Zacks Small-Cap Research

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CytoDyn Inc. (CYDY-OTC)

CYDY: Potential acquisition of CCR5 antibody may boost pipeline--Neutral

Current Recommendation	**Neutral**
Prior Recommendation	N/A
Date of Last Change	01/12/2012
Current Price (04/17/12)	$1.90
Twelve- Month Target Price	**$4.00**

OUTLOOK

CytoDyn is a biotech company focused on the development of novel anti-HIV/FIV antibodies. The Company's lead candidate Cytolin represents a new class of compound for the treatment of HIV/AIDS. Cytolin targets CD11a, a cellular protein that is also expressed on the HIV virion. Its unique mechanism of action makes it an ideal candidate for an early HIV/AIDS treatment option. An ex-vivo study of Cytolin is underway and CytoDyn plans to bring a human version of Cytolin into clinic this year.

Current risk/return profile is balanced at this point. We rate the Company's share a Neutral.

SUMMARY DATA

52-Week High	**$3.15**
52-Week Low	**$1.90**
One-Year Return (%)	**N/A**
Beta	**-0.01**
Average Daily Volume (sh)	**27,400**
Shares Outstanding (mil)	**28**
Market Capitalization ($mil)	**$55**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0.01**
Insider Ownership (%)	**32**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2012 Estimate	**N/A**
P/E using 2013 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**N/A**
Type of Stock	**N/A**
Industry	**Med-Biomed/Gene**
Zacks Rank in Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Aug)	Q2 (Nov)	Q3 (Feb)	Q4 (May)	Year (May)
2011	0.00 A	0.00 A	0.00 A	0.00 A	0.00 A
2012	0.00 A	0.00 A	0.00 A	0.00 E	0.00 E
2013					0.00 E
2014					0.00 E

Earnings per Share
(EPS is operating earnings before non recurring items)

	Q1 (Aug)	Q2 (Nov)	Q3 (Feb)	Q4 (May)	Year (May)
2011	-$0.03 A	-$0.05 A	-$0.05 A	-$0.05 A	-$0.18 A
2012	-$0.05 A	-$0.07 A	-$0.06 A	-$0.05 E	-$0.23 E
2013					-$0.16 E
2014					-$0.18 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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WHAT'S NEW

Possible Acquisition of PRO 140 May Boost Pipeline

On March 6, 2012, CytoDyn entered into a non-binding term sheet with **Progenics Pharmaceuticals, Inc.** to acquire from Progenics its proprietary humanized monoclonal antibody viral-entry inhibitor drug candidate, PRO 140.

PRO 140 is a humanized monoclonal antibody developed by Progenics that is directed at CCR5, a cell surface antigen that helps HIV gain entry to the immune cell for replication. PRO 140 has been shown in vitro to bind to CCR5 without interfering with normal cellular immune function and to block HIV entry into cells to which it is bound. Therefore, PRO 140 may have the potential to treat HIV.

Phase I and IIa clinical studies of PRO 140 have been substantially completed by Progenics.

According to the term sheet, the Parties will negotiate exclusively for a specific limited period toward an agreement whereby the Company would acquire all or substantially all of Progenics' worldwide tangible and intangible assets and contractual obligations relating to PRO 140.

But there is no guarantee that the Company and Progenics will be able to enter into a definitive agreement or complete the acquisition of PRO 140.

The possible acquisition of PRO 140 can diversify CytoDyn's pipeline, which is relatively weak with only two candidates. On the other hand, to complete the acquisition, the Company may need to raise new fund. Equity financing will dilute existing shareholder base.

CytoDyn Report Fiscal Third Quarter Financials

On April 16, CytoDyn reported fiscal third quarter financials ended Feb 29, 2012.

There was no revenue for the three months ended February 29, 2012.

Net loss was approximately $1.4 million or $0.06 per share for the three month ended Feb 29, 2012 compared to a net loss of approximately $1.1 million or $0.05 per share for the corresponding period in 2011. For the three months ended February 29, 2012 and February 28, 2011, operating expenses was approximately $1.4 million and $1.1 million, respectively consisting primarily of stock-based compensation, professional fees, research and development and salaries.

The increase in operating expenses of approximately $347,000 from the three-month period ended February 28, 2011 compared to the three months ended February 29, 2012 related primarily to increases in legal fees, stock-based compensation, consulting expenses, and accounting fees, offset by decreases in research and development. Research and development expenses are associated with the development of the Company's lead product, Cytolin.

As of Feb 29, 2012, CytoDyn had cash of $1.8 million and had a negative working capital of approximately $2.5 million. Current cash balance can last through fiscal fourth quarter of 2012. The Company may need to tap the capital market very soon to raise new funds for operations in our view.

The earnings report is a non-event. Investors should be more focused on the advancement of drug candidates. We will update investors when it's available.

KEY POINTS

- We maintain our Neutral rating on CytoDyn shares. Our 12-month price target is $4.00 per share.

- CytoDyn is a development stage biotech company focused on the discovery and development of novel anti-HIV and anti-FIV agents. The Company holds two proprietary platform technologies: Cytolin, a monoclonal antibody targeting HIV and CytoFeline, a monoclonal antibody targeting FIV.

- We are optimistic about the potential of the Company's lead candidate Cytolin, which is a monoclonal antibody targeting CD11a, a subunit of adhesion molecule LFA-1, which is involved in the process of HIV infection. But more data are needed to confirm Cytolin's clinical benefits.

- Unlike all other CD11a antibodies, Cytolin targets a different site of CD11a, without affecting CD11a's normal functions. Although CD11a exists in the surface of T-lymphocytes and dendritic cells, its presence on the HIV virion makes it a unique and potentially valuable target to interrupt HIV infection. This unique mechanism of action reduces resistance and makes Cytolin an ideal candidate for early treatment of HIV infection.

- Previous uncontrolled clinical work has shown that mouse Cytolin is safe and well tolerated. Favorable observations were made regarding global immunity and CD4 counts. Anecdotal data suggested an effect on viral burden.

