

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): August 11, 2011

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

Utah

000-53404

87-0652870

(State or other jurisdiction
of incorporation)

(Commission File Number)

(IRS Employer Identification No.)

2626 South Loop, Suite 180, Houston, Texas

77054

(Address of principal executive offices)

(Zip Code)

801-580-2326

(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))
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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 August 15, 2011, Bio-Path Holdings, Inc. (the “Company”) announced financial results for the second quarter ended June 30, 2011. Additional information is included in the Company’s press release.

A copy of the Company’s press release is attached hereto as Exhibit 99.1.

Item 8.01 Other Events.

On August 11, 2011, the Company issued a press release titled “First Cohort Successfully Completed in Bio-Path Holding’s Phase I Clinical Trial of Lead Product Candidate Liposomal Grb-2 in Leukemia.”

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 | Press Release dated August 15, 2011 |
| 99.2 | Press Release dated August 11, 2011 |

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: August 15, 2011

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

EXHIBIT INDEX

| Exhibit Number | Description |
|-------------------|-------------------------------------|
| 99.1 | Press Release dated August 15, 2011 |
| 99.2 | Press Release dated August 11, 2011 |



Bio-Path Holdings Reports Second Quarter 2011 Financial Results

FOR IMMEDIATE RELEASE

August 15, 2011 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 financial and operational results for the second quarter ended June 30, 2011.

SECOND QUARTER 2011 FINANCIAL AND OPERATIONAL HIGHLIGHTS

- Operational Highlights
 - o Bio-Path continued to enroll patients into the Phase I clinical trial of its lead product candidate, Liposomal Grb-2, which is a systemic treatment for blood cancers including acute myeloid leukemia (AML), chronic myelogenous leukemia (CML), acute lymphoblastic leukemia (ALL) and myelodysplastic syndrome (MDS). The trial is being conducted at the MD Anderson Cancer Center. In July of 2011 the Company completed the first cohort of the trial (dose of 5 mg/m²). There were no treatment-related serious adverse events and the data suggested some possible anti-leukemia activity.

The Company continues to enroll patients into the trial and started the second cohort, treating patients with a dose of 10 mg/m², of Liposomal Grb-2. The protocol for the clinical trial includes dose escalation of 5, 10, 20 and 50 mg/m².
 - o The Company completed a previously announced Private Placement, raising approximately \$1.8 million in total.
 - o Dr. Ana Tari 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.
 - o In June of 2011, the Company made a presentation at the OneMedForum investor conference in New York City. An archive of the presentation may be found at the Company’s website: www.biopathholdings.com.
 - o After the close of the quarter, the Company announced that it had relocated its corporate headquarters to Houston, Texas. Located on the south side of the Texas Medical Center, the office is located near the University of Texas MD Anderson Cancer Center and other life science entities.
 - Financial Highlights
 - o Net loss for the second quarter 2011 was \$(462,748), compared to a Net Loss of \$(426,814) in the second quarter 2010. The increase was primarily attributed to increased research and development expense from our expanding clinical trial, as well as increased expenses for legal, corporate communications and expenses related to being a public company. These expenses included non-cash stock option expense of \$120,684 and \$142,710 for the quarters ending June 30, 2011 and 2010, respectively. For the quarter, the Company reported a net loss per share of \$(0.01) based on 51,649,169 weighted average shares outstanding, compared to \$(0.01) per share for the same period last year.
 - o Operating expenses in the second quarter of 2011 increased by approximately nine percent to \$463,768 versus the second quarter 2010 primarily due to increased research and development expenses for the clinical trial and increased general and administrative expenses.
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- o As of June 30, 2011, the Company had cash of \$1,221,659, compared to \$238,565 at December 31, 2010. Net cash used in operating activities for the first six months of 2011 was \$(375,647) compared to \$(415,414) for the first six months of 2010.

“There have been several positive developments over the last few months, most notably the first cohort in our clinical trial has been successfully completed. The drug was well tolerated and, encouragingly, there was evidence of anti-leukemia activity, a surprising result in light of the very low starting dose,” said Peter Nielsen, President and Chief Executive Officer of Bio-Path. “We look forward to continue to progress Liposomal-Grb2 through the clinic and look forward to possibly presenting the results of the first cohort at the American Society of Hematology (ASH) Annual Meeting in December.”

