BB: BPTH) (“Bio-Path”), a biotechnology company developing a liposomal delivery technology for nucleic acid cancer drugs, today announced operational and financial results for the year ended December 31, 2011.

### 2011 OPERATIONAL AND FINANCIAL HIGHLIGHTS

- Recent Operational Highlights
  - Enrollment continues in the Phase I clinical trial of Bio-Path’s lead antisense cancer drug product Liposomal Grb-2 (also “BP-100-1.01”). To date, the Company has successfully completed the first two cohorts of the study. The drug has been well tolerated and possible anti-leukemia has been demonstrated. At the end of March 2012, a total of 24 patients have been enrolled in the study, of which 10 have been evaluable. The trial is in the third cohort treating patients with the third dose level of 20 mg/m<sup>2</sup>. Liposomal Grb-2 is a novel, systemic liposomal antisense treatment for blood cancers. Patients eligible for enrollment have refractory or relapsed Acute Myeloid Leukemia (AML), Philadelphia Chromosome Positive Chronic Myelogenous Leukemia (CML), Acute Lymphoblastic Leukemia (ALL), or Myelodysplastic Syndrome (MDS) and who have failed other approved treatments.

The clinical trial is a dose-escalating study to determine the safety and tolerance of escalating doses of Liposomal Grb-2, as well as the optimal biologically active dose for further development. The trial seeks a total of 18 to 30 evaluable patients and will evaluate five doses of Liposomal Grb-2 in five cohorts. An evaluable patient is a patient who has been able to complete the four-week treatment cycle. The protocol for the clinical trial includes five cohorts with dose escalation of 5, 10, 20, 40 and 50 mg/m<sup>2</sup>. The expected dose for treatment is 45 mg/m<sup>2</sup> based on pre-clinical studies in animals. The clinical trial is being conducted at The University of Texas MD Anderson Cancer Center.

It is important to note three patients who completed the full four week treatment cycle of the Phase I trial were placed on continuing treatment for additional cycles based on the Principal Investigator’s assessment that they were receiving benefit from treatment with Liposomal Grb-2. Two patients in the first cohort were treated for five months demonstrating stable disease before coming off study, and currently one patient in the third cohort has recently started to receive extended treatment. The Company expects that it can complete the Phase I clinical trial during 2012, subject to patient accrual rates.

In December of 2011, data from Liposomal Grb-2 was presented in a poster presentation at the 53<sup>rd</sup> Annual Meeting of the American Society of Hematology (ASH) held in San Diego, California. Jorge Cortes, M.D., Professor at the MD Anderson Cancer Center, lead author of the poster and Principal Investigator for the clinical trial, reported that preliminary results suggest that Liposomal Grb-2, at a dose of 5 mg/m<sup>2</sup> is well tolerated and there is suggestion of some possible anti-leukemia activity. Lab parameters for the six evaluable patients show each of these patients experienced transient reductions for blasts and bone marrow results. Two patients had transient improvement and/or stable disease and received a total of five cycles each. Two patients also had transient improvements in leukemia cutis lesions.

- In the second quarter of 2011, Dr. Ana Tari, PhD, MBA joined Bio-Path as Director Preclinical Operations and Research. As an expert in liposomal antisense therapeutics and a key member of the research team that performed the basic research and preclinical development of the Company’s liposomal

delivery technology, Dr. Tari brings a wealth of experience and knowledge that will be instrumental as Bio-Path progresses its research programs.

