Bio-Path Holdings, Inc.

Bio-Path Holdings, Inc. Provides Operations Update and Overview Of New Targeting Technology

Timeline Updated For Commencement Of The Company's Phase I Clinical Trial and New Liposome Targeting Technology Is Discussed

FOR IMMEDIATE RELEASE

June 23, 2009 HOUSTON, TX – Bio-Path Holdings, Inc., (OTC BB: BPTH), a publicly traded biotechnology company with drug development operations in Houston, Texas, issued a news release today in which the Company provided an update of drug development operations and also discussed a new liposome tumor targeting technology that it plans to develop.

Bio-Path is currently developing a neutral lipid-based liposome delivery technology for nucleic acid cancer drugs (including antisense and siRNA molecules). Antisense and siRNA drugs are targeted to block the expression of specific disease-causing proteins while having little or no effect on other healthy tissue. 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 without causing toxicity. Bio-Path's currently licensed neutral lipid-based liposome technology was developed to accomplish this, and studies have shown a significant increase in tumor cell uptake with this technology compared to other delivery methods. The Company's operations to date have focused on initiating a Phase I clinical trial for its lead cancer drug candidate, which potentially could demonstrate that the delivery technology is performing as expected.

After completing three rounds of private placement financings, Bio-Path became a public company through a reverse merger in February 2008 with sufficient funding to initiate drug development operations for a clinical trial in its lead drug compound. The Company subsequently submitted an Investigational New Drug application to the U. S. Food and Drug Administration (FDA) for its lead drug product BP-100-1.01 and began the process of selecting a current Good Manufacturing Practices (cGMP) contract manufacturing firm to manufacture the drug product needed for the clinical trial. In April 2008, the FDA review of the IND application resulted in a hold on the IND pending the Company submitting to the FDA:

- a few minor changes to the protocol for the clinical trial, and

- manufacturing and testing information from the clinical drug batch once it had been manufactured.

None of the requests described above were out of the ordinary or unexpected since the Company had planned to have the clinical drug batch manufactured and the testing information submitted to the FDA prior to commencing the clinical trial. As a result, Bio-Path continued with its operations plan to commence the clinical trial by the end of 2008.

Update to the Clinical Trial Protocol

During the course of reviewing FDA-requested changes to the protocol for the Bio-Path's Phase I Clinical Trial, the Company and the Principal Investigator (PI) for the trial agreed that the trial should be broadened from treating patients with Chronic Myelogenous Leukemia (CML) to include patients with refractory or relapsed Acute Myeloid Leukemia (AML), Acute Lymphoblastic Leukemia (ALL) and Myelodysplastic Syndrome (MDS). This action was taken to increase the rate of enrollment of patients, which is expected to enable the clinical trial to be completed on a more timely basis. However, the addition of the new disease indications required extensive editing to the protocol by the PI. The changes to the protocol were approved by the hospital's Institutional Review Board (IRB) and the revised protocol with the FDA-requested changes has been submitted to the FDA.

Development and Testing of the cGMP Drug Batch

After a several month evaluation process, in July 2008 Bio-Path selected a cGMP contract drug manufacturer to develop and manufacture the clinical drug batch. The manufacturer had a significant manufacturing backlog and the timetable to complete manufacturing drug development activities for Bio-Path's drug including a fill/finish validation and engineering prototype test runs resulted in November 2008 as the projected manufacturing date of the first clinical-grade batch of drug for the clinical trial. As part of the manufacturing development process, Bio-Path transferred its licensed manufacturing technology to the contract drug manufacturer.

Manufacturing problems were encountered during the first engineering prototype run. Additional information was requested by the Company from the licensor of the technology and a second engineering prototype test was conducted in December 2008, which again had problems.. At this point, the Company engaged a leading lyophilization expert to work with Bio-Path's management to develop and finalize a manufacturing procedure. Over the course of the next six months, the Company developed the manufacturing procedures for its liposomal based drug products and in the process, two additional pilot manufacturing runs, a new fill/finish validation run and another engineering prototype test run was performed. As a result of these development activities, cGMP manufacturing procedures were developed and Bio-Path's lyophilized drug product was able to be manufactured using the Company's new manufacturing

techniques. The difficulties described above can be related to moving from a research laboratory manufacturing process to a fully scaled-up cGMP manufacturing technology.

After the manufacturing development program was completed, the first open slot in the schedule to manufacture the clinical drug batch was in the later part of May 2009. However, the contract manufacturer has to remanufacture this batch due to manufacturing facility changes. This batch is now on-schedule to be produced during the last week of July 2009.

