Recent Stock Price (6/10/16)	$1.21
52-Week Range	$0.64-$1.57
Market Capitalization	$149.1 M
Shares Outstanding	123.3 M
Fiscal Year-End	May 31

OTC.QB: CYDY
www.cytodyn.com

PRO 140: First self-administered, injectable antibody therapy for HIV in late-stage clinical development

CytoDyn is focused on the clinical development and commercialization of PRO 140, a humanized monoclonal antibody for treating human immunodeficiency virus (HIV). PRO 140 is being evaluated in two Phase 3 trials, one in combination with the current standard-of-care HAART (Highly Active Anti-Retroviral Therapy) and the other as a long-term monotherapy to replace standard-of-care HAART, as well as in the monotherapy extension portion of a completed Phase 2b study. Clinical data thus far indicate that PRO 140 can significantly reduce viral load (by as much as 2.5log) in people infected with HIV and sustain such reduction without negatively affecting normal immune function. CytoDyn also has initiated a Phase 2 trial with PRO 140 in graft versus host disease (GvHD).

INVESTMENT HIGHLIGHTS

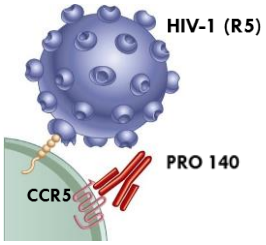
- **$15+ billion U.S. HIV therapeutics market** suffers from difficult dosing schedules, drug resistance, side effects, and toxicity with standard-of-care HAART therapy.
- **PRO 140 addresses HAART shortcomings** with no serious side effects, hardly any toxicity and no drug resistance in a dose/week, self-administered subcutaneous injections.
- **Phase 3 pivotal trial underway** with PRO 140 as a combination HIV therapy with Fast-Track designation, targeting BLA submission to the FDA in 2017.
- **Phase 3 trial initiated** for HIV as long-term monotherapy supported by long-term viral load suppression in monotherapy Phase 2b extension study.
- **Near-term milestones** provide multiple inflection points.
- **Phase 2 trial in GvHD underway** with further pipeline opportunities in cancer and autoimmune diseases.
- **Cost-efficient business model** supported by $20 million raise completed in 1Q16.

ABOUT PRO 140

PRO 140 belongs to a new class of HIV/AIDS therapeutics called viral-entry inhibitors, which are intended to protect healthy cells from viral infection. Importantly, PRO 140 does not appear to interfere with the normal function of CCR5 in mediating immune responses. PRO 140 does not have agonist activity toward CCR5, but does have antagonist activity to CCL5, which is a central mediator in inflammatory diseases.

- *PRO 140 has been designated a **"fast track"** product candidate by the FDA with possibility of accelerated approval.*
- *PRO 140 has been the subject of **7 clinical trials**, each **demonstrating efficacy by significantly reducing or controlling HIV level (viral load)**.*
- *The PRO 140 antibody appears to be a **powerful antiviral** agent leading to **potentially fewer side effects, hardly any toxicity, and less frequent dosing requirements** compared with daily drug therapies currently used my millions of patients.*

The NIH has granted $28 million over the past 12 years to advance the development of PRO 140



PRO 140 is a fully humanized IgG4 monoclonal antibody directed against CCR5, a molecular portal that HIV uses to enter T cells. PRO 140 blocks the predominant HIV (R5) subtype entry into T cells by masking this required co-receptor, CCR5. ~70% of HIV patients have the R5 strain and the prevalence rate is higher in treatment naïve patients (~90%).

PRO 140 COMPETITIVE ADVANTAGES

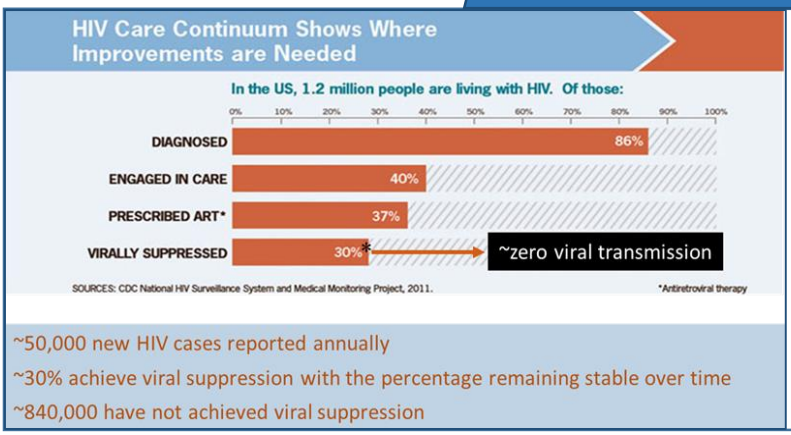
>27 drugs from 5 classes are approved for 1st- and 2nd-line therapy for HIV, with only 1 drug approved in a new class in the past 15 years. 1st-line standard of care HAART (Highly Active Anti-Retroviral Therapy) is 3 pills from 2 classes administered daily.

