CytoDyn, Inc.

BUY (CYDY, $0.58)

PRO 140 - Differentiated HIV Drug With Favorable Safety vs HAART, Phase 3 Data In 2Q17: Initiating BUY/$3 TP

- We are initiating coverage of CytoDyn, Inc. with a Buy rating and 12 month target price of $3. CytoDyn’s lead candidate, PRO 140, is a fully humanized antibody in Phase 3 development as a new class of therapy against CCR5-tropic HIV. Our valuation is based entirely upon projected revenue from PRO 140 for CCR5-tropic HIV infection in the US, where CytoDyn intends to market PRO 140 itself upon potential FDA approval. We project US approval and launch in calendar 1H19, and at an annual cost of about $10,000, we project over $400M in PRO 140 net sales in FY2022.

- The next most important investment catalyst for CytoDyn is the 2Q17 release of topline data from the 30-patient Phase 2b/3 PRO 140 combination therapy trial for HIV. The Phase 2b portion of the trial will evaluate the efficacy, safety and tolerability of PRO 140 in conjunction with a highly active antiretroviral therapy (HAART) regimen that treatment-experienced patients are currently failing, and the Phase 3 portion will subsequently evaluate the same patients in conjunction with optimized background therapy. The primary endpoint is the proportion of patients with ≥0.5 log10 reduction in HIV-1 RNA viral load from baseline at the end of the 1-week double-blind Phase 2b portion, a low hurdle in our view. If positive, the data will likely increase the chance of receiving Breakthrough Therapy Designation in 2H17, and support a 2018 BLA filing. The success of this trial will serve as the first path for PRO 140 approval for HIV in patients with multi-drug resistance.

- PRO 140 is also being evaluated in a Phase 2b/3 long-acting monotherapy trial with enrollment expected to complete in 2H17. The trial will assess the maintenance of viral suppression in 300 clinically stable CCR5-tropic HIV patients following substitution of HAART with 350 mg PRO 140 SC weekly for 48 weeks, and therefore evaluate PRO 140’s potential use as a single-agent maintenance therapy as well as in patients who choose to take holidays from HAART therapy. CytoDyn then plans to target the substitution benefits of PRO 140 as a label extension for maintenance monotherapy, serving the large general CCR5-tropic HIV population. The trial is actively enrolling at about 30 sites.

- PRO 140 offers competitive advantages over standard of care HAART in its once-weekly flexible dosing, as well as its far more favorable safety and tolerability profile. Compared to HAART’s strict once-daily oral regimen, PRO 140’s more flexible once-weekly SC dosing regimen provides a differentiated convenience, especially for those with difficulty adhering to a daily HAART regimen, or for patients who would like to take a break from HAART due to safety or tolerability. Most importantly, PRO 140 appears to demonstrate a safer profile with no serious side effects observed in trials and no negative impact on immune function. Also, no drug resistance has been seen in patients on monotherapy for up to 24 months, as compared to 76% of patients who experienced resistance to 1 or more of the drugs that comprise HAART.

- CytoDyn had about $7.8M in cash as of February 28, 2017 and is therefore clearly in need of additional financing to proceed with its BLA preparation after the imminent Phase 2b/3 data.

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*Note: pricing is as of market close on 5/24/17

Source: Company reports, Opus National Capital Markets estimates
Human immunodeficiency virus (HIV) attacks the body’s immune system, specifically the CD4 cells (T helper cells) that send signals to other immune cells in order to destroy the infectious particles, resulting in the patient’s vulnerability to many other opportunistic infections or infection-related cancers. HIV strains called M-tropic virus attack macrophages, another important immune cell. There are two types of HIV viruses: HIV-1 and HIV-2. Worldwide, the predominant HIV virus is HIV-1, which is the type of HIV that is generally referred to unless otherwise specified. When infected with HIV and not receiving treatment, patients will typically progress through three stages of disease: acute infection that is highly contagious and may last 2 to 4 weeks, followed by clinical latency stage when the infection is chronic and asymptomatic and may last between a decade and several decades (during which the immune system and HIV fiercely battle), and lastly, the acquired immunodeficiency syndrome (AIDS) stage when the infection is most severe and often fatal.