Manufactured Drug Testing Program and Pharmacokinetic Studies

While manufacturing development continued, the Company was able to make significant progress resolving manufactured drug product testing open issues and developing assays needed for pharmacokinetic testing. Testing of the manufactured drug product involves the methods and assays used to demonstrate that Bio-Path's drug product manufactured is safe and manufactured to specifications, that the delivery component is intake and that the active drug ingredient is present. In addition, assays were needed to measure the amount of drug substance in a patient's plasma and urine for pharmacokinetic studies, which are particularly important because these studies are critical to understanding if the delivery technology is performing in a manner expected. However, the key manufacturing and pharmacokinetic assays which were supposedly part of the technology transfer to the Company, upon further examination, were not applicable to Bio-Path's drug product. As a result, Bio-Path searched and identified assays and methods for these tests and is now in the process of funding development and validation.

In retrospect, the difficulty in developing methods and assays for Bio-Path's lead drug product is understandable. The basic property of the antisense in Bio-Path's lead drug, the charge neutral p-ethoxy backbone, is the same feature that results in the absence of toxicity in animal studies. However, most of the industry testing has been developed around antisense backbone technology that has a net charge because it contains sulfur, a recognized cause of toxicity. The result of a net charge is that it is much easier to handle and manipulate the antisense drug substance in testing. As a result, the very feature that is expected to produce little or no toxicity in the Company's antisense makes it much more difficult to develop the assays for testing required of the product. Consequently, Bio-Path's development of key methods and assays for the p-ethoxy antisense manufacturing testing and pharmacokinetic assays is a very significant addition to the Company's technology.

Updated Timing for the Clinical Trial

Based on the timing for the manufacture of the clinical batch and the subsequent time required to complete testing of the drug manufactured, the Company now expects that it will be able to submit the manufacturing data from the clinical batch to the FDA in the first week of September 2009. Assuming the FDA is satisfied with the data in the submission, the Company should be released to commence the clinical trial during September or by the beginning of October 2009.

Peter Nielsen, President and Chief Executive Officer of Bio-Path Holdings, Inc. commented, "The delay in starting our first Phase I clinical trial is frustrating but, after reviewing the situation, understandable. The technology that the Company licensed was based upon manufacturing techniques used in a research laboratory. When going to full clinical development, manufacturing techniques needed to be developed that would allow cGMP manufacturing of our drug products on a much larger scale. The good news is that this has been completed and we can most likely file for new intellectual property for our manufacturing processes."

Cash Resources

Management has prepared a new budget plan for the upcoming period including the clinical trial. There is sufficient funding to continue operations and commence the clinical trial, including purchase of the clinical drug batch. However, the extended drug development effort, including multiple additional manufacturing test runs, has stretched the Company's resources. As a result, the Company is in the process of raising additional capital, and recently, raised approximately $165,000. The Company has verbal commitments for $500,000 in funding over the next few months, including the amounts already raised. The Company's strategy for raising the next round of capital has been to wait until there is patient data midway through the first clinical trial, which could potentially demonstrate that the drug delivery technology is performing as expected. Patient data from the clinical trial that demonstrates effectiveness of the delivery technology is expected to increase Bio-Path's valuation, which should enable the Company to raise a significant amount of capital for the next stage of development without being excessively dilutive. The Company currently expects to be midway through the clinical trial by the end of the first quarter 2010, assuming the FDA releases the IND to commence the trial by October 2009 and that there are not significant delays enrolling patients in the trial. In order to further stretch funds in the short term, management has deferred approximately sixty percent (60%) of their cash salaries.

New Liposome Targeting Technology

Bio-Path is currently in the process of licensing new tumor targeting technology that represents next-generation development of its liposome delivery technology. The new technology being licensed will enhance the Company'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 a reported 80% of metastatic epithelial tumors. The Company believes this tumor-targeting technology for antisense and siRNA delivery represents a highly promising strategy for treating primary and metastatic cancers.

The new tumor targeting technology being licensed will be developed as an extension of the Company's current delivery technology, with a goal towards more powerfully focusing delivery of the antisense and 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.

Peter Nielsen, President and Chief Executive Officer of Bio-Path Holdings, Inc. commented, "Tumor targeting represents a next generation approach to development of our core neutral lipid-based delivery technology for antisense and siRNA. Focusing our drugs more towards diseased tissue and away from healthy tissue is expected to increase the efficacy of our drugs while reducing further any potential for toxic side-effects. The combination of these benefits potentially represents sustainable treatment advantages for future Bio-Path's drugs. An additional strategic benefit of this technology for Bio-Path is that tumor targeting applied to our core delivery technology provides an opportunity to reinvent our intellectual property portfolio, affording new patent protection well into the future."

About Bio-Path Holdings, Inc.

Bio-Path is developing leading edge, patented, liposomal drug delivery systems developed at The University of Texas M. D. Anderson Cancer Center with two clinical cancer drug candidates ready for the clinic and a third siRNA cancer drug undergoing final pre-clinical development. Bio-Path's drug delivery technology distributes nucleic acid drugs systemically, 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.

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