
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 8-K

**CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of Report (Date of earliest event reported): March 30, 2017

CytoDyn Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

000-49908
(SEC
File Number)

75-3056237
(I.R.S. Employer
Identification No.)

1111 Main Street, Suite 660
Vancouver, Washington
(Address of principal executive offices)

98660
(Zip Code)

Registrant's telephone number, including area code: (360) 980-8524

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 8.01. Other Events.

On March 30, 2017, CytoDyn Inc. (the “Company”) posted an updated version of the investor presentation deck titled “PRO 140: First self-administered antibody therapy for HIV in late-stage clinical trials” to its website at www.cytodyn.com. A copy of the investor presentation is filed as Exhibit 99.1 to this Form 8-K.

The Company does not intend to incorporate any contents from its website into this Form 8-K.

Item 9.01. Financial Statements and Exhibits

	Exhibit	
(d)	<u>No.</u>	<u>Description.</u>
	99.1	Investor Presentation.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CytoDyn Inc.

March 30, 2017

By: /s/ Michael D. Mulholland

Name: Michael D. Mulholland

Title: Chief Financial Officer

EXHIBIT INDEX

(d)	<u>Exhibit No.</u>	<u>Description.</u>
	99.1	Investor Presentation.



PRO140

First self-administered antibody therapy for HIV
in late-stage clinical trials



Investor Presentation
March 2017

Forward-Looking Statements



This presentation includes forward-looking statements and forward-looking information within the meaning of United States securities laws. These statements and information represent CytoDyn's intentions, plans, expectations and beliefs, and are subject to numerous risks, uncertainties and other factors, of which many are beyond CytoDyn's control. These factors could cause actual results to differ materially from such forward-looking statements or information. The words "believe," "estimate," "expect," "intend," "attempt," "anticipate," "foresee," "plan," and similar expressions and variations thereof, identify certain of such forward-looking statements or forward-looking information, which speak only as of the date on which they are made.

CytoDyn disclaims any intention or obligation to publicly update or revise any forward-looking statements or forward-looking information, whether as a result of new information, future events or otherwise, except as required by applicable law. Readers are cautioned not to place undue reliance on these forward-looking statements or forward-looking information. While it is impossible to identify or predict all such matters, these differences may result from, among other things, the inherent uncertainty of the timing and success of and expense associated with research, development, regulatory approval, and commercialization of CytoDyn's products and product candidates, including the risks that clinical trials will not commence or proceed as planned; products appearing promising in early trials will not demonstrate efficacy or safety in larger-scale trials; future clinical trial data on CytoDyn's products and product candidates will be unfavorable; funding for additional clinical trials may not be available; CytoDyn's products may not receive marketing approval from regulators or, if approved, may fail to gain sufficient market acceptance to justify development and commercialization costs; competing products currently on the market or in development may reduce the commercial potential of CytoDyn's products; CytoDyn, its collaborators or others may identify side effects after the product is on the market; or efficacy or safety concerns regarding marketed products, whether or not scientifically justified, may lead to product recalls, withdrawals of marketing approval, reformulation of the product, additional pre-clinical testing or clinical trials, changes in labeling of the product, the need for additional marketing applications, or other adverse events.

CytoDyn is also subject to additional risks and uncertainties, including risks associated with the actions of its corporate, academic, and other collaborators and government regulatory agencies; risks from market forces and trends; potential product liability; intellectual property litigation; environmental and other risks; and risks that current and pending patent protection for its products may be invalid, unenforceable, or challenged or fail to provide adequate market exclusivity. There are also substantial risks arising out of CytoDyn's need to raise additional capital to develop its products and satisfy its financial obligations; the highly regulated nature of its business, including government cost-containment initiatives and restrictions on third-party payments for its products; the highly competitive nature of its industry; and other factors set forth in CytoDyn's Annual Report on Form 10-K and other reports filed with the U.S. Securities and Exchange Commission.