- Based on the observations from mouse Cytolin, the Company plans to focus on humanized Cytolin for future clinical trials. A fully humanized Cytolin has been constructed and an ex-vivo study is under way to determine the in-vitro immunologic and virology activity of Cytolin. CytoDyn plans to initiate a Phase I clinical trial for humanized Cytolin in 2012.

- Based on the Cytolin concept, CytoDyn plans to develop CytoFeline monoclonal antibody to specifically treat feline immunodeficiency virus (FIV), which will be complementary to Cytolin and diversify the Company's pipeline.

- Risk/return profile of CytoDyn is balanced at this point. Although Cytolin/CytoFeline has potential to become a new class of agents to combat HIV/FIV, risk is high considering the early stage of development. Cash burn is also a major concern.

OVERVIEW

CytoDyn Inc. (CYDY) is a development stage biotechnology company focused on discovering and developing a new class of therapeutic **monoclonal antibodies** to treat Human Immunodeficiency Virus **(HIV)** and Feline Immunodeficiency Virus **(FIV)**.

CytoDyn acquired its lead drug candidate **Cytolin,** a monoclonal antibody to CD11a, and related intellectual property in 1994 from Allen D. Allen covering three United States patents along with foreign counterpart patents which describe a method for treating HIV disease with the use of monoclonal antibodies.

The license acquired gives the Company the worldwide, exclusive right to develop, market and sell compounds disclosed by the patent claims, practice methods taught by the patent claims, and exploit specified technology related to the patents. The term of the license agreement is for the life of the patents of which the first will expire in 2013.

Until recently, the Company's Cytolin-related patents were for a **murine (mouse) version** of the product. In addition, all of the research the Company has done so far on Cytolin has utilized the current murine version of the product.

However, on September 23, 2011, the Company filed a provisional patent application in the United States for its **humanized version** of its lead product Cytolin, a monoclonal antibody for the treatment of HIV Infection. This application resets the Cytolin patent life from 2011.

On May 16, 2011, CytoDyn formed a wholly owned subsidiary, **CytoDyn Veterinary Medicine LLC (CVM),** which will explore the possible application of the Company's existing proprietary monoclonal antibody technology to the treatment of **Feline Immunodeficiency Virus (FIV).** On June 17, 2011 the Company filed for a provisional patent in the United States for the use of these antibodies as well as selected small molecule antagonists and agonists for the treatment of FIV, a retroviral infection in cats. The Company anticipates it will apply to trademark this product under the name **CytoFeline**.

On January 30, 2007, CytoDyn acquired, from Utek Corp., its subsidiary **Advanced Genetic Technologies, Inc.**, which holds the exclusive worldwide licenses for the treatment of HIV using the monoclonal antibodies TS1-18 and TS1-22, and the non-exclusive rights to the bacterial plasmid 8630. **TS1-18**, is specific for the human CD18 antigen and **TS1-22** is specific for the CD11a antigen. Together, the CD18 and CD11a antigens make up the adhesion molecule **lymphocyte function-associated antigen-1 (LFA-1)**, a documented potential target for HIV infection. The bacterial plasmid 8630 encodes for the complete sequence of the human CD11a gene. These antibodies and plasmid were developed by Dr. Timothy Springer, a senior investigator at the CBR institute for Biomedical Research, an affiliate of Harvard Medical School. CytoDyn intends to explore the use of TS1-22 and TS1-18 antibodies as second generation therapeutics for HIV and FIV.

CytoDyn is the survivor entity of the reverse merger between RexRay Corporation and CytoDyn in October 2003. CytoDyn is a Colorado corporation, with its principal business office at 110 Crenshaw Lake Road, Lutz, Florida.

INVESTMENT THESIS

Cytolin Represents a New Class of Agent to Treat HIV

CytoDyn's former Chairman of Board of Directors, Allen D. Allen, has been researching treatments for HIV/AIDS since 1987. In 1994, Allen licensed Cytolin and related intellectual property to the Company, which cover the use of certain antibodies for treating patients with HIV/ADIS.

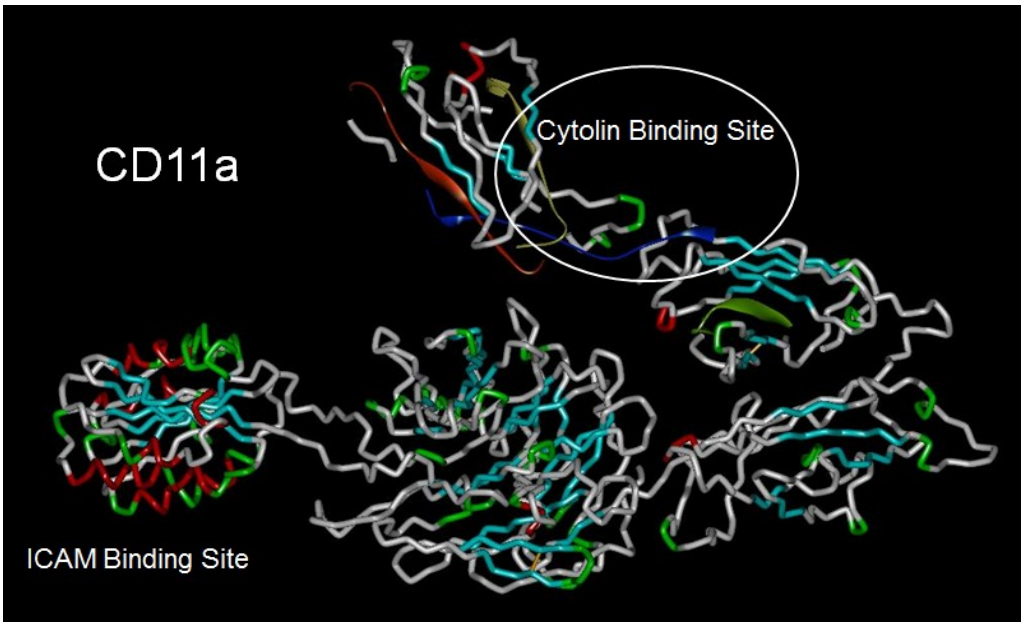
The Company's leading drug candidate, **Cytolin**, is a monoclonal antibody, which targets the CD11a, an alpha subunit of cellular adhesion molecule: lymphocyte function-associated antigen-1 (**LFA-1),** which comprises of **CD11a and CD18.**

Cytolin is a **mouse monoclonal antibody** that was originally developed to identify a specific type of immune cell called a cytotoxic T cell (CTL). Subsequent work showed that the antigen Cytolin bound to was the cellular antigen CD11a, which along with CD18 makes up the cellular adhesion molecule LFA-1(CD11a/CD18).

