

BIO-PATH HOLDINGS INC

Form 8-K

March 15, 2010

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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 12, 2010

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

Utah  
(State or Other Jurisdiction of Incorporation)

000-53404  
(Commission File Number)

87-0652870  
(IRS Employer Identification No.)

3293 Harrison Blvd., Ste. 230, Ogden, UT  
(Address of Principal Executive Offices)

84403  
(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 8.01 Other Events.

On March 12, 2010, Bio-Path Holdings, Inc. issued a press release announcing that the US Food and Drug Administration (FDA) has allowed an IND (Investigational New Drug) for Bio-Path's lead cancer drug candidate liposomal Grb-2 to proceed into clinical trials. The IND review process was performed by the FDA's Division of Oncology Products and involved a comprehensive review of data submitted by Bio-Path covering pre-clinical studies, safety, chemistry, manufacturing and controls, and the protocol for the Phase I clinical trial.

Bio-Path is developing a neutral lipid-based liposome delivery technology for nucleic acid cancer drugs (including antisense and siRNA molecules). Bio-Path's drug candidate liposomal Grb-2 (BP-100-1.01) is an antisense drug substance targeted to treat several types of cancer. The FDA's clearance of the IND allows Bio-Path to proceed with a Phase I clinical trial in patients with chronic myelogenous leukemia (CML), acute myeloid leukemia (AML), acute lymphoblastic leukemia (ALL) and myelodysplastic syndrome (MDS). Commencement of the trial will occur after patients are enrolled and administrative details are finalized. Bio-Path does not expect significant delays for these steps.

Item 9.01 Financial Statements and Exhibits.

B.Exhibits 99.1 - Press Release  
(attached)

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: March 15, 2010

BIO-PATH HOLDINGS, INC.

By: /s/ Peter Nielsen  
Chief Executive Officer



