CytoDyn, Inc. (CYDY – Pink Sheets)

Novel HIV Therapy Could Revolutionize Global Treatment Regimens; Promising Drug Does Not Breed Resistant HIV Strains and is Currently in Clinical Trials

Strong Speculative Buy

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Recent Price: US$2.05

Summary and Investment Opportunity

- **HIV is a Global Pandemic Affecting Over One Million People in the U.S. Alone**
  
  HIV was introduced to the United States in the late 1970s, and now affects over 1.1 million Americans and over 33 million people worldwide. This global pandemic is likely to continue growing until a cure or vaccine for HIV becomes available; at this time no promising cures or vaccines exist. This means that any effective treatment for HIV will immediately have an exceptionally large market, much of which is relatively insensitive to price. This means that such a therapy, were it to become available, would have a total addressable market in the tens of billions of dollars per year on a worldwide basis.

- **Current Anti-retroviral Therapies, While Mostly Effective, Breed Resistant Virus**
  
  Currently available HIV therapies are comprised of several anti-retroviral drugs, and act through various mechanisms to block the HIV virus’ ability to infect new cells or replicate once inside of new cells. These therapies have been very effective at prolonging the lives of those who have HIV, at least so far. However, the process of natural selection is now breeding strains of HIV virus that have a resistance to these drugs, bringing their long-term efficacy into question. Obviously new therapies are in very high demand as a result.

- **CytoDyn has a Novel Therapeutic Approach That Complements Current Regimens**
  
  CytoDyn’s flagship drug Cytolin has shown great promise in supplementing anti-viral medications in the treatment of HIV. Unlike other treatments, Cytolin does not directly attack HIV – instead it prevents the body’s own immune system from attacking itself in the later stages of HIV infection. Early trials of the drug show great promise, with an excellent safety profile, few side effects, and a reduction in viral load of as much as 90%. The Company trades on the Pink Sheets and is based in Santa Fe, New Mexico.

Company Overview

CytoDyn is a drug development company with a single, promising drug: Cytolin. Cytolin is in clinical trials for the treatment of HIV infection. Unlike currently-available anti-viral regimens, Cytolin acts by correcting HIV-induced errors in the human immune system that cause it to attack itself in the later stages of HIV infection. Early trials of the drug show great promise, with an excellent safety profile, few side effects, and a reduction in viral load of as much as 90%. The Company trades on the Pink Sheets and is based in Santa Fe, New Mexico.

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Please see analyst certification and required disclosures on page 12 of this report.
Industry Background

What is HIV?
HIV stands for Human Immunodeficiency Virus, and is thought to have come from or be related to SIV, which affects non-human primates on the continent of Africa. HIV is a slow-acting retrovirus (known as a lentivirus), which means that while its infection can initially be quite aggressive, it typically takes many years before infected individuals experience related disease symptoms. A single HIV particle, known as a virion, measures just one $10,000^{th}$ of a millimeter across, and is comprised of a complex structure of protein anchoring particles, a lipid wall, and an interior capsid, which contains the viral genes and other chemicals that help the virus infect human cells and then replicate once therein.

How Does HIV Cause AIDS?
The HIV infection has three primary stages of infection in humans; AIDS and the life-threatening opportunistic infections that typically accompany it do not occur until Stage III. The median times from HIV infection to the development of AIDS is 10 to 12 years in the United States, based on various epidemiological studies.¹

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¹ National Institute of Allergy and Infectious Diseases, 2007.
Stage I
During Stage I, HIV infects the body’s primary immune cells, known as CD4+ T cells, typically through direct exposure to blood or through certain mucous membranes located in the genitals of either males or females. In the first few weeks of infection HIV is very aggressive in its attack on the human immune system, infecting a variety of immune-related cells and multiple body systems, especially the lymph system. This initial attack typically causes extremely high viral loads and eventually provokes a strong immune response. During this stage of infection, which lasts for just a few weeks after initial exposure, approximately 70% of individuals report experiencing flu-like symptoms. Also, it is during this time that some of the virus integrates into the DNA of inactive CD4+ cells, which allows it to form a “reservoir” that can fuel subsequent infectious activity at a later date.