- **Late-stage development of antibody for HIV therapies (two Phase 3 trials underway)**
- **Large market of approximately \$20 billion⁽¹⁾**
- **Big players with significant market share (2015)⁽²⁾**
 - Gilead 56%
 - GSK 16%
 - BMS 12%
 - JNJ 9%
 - Merck 8%
- **CytoDyn's PRO 140 offers strong and compelling differentiators for the market and its 1.3 million⁽³⁾ patients (US only)**
 - Safe
 - Efficacious
 - Minimal toxicity
 - Minimal side effects
 - Ease of compliance

Source: (1) <http://www.transparencymarketresearch.com/hiv-market.html>

(2) Compilation from *MedAdNews*, Aug. 2016 from 2015 annual reports

(3) GlobalData EpiCast September 2015

HIV is a virus called **H**uman **I**mmunodeficiency **V**irus



- Once HIV is transmitted, it can only survive by entering T-cells
- HIV half life = 24 hours
- Viral Load (**VL**) is number of virus (HIV) particles per mL of blood
- If **VL < 40 copies/mL** then the **Transmission Rate ~ Zero** ⁽¹⁾
 - High viral load is a major risk factor for transmission of HIV
 - Effective antiretroviral therapy can reduce transmission of HIV by more than 96% ⁽¹⁾

- **Treatment options (HAART – Current standard of care)**
 - HIV replication process is called HIV life cycle and has 7 stages
 - Different classes of antiviral drugs are designed to stop HIV at different stages of HIV life cycle
 - HAART is comprised of 3 drugs from 2 classes – Today's HIV drugs are oral pills

- **Problems with HAART**
 - Compliance
 - Side Effects
 - Toxicity

Source: (1)

[https://www.hivlawandpolicy.org/sites/www.hivlawandpolicy.org/files/Undetectable%20Blood%20Viral%20Load%20and%20HIV%20Transmission%20Risk%20-%20Results%20of%20a%20Systematic%20Review%20\(CATIE\).pdf](https://www.hivlawandpolicy.org/sites/www.hivlawandpolicy.org/files/Undetectable%20Blood%20Viral%20Load%20and%20HIV%20Transmission%20Risk%20-%20Results%20of%20a%20Systematic%20Review%20(CATIE).pdf)

PRO 140 Advantages vs. Currently Approved Therapies



No drug resistance in patients on monotherapy for ~24 months
Once-a-week , simple, painless, sub-cutaneous injections
No negative impact on immune function No serious adverse events (SAEs)
No serious side effects seen in 200 patients in more than 7 clinical trials

76% of patients have resistance to 1 or more drugs*
Lifelong adherence with only 30% of patients achieving suppressed viral load
Incomplete recovery of immune function
Toxicity ranges from mild to severe. Many problems with long-term toxicity .

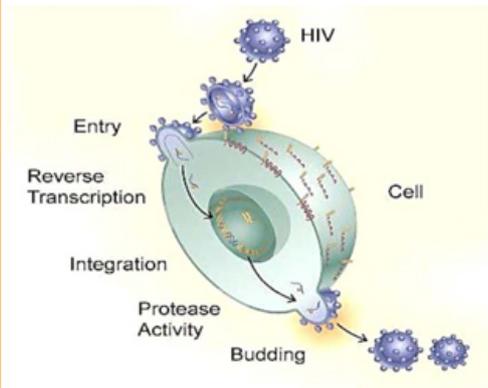
* The prevalence of antiretroviral drug resistance in the United States. <http://www.ncbi.nlm.nih.gov/pubmed/15199315>

