BIO-PATH HOLDINGS INC
Form 8-K
September 24, 2009

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 27, 2009

BIO-PATH HOLDINGS, INC.
(Exact Name of Registrant as Specified in Its Charter)

Utah
(State or Other Jurisdiction of Incorporation)

| 000-53404 | 87-0652870 |
|---|---|
| (Commission File Number) | (IRS Employer Identification No.) |
| 3293 Harrison Blvd., Ste. 230, Ogden, UT | 84403 |
| (Address of Principal Executive Offices) | (Zip Code) |

801-399-5500
(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 1.01 Entry into a Material Definitive Agreement.

Effective August 27, 2009, Bio-Path Holdings, Inc. (the "Registrant") entered into an exclusive License Agreement (the "Agreement") with The University of Texas M. D. Anderson Cancer Center to develop liposome tumor targeting technology. Bio-Path is currently developing a neutral-lipid based liposome delivery technology for nucleic acid cancer drugs (including antisense and siRNA molecules). The new technology, being licensed in the field of neutral lipid-based liposome delivery of antisense technologies and FAK siRNA, is projected to enhance the Registrant's liposome delivery technology by adding vectors to the liposomes targeted to a receptor that is specifically over-expressed on a majority of solid and hematological tumors and on 80 percent of metastatic epithelial tumors. The Registrant believes this liposome tumor-targeting technology for antisense and FAK siRNA delivery is a highly promising strategy for treating primary and metastatic cancers.

The historical perspective of cancer treatments has been drugs that affect the entire body. Advances in the past decade have shifted to treating the tumor tissue itself. One of the main strategies in these developments has been targeted therapy, involving drugs that are targeted to block the expression of specific disease causing proteins while having little or no effect on other healthy tissue. Nucleic acid drugs, specifically antisense and siRNA, are two of the most promising fields of targeted therapy. Development of antisense and siRNA, however, has been limited by the lack of a suitable method to deliver these drugs to the diseased cells with high uptake into the cell and without causing toxicity. Bio-Path's currently licensed neutral-lipid based liposome technology is designed to accomplish this. Studies have shown a tenfold to thirtyfold increase in tumor cell uptake with this technology compared to other delivery methods. The Company's first drug with this delivery technology is scheduled to commence a Phase I clinical trial in the fourth quarter 2009.

The new liposome tumor targeting technology being licensed will be developed as an extension of the Registrant's current delivery technology, with a goal toward more powerfully focusing delivery of the antisense and FAK siRNA cancer treatments to the tumor tissue. Adding a vector to the liposome that targets a receptor that is highly expressed on the surface of tumor cells is expected to drive uptake of the liposomes into the tumor tissue, enhancing relative deposition in the target tumor tissue. In animal studies conducted at M. D. Anderson Cancer Center, researchers demonstrated an ability for vector targeted neutral lipid-based liposomes to increase transfection efficiency and siRNA molecule uptake fivefold to eightfold into cancer cells compared to those of untargeted liposomes and controls. These efficiencies are in addition to the delivery efficiencies noted above from the core neutral lipid-based liposome delivery technology.

Pursuant to the License Agreement, the Registrant is obligated to various one time and recurring fees, expenses, royalties, milestone payments and other compensation and expenses to the licensor.

Item 9.01 Financial Statements and Exhibits.

B. Exhibits Item 10.1 – Drug Product Development and Clinical Supply Agreement (attached)

Item 99 -- Press Release (attached)

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SIGNATURES

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

Dated: September 24, 2009

BIO-PATH HOLDINGS, INC.

By: /s/ Peter Nielsen
Chief Executive Officer