The body’s immune response is typically led by CD8 “killer” T cells, which identify and kill other HIV-infected cells en masse. Killer T cells also secrete a variety of compounds that slow or otherwise inhibit HIV replication, and during late Stage I they are typically quite successful in dramatically reducing HIV viral loads. However, due to the complex infection mechanisms employed by the HIV virus, they are never 100% successful in eradicating HIV from the body, once an infection has occurred.

Stage II
The second stage of HIV infection, also known as the latency stage, typically lasts from 2 to 10 years or more, and is characterized by the virus slowly emerging from latency to overwhelm the immune system. However, the mechanism(s) by which the virus accomplishes this erosion of the immune system are complex and in some cases not well understood. There is some evidence that the eventual scarring that occurs in the lymph nodes prevents them from being able to adequately replenish CD4+ cells as the virus kills them, which eventually tips the balance in the virus’ favor. However, other evidence suggests that the body’s own CD8 “killer” T cells become increasingly unable to differentiate between HIV-infected CD4+ cells (which need to be destroyed) and those which merely have HIV proteins on their surfaces and hence are still uninfected. By indiscriminately killing both of these CD4+ cell groups, the body’s own CD8 cells may be inadvertently weakening the immune system to the point where HIV gains the upper hand and overwhelms the entire system.

The typical healthy individual has 1,000 – 1,200 CD4+ T cells in each cubic millimeter of blood, a level which may also be found in early Stage II HIV patients. However, when the concentration of these cells falls to or below 200 cells/mm³, the immune system ceases to function properly, and a host of opportunistic infections and certain cancers are able to take root. It is this lack of fighting ability in the body’s CD4+ population that ushers in Stage III: AIDS.

Stage III
The third and final stage of HIV infection is known as AIDS, which stands for Acquired Immunodeficiency Syndrome. In the U.S. the mean survival rate after AIDS onset, if untreated, is approximately two years. During full-blown AIDS, a host of opportunistic infections successfully attack the lungs, skin, brain, and other vital organs, eventually causing the host body to succumb to these infections and die. Because of the eventual lethality of AIDS and the pandemic status of HIV infection, the treatment of and/or prevention of HIV is the world’s top medical priority at this time.

How Widespread is HIV Infection, and AIDS?
As of 2007, the National Institute of Allergy and Infectious Disease estimated that there were 33 million people with AIDS worldwide, and 2.7 million people newly infected on an annual basis. Although most of these infections and deaths occurred in developing countries, there are over 1.1 million individuals in the United States alone that test HIV positive. These stats make HIV the most serious global pandemic of our generation, and unfortunately, one that is getting worse in most parts of the world.
Current Treatments for HIV
In the United States there are over 20 anti-viral drugs approved for use in combating HIV infection. The vast majority of these drugs act directly on the HIV virion by either blocking its ability to attach to and enter various cells, or by blocking its ability to replicate once inside of these cells. These drugs are often complementary in their mechanisms of action, and hence are typically prescribed in groups of 3 or more, known as “cocktails” or, in more technical circles, Highly Active Anti-Retroviral Therapy (HAART) regimens. HAART has been shown to be extremely effective in reducing viral load during both Stage II and Stage III infections, and in some cases has allowed even Stage III patients to survive almost indefinitely.

However, despite the well-documented efficacy of HAART regimens in controlling viral load and postponing full-blown AIDS, they do entail several rather severe problems. One of these problems is related to cost: in the United States, typical HAART therapy costs approximately $16,000 per year per person, which is particularly challenging for the uninsured. Secondly, HAART regimens require highly structured dosing schedules which individuals often find extremely cumbersome, and “non-compliance” with these schedules is a real problem. Thirdly, HAART regimens frequently cause moderate to severe side effects, which can include loss of appetite, nausea, and a host of other problems, and also create non-compliance issues.