- In July of 2011, Bio-Path announced the relocation of its corporate office to a location near the Texas Medical Center, MD Anderson Cancer Center and other life science entities.
  - From the fourth quarter 2010 through 2011, Bio-Path raised \$2.5 million from several sources. In April of 2011, the Company completed a private placement sale of common stock raising approximately \$1.8 million. At the end of September 2011 through early October timeframe, investors exercised warrants to purchase common stock, raising approximately \$0.6 million. Finally, the Company raised \$125,000 from the sale of common stock to Lincoln Park Capital Fund, LLC (“LPC”), a Chicago-based institutional investor, in three separate transactions pursuant to Bio-Path’s equity purchase agreement with Lincoln Park Capital for the purchase of up to \$7 million in shares of the Company’s common stock.
  - At the end of the first quarter 2012, the Company commenced a new private placement fund raising campaign to raise up to \$2 million through the sale of shares of the Company’s common stock.
  - During 2011, Bio-Path continued to increase its profile and presented at four industry conferences including the Biotech Showcase™ in San Francisco, the OneMedForum in New York City, the Rodman and Renshaw Annual Global Investor Conference in New York City and the BIO Investor Forum 2011 in San Francisco.
  - Recently, Bio-Path entered into a services agreement with Los Angeles-based investor relations firm PondelWilkinson to assist the Company in implementing an investor and public relations program geared to the individual retail investment community. Bio-Path also has an active services communications engagement with Rx Communications, LLC, based in New York City, for communications strategy and interface targeted to institutional investors, investment banking firms and industry analysts. Increasing awareness of the Bio-Path story, including our recent clinical success and the potential of the Company, to both the individual and institutional investor communities is an important mission as the Company endeavors to increase shareholder value in the near term.
- Financial Highlights
    - Net loss for the year 2011 was \$(2,363,344), compared to a net loss of \$(2,081,500) for the year 2010. The increased net loss was primarily due to a reduction of \$242,658 in other income. In 2010, the Company received a one-time grant award totaling \$244,479 that was recorded in other income and which was not similarly matched in 2011. General and administrative expense increased \$97,822 in 2011, primarily as a result of an active program that commenced in 2011 involving the Company’s travel to and participation in industry conferences. Research and development expenses were lower in 2011 by \$58,636, primarily the result of lower expenses for drug material for testing, which more than offset an increase in clinical trial expense and expense for technology impairment. For the year 2011, the Company reported a net loss per share of \$(0.04) based on 53,844,195 weighted average shares outstanding, compared to a net loss per share of \$(0.04) for the year 2010.
    - Operating expenses for 2011 increased by approximately two percent to \$2,365,615 versus 2010. Operating expenses in 2011 included a one-time technology impairment expense of \$345,000, which is included in related party research and development expense. Reductions in 2011 for research and development expense for drug material for testing and lower stock option expense in 2011 substantially offset the technology impairment expense.
    - As of December 31, 2011, the Company had cash of \$952,252 compared to \$238,565 in cash and \$244,479 in grants receivable at December 31, 2010. Net cash used in operating activities for the year 2011 increased by \$1,755, or less than one percent.

“Significant progress in key areas was made in 2011 and the Company continues to gain momentum,” said Peter Nielsen, President and Chief Executive Officer of Bio-Path. “After a frustratingly slow start to our clinical trial, it appears that we are starting to progress through trial cohorts at a faster pace. The fact that our principal investigator for the clinical trial continues to see possible anti-leukemia benefits in patients, supported by some patients reaching stable disease for a period of time with extended treatments, may be helping in recruiting new patients.”

Mr. Nielsen continued, “In the first quarter of 2012, the Company’s Board of Directors made a decision to focus the Company’s efforts strictly on developing antisense RNA interference due to the progress that has been made in

developing our lead liposomal antisense drug candidate Liposomal Grb-2. As such, the Company will stop any further development of liposomal siRNA and make an appropriate reduction to the carrying value of our technology license other asset, effective as of December 31, 2011. Concentrating our focus in one area of RNA interference will avoid duplicating development costs and speed time-to-market of additional liposomal antisense drug candidates.” Finally, Mr. Nielsen commented, “During 2011, Bio-Path successfully launched a communications program involving the Company’s participation as a presenting company at several large biotech investor conferences. We are starting to see signs that recognition of Bio-Path among key investor groups is increasing. In addition, Bio-Path continued to have success raising additional capital to finance our Phase I clinical trial and on-going operations. We have commenced a new private placement with the goal of raising up to \$2 million over the next several months through the sale of shares of the Company’s common stock.”