PRO 140		HAART
No drug resistance in patients on monotherapy for ~17 months	VS.	76% of patients have resistance to 1 or more drugs*
Viral load suppression in patients on monotherapy for ~17 months		Lifelong adherence with only 30% of patients achieving suppressed viral load
No serious adverse events (SAEs)		Toxicity ranges from mild to life threatening
No serious side effects seen in >200 patients to date		Numerous side effects including nausea, vomiting, diarrhea, fatigue weakness and dizziness
No impact on immune function Binds to CCR5		Incomplete recovery of immune function

PRO 140		IM HAART Therapy (in development)
Subcutaneous injection is well tolerated As an antibody, no SAEs At-home self-administration by the patient	VS.	Potential tolerance issues from IM route Inability to remove if AEs occur (lasts 30-60 days) In-hospital administration by a professional

*The prevalence of antiretroviral drug resistance in the United States. http://www.ncbi.nlm.nih.gov/pubmed/15199315

ADDRESSING LARGE MARKETS



~50,000 new HIV cases reported annually

~30% achieve viral suppression with the percentage remaining stable over time

~840,000 have not achieved viral suppression

Indication	# of Patients	U.S. Market Size
Combination Therapy	207,000*	>$5B
Monotherapy	460,000*	~$11B
GvHD – Prophylaxis	12,000	~$500M

* CCR5-tropic HIV-1 (R5) patients only

Patients sometimes experience viral breakthrough
Source: www.aids.gov/federalresources/policies/care-continuum/
Source: EU data - WHO

PRO 140 IN HIV: CLINICAL TRIAL OVERVIEW

Trial				Stage			
Study	# Subjects	Design / Findings	Status	POC	Ph1	Ph2	Ph3
2 Phase 1 studies	54	Healthy subjects, no safety concerns	Complete				
1302 IV Phase 1 study	39	Intravenous, single-dose VL reduction for 3 weeks	Complete				
2301 IV Phase 2 study	31	Intravenous, single-dose VL reduction for 3 weeks	Complete				
2101 SC Phase 2 study	44	Subcutaneous, long-acting, self-administered, proof-of-concept shown	Complete				
CDI-01 Phase 2b	40	12-week drug-substitution **monotherapy** Long-term **monotherapy** extension (14 subjects with VL suppression at 12 weeks)	Complete 1/15 Ongoing				
CDI-14 Phase 3*	300	2nd-line combination therapy in HAART failures, 1 week efficacy + 24 weeks durability	Began 10/15				
CDI-18 Phase 3**	300	Long-term **monotherapy**	Protocol submitted				

These trials are in HIV subjects with the R5 strain

* Potential FDA registration trial
** Planned as a label-extension trial; FDA data package to include Phase 2b trial results along with extension subjects

Ongoing PRO 140 Trials

- Phase 2b HIV monotherapy extension with 10 patients achieving full virologic suppression for up to 20 months (Apr. 2016)
- Enrollment open in 300-patient Phase 3 pivotal trial as combination HIV therapy with HAART; anticipated as fastest path to FDA approval
- 300-patient Phase 3 trial as long-term HIV monotherapy protocol dialogues underway with FDA
- Phase 2 GvHD trial enrolling 60 patients with AML or MDS undergoing allogeneic stem-cell transplantation. Orphan Drug designation filed (Dec. 15)

CLINICAL AND REGULATORY MILESTONES

Phase 3 Combination Therapy Pivotal Trial	Timeline	Status
Submit protocol amendment to FDA	1Q16	Done
Last patient enrolled	?	
BLA rolling submission to FDA initiated	2017	
Phase 3 Long-term Monotherapy Trial		
Submit protocol to FDA	2016	Done
Begin patient enrollment	2016	
BLA rolling submission to FDA initiated	2017	
Phase 2 GvHD Trial		
Submit protocol to FDA	4Q15	Done
File for Orphan Drug Designation	4Q15	Done
Begin Patient enrollment	2016	
File for Breakthrough therapy Designation	2016	
Complete Phase 2 trial	2017	
Compassionate Use Protocol approved	4/2016	Done

PHASE 2b MONOTHERAPY TRIAL DATA

Evaluate the efficacy, safety and tolerability of PRO 140 monotherapy for the maintenance of viral suppression

40 subjects who were stable on daily oral combination antiretroviral therapy

Shifted to PRO 140 monotherapy; weekly subcutaneous injection for up to 12 weeks- D/M from Quest tropism test were excluded.

Trial completed in January 2015

4 weeks: PRO 140 Pass 98% (39/40) vs. Historical data Pass 50%

8 weeks: PRO 140 Pass 82% (23/28) vs. Historical data Pass 0%

12 weeks: PRO 140 Pass 75% (21/28) vs. Historical data Pass 0%

No drug-related serious adverse events

Pass = viral load <400; Fail = viral load >400 for 2 consecutive weeks

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