The most important drawback to HAART therapy, however, has to do with the HIV antigen itself. As HIV infection progresses, the virus makes as many as 1,000,000,000 (1 billion) copies of itself each day. This process involves the viral RNA creating a specialized DNA molecule within the host cell, which then cranks out copies of new viral RNA which in-turn becomes the cores of new virions. For reasons beyond the scope of this report, this process is highly error-prone, and leads to the creation of RNA molecules that differ in some way from the original. In HIV, the RNA molecule contains all nine of HIV’s genes, so an error in copying this molecule means that one or more genes have been copied incorrectly, a phenomenon called mutation. And while most mutations are harmful to the HIV virus, and cause the newly mutated virus to be unable to function, a very small percentage of these mutations are actually helpful to HIV. Since HIV makes 1 billion copies of itself each day, even infinitesimally small percentages of helpful mutations can lead to high numbers of these virions in the host.

Here’s where HAART runs into problems. In a very, very small percentage of mutation cases, the mutation changes the part of the virus that the anti-viral drug interferes with, rendering it useless against this particular virion – this works in a similar way to that in which bacteria develop resistance to antibiotics. Since this mutant virion is now unaffected by the anti-viral in question, it has a higher chance of successfully replicating within the host – and each successful mutant virion can give rise to hundreds of first-generation progeny, each of which carry its mutation. These in turn have a survival advantage due to the mutation, and each gives rise to hundreds more, and so on. So eventually, an individual will harbor more and more virus that is resistant to the prescribed anti-viral regimen, eventually rendering it ineffective at stopping the virus. Also, note that such an individual, were he or she to infect others, would likely pass the new mutant HIV on. The net effect of this is that over time we are seeing the HIV virus (even in new infections) demonstrate higher and higher levels of HAART resistance, potentially rendering HAART therapy partially or even completely ineffective in the future.

HIV Therapeutic Market
Current estimates suggest that 33 million individuals are currently living with HIV in the world today, and that over 25 million have died of AIDS-related infections and cancers. In the United States, approximately 1.1 million individuals currently carry the HIV virus, and this number is growing at approximately 5% per year, far more quickly than is the general population. So in the U.S. and in the rest of the world, HIV is systematically infecting a larger and larger percentage of the population each year.

Conclusion
HIV is a global pandemic that currently shows no signs of abating. The virus’ complex attack patterns and ability to mutate at such a high rate has so far confounded medical researchers’ efforts to create a viable and effective vaccine or other prophylactic measure. Until this changes, HIV is likely to continue to plague the
world with high numbers of new infections each year, and an increasingly high number of AIDS-related deaths each year.

Because prevention efforts are moderately effective at best, much of the medical community is focused on treating the disease so that those infected never develop AIDS and can live out a fairly normal life. Although current HAART treatment regimens are relatively effective in accomplishing this, their high cost and potential to become less effective over time suggests that alternative treatment strategies are warranted and in fact will be in high demand once developed. Based on currently available clinical studies, we believe that CytoDyn may have discovered just such a novel treatment. If this is confirmed by additional research, which seems likely, this will be a huge boon to the HIV community around the world, and would surely mean a large windfall for all investors in CYDY shares.
Company Analysis

Corporate History and Overview

CytoDyn is a drug-development company with its sole focus on the development and commercialization of the drug Cytolin. This drug is indicated for early HIV infection when HAART therapy is typically not yet appropriate, due to concerns that the HIV will develop anti-viral drug resistance that will prevent HAART from being effective in later stages of the disease, and for later stages of HIV infection, when all other treatments have lost their efficacy. Although CytoDyn was founded in 2003, the drug Cytolin has been in existence since the mid 1990s, when the drug was initially used to treat HIV/AIDS patients. Despite the success and promise Cytolin showed at that time, the drug was not further developed until just recently, when CytoDyn brought it to Dr. Rosenberg at Massachusetts General Hospital. The drug Cytolin acts through a unique mechanism to reduce or entirely prevent CD8 “killer” T cells from indiscriminately attacking and destroying an individual’s healthy CD4+ cells, which may be a key variable in the onset and severity of the AIDS that ensues.

The Company is based in Santa Fe, New Mexico, and trades on the Pink Sheets under the symbol CYDY. The Company does hope to upgrade its listing to the over-the-counter bulletin board in the near future, perhaps as early as late spring of 2010.