The World Health Organization (WHO) reported that as of 2013, approximately 35 million people were living with HIV globally. Without treatment, the average survival time with HIV is estimated to be 9 to 11 years, according to the Joint United Nations and WHO Program. According to the Centers for Disease Control and Prevention (CDC; Exhibit 2), more than 1.2 million people in the US were living with HIV infection as of 2013, translating to approximately a 0.38% prevalence rate in the US. However, only 20% of the 1.2 million HIV-infected patients were adherent to their treatment and were able to maintain their viral load at an undetectable level. The current standard of care (SOC) for HIV infection is highly active antiretroviral therapy (HAART), a treatment that uses a customized combination of different classes of medications based on viral load, strain of virus and CD4 cell count. Because HAART cannot eradicate an HIV infection, the oral treatment must be taken on a daily basis for the rest of the life, causing both an economic and medical burden for patients. Most importantly, antiretroviral toxicity has become an increasingly important issue with HAART and it results in a low compliance rate with the treatment, as many patients on HAART experience side effects, including immune disorders, bone disorders, muscular disorders, liver dysfunction, metabolic abnormalities and glucose abnormalities. Failing to adhere to the treatment often leads to disease rebound, rising viral load and falling CD4 counts in a majority of the patients. Given such poor disease management, the HIV space is in need of a key differentiator, like PRO 140, that is safer and delivers at least non-inferior efficacy, with a potentially less frequent dosing regimen to improve quality of life and disease control.
PRO 140 is one of the most advanced developmental stage monoclonal antibodies for HIV treatment. The drug has been studied in 7 clinical trials, each demonstrating efficacy by significantly reducing or controlling HIV viral load in human test subjects. Over 140 HIV-infected patients have been treated with PRO 140 in placebo-controlled, open-label pivotal trials. According to the CDC, 33% of HIV patients refuse to start HAART therapy for various reasons, one of those reasons being the therapy’s taxing, once-daily oral regimen. Since PRO 140 offers a convenient once-weekly flexible dosing regimen, along with a simple, painless, subcutaneous injection administered via a syringe, it provides a true competitive advantage over HAART, especially for patients having difficulty adhering to the daily HAART regimen, or for patients who would like to take a break from HAART. Most importantly, PRO 140 appears to demonstrate a safer profile with no serious side effects observed in trials and no negative impact on immune function. Also, no drug resistance was seen in patients on monotherapy for up to 24 months, as compared to 76% of patients who experienced resistance to 1 or more drugs in HAART. The differentiated safety features, along with a long serum half-life that allows for a conveniently low dosing frequency, afford PRO 140 the opportunity to maximize the therapeutic window and mitigate an unmet need in HIV disease management.

Exhibit 2: Prevalence of HIV among US population by sex, age and race (2013)

![Exhibit 2: Prevalence of HIV among US population by sex, age and race (2013)](image)

Source: CDC, 2010-2013; *AI/AN = American Indian/Alaska Native NH/PI = Native Hawaiian/Pacific Islander

**Mechanism of action and history of PRO 140**

PRO 140 is a breakthrough viral entry inhibitor being developed as a new class of HIV/AIDS therapy intended to protect healthy cells from viral infection. It is a fully humanized lgG4 monoclonal antibody directed against CCR5-tropic HIV (also known as R5-HIV), accounting for the majority of HIV infections. The HIV envelope glycoprotein gp120 attaches to CCR5, serving as a portal for HIV to enter into CD4 cells. The binding of PRO 140 to CCR5 at a precise site, which is an extracellular epitope that spans multiple hydrophilic domains, prevents HIV from entering and infecting cells (Exhibit 3). Notably, CCR5 also has beneficial activity, functioning as the receptor for the chemokine responsible for immune cell trafficking and T cell migration to sites of inflammation; therefore, it is favorable that PRO 140 is able to preserve the normal activity of CCR5 (Exhibit 4), unlike competitor Maraviroc (branded name, Selzentry) which blocks CCR5’s natural function. Maraviroc was initially approved in 2007 in the US and EU to be used in combination with other antiretroviral agents in treatment experienced patients that have CCR5-tropic HIV-1, but was later approved for use in combination with other antiretroviral agents in treatment-naive patients who are infected with only CCR5-tropic HIV-1. By contrast to conventional direct antiretroviral drugs, PRO 140 is an antibody, rather than a small molecule drug, and thus does not appear to have the toxicity often seen with HAART. Also, results from previous short-term trials have shown that PRO 140 does not induce the development of resistant virus.

PRO 140 is also being developed for certain inflammatory diseases, autoimmune diseases, transplantation, and cancer. PRO 140 was originally named PA 14 and developed by Progenics Pharmaceuticals (NASDAQ:PGNX-Buy $6.83) as a treatment for HIV and was acquired
by CytoDyn in 3Q12 for an initial cash payment of $3.5 million, plus an additional development milestone payment (i.e., CytoDyn still owes Progenics $5 million upon the first PRO 140 approval, regardless of region, if approved) and royalties of up to 5% on any sales. PRO 140 was granted Fast Track designation in 2006 based on its more favorable safety profile and lower drug resistance rate, and CytoDyn filed for Breakthrough Therapy Designation in 1Q17, which, if granted, could expedite PRO 140’s approval process. CytoDyn filed for Orphan Drug Status for PRO 140, but the FDA said that its potential utility in a far broader segment of HIV infection (more than just the subset of multi-drug resistant patients) rendered the drug ineligible for such status, which has both its immediate negatives and longer term potential positives.

**Exhibit 3: Mechanism of action of PRO 140**

![Mechanism of action of PRO 140](source: Company documents)

**Exhibit 4: PRO 140 inhibits R5 HIV-1 without blocking the natural activity of CCR5 in vitro**

![PRO 140 inhibits R5 HIV-1 without blocking the natural activity of CCR5 in vitro](source: Company documents)

**PRO 140 Clinical trials overview**

In a completed Phase 2b trial (n=40), known as the “treatment substitution trial”, 98% of patients experienced suppressed virologic failure after 4 weeks of PRO 140 monotherapy. By week 11 (maximum allowable monotherapy duration without an extension study), 75% (30/40) of patients still attained suppressed viral load. 16 of the 30 patients were qualified to participate in an extension trial, of which 10 reached viral load suppression with PRO 140 monotherapy for over 2 years, 7 of whom experienced viral load as low as <1 copy/mL. Another Phase 2 trial demonstrated that a significant amount of patients successfully completed PRO 140 therapy with a statistically significant change in viral load as compared to patients on placebo. In 3Q15, CytoDyn initiated its first Phase 3 trial with PRO 140 as part...
of an HIV combination therapy with current SOC, and in 3Q16, CytoDyn initiated another Phase 3 trial with PRO 140 as monotherapy in HIV patients. In order to expedite PRO 140 through Phase 3, CytoDyn signed a new contract with Amarex Clinical Research as its CRO.

