CEO CFO

Bio-Path Holdings, Inc.

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Bio-Path Holdings, Inc. is Focused on the Exciting New Field of Antisense and siRNA Therapeutics for Cancer - Where There is the Prospect of Treating Disease Without Side-Effects

Biotech
Drug Delivery
(BPTH-OTC: BB)

Bio-Path Holdings, Inc.

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Peter H. Nielsen
Co-Founder, Chairman, President, and CEO

BIO:
Peter Nielsen is a co-founder of Bio-Path, serving as its President and Chief Executive Officer, and has been a director of the Company since its founding. Peter has developed a close working relationship over the last five years with key individuals at M. D. Anderson and suppliers of the Company's lead drug product while coordinating pre-clinical and manufacturing development of Bio-Path's lead product. He has also worked with several other biotech companies in a senior management capacity and as a Director, developing and executing on strategies for growth. Mr. Nielsen has a broad management background in senior management and has significant negotiating experience. He has engineering and MBA degrees from U.C. Berkeley.

Company Profile:
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.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFOinterviews.com

CEOCFO: Mr. Nielsen, what was the vision when you founded Bio-Path Holdings and where are you today?
Mr. Nielsen: Antisense and siRNA therapeutics are a new field of treatment that have great potential and have a lot of people excited about the prospect of treating disease without really having side-effects. One of the missing ingredients, the main one, is being able to successfully deliver those drug substances to the cell. When Bio-Path was founded, we envisioned taking lipid delivery technology developed at the M. D. Anderson Cancer Center and developing it into effective therapeutics for those kinds of drugs. Where are we now? We have had some success. It has taken a while, but we are currently in the clinic with our lead liposomal antisense drug. We are treating several blood cancers CML, AML, ALL, so we are excited about our progress.

CEOCFO: What are you doing that is different?
Mr. Nielsen: The method we have to do this is to use lipids, which are fat substances, and we make a drug that basically takes the drug substance and incorporates it into liposomes that are formed. Then these liposomes are injected into the patients for intravenous treatment and these are the vehicles that without toxicity can get the drug substances to the disease cells.

CEOCFO: Is this an area that is being worked on by many people today, or is it something that is somewhat unique to Bio-Path?
Mr. Nielsen: There is some uniqueness and there is some commonality to other approaches. People have seen the attractiveness of trying to use a liposome delivery technology, practically all of the effort though has been in so-called cationic lipid systems. These are systems that have a positive charge and they use it because it is easier to incorporate the drug substance. We use a neutral lipid system, and the neutral lipids do not have a charge. Because of that, we do not expect and we haven't shown any toxicity, whereas with the cationic system, the charge has some toxicity created within the body.

CEOCFO: How did you decide what types of cancer to focus on or what to try with the lipids?
Mr. Nielsen: It depends on the initial protein target and that target is involved in cell proliferation in these various CML, AML, ALL, blood cancers. Also, the drug is expected to have efficacy treating late-stage breast cancer patients as an anti-tumor agent. The first trial in blood cancers was chosen due to the ability and the ease to be able to extract

blood samples in order to really test if, indeed, the drug is doing what is expected to be done.

CEOCFO: What is the timetable going forward?

Mr. Nielsen: We are currently in a Phase I clinical trial with our first drug, Liposomal Grb-2, in blood cancers. The Phase I trial is a dose-escalating trial that goes up successively higher doses in anticipation of testing for any toxicity in the human patient. It is a lengthy process because we are treating patients that are basically resistant to the existing current therapies and they are far along in the disease, so it has taken a while to recruit those patients. We expect as we go further along in the trial and we get into higher doses that we will be able to recruit faster. We should be able to have some results that we can review with the public in 2011 and certainly we will finish the trial probably early in 2012 or maybe late 2011. It all depends on how quickly we can recruit patients.

CEOCFO: You have a number of other products as well!

Mr. Nielsen: We have a second drug, which is a liposomal antisense product. It is a broad based anti-tumor agent that we think treats 40% of tumors. We also have a liposomal siRNA drug. Our strategy is to focus on the initial drug and get our proof of principle and once that is done then we will move fairly quickly to develop other drug candidates.

CEOCFO: Are there partnerships or relationships in place or upcoming which are important for Bio-Path?

Mr. Nielsen: We are a licensee of the M. D. Anderson Cancer Center, one of the most prestigious cancer centers in the world, and the technology was generated from there. There is no formal partnership, but they are a stakeholder in this company, they have shares in Bio-Path. Going forward, I have now had several expressions of interest from Pharmaceutical companies in having certain licensing rights to the development of Grb-2. But right now, for us, it makes a lot of sense to be a little bit further along in the development of this drug and validate the value proposition before we start getting into greater detail with those kinds of situations.

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CEOCFO: What is the financial position like for Bio-Path today?

Mr. Nielsen: We are in the process of raising some more money, although we have sufficient resources to operate on our 2011 plan. We have a $7 million equity line established and we have only used half a million of that. It is fairly new and was just done in the 3rd Quarter. We are also raising another $1 to $2 million right now, so we have plenty of money to take us to the next value proposition, which would be to have sufficient data from this first Phase I trial, so that we can validate the technology and likely see some share appreciation. At that point we would raise sufficient money to continue with the trial, the next phase trial and also concurrently to start developing some of these other drugs. Our financing strategy has always been to not over-raise funds because we are very conscious to not spend money unnecessarily.

CEOCFO: In closing, there are many companies in your arena for investors to choose from; why does Bio-Path Holdings stand out?

Mr. Nielsen: Bio-Path offers a very unique value proposition. Antisense and siRNA are recognized by the scientific and medical communities to have great potential. We think that we will be the technology that finally makes those drugs viable for treatment. We are in a human clinical trial, so it is not an early-stage research effort. Therefore, the timeline relative to the potential pickup in value is pretty significant. In terms of the stock, this is actually the kind of thing you always want to put a piece of your portfolio in; a high-return potential investment and this certainly fits that criteria.

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