The Product: Cytolin

Cytolin is an intravenously administered drug that is indicated for the treatment of HIV patients. Unlike currently available anti-retroviral drugs, which act against the virus itself, Cytolin acts by improving the action of the patient’s immune system as it combats HIV. Specifically, in later stages of HIV infection, patients’ killer T cells indiscriminately hunt down and kill healthy CD4+ T cells, in addition to those infected with HIV, which severely inhibits the immune system from acting effectively against any type of infection or cancer. The Company believes that this indiscriminate killing of healthy CD4 cells is the reason HIV patients develop AIDS,2 and thus an effective blocking of this process would in essence block the emergence of AIDS itself.

In previous use, Cytolin has been shown to reduce viral load in patients experiencing stage III HIV infection by as much as an order of magnitude (10x), and has clearly demonstrated an excellent safety profile. This initial data supports the Company’s belief that Cytolin can become a globally-accepted treatment for HIV infection, although more study is necessary to validate these initial results and substantiate the Company’s stated belief in the drug.

We believe it is particularly relevant that Cytolin is not an anti-viral drug and in fact has no direct action on the HIV virus. This is of crucial importance because it means that since Cytolin cannot attack HIV, HIV cannot develop a resistance to Cytolin. This means that over time Cytolin should maintain its efficacy and in fact may postpone the onset of AIDS indefinitely, especially in those patients who begin taking the drug early in the HIV infection cycle. At the very least, Cytolin could delay the need for anti-viral treatments for several years, clearly extending the life and health cycle of the patient.

CytoDyn is developing Cytolin for a single indication at this time – for treating patients who are too early in the HIV infection cycle to warrant a HAART regimen. However, given that doctors are free to use any FDA-approved drug for any medical reason they see fit, we believe that if approved for this single indication, Cytolin may very well be prescribed for HIV in all stages of infection. This “off label” use would of course dramatically expand the already large potential market for Cytolin, both in the United States and overseas. Furthermore, for humanitarian reasons, it is highly likely that the Company will pursue a late-stage “salvage” indication for Cytolin.

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2 As first shown by Zarling, et al in 1990 (Journal of Immunology, vol. 144, page 2992), the ability of these killer T cells to indiscriminately destroy CD4 T cells is a trait unique to humans, explaining why HIV infection does not cause disease in the other species the virus can infect.
Intellectual Property and IP Protection

No discussion of a candidate drug therapy would be complete, in the context of investment potential, if it did not include an analysis of the intellectual property protection surrounding that candidate therapy. In the case of CytoDyn, the Company’s intellectual property protection is quite robust, as the Company holds multiple patents both in the United States and in Europe. The central IP in the patent portfolio is the use of Cytolin, a monoclonal antibody, for the treatment of the HIV virus. This broadness of definition gives the Company solid protection from would-be competitors who might endeavor to use similar compounds in the treatment of HIV infection.

Although the Company’s U.S. patents are currently set to expire beginning in 2014, current patent law regarding new drug development allows these to be extended by the amount of time that a drug has been in development (since the last filing), which in this case means that Cytolin could enjoy as much as 15 years of patent protection upon eventual FDA approval. We believe any protection extending beyond 10 years would be more than enough to give a Cytolin approval very high value to CytoDyn, as well as to any large would-be acquirer or development, manufacturing, and distribution partner. Since the Company’s European patents are younger than their U.S. counterparts, this would be even truer in the European markets.

Drug Development Strategy

The Company is pursuing what we believe is a very rational drug development program, which it has formulated to systematically confirm earlier established results, and then extend those results in an FDA Phase IIB trial. If successful, this should allow the drug to rapidly gain FDA approval and begin helping those afflicted with HIV both in the U.S. and abroad.

Circa 1995, before effective anti-viral medications had become effective, various doctors treated several hundred “salvage” patients with Cytolin in what was then known as mercy treatment. Of those patients, the Company has been able to secure complete medical history on 188 patients. Several of these patients have offered anecdotal evidence that the Cytolin saved their lives, and clinical data from this study showed a pronounced drop in HIV viral load in these individuals – in some cases as much as a full order of magnitude. This study was extremely promising in terms of initial results, and the Company’s main goal in its current clinical work is to confirm these results in a tightly-controlled setting, which should help it raise additional capital and continue working towards FDA approval.