Ongoing Phase 2b/3 trials for PRO 140 – pivotal combination therapy trial (NCT02483078)

In 3Q15, CytoDyn initiated a randomized, double-blind, placebo-controlled, multi-center, two-part, Phase 2b/3 trial for PRO 140 to confirm viral load reduction in 30 treatment-experienced CCR5-tropic HIV-1 patients whose disease is poorly controlled by HAART therapy (Exhibit 5). The trial will evaluate the efficacy, safety and tolerability of PRO 140 in conjunction with existing antiretroviral therapy, a regimen that the patients are currently failing, in the Phase 2b portion of the trial, and in conjunction with optimized background therapy in the Phase 3 portion of the trial. Patients are randomized to receive either 350 mg subcutaneous (SC) PRO 140 weekly in the treatment arm or placebo in the control arm plus existing antiretroviral therapy for 1 week, followed by single-arm, open-label treatment of weekly SC injection of 350 mg PRO 140 with optimized background therapy for 24 weeks for all patients. In October 2015, CytoDyn injected its first patient in this trial and is actively recruiting patients from about 40 clinical sites. The primary endpoint is the proportion of patients with ≥0.5 log10 reduction in HIV-1 RNA viral load from baseline at the end of the 1-week double-blind treatment period. After the first week, all patients will enter a 24-week PRO 140 plus optimized background therapy treatment period, where secondary outcome measures will be assessed. In particular, safety, tolerability, along with proportion of patients achieving HIV-1 RNA <400 copies/mL and <50 copies/mL will be measured at week 25. Several patients already concluded the first portion of the trial and are now in the second portion of the trial. The success of this trial will serve as the first path for the approval of PRO 140 for HIV in patients with multi-drug resistance and failing HAART. Topline data on the primary endpoint is expected in 2Q17, which, if positive, will likely increase the chances for receiving Breakthrough Therapy Designation in calendar 2H17, and the filing of a subsequent Biologics License Application (BLA) in calendar 2018.

Exhibit 5: Phase 2b/3: 1st approval diagram (modified Murray design) – pivotal combination therapy trial

Ongoing Phase 2b/3 PRO 140 long-acting monotherapy pivotal trial (NCT02859961)

In 3Q16, CytoDyn initiated its second Phase 2b/3 trial, following clearance from the FDA regarding the filing of the protocol and the encouraging topline safety results from the Phase 2b treatment substitution extension trial. This long-acting, single-arm monotherapy trial will assess the maintenance of viral suppression in 300 clinically stable CCR5-tropic HIV patients following substitution of HAART with 350 mg PRO 140 SC weekly for 48 weeks, and therefore evaluate PRO 140’s potential use as a single-agent maintenance therapy as well as in patients who choose to take drug holidays from HAART. Patients will be shifted from their combination antiretroviral regimen to weekly PRO 140 monotherapy for 48 weeks during the treatment phase with a one week overlap of their existing antiretroviral regimen and PRO 140 at the beginning of the study and also a one week treatment overlap at the end of the treatment in patients who do not experience virologic suppression from the PRO 140 monotherapy. CytoDyn plans to target the substitution benefits of PRO 140 as a label
extension for maintenance monotherapy, serving the general CCR5-tropic HIV population along with those who would like to take a break from daily HAART, especially since the FDA currently lacks any guidance regarding drug holidays on HAART. The trial is undergoing active recruitment at about 30 clinical sites and enrollment should complete in 2H17.

**Phase 2b treatment substitution trial: PRO 140 – CD 01 trial (NCT02175680)**

In 2Q14, CytoDyn initiated a single-arm, open-label, Phase 2b trial to evaluate the efficacy, safety, and tolerability of PRO 140 monotherapy for the maintenance of viral suppression in HIV-1 infected patients who were stable on antiretroviral therapy. A total of 40 HIV-1 patients shifted from their combination antiretroviral regimen to 350 mg PRO 140 weekly SC for 12 weeks. Total treatment duration with PRO 140 was 14 weeks with a one week overlap of existing antiretroviral regimen and PRO 140 at the beginning of study treatment, and a one week overlap at the end of the treatment in patients who did not experience virologic reduction. At entry, patients exclusively had CCR5-tropic virus and were on antiretroviral therapy for at least the preceding 12 months. The primary endpoint was virologic failure, where virologic failure was defined as two consecutive HIV-1 RNA level measurements of ≥400 copies/mL separated by at least 3 days. Secondary outcome measures were proportion of patients with virologic failure at or prior to week 14 and mean changes in viral load and CD4 cell count within the 14-week treatment phase.

CytoDyn read out full results from this trial in 1Q15. After 4 weeks of monotherapy, 39 of the 40 enrolled patients (98%) did not experience virologic failure. And the majority of patients reported improvements in quality of life, such as reductions in insomnia, headaches, and enhancement of energy level. 91% of patients successfully passed 6 weeks of monotherapy with no virologic failure, and 82% passed 8 weeks of monotherapy without same. After 11 weeks of monotherapy (maximum allowable monotherapy without being in the extension study), 75% of patients still had no virologic failure. Notably, no drug-related serious adverse events were reported.