All T cells and some macrophages and neutrophils express LFA-1. It is thought to be the most important adhesion molecule for T-lymphocyte activation, because antibodies to LFA-1 effectively inhibit the activation of both naive and armed effector T cells.

While **CD4** and the **chemokine** receptors are the principal receptors for human immunodeficiency virus (HIV), recent studies also suggest that LFA-1 appears to be critical for HIV infection, therefore making it a target for anti-HIV treatment.

LFA-1 normally functions in the body as an adhesion molecule and is a critical component of the immune response. Under normal circumstances LFA-1 on immune cells binds to its cognate receptor (called **ICAM**) on the other cells and allows for a tight connection between cells so that a productive immune response can occur. Interestingly, virtually all other anti-CD11a antibodies available are targeted to the site of the CD11a molecule that bound to ICAM, resulting in antibodies that block immune activity. However, the results of the binding studies with Cytolin showed that unlike other CD11a specific antibodies, Cytolin did not bind to the ICAM binding region of the molecule. As a consequence of this unique specificity, **Cytolin does not block the normal function of CD11a.**



Cytolin binding site does not block the action of CD11a on normal cells

These observations, along with the unique reactivity of Cytolin for CTLs, prompted the Company to explore the administration of Cytolin to HIV-infected people to determine if it could perturb the natural course of HIV infection. These uncontrolled clinical studies showed treatment with Cytolin appeared to stabilize immunity and in some cases reduce viral burden.

Further work showed that in addition to cytotoxic T lymphocytes (CTLs) Cytolin also appears to bind another type of immune cell called dendritic cells (DCs). Both of these cells are critical to the control of viral burden in HIV infected individuals. By binding to these cells, Cytolin may induce an antiviral activity that can impede infection of new cells and presumably lead to a reduction in viral burden.

Preliminary Results of Mouse Cytolin have been Promising

Based on Cytolin's unique mechanism of action, CytoDyn conducted some uncontrolled clinical trials of mouse Cytolin in HIV patients.

In 1993, six HIV-infected patients were treated with Cytolin. Blood and skin tests of these patients suggested that the antibody might be producing improvements in the immune function of each patient.

Based on the results of this pilot study, a compassionate use trial was initiated. In this study a relatively small number of physicians in the United States administered Cytolin to their HIV-infected patients over two years. As results from this initial use became available, other physicians obtained and administered Cytolin to their patients as well. Four of the doctors using Cytolin allowed CytoDyn's predecessor to send in an independent Institutional Review Board to inspect the medical records of approximately **200 patients treated with Cytolin** once or twice a month over 18 months. Data were recorded and summarized and formed part of the material presented to the U.S. Food & Drug Administration (FDA) as an early indication of the safety and potential efficacy of Cytolin.

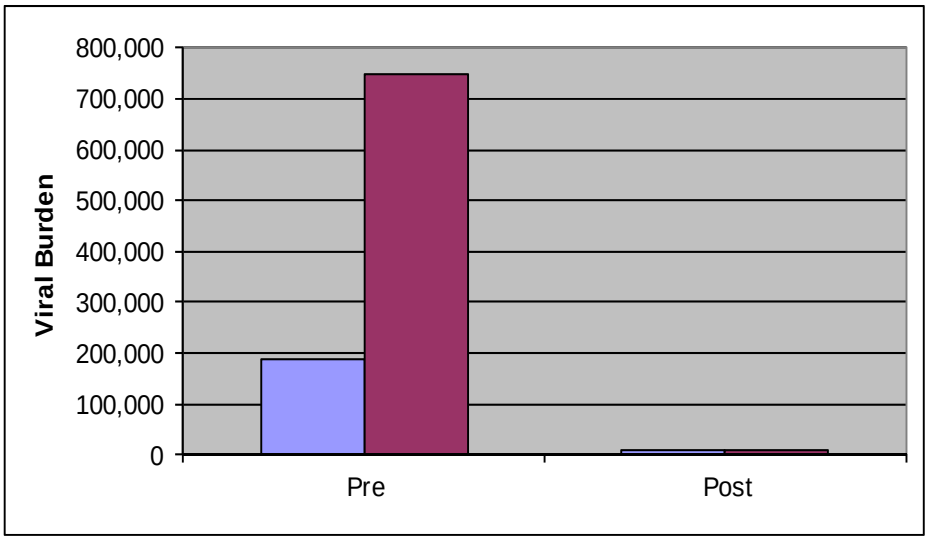
In 1996, the FDA approved a drug master file, designated BB-DMF#6836, for the manufacture of Cytolin at **Vista Biologicals Corporation**. CytoDyn and Vista Biologicals worked cooperatively to develop the drug master file. In accordance with the practice of the FDA, the drug master file was issued to and became the property of the entity with the capacity to manufacture the drug, in this case Vista Biologicals Corporation. By contract with Vista Biologicals Corporation, CytoDyn had the exclusive right to reference the drug master file, that is, to authorize Vista Biologicals Corporation to manufacture Cytolin in accordance with the terms of the drug master file.

In 1996, the FDA also designated investigational new drug application (IND) for Cytolin as BB-IND #6845, and subsequently approved a clinical trial. In 2002, **Symbion Research International**, a contract research organization, completed a **Phase I a/b** clinical trial of Cytolin. The trial was sponsored by Amerimmune, Inc., the previous licensee of Cytolin, but Symbion was never paid for its work. As a result, its work product became Symbion's. CytoDyn entered into a buy-sell agreement with Symbion to purchase the Phase Ia study data in 2004. The Phase Ia study, conducted in 13 subjects suffering from HIV/AIDS, found Cytolin to be safe and well tolerated. The initial safety study supported the safety and tolerability of the drug in these dose groups. Some of the data were presented as an abstract and poster session, entitled "Phase I Study of Anti-LFA-1 Monoclonal Antibody (Cytolin in Adults with HIV Infection)" at the 9th Conference on Retroviruses and Opportunistic Infections held in Seattle, Washington on February 24-28 2002 as well as the 16th International AIDS Conference held August 2006 in Toronto, Canada. The Company then went through a period of years where legal issues delayed the progress of this treatment.

