# 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 16, 2012

# **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)  |
| (Regist  | (832) 971-6616 rant's Telephone Number, Including                          | Area Code)  |
| (Regist  | rain 5 Telephone Paintoer, merading  | Theu Code)  |
| (Former Nar  | ne or Former Address, if Changed Si  | nce Last Report)  |
|  | if the Form 8-K filing is intende<br>y of the following provisions (see Ge | d to simultaneously satisfy the filing neral Instruction A.2. below): |
| ☐ Written communications pursu   | uant 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 commun 240.14d-2(b))  | ications pursuant to Rule 14d-2(b  | ) under the Exchange Act (17 CFR                                      |
| ☐ Pre-commencement communic  | cations pursuant to Rule 13e-4(c) und                                      | der 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 August 16, 2012, Bio-Path Holdings, Inc. (the "Company") announced financial results for the second quarter ended June 30, 2012. 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. The foregoing description of the press release is qualified in its entirety by reference to the attached exhibit.

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit

Number <u>Description</u>

99.1 Press Release dated August 16, 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.

Dated: August 16, 2012

**BIO-PATH HOLDINGS, INC.** 

By: /s/ Peter H. Nielson

Peter H. Nielson

President and Chief Executive Officer

# EXHIBIT INDEX

Exhibit

Number Description

99.1 Press Release dated August 16, 2012



#### Bio-Path Holdings Reports Second Quarter 2012 Operational and Financial Results

- Lead Product Candidate, Liposomal Grb-2 Continues to Progress through Clinic -

**August 16, 2012; HOUSTON, TX** – Bio-Path Holdings, Inc., (OTCQX: BPTH) ("Bio-Path"), a biotechnology company developing a liposomal delivery technology for nucleic acid cancer drugs, today announced operational and financial results for the quarter ended June 30, 2012.

#### SECOND QUARTER 2012 OPERATIONAL AND FINANCIAL HIGHLIGHTS

- Recent Operational Highlights
  - o Bio-Path completed treatment of the third 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 University of Texas MD Anderson Cancer Center. The drug was well tolerated with no treatment-related serious adverse events reported and data continues to suggest possible anti-leukemia activity. A total of three patients were enrolled and dosed in the third cohort of the study. All three patients completed the 28-day treatment cycle and were evaluable. In addition, in the opinion of the principal investigator for the study, all three of these patients were stabilized during their treatment. To date, the Phase I trial has included 12 evaluable patients.

Time for completion of a cohort, number of patients enrolled and the percentage of evaluable patients that received extended treatments has shown significant uptick during the trial. An important measure of benefit from treatment with the drug is stabilization and being placed on extended treatment cycles. This trend is also very positive, with all three patients from Cohort 3 being placed on extended treatment plans. It is worth noting that half of all evaluable patients from the study have received extended treatment.

Liposomal Grb-2 is systemically delivered by intravenous injection. Patients in the third cohort received a dose of  $20 \text{mg/m}^2$  twice a week for four weeks, for a total of eight doses. The protocol for the clinical trial includes dose escalation of 5, 10, 20, 40 and 50  $\text{mg/m}^2$ . The expected dose for treatment is 45  $\text{mg/m}^2$  based on pre-clinical studies in animals. Enrollment is currently underway for Cohort 4.

O As previously reported, the Company added new suppliers for the Grb-2 drug substance and for the final drug product in order to increase the capacity of its drug supply chain. The necessity for increased drug supply is based on the experience with treating patients in Cohort 3 of the clinical trial, when all three patients benefited from treatment with Liposomal Grb-2 and, in the opinion of the principal investigator, were stabilized. Based on this initial success, the need for additional drug requirements for Cohort 4 and beyond has increased significantly. The first batch of drug from the new supply chain was delivered to the Company in July of 2012.