A two-year update on the ongoing extension trial for PRO 140 – CD 01-Extension, was announced at the 2017 Conference on Retroviruses and Opportunistic Infections in 1Q17. 16 patients infected with CCR5-tropic HIV-1 were enrolled after maintaining virologic suppression (two consecutive viral load measurements of below 400 RNA copies/mL) following 12 weeks of weekly, subcutaneous injections of PRO 140 (350 mg) as a single agent from the initial treatment substitution trial. These patients were trained to self-administer PRO 140 (1 mL drawn out of a vial) via a syringe and were allowed to continue weekly subcutaneous injections as a monotherapy for up to three years. Of 16 enrolled patients, 13 patients (81%) maintained complete virologic suppression for more than 40 weeks, and 10 patients (63%) maintained complete virologic suppression for nearly two years and are still continuing on the PRO 140 monotherapy regimen (Exhibit 6). One patient discontinued at week 47 with complete virologic suppression due to relocation, and five patients experienced virologic rebound. The mean time to virologic rebound was 329 days (range of 106-691 days). The 10 patients with long duration single-copy HIV RNA assay levels (to quantify the viral load below the limit of detection from commercially available assays) were evaluated at the 2-year time point. 7 of these 10 patients reported a viral load of <1 RNA copy/mL, and another 3 patients reported values of 4, 10, and 19 RNA copies/mL. The 7 patients with less than a single-copy HIV-1 RNA/mL provide further evidence of the potent antiretroviral activity of PRO 140. Importantly, PRO 140 was generally well tolerated with no drug-related major adverse events or treatment discontinuation reported. All definitely and probably related adverse events were limited to local injection site reactions of mild or moderate intensity.

We believe such positive safety and efficacy results support the continued development of PRO 140 as a maintenance monotherapy for patients with CCR5-tropic HIV-1.

**Exhibit 6: Time to loss of virologic response**

![Exhibit 6](image-url)
Phase 2a Subcutaneous administration trial – PRO 140 2101 (NCT00642707)

In 1Q08, a randomized, double-blind, placebo-controlled, Phase 2 trial was initiated with PRO 140 for the treatment of adult CCR5-tropic HIV-1 infection. A total of 44 HIV-1 patients were randomized to the following 4 cohorts (3 cohorts were given varying doses of PRO 140 while 1 cohort was given placebo): Arm 1, 162 mg SC PRO 140 at days 1, 8, and 15; Arm 2, 324 mg SC PRO 140 at days 1, 8, and 15; Arm 3, 324 mg SC PRO 140 at days 1, 15 plus placebo dosed at day 8; Arm 4, placebo dose at days 1, 8, and 15.

Upon completion of dosing, patients were monitored 59 days for maximum change in viral load, as the primary endpoint. PRO 140 was shown to successfully decrease viral load significantly in patients by a mean value of -0.99 log10 copies/mL in Arm 1, -1.65 log10 copies/mL in Arm 2, -1.37 log10 copies/mL in Arm 3, compared to placebo at -0.23 log10 copies/mL (Exhibit 7). One patient withdrew from Arm 1, while two patients withdrew from Arm 4 (placebo arm) due to adverse events. Three serious adverse events (SAEs) were reported for Arm 3, including 1 case of viral meningitis, 1 case of scrotal abscess, and 1 case of anal cancer stage 1, all of which were deemed unrelated to PRO 140.

Exhibit 7: Antiretroviral effects of short-term monotherapy with SC – PRO 140 2101 study

Source: Company documents

Phase 2 IV trial – PRO 140 2301 (NCT00613379)

In 4Q07, a randomized, double-blind, placebo-controlled, single-dose Phase 2 trial was initiated with PRO 140 for the treatment of CCR5-tropic HIV-1 patients with screening plasma HIV-1 RNA ≥5,000 copies/mL. A total of 31 HIV patients were randomized to receive one of two doses of PRO 140 (10mg/kg, 5mg/kg, n=20) or placebo (n=11). Patients had CCR5-tropic virus and a CD4 T-lymphocyte cell count of ≥300 cells/mm³ at screening. The primary endpoint was the maximum change in viral load over 59 days, and there were no secondary outcome measures. Results showed that mean maximum change in viral load following initiation of treatment were -1.83 log10 copies HIV-1 RNA/mL for PRO 140 5mg/kg group and -1.67 log10 copies HIV-1 RNA/mL for PRO 140 10mg/kg, compared to -0.32 log10 copies HIV-1 RNA/mL for placebo, again, showing the antiretroviral efficacy of PRO 140.

Receptor occupancy of CCR5 was determined by flow cytometry using fluorescently labeled PRO 140. Mean cell counts were shown over time by treatment group, and error bars depicted standard deviation (p<0.01 relative to placebo for 5mg/kg PRO 140 at all-time points from day 3 through day 29, and for 10mg/kg PRO 140 at all-time points from day 3 through day 43; p>0.05 relative to placebo at all other time points). CCR5 cells were not depleted from circulation. Patients received a single infusion of PRO 140 on day 1. Notably, 10mg/kg PRO 140 did not demonstrate any dose-dependent pattern of adverse events relative to placebo or 5mg/kg PRO 140 (Exhibit 8, 9 and 10). Such findings not only strengthen the efficacy argument for PRO 140, but also demonstrate strong pharmacologic, pharmacokinetic, and safety profile of the drug.