#### About Bio-Path’s Delivery Technology

Bio-Path’s drug delivery technology involves microscopic-sized liposome particles that distribute nucleic acid drugs systemically and safely throughout the human body, via simple intravenous infusion. The delivery technology can be applied both to single stranded (antisense) nucleic acid compounds and double stranded (siRNA) with the potential to revolutionize the treatment of cancer and other diseases where drugable targets of disease are well characterized. However, the Company is currently only developing liposomal antisense drug candidates. Bio-Path also anticipates developing liposome tumor targeting technology, representing next-generation enhancements to the Company’s core liposome delivery technology.

#### About Growth Receptor Bound protein-2 (Grb-2)

The adaptor protein Growth Receptor Bound protein-2 (Grb-2) is essential to cancer cell signaling because it is utilized by oncogenic tyrosine kinases to induce cancer progression. Suppressing the function or expression of Grb2 should interrupt its vital signaling function and have a therapeutic application in cancer. BP-100.1.01 is a neutral-charge, liposome-incorporated antisense drug substance designed to inhibit Grb-2 expression.

#### **About Bio-Path Holdings, Inc.**

Bio-Path is a biotechnology company focused on developing therapeutic products utilizing its proprietary liposomal delivery technology designed to systemically distribute nucleic acid drugs throughout the human body with a simple intravenous transfusion. Bio-Path’s lead product candidate, Liposomal Grb-2, is in a Phase I study for blood cancers. Bio-Path’s second drug candidate, also a liposomal antisense drug, is ready for the clinic where it will be evaluated in lymphoma and solid tumors.

*Any statements that are not historical facts contained in this release are forward-looking statements that involve risks and uncertainties, including Bio-Path’s ability to raise needed additional capital on a timely basis in order for it to continue its operations, have success in the clinical development of its technologies, the timing of enrollment and release of data in such clinical studies and the accuracy of such data, limited patient populations of early stage clinical studies and the possibility that results from later stage clinical trials with much larger patient populations may not be consistent with earlier stage clinical trials, and such other risks which are identified in the Company’s most recent Annual Report on Form 10-K and in any subsequent quarterly reports on Form 10-Q. These documents are available on request from Bio-Path Holdings or at [www.sec.gov](http://www.sec.gov). Bio-Path disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.*

For more information, please visit the Company's website at <http://www.biopathholdings.com>.

#### Contact Information:

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## **Bio-Path Holdings Engages PondelWilkinson for Retail Investor Relations Program**

**March 29, 2012; HOUSTON, TX** – Bio-Path Holdings, Inc., (OTC BB: BPTH) (“Bio-Path”), a biotechnology company developing a liposomal delivery technology for nucleic acid cancer drugs, today announced that it has entered into a services agreement with Los Angeles-based investor relations firm PondelWilkinson to assist the Company in implementing an investor and public relations program geared to the individual retail investment community.

PondelWilkinson is experienced in fostering a long-term, credible foundation among the retail investment community for its client companies. The firm will launch a scalable investor relations program to build awareness for Bio-Path among individual investors, leveraging the Company’s recent clinical successes and future milestones. Formed in 1968 and under present management since 1986, PondelWilkinson is experienced in representing emerging oncology-focused biotech/life science companies, and tailors programs that combine traditional public relations/media relations, “new” media, and investor relations. This unique combination of skills has been a differentiating strategy that is expected to be deployed on behalf of Bio-Path.

Bio-Path also has an active services communications engagement with Rx Communications, LLC, based in New York City, for communications strategy and interface targeted to institutional investors, investment banking firms and industry analysts. The Company intends to continue working with Rx Communications to address these investor and industry segments, which are expected to play a significant future role in the Company’s shareholder mix as Bio-Path advances development of its lead drug candidate.

“Increasing shareholder value is a top priority at Bio-Path and we are very excited about PondelWilkinson joining our communications team,” said Peter Nielsen, President and Chief Executive Officer of Bio-Path. “Increasing awareness of the Bio-Path story, including our recent clinical success and the potential of the company, to both the individual and institutional investor communities is an important mission and we believe we have aligned ourselves with high quality professionals to achieve our goals.”

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