Late last year, the Company reached a research agreement with Dr. Eric Rosenberg, a renowned and widely cited HIV researcher, assistant professor at Harvard Medical School, and staff physician at Massachusetts General Hospital. Under the terms of this agreement, Dr. Rosenberg will conduct one study of Cytolin at Massachusetts General in what is known as an ex-vivo study, wherein the blood of 10 early-stage HIV patients and 10 healthy “control” patients will be treated with Cytolin to demonstrate that Cytolin does indeed prevent killer T cells from attacking healthy CD4 cells in HIV infected blood. The fact that this is an ex-vivo study has several advantages for CytoDyn, most notably that it does not require FDA approval to conduct.

Assuming that this first study is successful in confirming previously reported results, which the Company is quite confident that it will be, the Company (and hopefully Dr. Rosenberg) will conduct a second FDA-authorized in-vivo study. The purpose of this study will be to unequivocally demonstrate that Cytolin is effective in lowering HIV patients’ viral loads, through a mechanism not related to anti-retrovirus therapy, in live human patients. We and the Company agree and believe that if not sooner, upon the successful completion of this study further drug development will fall to a large pharmaceutical company with vastly superior development, manufacturing, and distribution resources – assuming that the results of these studies are consistent with the Company’s expectations and past medical data.

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3 Full-text versions of the Company’s U.S. Patents are available for review at www.uspto.gov.
4 According to U.S. News and World Report, Harvard Medical School was ranked #1 in the United States in 2009
Shareholder Liquidity Strategy
Assuming that Cytolin’s previously-demonstrated efficacy and safety profile is confirmed by the ongoing studies at Massachusetts General, there is no question that CytoDyn will quickly become an extremely valuable company and that CYDY shares will reflect that value. However, there is some complexity in terms of the path CytoDyn can take in order to maximize the eventual value returned to shareholders: the goal is to choose the path that delivers the best risk-adjusted value to investors on a present-value basis.

The shortest path to realizing appreciation for shareholders would be to sell the Company to a large pharmaceutical company after the current initial Massachusetts General study is completed. However, this may not be the best path, as CYDY’s value in an acquisition could be much higher if it were to also successfully complete its next planned in-vivo study before contemplating a sale. Also, there can be no guarantee that such a buyer could be found after the current ex-vivo study is completed, as such buyers might want to wait until the drug’s efficacy and safety profile were more clearly established in live subjects before making an acquisition.

Waiting until the next planned study is also completed may have significant drawbacks as well, however. For one thing, the Company will need to raise several million dollars more in either debt or equity capital to complete this next study and the additional drug manufacturing it will require; depending on market conditions, this capital might be extremely dilutive or even outright unavailable to the Company. Furthermore, the study may not be as promising as hoped for, suggesting that the Company and its investors would have been better off in an earlier liquidity event.

The third path available to the Company would be to continue to develop Cytolin beyond the currently planned studies. While this could in theory maximize the eventual value of the Company to shareholders, pursuing this path would require the Company to secure far more capital and might cause it to incur many developmental delays. For these and many other reasons, we do not believe that this is the best path for the Company to pursue. Which of the other two paths is better, however, remains to be seen.

Key Leadership
Allen D. Allen, President and Chief Executive Officer
Mr. Allen attended the University of California at Berkeley from 1955 through 1956, and UCLA from 1956 through 1957, after which he left campus to work on defense-related research. Over the past thirty years, Mr. Allen has published scores of scholarly papers in the peer review science and medical journals. During this time he also served as an investigator on clinical research sponsored by major pharmaceutical companies, including Roche and Ortho Biotech (Johnson & Johnson).

Nader Pourhassan, Ph. D., Chief Operating Officer
Dr. Pourhassan was born in Tehran in 1963, 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 Master of Science from Brigham Young in 1990, and his PhD from the University of Utah in 1998. After being an instructor in engineering and mathematics, he became a successful self-made businessman, and is now the Chief Operating Officer of CytoDyn.