May 25, 2017
Exhibit 8: Relationship between viral load reductions and PRO 140 exposure modeled using a hyperbolic $E_{\text{max}}$ equation – PRO 140 2301

A

![Graph showing viral load reductions and PRO 140 exposure over study days.](image)

$E_{\text{max}} = -2.06 \log_{10}$

$AUC_{50} = 34 \text{ mg*day/L}$

Source: Company documents

Exhibit 9: Receptor occupancy of CCR5 cells – PRO 140 2301

![Graph showing receptor occupancy of CCR5 cells over study days.](image)

Source: Company documents
Earlier trials

In addition to the aforementioned trials with PRO 140, multiple Phase 1 trials have been completed involving healthy volunteers and HIV infected patients. In these early trials, PRO 140 was well tolerated with no SAEs reported and with the drug eliciting the expected dose responsive decreases in HIV viral load. The most common potentially drug related AEs were diarrhea, headache, swollen lymph nodes, and high blood pressure.

- **Phase 1 PRO 140 1302 trial.** This multi-center, double-blind, randomized, placebo-controlled, Phase 1b trial examined three single escalating intravenous doses of PRO 140: 0.5mg/kg, 2mg/kg and 5mg/kg in 39 HIV infected patients who had taken no antiretroviral therapy within the preceding three months and who had viral loads greater than or equal to 5,000 RNA copies/mL. All patients were screened for exclusivity of CCR5-tropic HIV. In each dose cohort, 10 patients were on PRO 140 and 3 were on placebo. No SAEs were reported. A single dose of the two highest doses tested exhibited significant dose responsive decreases in viral load (Exhibit 11).

Exhibit 11: Antiretroviral effects following a single IV injection – PRO 140 1302

- **Phase 1 PRO 140-1101 trial (NCT00110591).** In 2Q04, a randomized, double-blind, placebo-controlled, single-dose Phase 1 trial was initiated with PRO 140 in healthy male volunteers. Dose dependent binding of PRO 140 to CCR5 was seen with significant receptor occupancy being maintained for more than 60 days at the 5mg/kg dose, with no change in lymphocyte count, plasma CMV level, or development of anti PRO 140 antibodies. A total of 20 HIV-1 negative men were randomized to intravenously receive one of four doses of PRO 140 (0.1mg/kg, 0.5mg/kg, 2mg/kg, or 5mg/kg, n=16) or placebo (n=4). PRO 140 was generally
well tolerated, with no reported SAEs. The half-life of PRO 140 was about 2 weeks with serum concentrations increasing proportionally with dosage. Notably, even at the highest dosage, there was no change in lymphocyte count, plasma RANTES level or development of antibodies to the drug.

Competitive landscape for PRO 140

Highly active antiretroviral therapy (HAART). Currently, HAART is the standard of care for HIV infected individuals. HAART is used to suppress HIV replication, and impedes progress of the disease in the overwhelming majority of patients. HAART combines three or more different classes of drugs, such as nucleoside reverse transcriptase inhibitors (NRTIs), protease inhibitors, or non-nucleoside reverse transcriptase inhibitors (NNRTIs). We believe that PRO 140 has the potential to be highly favorable over HAART due to the safety, tolerability, and resistance advantages it provides. PRO 140 is administered via a weekly subcutaneous injection using a syringe, while HAART normally requires a daily regimen of at least one pill (one pill often contains a combination of drugs). PRO 140 has also shown no apparent side effects or toxicity whereas HAART regimens often lead to toxicity and/or intolerability. If patients do not comply with the strict dosing regimen, HIV will more easily be able to develop resistance to HAART, thus increasing viral load in those patients. By contrast to direct antiretroviral drugs, PRO 140 has not been shown to promote drug-resistant virus.

CCR5 receptor antagonist. Selzentry (maraviroc) is the only FDA approved CCR5 receptor antagonist. However, PRO 140 sales could be greater than Selzentry’s US sales, which were only $108 million in 2014, due to its many potential advantages over Selzentry (Exhibit 12). Selzentry is an oral drug taken twice daily on a strict time schedule, whereas PRO 140 is a weekly subcutaneous injection taken on a relatively flexible schedule. Selzentry and other small molecule CCR5 antagonists under development have cardiac or neurological toxicities in some patients, whereas PRO 140 has shown no apparent toxicity issues. The CCR5 binding sites for these CCR5 antagonists are the common hydrophobic pockets, defined as transmembrane regions of CCR5. By contrast, the PRO 140 binding site on CCR5 is the extracellular epitope that spans multiple hydrophilic domains, affording a higher selectivity for PRO 140. Viral cross resistance with the small molecules is significant compared to the limited viral cross resistance with them and PRO 140. At week 40 in vitro, there was no sign of viral resistance, whereas Selzentry and the other CCR5 antagonists showed development of resistance in vitro from week 6 to 19. A drug-drug and food interaction with PRO 140 is also unlikely due to its nature of being an antibody, whereas the other CCR5 antagonists have significant interactions with other drugs or food. PRO 140 also has the advantage of not reducing the normal activity of CCR5 receptor, thereby allowing for more normal immune system activity, which should enhance fighting HIV infection.

