

Due Diligence Report: Breakthrough Therapy Designation May Be the Breakthrough the Company Needs

Summary:

CytoDyn Inc., incorporated on May 2, 2002, is a biotechnology company focused on discovering and developing a class of therapeutic monoclonal antibodies to treats Human Immunodeficiency Virus (HIV) infection. Its lead product candidate, PRO 140, belongs to a class of HIV therapies known as entry inhibitors. These therapies potentially block HIV from entering into and infecting certain cells. Although CytoDyn intends to focus its efforts on PRO 140, the Company also holds certain rights in two platform technologies: Cytolin, a monoclonal antibody targeting HIV with a mechanism of action which may prove to be synergistic to that of PRO 140 and other treatments, and CytoFeline, a monoclonal antibody targeting Feline Immunodeficiency Virus (FIV). The Company's PRO 140 antibody is a powerful anti-viral agent while not being a drug, which means fewer side effects and less frequent dosing requirements. The PRO 140 antibody belongs to a class of HIV therapies known as entry inhibitors that block HIV from entering into and infecting certain cells. PRO 140 blocks HIV from entering a cell by binding to a molecule called CCR5, a normal cell surface receptor protein to which HIV attaches as part of HIV's entry into a cell. The product had completed Phase II clinical trials. CytoFeline is an Anti-LFA-1 antibody for the treatment of Feline Immunodeficiency Virus (FIV) infection. FIV has a primary tropism for lymphocytes and gradually destroys sub-populations of T lymphocytes. This cytopathic effect causes a progressive loss of CD4+ lymphocytes, inversion of the CD4/CD8 ratio, and eventual loss of CD8+ lymphocytes in the late stages of infection. Cell-mediated immunity is impaired to a greater extent than antibody-mediated immunity. Impaired production and dysregulation of various cytokines also play a role in the pathogenesis of disease. The product had completed Phase II clinical trials. Cytolin is also a humanized monoclonal antibody for the treatment of HIV infection. It targets a normal cell molecule called CD11a, part of the heterodimer that makes up the cell adhesion molecule lymphocyte function cell associated antigen. In addition to cytotoxic T lymphocytes (CTLs), Cytolin® also appears to bind another type of immune cell called dendritic cells (DCs). The product is in the pre-clinical trials.

CytoDyn Inc. has a current market capitalization of \$103.88 M with 98.94 M outstanding shares. Its daily average volume traded is 0.17 M shares.

Key Indicators (Q3 2015)

Performance (6 months)

Shares Outstanding	98.94 M
Revenue	Nil
Gross Profit	Nil
Net Loss (basic/diluted)	-8.90 M
Cash and Short-term Inv	2.83 M

Total Debt 2.99 M



Recent News and Analysis:

Most recently, the company announced that it had named Denis R. Burger, Ph.D., who is currently a member of the Company's Board of Directors, as Chief Science Officer (CSO) of CytoDyn. In this capacity, through an expansion of Dr. Burger's existing consulting relationship with the Company, Dr. Burger will assist with the development of PRO 140 for HIV and non-HIV clinical indications, including transplantation, autoimmune diseases and cancer. He recently initiated the Company's evaluation of PRO 140 for Graft vs. Host Disease (GvHD) and the Company's Phase 2 protocol for this transplantation indication for patients requiring bone marrow stem cell transplants. On December 11, 2015, the FDA cleared CytoDyn to proceed into a clinical trial for GvHD. PRO 140 is currently in a pivotal Phase 3 trial for adjunct therapy for HIV patients with FDA approval for this indication expected in 2017.

Last week the company announced that it has filed a request for Breakthrough Therapy Designation of its PRO 140 HIV treatment. The company has been at this for quite a while, developing its product pipeline for over a decade now. It's unreasonable to expect this sort of mammoth task to be completed overnight, but this is certainly a step towards completion.

Due to the fact that CYDY hasn't been following the sectors that have been trending over the years, which usually provide for the volatility of most OTC enterprises, the company stock has been rather illiquid and we haven't seen many major percentile movements. The numbers contained in the latest report also suggest this. With significant cash in the bank, it would appear that CYDY is well equipped, compared to other OTC companies, but that usually suggest the lack of interest from the volatility-loving crowd that trades such stocks. Still, some recent news managed to stir things up a bit.

Conclusions:

The company had a respectable \$3.3 million in the bank as of its latest quarterly for the three months ended Nov 2015. That money will probably be put to good use in advancing PRO 140 along, as CYDY

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informed the company applied for breakthrough therapy designation just last week. It was this news that triggered the considerable swell in volume, after CYDY was trading mostly in five-digit daily volumes for the past couple of months. The company's outstanding share count is also creeping up, with some freshly issued shares well below current prices. CYDY had 70 million OS as of June 2015. This figure is now around the 98.9 million reported as of Dec 31, with a new 5.9 million issued at \$0.75 per share in mid-December. Only time can tell whether CYDY will obtain the breakthrough therapy designation it applied for and whether its product will see commercialization within the foreseeable future.

Sources:

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