Eric Rosenberg, M.D., Assistant Professor, Harvard Medical School; Staff Physician Massachusetts General Hospital
Dr. Rosenberg has an extensive background studying HIV. He is best known for his research on early HIV infection, also known as primary HIV infection. His important findings of immune control of HIV infection during structured treatment interruptions in primary infection were previously published and highly cited in journals, including Science and Nature. Dr. Rosenberg is board-certified in Internal Medicine and Infectious Diseases. His research and clinical practice is focused on the immunopathogenesis of HIV infection with additional work related to infectious disease and transplant medicine.
Dr. Rosenberg is an Assistant Professor of Medicine at Harvard Medical School, where he has been appointed in various academic capacities since 1995, and is a Staff Physician at the Massachusetts General Hospital in Boston, where he has also been appointed since 1995. He serves in the capacities of Associate Director of the Clinical Microbiology Laboratory, and Director of the Education Unit of the Clinical Research Program at Massachusetts General Hospital. Dr. Rosenberg is a member of several professional societies and associations, editorial board member of the Journal of Immune-Based Therapies and Vaccines, and Associate Editor of AIDS Clinical Care. Dr. Rosenberg is Chair of the Treatment Working Group of the National Institutes of Health Acute Infection Early Disease Research Program, and a member of the Massachusetts General Hospital Clinical Research Council.

Dr. Rosenberg has been co-chair, co-principal investigator, and principal investigator of clinical trials focused on HIV treatment, and has been the beneficiary of several NIH awards. He is a regular presenter in the field of HIV infection and has published over 50 articles in the literature. Dr. Rosenberg obtained his MD from the Mount Sinai School of Medicine in New York and completed his internship, assistant residency and chief residency in Internal Medicine at the University of North Carolina.

**Competition**

At this point in time, we know of no other drugs in development for the treatment of HIV infection that compete directly with CytoDyn’s drug, and in fact the Company tells us that no monoclonal blocking antibodies are presently approved for the treatment of any disorder, although many clearing antibodies are routinely used for the treatment of various cancers. Therefore, the primary competitive threat that we see in the future will be related to other companies basing other therapies on CytoDyn’s intellectual property. This is not likely to be a near-term threat for the Company, and in fact is very unlikely to emerge while CytoDyn is an independent entity. Once (and if) it is acquired by a larger diversified pharmaceutical company, as we think is likely in a research-success scenario, this new company should have the resources to defend against such infringement.

Other competition could come from existing or novel treatments that are or may come on to the market. However, since Cytolin is complementary to these treatments, they are not likely to constitute a competitive threat once its efficacy in this regard has been demonstrated. Also, given the overall size of the global market for HIV treatment, we believe there is plenty of room for many successful companies and drugs. Therefore we believe the overall competitive risk for CytoDyn will be quite low.

**Other Risks**

Without a doubt, the greatest risk that CytoDyn currently faces is research / drug-efficacy related, as a failure to replicate past results in the current trial would likely constitute a death knell for the Company. However, we believe it is highly relevant to note that Dr. Rosenberg would have been very unlikely to accept this research project, given his status as a Harvard Medical School professor and leading expert in the field, unless he had a high confidence level in the likely outcome of the study. Based on these factors, we also have high hopes for the results and believe a good outcome is likely, although unfortunately far from certain.

Another risk the Company faces is related to its ability to continue to raise equity and/or debt capital to fund its operations. As of this writing, the Company has nearly US$1.4 million in net cash and has just completed a round of financing. It has already paid for 50% of the Massachusetts General Study for which it still owes a little under $200K, and is burning approximately $100K/month to fund general operations. So, based on these numbers, the Company should have no problem operating well into 2011 on current cash, given current expenses. However, given the uncertainty regarding finding a large partner or being acquired in the near-term, the Company plans to begin manufacturing more Cytolin in preparation for its next trial, which should begin after the current trial is completed and (hopefully positive) results are in. This will of course cause the Company to incur a significant expense above and beyond its normal operating expenses; to defray this expense and to expand its capital base it plans to begin a new capital raise in the late Spring of this year. Given that the Company was just able to raise US$3 million in its just-closed offering, we believe it will be able to raise more capital this summer, although this ability is inherently uncertain. If the current financial market environment
were to change for the negative during the next few months, the Company might be unable to raise this additional capital, thus extending the Company’s research timetable or even putting the ongoing viability of the enterprise at risk. While we do not believe this risk event is particularly likely to occur, it is something of which investors should be aware.