Following are the summary of the clinical results for the mouse version of Cytolin:

- Cytolin was safe and well tolerated in over 200 subjects;
- Favorable observations were made regarding global immunity, CD4 counts and viral burden;
- The kinetics of the viral burden results suggested that there is a direct anti-viral effect.

Patient responses on Cytolin monotherapy



Source: Company presentation

Studies of Humanized Cytolin are Planned

Based on the positive preliminary clinical results of mouse Cytolin, the Company plans to test a fully humanized version of Cytolin this year to confirm and extend the understanding of how to apply this new approach to the treatment of HIV/AIDS.

The humanized antibody construct is completed and discussion is underway for manufacturing clinical grade humanized antibody.

CytoDyn has a clinical trial agreement with Massachusetts General Hospital (MGH). Pursuant to the agreement, MGH agreed to conduct an **ex-vivo study** of Cytolin in accordance with a study protocol entitled "An observational study to determine the in-vitro immunologic and virology activity of Cytolin" in exchange for a research grant by CytoDyn. In addition to providing financial support for the study, CytoDyn agreed to provide MGH with supplies of Cytolin needed for the Study. Under the agreement, **Eric S. Rosenberg, M.D**. is designated as the principal investigator for the study.

Human subjects have been recruited for the study from Dr. Rosenberg's clinic. The study has enrolled 10 adults with early HIV infection and 10 healthy adults as the control arm, all of whom will be required to participate for six months. None of the patients enrolled in the study will receive injections of Cytolin; rather they will donate blood to allow one to examine the effects of Cytolin when it is added in the test tube to their peripheral blood mononuclear cells. In July, 2010, the enrollment closed and the study began. The study will be completed at the end of 1Q2012 or early 2Q2012. Upon completion of this study Dr. Rosenberg may elect to either publish his findings or present them at a scientific conference.

The Study is a science-intensive research study and is not intended to function as a registrational study. CytoDyn contemplates that the study will be followed by a clinical trial that may or may not be conducted at MGH or with Dr. Rosenberg as the Principal Investigator. The Company's intention is to either fund additional clinical trials and/or attempt to enter into a strategic alliance with a third party concerning its Cytolin brand monoclonal antibodies.

CytoDyn is currently developing a clinical trial plan for its **Phase Ia and Ib** studies of humanized Cytolin. These designs will be decided upon by a coordinated effort from the Company, the clinical investigator, an outside consulting group specializing on clinical trial development and discussions with the FDA. The Company expects that the Phase Ia will be in HIV-infected subjects with antiretroviral experience but who are currently not taking any anti-retroviral drugs or other anti-viral medications.

Cytolin Targets the large HIV/AIDS Market

HIV/AIDS is a global epidemic. Over 40 million people are living with HIV/AIDS in the world and among them over 25 million in Sub-Saharan Africa. In the United States, more than one million people are living with HIV and about 56,300 Americans become infected with HIV each year. More than 18,000 people with AIDS still die each year in the US. Therefore, new treatments are of significant interest.

According to GlobalData's estimates, global HIV/AIDS market was worth $12 billion in 2009. It is forecast to grow at a compound annual growth rate (CAGR) of 2% for the next seven years to reach $13.7 billion by 2016. The global HIV infection market will continue to grow between 2009 and 2016 at a slower rate due to a series of patent expiries during this period. The growth rate is likely to decline from 2012 onwards due to the impact of the patent expiry of key drugs. The market is characterized by a high unmet need of drugs which can cure the disease.

Clearly, HIV/AIDS market is huge. There are currently over two dozen drugs approved for the treatment of HIV-infection by the FDA. The three primary classes of treatment are **Non-nucleoside** Reverse Transcriptase Inhibitors, **Nucleoside Analog** Reverse Transcriptase Inhibitors, and **Protease Inhibitors**. **Fusion or Entry Inhibitors** are a newer class of anti-HIV medications. Current antiviral treatments for HIV/AIDS are drug combinations that are expensive, difficult to access in many areas of the world, and

accompanied by a number of complications, including moderate to severe side effects, onerous dosing regimens, multiple drug interactions, and the development of drug resistant strains of the HIV virus.

The treatment of HIV/AIDS has evolved in the last 20 years since the beginning of the epidemic from no treatment to treatment with a single drug (AZT) to dual-drug therapy and, now, to highly active antiretroviral therapy (**HAART**). Currently, HAART is the **standard of care** for HIV/AIDS treatment. HAART is defined as treatment with at least three active anti-retroviral medications (ARV's), typically two nucleoside reverse transcriptase inhibitors (NRTI's) plus a non-nucleoside reverse transcriptase inhibitor (NNRTI) or a protease inhibitor (PI) or another NRTI called abacavir (Ziagen).HAART is often called the drug **"cocktail**" or **triple-therapy**. HAART affords a potent way of suppressing viral replication in the blood while attempting to prevent the virus from rapidly developing resistance to the individual ARV's. Suppressing viral replication with HAART allows the body time to rebuild its immune system and replenish the destroyed CD4 T cells. HAART has been clearly shown to delay progression to AIDS and prolong life.

However, HAART drug regimens are complex, often requiring 10 or more pills a day; expensive, costing upwards of $10,000-$20,000 per patient per annum in the United States; and are associated with moderate to severe gastro-intestinal, neurological, and hematological side effects that adversely impact the patient's quality of life. Furthermore, HIV patients who use the drugs for a long period of time tend to develop resistance to the drugs, resulting in the drugs becoming less effective and engendering resistant strains of the HIV virus. Many patients receiving standard HAART are resistant to one or more of the primary classes of HIV/AIDS drugs.