Exhibit 12: PRO 140 inhibits maraviroc-resistant virus

Source: Company documents

Follow-on indication development for PRO 140

PRO 140 is also in clinical development for non-HIV indications, such as certain inflammatory diseases, autoimmunity, transplantation, and cancer. CytoDyn has selected a transplantation related indication called Graft Versus Host Disease (GvHD) as its first non-HIV clinical indication. GvHD can occur after a stem cell or a bone marrow transplant when the newly transplanted donor cells attack the transplant recipient’s body, as the cells detect their new environment as foreign, resulting in a 40-60% one-year survival rate, with relapsed GvHD as the leading causes of death. The CCR5 receptor is believed to be an important mediator of GvHD, especially in relation to the organ
damage that usually causes death in GvHD patients. The mechanism of CCR5 and its ligands in GvHD was previously studied in murine models. Results demonstrated that CCR5+CD8+ T cells mediate liver injury in murine GvHD, and that inhibiting CCR5 mitigates such damage, suggesting that genetic deletion of CCR5 in the donor could reduce GvHD. Targeting CCR5, PRO 140 has potential to reduce the severity of GvHD and expand the patient pool for bone marrow transplantation. In a preclinical study conducted by CytoDyn, human bone marrow stem cells were administered to immunocompromised mice, leading to severe GvHD culminating in death. PRO 140 was administered to the mice and completely eliminated any signs of GvHD. In addition, effects of stem cell engraftment was apparent in blood, spleen and bone marrow of the mice without signs of GvHD. CytoDyn plans to submit the results on this preclinical study to the FDA in support of the drug’s Orphan Drug Designation application, and publish the data in the forthcoming future. CytoDyn has initiated a randomized, double-blind, placebo-controlled, multicenter 100-day, Phase 2b trial for GvHD to evaluate the safety and efficacy of PRO 140 with an equal number of patients receiving PRO 140 and placebo. The trial expects to enroll 60 patients with acute myeloid leukemia or myelodysplastic syndrome undergoing bone marrow transplant, and dosed the first patient in May 2017. If CytoDyn receives positive results from this Phase 2 study, the company expects to file for Breakthrough Designation with the FDA to expedite the commercialization of PRO 140 for this indication. Any success on this follow-on indication of PRO 140 would provide upside to our valuation.

Cytolin

CytoDyn’s other HIV treatment, Cytolin, is a mouse anti-human LF-1 monoclonal antibody that was tested in small uncontrolled clinical trials back in the mid-1990s where monotherapy resulted in a 0.2-1 log10 drop in viral RNA and a modest increase (range 70–200 cells/mL) in CD4 T cell count in HIV infected individuals. More recently, when Cytolin was administered to HIV infected primary isolated human cells, the antibody appeared to induce the production of a soluble factor that inhibits HIV replication. Cytolin binds to the antigen CD11a, which makes up the cellular adhesion molecule LFA-1 when complexed with CD18. LFA-1 functions as an adhesion molecule under normal conditions and is an important component of the immune system. LFA-1 binds to its cognate receptor, ICAM, on immune cells and facilitates a productive immune response. Studies have shown that, unlike other CD11a specific antibodies, Cytolin does not bind to the ICAM binding region of the molecule, and therefore does not interfere with the normal function of CD11a. Cytolin also appears to bind dendritic cells, which are necessary for reducing viral burden. By binding to these cells, Cytolin has been shown to reduce both infection of new cells and viral burden in preclinical studies.

Importantly, Cytolin does not directly affect viral replication, which could potentially reduce the chance for viral resistance after prolonged exposure to Cytolin. This is similar to the case with PRO 140, by contrast to conventional direct antiretroviral drugs which often lead to the evolution of drug-resistant virus. Consequently, Cytolin could be utilized early in infection in order to delay the natural progression of the disease, and therefore delay the time when direct antiretroviral drugs are inevitable. Cytolin has been de-prioritized after PRO 140, but its clinical development will most likely restart once CytoDyn has sufficient cash to continue investment in the program.

CytoFeline

CytoFeline is an anti-LFA-1-antibody for the treatment of Feline Immunodeficiency Virus (FIV) infection, which infects 1-4% of house cats, and a greater percent of feral cats. FIV represents a large potential market opportunity in the US and EU, as more than $2,000 is spent on a FIV infected domestic cat annually, on a population of 83 million infected cats. FIV primarily binds to lymphocytes and kills T-lymphocytes gradually. Due to the cytopathic effect, CD4 lymphocytes are lost, the CD4/8 ratio is inverted, and CD8 lymphocytes are lost in late stages of the infection. Because FIV is genotypically and phenotypically similar to HIV, strategies for HIV treatment could also be used for FIV. However, antiretroviral therapy appears to be too toxic for animals, leaving no human antiretroviral therapy approved for FIV. CytoDyn has identified an anti-CD11a antibody that can bind to feline cells, and has measured its ability to suppress FIV in vitro. Following these studies, CytoDyn may undertake additional studies to explore multiple dosing with the antibody, but clearly requires additional cash to continue this program in earnest. We would expect the company to be more likely to license this program to a company specializing in veterinarian medicine in exchange for much needed cash. CytoFeline does not factor into our CytoDyn valuation.