Valuation and Investment Opinion
Unlike most other types of businesses, single-product biotechnology companies are inherently difficult to value, and we are not at this time going to try to precisely estimate what the shares of CYDY should currently be worth. However, we will undertake a general analysis that will help elucidate the potential value under various scenarios, and then provide several “comparables” which are essentially cancer drug research companies with similar revenue and appreciate potential.

In addition to looking at the valuations of comparable biotech / drug-development Companies (which we do below), the most useful valuation analysis we can conduct of CytoDyn is based on the sales and gross profit potential of its drug Cytolin, under a full FDA approval scenario. Based on the current level of HIV infection in the United States of 1.1 million individuals, we believe that the Company might reasonably expect to become a standard treatment for as much as 10% - 20% of this group, suggesting a total U.S. market of 100,000 to 200,000 individuals at this time. However, to keep our numbers extremely reasonable, we have modeled a patient adoption range here of between just approximately 10,000 (9,546) and 20,000 (21,479), which we believe is at least one order of magnitude too low for the U.S. market alone. If one were to fully think through the implications of a new, non-anti-retroviral treatment for HIV that was indicated for monthly use years before HAART was indicated, and was as a consequence broadly adopted in the developed world, then “reasonable” adoption numbers would clearly be 10x-50x or more those used in our analysis.

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5 Manufacturing cost estimates provided by the Company
Based on the manufacturing cost numbers provided by the Company, and under the scenario we suggest, Cytolin gross costs will trend towards approximately $50 per dose as manufacturing economies of scale kick in. The Company believes that a monthly price point of $2,000 - $2,500 is appropriate, but again to keep our numbers conservative, we have modeled just $1,000 per month. Given these conservative assumptions, and given a high and unique efficacy and FDA approval, this would lead us to a total U.S. market as follows:

### Scenario Analysis Based on FDA Approval and High Efficacy at $1,000/dose

<table>
<thead>
<tr>
<th></th>
<th>At 9,546 patients per year</th>
<th>At 21,479 patients per year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual Gross Sales</td>
<td>$114,557,000</td>
<td>$257,748,000</td>
</tr>
<tr>
<td>Annual Gross Costs</td>
<td>$7,250,313</td>
<td>$9,900,331</td>
</tr>
<tr>
<td>Annual Gross Profits</td>
<td>$107,306,687</td>
<td>$247,847,669</td>
</tr>
</tbody>
</table>

We realize that this analysis is at best sophomoric and we do not believe that our numbers will have any precision in their predictive value. What we mean to show is simply this: if Cytolin is approved by the FDA, and shows efficacy and a safety profile consistent with previously-generated data, then it is likely to generate a truly immense market both in the U.S. and overseas. So while we find it almost impossible to quantify the present value of such a market on a risk-adjusted basis, we do believe that CytoDyn shares could be worth well over ten times their current value (and perhaps much more than that) if Cytolin is approved by the FDA and is vindicated in terms of efficacy and safety by current and future research. This is by no means certain, but CytoDyn shares could prove attractive to risk-tolerant investors on a risk-reward basis.

### Peer Group Analysis – CytoDyn (CYDY – Pink Sheets)

<table>
<thead>
<tr>
<th>Company Name and Symbol</th>
<th>Price per Share*</th>
<th>Market-Cap*</th>
<th>Drug Indication</th>
<th>FDA Trial Stage</th>
<th>Estimated Addressable U.S. Market ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CytoDyn, Inc. (CYDY – Pink Sheets)</td>
<td>2.05</td>
<td>51.3M</td>
<td>Early HIV</td>
<td>IIb</td>
<td>$200M+</td>
</tr>
<tr>
<td>ImmunoGen, Inc. (IMGN - NasdaqGM)</td>
<td>8.18</td>
<td>469M</td>
<td>Cancer</td>
<td>I and IIa</td>
<td></td>
</tr>
<tr>
<td>Allos Therapeutics (ALTH - NasdaqGM)</td>
<td>7.95</td>
<td>833M</td>
<td>Cancer</td>
<td>I and IIa</td>
<td></td>
</tr>
<tr>
<td>Micromet, Inc. (MITI - NasdaqGM)</td>
<td>8.32</td>
<td>576M</td>
<td>Cancer</td>
<td>I and IIa</td>
<td></td>
</tr>
<tr>
<td>Novavax, Inc. (NVAX - NasdaqGM)</td>
<td>2.38</td>
<td>239M</td>
<td>Vaccines</td>
<td>I</td>
<td></td>
</tr>
</tbody>
</table>