Bio-Path is developing a neutral lipid-based liposome delivery technology for nucleic acid cancer drugs (including antisense and siRNA molecules), a delivery technology that forms microscopic-sized vehicles to safely deliver these drugs to their intended target cancer cells.

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 double stranded (siRNA) and single stranded (antisense) nucleic acid compounds with the potential to revolutionize the treatment of cancer and other diseases where drugable targets of disease are well characterized. Bio-Path also anticipates developing liposome tumor targeting technology, representing next-generation enhancements to the Company’s core liposome delivery technology.

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, and its third candidate is a liposomal siRNA cancer drug that is in the final pre-clinical development stage. These product candidates and the delivery technology have been licensed from The University of Texas MD Anderson Cancer Center.

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. 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>.

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First Cohort Successfully Completed in Bio-Path Holding's Phase I Clinical Trial of Lead Product Candidate Liposomal Grb-2 in Leukemia

- Drug Well-Tolerated and Activity Seen at Low-Starting Dose

FOR IMMEDIATE RELEASE

August 11th, 2011 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 completed treatment of the first dosage cohort in the Company’s Phase I clinical trial of its lead product candidate, BP-100-1.01 (Liposomal Grb-2), which is a systemic treatment for blood cancers including acute myeloid leukemia (AML), chronic myelogenous leukemia (CML), acute lymphoblastic leukemia (ALL) and myelodysplastic syndrome (MDS). The trial is being conducted at the MD Anderson Cancer Center. The drug was well tolerated with no treatment-related serious adverse events reported and data suggests some possible anti-leukemia activity.

A total of 14 patients were enrolled in the first cohort of the study. All patients had failed prior therapies. Of the 14 patients, one patient withdrew prior to treatment and 13 were treated. Of the treated patients, six were evaluable and seven failed to complete a full 28-day cycle because of disease progression. Liposomal Grb-2 is systemically delivered by intravenous injection. Patients received a dose of 5 mg/m² twice a week for four weeks, for a total of eight doses. Six evaluable patients comprised the completed first dose cohort. Preliminary results suggest that Liposomal Grb-2, at a dose of 5 mg/m² is well tolerated. In addition, there is already a suggestion of possible anti-leukemia activity, even at the low starting dose used in the first cohort. The protocol for the clinical trial includes dose escalation of 5, 10, 20, 40 and 50 mg/m².

Of the six evaluable patients, lab parameters for blasts and bone marrow demonstrated possible anti-leukemia activity. Two patients had transient improvement and/or stable disease and received a total of five cycles each, representing five months on treatment with the drug. In addition, two patients had transient improvement on leukemia cutis lesions.

In addition to the six evaluable patients, a patient with CML blast phase who had failed all available TKI (tyrosine kinase inhibitor) and other experimental options showed a significant reduction in blasts from 81 percent to four percent. Unfortunately, this patient discontinued study treatment due to progression of disease into the central nervous system and had to discontinue therapy.

“The preliminary results being reported today for the first cohort of our clinical trial are extremely promising. The suggestion of possible anti-leukemia activity, in particular, was an unexpected and very positive result, especially because of the low dose used in the cohort. For reference, efficacy studies of Liposomal Grb-2 in animals used a dose of 45 mg/m²,” said Peter Nielsen, President and Chief Executive Officer of Bio-Path. “We look forward to proceeding through the next cohorts of the clinical trial to determine if higher doses of the drug will increase favorable anti-leukemia effects on patients.”

The Principal Investigator for the clinical trial is preparing, with the assistance of the Company, an abstract for submission to the American Hematology Society Annual Meeting later this year in San Diego and potential other important scientific conferences later in the year. The study continues to accrue patients and Cohort 2 is open with dosing at 10 mg/m².

About the 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 double stranded (siRNA) and single stranded (antisense) nucleic acid compounds with the potential to revolutionize the treatment of cancer and other diseases where drugable targets of disease are well characterized. 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.

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