Cytolin May Be a Unique Treatment for Early HIV Infection

The current **standard of treatment** for HIV/AIDS allows for withholding antiviral drugs until the disease has progressed to the point where the drugs are required to maintain a patient's health, typically a period of about five years from initial infection. A chief reason for withholding treatment during the early years of HIV infection is that antiviral drugs attack the virus directly. As a result, natural selection promotes the evolution of HIV into species that are resistant to those drugs. If antiviral drugs were prescribed too early, then the virus might become resistant to those drugs, rendering them ineffective, by the time they were necessary to maintain a patient's health. Additionally, other treatment regimens call for intermittent drug use to minimize toxicities from the anti-retroviral drugs. These treatment interruptions also can contribute to the generation of resistant viruses.

The US Department of Health and Human Services (DHHS) guidelines, as revised in 2009, recommend initiating treatment at CD4 cell counts between 350 and 500 cells/mm^3.

Cytolin was originally thought to act to prevent the wholesale destruction of helpful CD4 T cells by blocking the unwanted activity of an HIV-infected person's own killer T cells. Compassionate use and subsequent uncontrolled clinical trials of Cytolin showed that treatment was associated with favorable results in selected markers of disease progression. Subsequent studies and analysis of the activity of Cytolin has shown that this antibody does not block cytotoxic T cells. However, in addition to being expressed on CTLs, the CD11a protein has also been reported to be present on the surface of the HIV virion, presumably to assist in the infectious cycle of the virus. This opens the possibility that Cytolin may **bind and neutralize HIV**, providing a direct action against the virus in the bloodstream. The exact mechanism of action through which this antibody may exhibit antiviral activity is still under investigation.

With respect to the decline of CD4 cells after HIV infection, researchers have provided an alternate theory for the decline in CD4 T cells through a process of cellular suicide or cellular self-destruction called apoptosis. This process is initiated when the virus enters the target cells but does not complete its infectious cycle. **Since Cytolin targets a cellular protein that is also present on the virus, it potentially should not induce the expansion of resistant virus** because its target protein is not under the genetic control of the virus. This is in contrast to the antiviral drugs that target viral proteins and thus

allow for the generation of drug-resistant viruses. Research is currently underway to understand exactly how this antibody can disrupt HIV infection.

The anti-resistance characteristic of Cytolin opens the door for early treatment of HIV/AIDS. This niche market of HIV/AIDS treatment itself is huge and represents an excellent opportunity for Cytolin commercialization if approved.

Because **Cytolin** is a monoclonal antibody, it can be administered either by intravenous infusion or subcutaneous injection.

The Cytolin difference

- **Safety:** Cytolin is safe and well tolerated. It also does not block the normal function of LFA-1 on CTLs and other cells.
- **Clinical Administration:** Cytolin is delivered by infusion. This brings the patient to a clinical setting; greatly increase the opportunity for interaction between the patient and their care giver to provide counseling and other auxiliary care.
- **Reduced chance of resistance:** Because Cytolin's target is not made by the virus it cannot be mutated by the virus to escape the action of the antibody.
- **Novel activity:** Cytolin's target (LFA-1) is a cellular antigen that is also expressed on the surface of the virus. This allows for a direct action against the virus in the bloodstream.

CytoFeline May be Applicable to the Treatment of Feline Immunodeficiency Virus

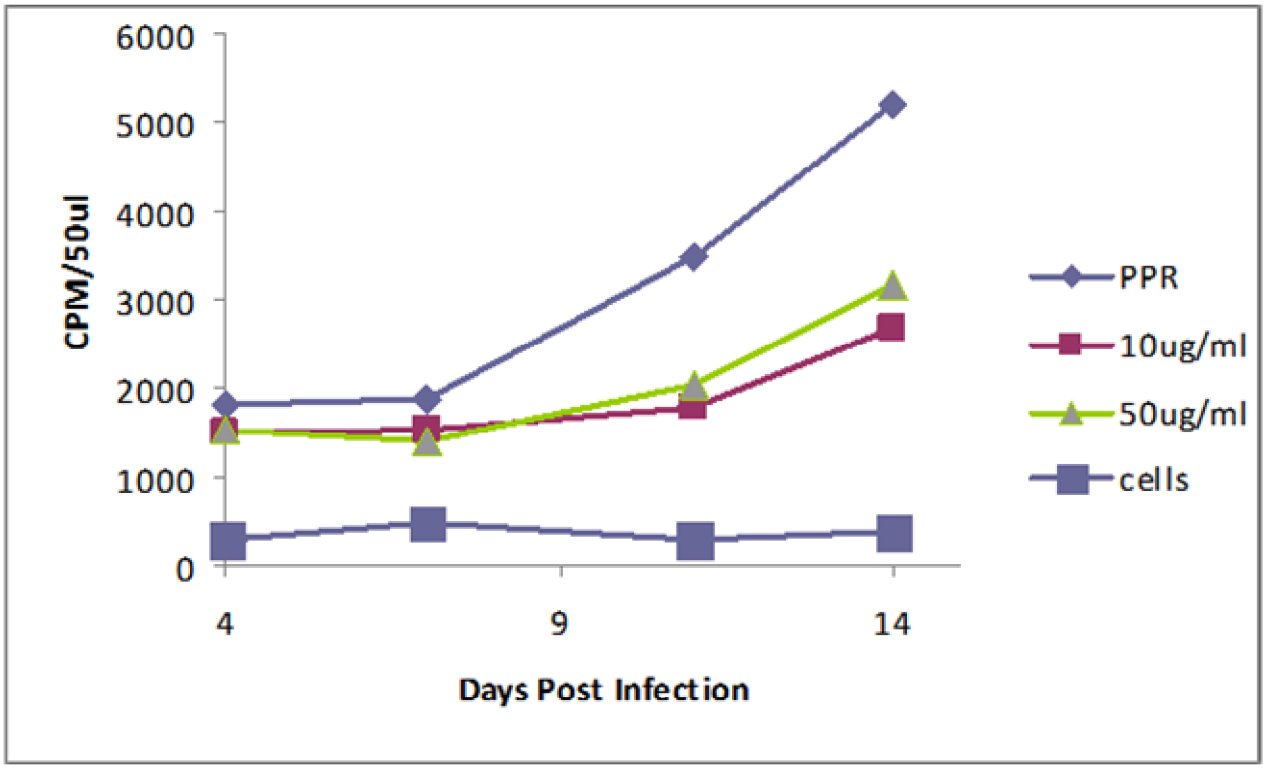
CytoDyn's wholly owned subsidiary CytoDyn Veterinary Medicine LLC (CVM) is exploring the possible application of the Company's existing proprietary monoclonal antibody technology to the treatment of **Feline Immunodeficiency Virus (FIV)**. On June 17, 2011 the Company filed for a provisional patent in the United States for the use of these antibodies as well as selected small molecule antagonists and agonists for the treatment of FIV, a retroviral infection in cats. The Company anticipates it will apply to trademark this product under the name **CytoFeline**.