*Market Data as of market close, 4/5/10 provided by Yahoo! Finance; Market Capitalization of CYDY computed on a fully-diluted basis

Note that these comparable companies are almost exclusively engaged in the development of cancer drugs (other than NVAX) with various mechanisms of operation. While we believe these Companies are useful to consider from a comparative analysis point of view, the science behind these companies and its comparison to the science behind CytoDyn is beyond the scope of this report.

### Conclusion

Without a doubt, CytoDyn has huge potential for investors and for helping those who suffer from HIV infection. Their therapy seems to make sense, and it certainly has benefits vis-à-vis those therapies that breed drug-resistant strains of HIV. However, although things look promising, it still remains to be seen if Cytolin’s promise will be borne out by the studies now being undertaken at Massachusetts General Hospital by Dr. Rosenberg.

Overall, we believe there is a high enough likelihood of a favorable outcome to recommend CYDY shares for risk-tolerant investors who understand the likely binary outcome of the research process. We are therefore initiating coverage of CYDY with a rating of Strong Speculative Buy. While we are not issuing a price target at this time, we recognize that a successful result in either the current or the next planned study will probably lead to a very large increase in the value of CytoDyn and its shares, while also significantly lowering their investment risk profile.
Our Rating System
We rate enrolled companies based on the appreciation potential we believe their shares represent. The performance of those companies rated “Speculative Buy” or “Strong Speculative Buy” are often highly dependent on some future event, such as FDA drug approval or the development of a new key technology.

<table>
<thead>
<tr>
<th>Rating</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>STRONG BUY</td>
<td>We believe the enrolled company will appreciate more than 50% relative to the general market for U.S. equities during the next 12 to 24 months.</td>
</tr>
<tr>
<td>BUY</td>
<td>We believe the enrolled company will appreciate more than 30% relative to the general market for U.S. equities during the next 12 to 24 months.</td>
</tr>
<tr>
<td>STRONG SPECULATIVE BUY</td>
<td>We believe the enrolled company could appreciate more than 50% relative to the general market for U.S. equities during the next 12 to 24 months, if certain assumptions about the future prove to be correct.</td>
</tr>
<tr>
<td>SPECULATIVE BUY</td>
<td>We believe the enrolled company could appreciate more than 30% relative to the general market for U.S. equities during the next 12 to 24 months, if certain assumptions about the future prove to be correct.</td>
</tr>
<tr>
<td>NEUTRAL</td>
<td>We expect the enrolled company to trade between -10% and +10% relative to the general market for U.S. equities during the following 12 to 24 months.</td>
</tr>
<tr>
<td>SELL</td>
<td>We expect the enrolled company to underperform the general market for U.S. equities by more than 10% during the following 12 to 24 months.</td>
</tr>
</tbody>
</table>

Analyst Certification
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**Analyst Highlight**

**Brian R. Connell, CFA**  
Senior Research Analyst

Mr. Connell has over 15 years’ experience in the securities industry, as an equity analyst and portfolio manager, and as the founder and CEO of StreetFusion (acquired by CCBN/StreetEvents), a software company serving the institutional investment community. On the sell-side, Mr. Connell served as the technology analyst for Neovest, an Atlanta-based boutique, and as a Senior Analyst - Internet for Preferred Capital Markets, an investment bank based in San Francisco. Mr. Connell has also held the position of Executive Director of Marquis Capital Management, a technology-focused investment management organization.

Mr. Connell holds degrees in Economics and Psychology from Duke University, and is a CFA Charter holder.

Mr. Connell is also associated with StreetCapital, an Atlanta-based broker-dealer. By written policy, Harbinger Research does not work with StreetCapital clients in any capacity, and StreetCapital does not work with Harbinger Research clients in any capacity.