

# **Bio-Path Holdings Reports Fiscal Year 2010 Operational and Financial Results**

### FOR IMMEDIATE RELEASE

**March 31, 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 year ended December 31, 2010.

## 2010 FINANCIAL AND OPERATIONAL HIGHLIGHTS

- Operational Highlights
  - Enrollment continues in the Phase I clinical trial of its lead cancer drug product Liposomal Grb-2 (also "BP-100-1.01"). Through the end of the first quarter 2011, seven patients have been enrolled into the study, with another two additional patients in the process of being enrolled at the end of March 2011. Patients eligible for enrollment have refractory or relapsed Acute Myeloid Leukemia (AML), Philadelphia Chromosome Positive Chronic Myelogenous Leukemia (CML) and Acute Lymphoblastic Leukemia (ALL), or Myelodysplastic Syndrome (MDS) and who have failed other approved treatments. At the low initial dose levels in the clinical trial, it has taken longer than expected for the Principal Investigator to recruit patients into the trial. In addition, four of the initial patients were unable to stay on the entire four week treatment cycle because of progressive disease, which was unrelated to treatment with Liposomal Grb-2, and consequently, had to be withdrawn from the study before completion of testing.

It is important to note two of the three patients that completed the full four week treatment cycle of the Phase I trial were placed on continuing treatment for additional cycles based on the Principal Investigator's assessment that they were receiving benefit from the drug. Bio-Path's FDA-approved protocol for the Phase I clinical trial provides that the Principal Investigator may continue treatment of a patient beyond the initial cycle if, in the Principal Investigator's opinion the patient is exhibiting stable disease, or else, have improvement of their disease. In the circumstance where a patient is continuing treatment beyond the requirements of the Phase I trial, the Company is required to supply drug at no charge for the continuing treatments but does not incur additional hospital costs. Although it is too early to draw any scientific conclusions about any effect that the Company's drug candidate Liposomal-Grb-2 has on patients being treated in the trial, the

effects of apparent stabilization in some patients is expected to help in recruiting new patients into the clinical trial. In this regard, the Company was very encouraged by the recent new enrollment of two new patients into the trial.

- It is now expected that an additional 12 months could be required to complete the Phase I clinical trial. We are seeking an additional 13-16 patients to complete the trial. Since, at the Principal Investigator's recommendation, some patients who are benefiting from the treatment are being placed on continuing therapy beyond the requirements of the clinical trial, additional expenses may be incurred as the Company is required to supply drug at no charge for the continuing treatment. Additional costs to completion of the Phase I clinical trial are estimated to range from \$750,000 to \$1.2 million. Bio-Path believes it has sufficient resources and access to additional resources if needed to meet its obligations in this regard.
- The Company has raised approximately \$1.4 million in connection with a planned private placement, with an amount in excess of \$1 million already collected and the balance expected to be in escrow as of March 31, 2011.
- Financial Highlights
  - Net loss for the year 2010 was \$(2,081,500), compared to a Net Loss of \$(1,969,738) for the year 2009. The increased Net Loss was due to an increase of \$480,953 in research and development expenses related to the commencement in July of the Phase I clinical trial of Liposomal Grb-2. This was partially offset by a decline of \$16,145 in general and administrative expense and a decline of \$111,501 for 2010 in stock option expense in 2010. The Company also had Other Income of \$244,479 representing a grant award from the U. S. Government. For the year 2010, the Company reported a net loss per share of \$(0.04) based on 48,153,321 weighted average shares outstanding, compared to net loss per share of \$(0.05) for the year 2009.
  - Operating expenses for 2010 increased by 18 percent to \$2,326,429 versus 2009 primarily due to increased research and development expenses for the clinical trial of Liposomal Grb-2.
  - As of December 31, 2010, the Company had cash and grants receivable of \$483,044 compared to \$567,249 at December 31, 2009. The amount at December 31, 2010 is comprised of \$238,565 in cash and a \$244,479 grant receivable from the U. S. Government that was received in February 2011. Net cash used in operating activities for the year 2010 was reduced by \$419,290, or 27 percent, compared to 2009. As previously stated, the Company has subsequently received, since the end of the fourth quarter, approximately \$1 million from a private placement with another \$400,000 committed and expected to be in escrow as of March 31, 2011.

Peter Nielsen, President and Chief Executive Officer of Bio-Path commented, "2010 was an important year for Bio-Path Holdings. The Company commenced a Phase I clinical trial with its lead drug product candidate Liposomal Grb-2 for treatment of several blood cancers. While patient enrollment has been slower than expected at the early stage of the trial, which involves the lower dosages, we are very encouraged with some of the early results. In particular, we

believe the effects of apparent stabilization in some patients from treatment with Liposomal Grb-2 could help in recruiting new patients into the clinical trial."

Mr. Nielsen continued, "Bio-Path continues to have success raising additional capital to finance the Phase I clinical trial and on-going operations. Since the fourth quarter 2010, Bio-Path has received approximately \$1 million out of \$1.4 million in commitments through the sale of shares of common stock under a private placement memorandum. In addition, in the fourth quarter 2010 Bio-Path sold shares of common stock for cash under the \$7 million equity purchase line that was established in the second quarter with an institutional investor. The amount of additional capital raised is expected to fund operations through the next key milestones."

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 M. D. 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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