FIV has been reported to cause an AIDS-like syndrome in the domestic cat and is a distant relative of HIV. It is estimated that 2% - 25% of the global domestic cat population is infected with FIV. Currently there is no satisfactory therapeutic treatment for FIV on the market. Many drugs available for HIV treatment do not work against FIV or are too toxic for cats, leaving virtually no effective treatment for the cat virus.

Because of its genotypic and phenotypic similarity to HIV, CytoDyn's strategy to control HIV infection may be effective to treat FIV infection as well.

To test this hypothesis the Company has identified anti-CD11a monoclonal antibodies that bind to feline cells. Preliminary data have shown that pre-incubation of target cells with an anti-CD11a antibody appears to inhibit infection in vitro.

CytoFeline Pre-incubation of feline 104-C1 cells inhibits FIV infection



Source: Company presentation

CytoDyn has established **a research collaboration** with Dr. John Elder at the Scripps Research Institute (TSRI) to study the treatment of FIV using CytoFeline. A pilot study in infected cats is planned for 1Q 2012.

In addition to the domestic and feral cats, the Company intends to study whether CytoFeline may potentially benefit the large cat population, specifically lions, tigers and other big cats found in zoos.

Clearly, CytoFeline is complementary to the Company's lead candidate Cytolin. The CytoFeline asset enhances the Company's intellectual property and diversifies its pipeline. Both Cytolin and CytoFeline will contribute to the growth of CytoDyn in the coming years.

Experienced Management Team

Kenneth J. Van Ness, Chairman, President and CEO
Mr. Van Ness has been Chairman since July 2011, President and CEO since December 2010, and a director since June 2010. Prior to joining the Company, in the past decade he had focused as a merchant mortgage banker and investor. Currently he is managing director of Greenwood Hudson Portfolio LLC and was managing director of Technology Capital Services LLC until April 2011. These companies are comprised of investments in over 20 public companies. In addition to these companies, Mr. Van Ness has been a managing director of Hudson Pointe LLC, Debuel Development LLC, Grande Villas LLC and Grande Estates LLC since 2006, and Greenwood Management since 1997. During the past 25 years he has held various C-level positions (positions at the highest level of management), including as Chairman, Chief Executive Officer, Chief Operating Officer, and Managing Director, in both domestic and international public and private companies, including, without limitation, as Chief Operating Officer of International Division of Royal Resorts, Managing Director of Buena Vista Hospitality, Chairman and Chief Executive Officer of International Resort Services, Managing Director of Medallion Mortgage and Financial Services, Managing Director Bankers Financial, and Chief Marketing Officer of Lasergate Systems. His responsibilities combined senior management positions with profitability, marketing,

operations, staff and investor relations oversight. Throughout his career he has participated in equity and debt transactions in excess of $500M. In addition, Mr. Van Ness provided consulting services to real estate investors with complex financial challenges.

Mr. Van Ness received his Bachelor of Science degree from the University of Florida in 1973.

Andy Libby, Chief Financial Officer, Corporate Secretary
Mr. Libby has over 35 years of professional experience in managing financial and operational aspects of private companies, public agencies and publicly traded companies. His direct experience includes strategic planning for companies involved in the research, manufacture and distribution of nutraceutical and healthcare products. Mr. Libby previously served as Director of Finance & Accounting of the 400 doctor medical faculty practice at USF College of Medicine, where he was directly involved with the financial aspects of 200 pharmaceutical grants. Additionally, he was responsible for all accounting, tax, insurance, audit, banking and investing activities. Prior experience includes practicing as a CPA, serving at the executive level in local government and serving on the accounting faculty of the Business University of Tampa. Mr. Libby received an MBA and Post-Graduate Certificate in Accounting from the University of Tampa and BA degrees in both Accounting and Management from the University of South Florida. He is a Certified Public Accountant in Florida and a member of the American and Florida Institutes of CPA's. He is also a Certified Internal Auditor.

Nader Z. Pourhassan, PhD, Managing Director of Business Development
Dr. Pourhassan became the Company's Managing Director of Business Development in June 2011. Prior to that, he was the Chief Operating Officer from May 2008 to June 2011. Born in Tehran, Iran in 1963, Dr. Pourhassan immigrated to the United States in 1977 and became a U.S. citizen in 1991. He received his Bachelor of Science from Utah State University in 1985, his Masters of Science from Brigham Young University in 1990 and his PhD in Mechanical Engineering from the University of Utah in 1998. Prior to joining the Company from 2006 to 2008, Dr. Pourhassan was an instructor of Mechanical Engineering at The Center for Advanced Learning in Oregon, and from 2005 to 2006 was an instructor at Mount Hood Community College. Over the past twenty years, Dr. Pourhassan has also managed a family-owned export/import and manufacturing businesses.