Intellectual property

Globally, CytoDyn has 42 patents granted for PRO 140 and methods of HIV inhibition across 17 countries and regions. In the US, CytoDyn has one issued patent covering a method for reducing HIV-1 viral load in an HIV-1 infected human subject. The patent covers administration to a subject at a predefined interval, HIV-1 viral load-reducing doses of (a) a humanized antibody designated PRO 140, or of (b) an anti-CCR5 receptor monoclonal antibody. The issued patent is expected to expire in 2026, exclusive of any potential patent term.
extensions or adjustments. This invention also provides a method for inhibiting in a human subject the onset or progression of an HIV-1-associated disorder, the inhibition of which is effected by inhibiting fusion of HIV-1 to CCR5/CD4 target cells in the subject. Composition of matter protection for PRO 140 consists of issued patents in South Africa, New Zealand and Singapore, and pending patent applications in the US, EU, Japan and 10 other countries. Patent rights covering certain compositions regarding PRO 140 are held by a third party, but the patent has already expired. CytoDyn has one patent pending in the US on the method for preventing HIV-1 infection of CD4 cells. Notably, in April 2017, the FDA rejected CytoDyn’s application for Orphan Drug Designation (ODD) on PRO 140, because PRO 140 appears to have the potential to treat more than just the subset of multi-drug resistant HIV patients for which the designation was requested. In particular, in addition to the pivotal Phase 3 trial with PRO 140 in combination with other antiretroviral agents in the patient population submitted for ODD, CytoDyn is conducting a 300-patient Phase 3 trial with PRO 140 as single-agent maintenance therapy for HIV-infected patients, which is a US patient population that far exceeds the 200,000-patient threshold for ODD. Regarding FIV, CytoDyn has three patents pending related to treatment of retroviral infections in felines in the US, Canada and the EU. CytoDyn has one trademark registered with the US PTO for Cytolin.

Financials

Revenue. Projected revenue stems from PRO 140 sales for the treatment of HIV patients in the US. We project CytoDyn to commercialize PRO 140 in the US by itself and partner PRO 140 in ex-US territories. We project FDA approval in late FY2019 (calendar 1H19; fiscal year ends in May) and US launch of PRO 140 for HIV treatment in early FY2020 (calendar 2H19). With an assumed annual treatment cost of about $10,000 for PRO 140 in the US, we project PRO 140 to generate about $400 million in US sales in FY2022.

Expenses. We assume CytoDyn to bear all expenses related to PRO 140 in the US, as the company plans to develop and commercialize PRO 140 in the US on its own. We project COGS for PRO 140 to be 15% initially and to very gradually decrease, given it would be unrealistic to assume CytoDyn would initially reach significant economies of scale. We project R&D expense to increase by almost 30% to $28 million in FY2018, given the ongoing two Phase 3 trials for HIV, then drop thereafter. We also project SG&A expense to increase substantially in FY2019 as CytoDyn ramps up to launch PRO 140, with an annual growth rate of about 180% in FY2019 pre-launch, with launch projected early in FY2020.

Bottom Line. We project CytoDyn to be profitable in FY2020, due primarily to PRO 140 sales in the US. The FY2019 diluted share count takes into consideration outstanding warrants, stock options and convertible debt, which can be exercised for a total of about 140 million additional common shares. As of March 31, 2017, CytoDyn had about 150 million shares of common stock outstanding. Finally, we are projecting a 25% income tax rate in FY2021 and 35% income tax rate in FY2022 and thereafter, as the current $69 million in NOLs are consumed.

Balance Sheet. CytoDyn had about $7.8 million in cash as of February 28, 2017 and is therefore clearly in need of additional financing to proceed with its BLA preparation after the impending data. Near term, we expect significant stock price appreciation after the release of our expected positive results on the primary endpoint of the Phase 3 PRO 140 combination therapy trial in calendar 2Q17, and for CytoDyn to await this data before doing any significant financing.
Risks

- **Clinical risk.** PRO 140 could fail to deliver statistically significant results in late stage clinical trials, substantially reducing the value of CytoDyn and therefore our target price.

- **Regulatory risk.** PRO 140, even if successful in the clinic, could fail to be approved by domestic and/or foreign regulatory bodies, which would reduce CytoDyn value and therefore our target price.

- **Financing risk.** CytoDyn will need capital to fund its operations at its current burn rate of $2 million per month, and thus is reliant on obtaining additional outside funding, which may not occur or which could be substantially dilutive to existing investors.

- **Competitive risk.** Even if PRO 140 is approved, it may not be well adopted in a competitive marketplace, which would adversely affect CytoDyn’s value and therefore our target price.

- **High stock price volatility.** This issue is common among small-cap biotechnology companies with relatively low trading volumes.
## CytoDyn Inc.

### Income Statement

Fiscal Year ends May 25, 2017 (in '000 except per share items)