- o Bio-Path's common stock began trading on the quality-controlled OTCQX on Friday June 1, 2012. OTCQX is the highest tier, premier trading platform for OTC companies and Bio-Path is very pleased to have qualified for the OTCQX, given its high standards. The Company also announced that it retained Roth Capital Partners to serve as the Company's Designated Advisor for Disclosure ("DAD") on OTCQX, responsible for providing guidance on OTCQX requirements.
  - The OTCQX is a premier platform that distinguishes the best companies traded over-the-counter from the thousands of securities traded on the OTC Bulletin Board who are not required to meet any financial standards or undergo a qualitative review. Bio-Path's commencement of trading on the OTCQX attests to the quality of the Company's financial reporting and its technology.
- O During the quarter, the Company launched an all-new website providing more detailed and upto-date information on Bio-Path, it's technology, product pipeline and clinical trial advancements. The website can be accessed at: <a href="www.biopathholdings.com">www.biopathholdings.com</a>.
- o As of the second week in August, 2012, the Company has enrolled two patients in Cohort 4 with the first patient more than half way through the cycle. As was the case with Cohort 3, only three evaluable patients are needed to complete Cohort 4.
- O During the second quarter, Bio-Path initiated a private placement to raise up to \$2 million through the sale of shares of the Company's common stock to accredited investors. Through the second week of August, 2012, the Company has raised approximately \$1 million, which is in various stages of being processed and collected through an escrow account including approximately \$460,000 processed into the Company's accounts.

### • Financial Highlights

- Net loss for the second quarter 2012 was \$(787,838), compared to a Net Loss of \$(462,748) in the second quarter 2011. The increased net loss for the second quarter 2012 was a result of an increase in research and development expense related partly due to a non-cash, technology impairment expense item that was recognized in the quarter ending June 30, 2012. For the second quarter, the Company reported a net loss per share of \$(0.01) based on 58,868,713 weighted average shares outstanding, compared to \$(0.01) per share for the same period last year.
- Operating expenses of \$787,782 in the second quarter of 2012 were higher by \$324,014 compared to the second quarter 2011, primarily due to the result of a technology impairment expense item that was recognized in the quarter, offset to some extent, by reduced administrative expenses for management stock options.
- As of June 30, 2012, the Company had cash of \$162,440, compared to \$952,252 at December 31, 2011. Net cash used in operating activities for the first six months of 2012 was \$(1,029,521) compared to \$(375,647) for the first six months of 2011. The primary reasons for the increase in net cash used in operations between the comparable six month period is the scale up of clinical trial operations, as well as increased working capital requirements totaling \$303,846 and receipt in 2011 of a \$244,479 U.S. Government grant that was not matched in 2012. As previously noted, the Company has initiated a private placement to raise up to \$2 million through the sale of shares of the Company's common stock. The proceeds of this financing are not included in the cash balance stated above.

"We reached significant milestones during the second quarter with the completion of Cohort 3 of our Phase I clinical trial evaluating our lead drug candidate Liposomal Grb-2 and the arrival of our first drug batch from the increased capacity drug supply chain that we put in place. We are also very encouraged by the safety

performance of Liposomal Grb-2 and benefit that patients appear to be receiving from treatment with the drug. Patients in our trial are typically in advanced stages of the disease, and the fact that treatment with Liposomal Grb-2 is stabilizing their condition is very positive," said Peter Nielsen, President and Chief Executive Officer of Bio-Path Holdings. "It is also important to note that we already have two patients enrolled in Cohort 4, which indicates that the positive trend for shortened time to complete a cohort is continuing. Additional signs of positive benefit from treatment with Liposomal Grb-2 is that the principal investigator of the trial has placed six patients from the trial on extended treatment plans.

Finally, the Company has had good success to date raising funds through our latest private placement. We are confident that we will achieve our goal of raising \$2 million in cash from the sale of our common stock by the end of 2012, which is more than sufficient to support our current programs."

#### 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. The Company's current focus is on 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 Grb-2 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. 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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