Richard Trauger, PhD. Managing Director of Science
Dr. Richard Trauger received his PhD from the University Of South Carolina School Of Medicine in 1986 in biomedical science, specializing in retrovirology. He was awarded a post-doctoral fellowship at The Scripps Research Institute to study the origins of retroviruses and their interaction with the central nervous system in the respective laboratories of Dr. John Elder and Dr. Michael Wilson. Dr. Trauger left Scripps in 1989 to work with Dr. Jonas Salk at The Immune Response Corporation (IRC), a newly formed company developing a therapeutic vaccine for the treatment of HIV. While at IRC he was head of the immunology research group responsible for the design, validation and implementation of assays for assessing humoral and cellular immunity in patients enrolled in HIV and Cancer clinical trials. In 2001 Dr. Trauger left IRC to become the Director of Cancer and Infectious Disease at Hollis-Eden Pharmaceuticals, where he oversaw the company's research for its proprietary hormones for the treatment of HIV and cancer. Dr. Trauger has also worked extensively in business development and has traveled world-wide to assist in partnering discussions. He has also developed patient/physician outreach programs and presented at Grand Rounds in hospital settings and community meetings sponsored by activists to assist in the enrolment of clinical trials. He also has extensive experience identify and developing relationships with key opinion leaders in the HIV and cancer immunotherapy fields. Dr. Trauger joined CytoDyn in January, 2011.

VALUATION AND RECOMMENDATION

We maintain our Neutral rating on CytoDyn shares. Our 12-month price target is $4.00 per share.

CytoDyn is an early stage development biotech company. The Company holds two unique drug discovery platform technologies: Cytolin monoclonal antibody targeting HIV and CytoFeline monoclonal antibody targeting cat FIV.

We are optimistic about the Company's lead drug candidate Cytolin. Uncontrolled clinical studies of mouse Cytolin have shown some promise for the treatment of HIV/AIDS, but we would like to see more data especially advanced clinical trial data of humanized Cytolin to confirm the results of mouse Cytolin studies. In this regard, we are pleased to learn that the Company plans to move humanized Cytolin into clinic this year.

Cytolin and CytoFeline target the large HIV and FIV market respectively.

We think CytoDyn has entered into a transition period from a pure preclinical development stage company into a clinical stage biotech company. With an appropriate growth strategy in place, the Company is well positioned to deliver shareholder value in the next few years in our view.

Current risk/return profile is balanced for CytoDyn in our view based on the Company's fundamentals. We admit that it's always a pain to properly value a development stage biotech company, CytoDyn is no exception. We don't think absolute valuation such as free cash flow method is appropriate for CytoDyn since generating positive cash flow is still many years away. Without revenue and operating income in the foreseeable future, it's also very difficult to come up with a value using a relative valuation metrics.

Most small biotech companies of development stage are valued from $50 million to $250 million depending on how advanced the pipeline is and which indications the company is targeting. CytoDyn is still in an early development stage and pipeline is relatively weak. The Company's balance sheet is weak too. CytoDyn needs to tap the capital market soon and will continue to do so on a regular basis in our view. Considering the volatility of the Company's stock, we think a market cap between $50 and $150 million is fair to CytoDyn. Our price target of $4.0 per share corresponds to a market cap of $112 million based on 28 million shares outstanding.

If the Company establishes a major partnership this year with a big pharma or biotech company for either of its development programs, the Company's share could shoot up beyond our price target. However if it proves to be difficult to get much needed cash, the Company's shares could suffer.

RISKS

Cash Position Is Our Chief Concern

Like most small cap biotech companies, CytoDyn has a relatively weak balance sheet.

As of February 29, 2012, the Company had only $1.8 million in cash. The Company completed a private placement on December 31, 2011 by selling 2 million shares at $1.50 per share. Total proceeds were about $3 million.

Since inception, CytoDyn has financed its activities principally from the sale of public and private equity securities and proceeds from notes payable. The Company intends to finance future development activities and working capital needs largely from the sale of equity securities with some additional funding from other traditional financing sources.

As the Company prepares to bring Cytolin into clinic, R&D costs will increase dramatically.

We believe CytoDyn needs to tap the capital market soon and will continue to do so on a regular basis before the Company achieves revenue from product sales or establish any partnership with major pharma or biotech companies.

We remind investors that equity financing will dilute existing shareholder base.

Early Stage Of Development Poses Higher Risks

CytoDyn has two drug candidates Cytolin and CytoFeline. Both are in the early stage of development (pre-clinical) at this point.

Early stage of development poses greater risks as the drug candidate must navigate through the long clinical trials and regulatory review process in order to get into market.

We would like to see more data especially clinical data for the Company's drug candidates before we are bullish about the Company's stocks. We will update investors on this matter once the data are available.

Trading On OTC Market May Be Volatile And Sporadic

There is currently a limited market for the Company's common stock, which is quoted on the over-the-counter (OTC) market. Trading in stock quoted on the over-the-counter market is often thin and characterized by wide fluctuations in trading prices, due to many factors that may have little to do with the Company's operations or business prospects.

Moreover, the over-the-counter market is not a stock exchange, and trading of securities there is often more sporadic than the trading of securities listed on a quotation system like NASDAQ or a stock exchange like NYSE. There is no assurance that a sufficient market will develop or remain stable in the stock, in which case it could be difficult for stockholders to resell their stocks. Liquidity may be an issue for institutional investors.