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<thead>
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<td><strong>Collaborate revenue</strong></td>
<td></td>
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<tr>
<td>PRO 140</td>
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<td><strong>COGS</strong></td>
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<td>3,685</td>
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<td>6,534</td>
<td>6,861</td>
<td>21,465</td>
<td>6,930</td>
<td>6,999</td>
<td>7,069</td>
<td>6,928</td>
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<td>1,680</td>
<td>1,391</td>
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<td>6,038</td>
<td>1,616</td>
<td>1,632</td>
<td>1,796</td>
<td>2,155</td>
<td>7,199</td>
<td>20,157</td>
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<td>714</td>
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<td>250</td>
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<td><strong>Amortization &amp; depreciation</strong></td>
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<td>361</td>
<td>362</td>
<td>93</td>
<td>93</td>
<td>91</td>
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<td>82</td>
<td>345</td>
<td>327</td>
<td>311</td>
<td>295</td>
<td>281</td>
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<tr>
<td><strong>Total operating expenses</strong></td>
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<td>8,113</td>
<td>19,596</td>
<td>21,176</td>
<td>5,358</td>
<td>6,156</td>
<td>8,017</td>
<td>9,048</td>
<td>28,579</td>
<td>8,884</td>
<td>9,201</td>
<td>9,415</td>
<td>28,579</td>
<td>8,884</td>
<td>9,201</td>
<td>9,415</td>
<td>36,469</td>
<td>41,532</td>
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<tr>
<td><strong>Operating income (EBIT)</strong></td>
<td>(7,993)</td>
<td>(8,113)</td>
<td>(19,596)</td>
<td>(21,176)</td>
<td>(5,358)</td>
<td>(6,156)</td>
<td>(8,017)</td>
<td>(9,048)</td>
<td>(28,579)</td>
<td>(8,884)</td>
<td>(9,201)</td>
<td>(9,415)</td>
<td>(36,469)</td>
<td>(41,532)</td>
<td>(166,305)</td>
<td>(270,533)</td>
<td>(323,247)</td>
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<tr>
<td><strong>Total Other Income</strong></td>
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<td>(4,319)</td>
<td>(5,492)</td>
<td>(4,528)</td>
<td>4</td>
<td>689</td>
<td>(96)</td>
<td>4</td>
<td>601</td>
<td>250</td>
<td>500</td>
<td>250</td>
<td>(250)</td>
<td>750</td>
<td>900</td>
<td>1,080</td>
<td>1,296</td>
<td>1,555</td>
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<tr>
<td><strong>Net income (loss) before taxes</strong></td>
<td>(9,568)</td>
<td>(12,431)</td>
<td>(25,088)</td>
<td>(25,704)</td>
<td>(5,354)</td>
<td>(5,467)</td>
<td>(8,112)</td>
<td>(9,044)</td>
<td>(27,978)</td>
<td>(8,634)</td>
<td>(8,469)</td>
<td>(8,951)</td>
<td>(9,665)</td>
<td>(35,719)</td>
<td>(40,632)</td>
<td>(166,305)</td>
<td>(270,533)</td>
<td>(324,802)</td>
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<td><strong>Income tax expense (benefit)</strong></td>
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<td></td>
</tr>
<tr>
<td><strong>Net income (loss), GAAP</strong></td>
<td>(9,568)</td>
<td>(12,431)</td>
<td>(25,088)</td>
<td>(25,704)</td>
<td>(5,354)</td>
<td>(5,467)</td>
<td>(8,112)</td>
<td>(9,044)</td>
<td>(27,978)</td>
<td>(8,634)</td>
<td>(8,469)</td>
<td>(8,951)</td>
<td>(9,665)</td>
<td>(35,719)</td>
<td>(40,632)</td>
<td>(166,305)</td>
<td>(270,533)</td>
<td>(324,802)</td>
</tr>
<tr>
<td><strong>EPS basic</strong></td>
<td>(0.31)</td>
<td>(0.22)</td>
<td>(0.43)</td>
<td>(0.27)</td>
<td>(0.04)</td>
<td>(0.04)</td>
<td>(0.06)</td>
<td>(0.06)</td>
<td>(0.20)</td>
<td>(0.06)</td>
<td>(0.06)</td>
<td>(0.06)</td>
<td>(0.07)</td>
<td>(0.25)</td>
<td>(0.27)</td>
<td>1.11</td>
<td>1.32</td>
<td>1.34</td>
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<tr>
<td><strong>EPS diluted, GAAP</strong></td>
<td>(0.31)</td>
<td>(0.22)</td>
<td>(0.43)</td>
<td>(0.27)</td>
<td>(0.04)</td>
<td>(0.04)</td>
<td>(0.06)</td>
<td>(0.06)</td>
<td>(0.20)</td>
<td>(0.06)</td>
<td>(0.06)</td>
<td>(0.06)</td>
<td>(0.07)</td>
<td>(0.25)</td>
<td>(0.14)</td>
<td>0.57</td>
<td>0.69</td>
<td>0.71</td>
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<tr>
<td><strong>Basic shares outstanding</strong></td>
<td>30,908</td>
<td>55,753</td>
<td>58,376</td>
<td>95,438</td>
<td>124,412</td>
<td>136,024</td>
<td>142,176</td>
<td>143,597</td>
<td>136,552</td>
<td>144,315</td>
<td>145,037</td>
<td>145,762</td>
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<td>148,309</td>
<td>151,276</td>
<td>154,301</td>
<td>157,387</td>
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<tr>
<td><strong>Diluted shares outstanding</strong></td>
<td>30,928</td>
<td>55,753</td>
<td>58,376</td>
<td>95,438</td>
<td>124,412</td>
<td>136,024</td>
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<td>288,555</td>
<td>291,521</td>
<td>294,547</td>
<td>297,633</td>
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Source: Company reports, Opus National Capital Markets estimates
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Opus National Capital Markets is a DBA for
National Securities Corporation
410 Park Avenue, 14th Floor, New York, NY 10022

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Relevant Disclosures: 1, 7, and 10

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or more of the securities of the issuer

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Please see below for other relevant disclosures

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<th>Distribution of Ratings</th>
<th>Investment Banking*</th>
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<td>Rating</td>
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<tr>
<td>BUY</td>
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<td>NEUTRAL</td>
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*Investment banking services provided in the previous 12 months

MEANING OF RATINGS:

BUY: the stock is likely to generate a total return of at least 10% over the next 12 months and should outperform relative to the industry.

NEUTRAL: the stock is likely to perform in-line with the industry over the next 12 months.

SELL: the stock is likely to underperform (from a total return perspective) relative to the industry over the next 12 months.

NR: Not Rated

SP: Suspended

May 25, 2017
Charts – CYDY

Source: Big Charts

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<th>CYDY</th>
<th>Date</th>
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<th>Price Target</th>
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<td>BUY</td>
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