PROJECTED INCOME STATEMENT

	2011A (May)					2012E (May)					2013E (May)	2014E (May)	2015E (May)	2016E (May)
$ in million except per share data	Q1A	Q2A	Q3A	Q4A	FYA	Q1A	Q2A	Q3A	Q4E	FYE	FYE	FYE	FYE	FYE
R&D	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Grants and Others	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Total Revenues	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
CoGS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Gross Income	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**
Gross Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
R&D	$0.03	$0.23	$0.23	$0.00	$0.48	$0.17	$0.17	$0.07	$0.15	$0.56	$1.00	$2.50	$3.00	$3.50
% R&D	-	-	-	-	-	-	-	-	-	-	-	-	-	-
SG&A	$0.51	$0.76	$0.61	$0.65	$2.53	$0.64	$1.01	$1.07	$1.05	$3.78	$4.00	$4.20	$4.50	$5.00
% SG&A	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other expenses	$0.00	$0.00	$0.23	$0.45	$0.69	$0.34	$0.31	$0.27	$0.25	$1.18	$0.50	$0.60	$0.60	$0.60
% Other	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Operating Income	**($0.5)**	**($1.0)**	**($1.1)**	**($1.1)**	**($3.7)**	**($1.2)**	**($1.5)**	**($1.4)**	**($1.5)**	**($5.5)**	**($5.5)**	**($7.3)**	**($8.1)**	**($9.1)**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Net	($0.00)	($0.0)	($0.0)	($0.0)	($0.0)	($0.0)	$0.0	($0.0)	($0.0)	($0.0)	($0.1)	($0.1)	($0.1)	($0.1)
Pre-Tax Income	**($0.5)**	**($1.0)**	**($1.1)**	**($1.1)**	**($3.7)**	**($1.2)**	**($1.5)**	**($1.4)**	**($1.5)**	**($5.5)**	**($5.6)**	**($7.4)**	**($8.2)**	**($9.2)**
Income taxes(benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Reported Net Income	**($0.5)**	**($1.0)**	**($1.1)**	**($1.1)**	**($3.7)**	**($1.2)**	**($1.5)**	**($1.4)**	**($1.5)**	**($5.5)**	**($5.6)**	**($7.4)**	**($8.2)**	**($9.2)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Shares Out	*20.0*	*20.5*	*21.5*	*22.3*	*21.1*	*22.3*	*22.3*	*25.5*	*28.1*	*24.5*	*35.0*	*42.0*	*50.0*	*60.0*
Reported EPS	**($0.03)**	**($0.05)**	**($0.05)**	**($0.05)**	**($0.18)**	**($0.05)**	**($0.07)**	**($0.06)**	**($0.05)**	**($0.23)**	**($0.16)**	**($0.18)**	**($0.16)**	**($0.15)**
YOY Growth	-	-	-	-	-					-	-	-	-	-
One time charge	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*
Non GAAP Net Income	**($0.5)**	**($1.0)**	**($1.1)**	**($1.1)**	**($3.7)**	**($1.2)**	**($1.5)**	**($1.4)**	**($1.5)**	**($5.5)**	**($5.6)**	**($7.4)**	**($8.2)**	**($9.2)**
Non GAAP EPS	**($0.03)**	**($0.05)**	**($0.05)**	**($0.05)**	**($0.18)**	**($0.05)**	**($0.07)**	**($0.06)**	**($0.05)**	**($0.23)**	**($0.16)**	**($0.18)**	**($0.16)**	**($0.15)**

Source: Company filings and Zacks Investment Research

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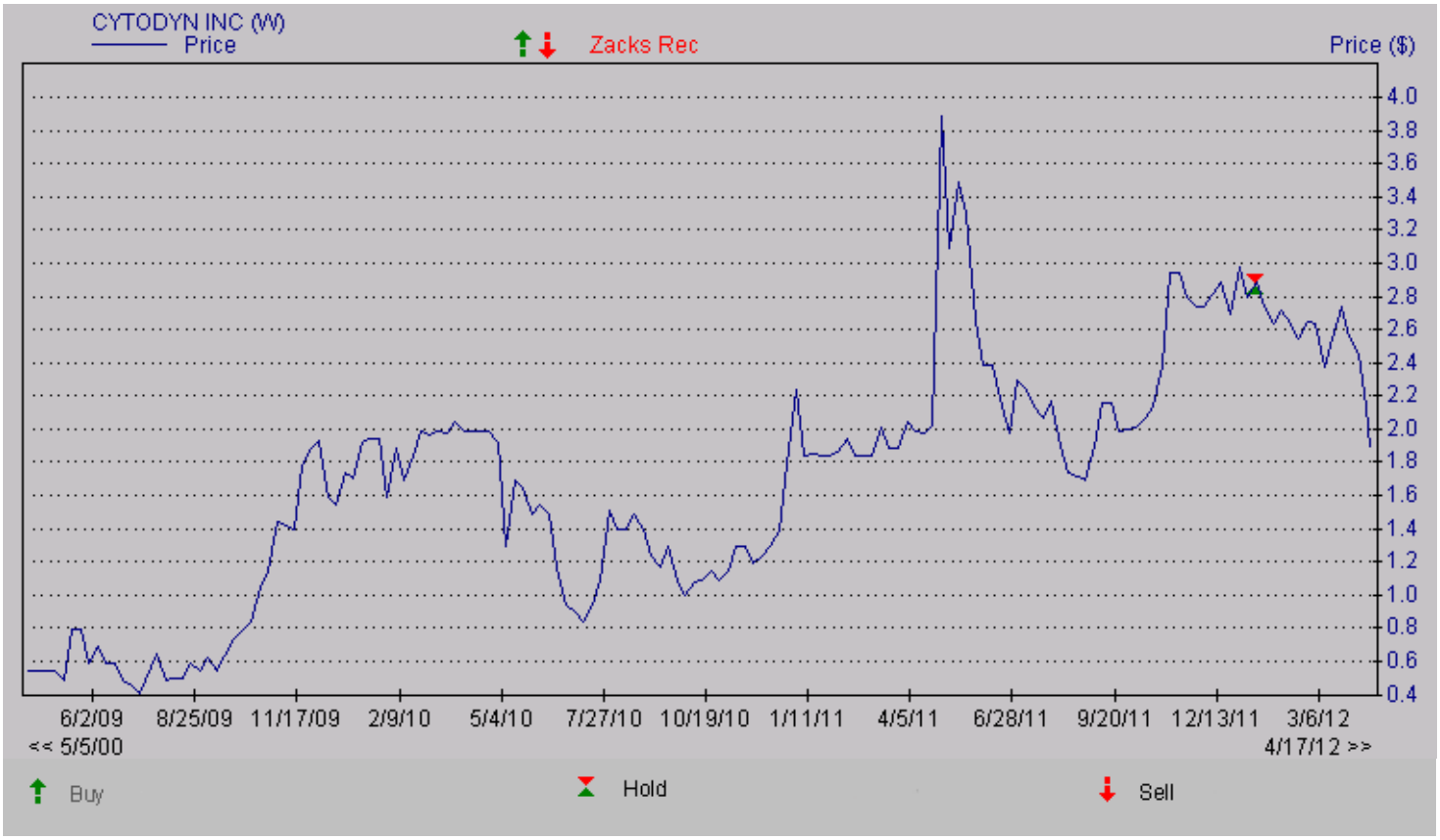
HISTORICAL ZACKS RECOMMENDATIONS



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