PRO 140 – A Monoclonal Antibody that Binds to the HIV Entry Receptor - CCR5

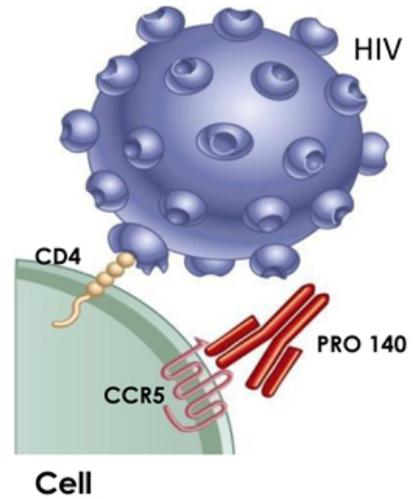


Humanized monoclonal antibody

Binds to CCR5 co-receptor on white blood cells



Blocks HIV entry into white blood cells

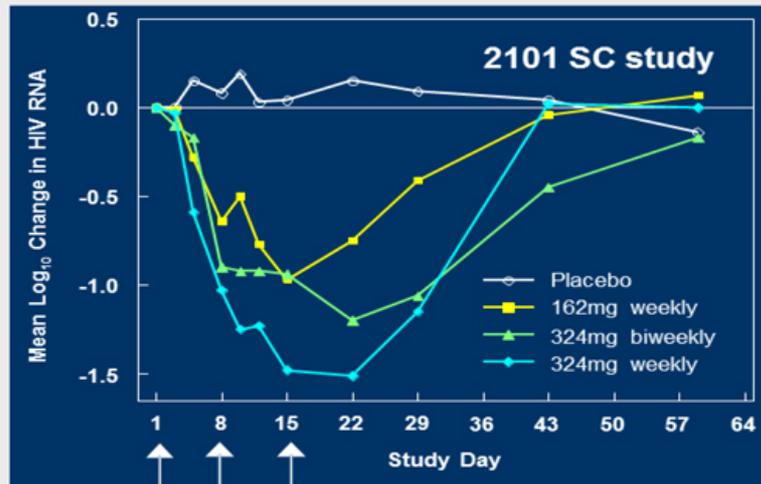


PRO 140 Viral Load Reduction in >200 HIV Patients (7 clinical trials)



Subcutaneous Administration

First proof of concept for a long-acting, self-administrable weekly HIV drug



PRO 140 Overview



- FDA Fast Track designation
- Currently under development in combination with HAART
- ...and for an alternative to HAART

Development of PRO 140



- Viral load drop as much as 2.5 log (>300 fold) with a single dose
- Very low toxicities or side effects
- No resistance observed in clinical trials

PRO 140 evaluated in 7 clinical trials with >200 patients



- HIV R5 strain represents 90% of newly diagnosed patients and ~70% overall
- Ongoing Phase 2b monotherapy extension study has exceeded 2 years of viral suppression
- **Phase 2b/3 Pivotal Trial** – 30-patient study for combination therapy w/HAART
- **Phase 2b/3 Investigative Trial** – 300-patient study for long-term monotherapy

Development of PRO 140 for treatment of HIV-R5 strain

PRO 140 for HIV: Clinical Trial Overview



Trial				Stage			
Study	# patients	Design / Findings	Status	P-Cl.	Ph1	Ph2	Ph3
2 Phase 1 studies	54	Healthy patients, 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	██████████	██████████		
CD01 Phase 2b	40	12-week drug-substitution monotherapy Long-term monotherapy extension: 14 patients with VL suppression at 12 weeks	Complete Jan. 2015 Ongoing	██████████	██████████		
CD02 Phase 2b/3 Pivotal-Fastest path to approval	30	Combination therapy in HAART failures, 1 week efficacy + 24 weeks durability	Injection of 1 st patient Oct. 2015	██████████	██████████	██████████	██████████
CD03 Phase 2b/3 Investigative Trial – Largest market size	300	Long-term monotherapy	Injection of 1 st patients Dec. 2016	██████████	██████████	██████████	██████████

Phase 2b Monotherapy Trial – PRO 140 Substitution for HAART



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

Shifted to PRO 140 monotherapy; weekly subcutaneous injections for up to 12 weeks

No drug-related serious adverse events



40 patients previously stable on daily oral combination antiretroviral therapy

Trial completed in January 2015

Trial Results: Suppressed VL		
Time of Evaluation	PRO 140 Monotherapy	Treatment Interruption Study Data ⁽¹⁾
4 weeks	98%	50%
11 weeks	75%	0%
After 11 weeks, 21 patients were qualified for extension Patient failures due to infections unrelated to PRO 140 were excluded		

Source: (1) Schooley RT, et. al. J Infect Dis, 2010; 202:705-716

Successful Monotherapy for over 2 years

10 patients analyzed with assay capable of detecting a single virus

7 patients	Viral load < 1 cp/mL
1 patient	Viral load ~ 2 cp/mL
1 patient	Viral load ~ 3 cp/mL
1 patient	Viral load ~ 40 cp/mL

Phase 2b/3 Investigative Monotherapy Trial

Protocol cleared by FDA; first of several patients treated in Dec. 2016



300 patients well-controlled by HAART at up to 30 clinical sites

Failure criteria: viral suppression of >200 cp/mL blood two consecutive weeks



PRO 140 to replace HAART

48-week Investigative trial

Phase 2b/3 Pivotal Combination Therapy Trial



- First path for approval for PRO 140
- To enroll 30 treatment-experienced HIV patients poorly controlled by HAART therapy. About 40 clinical sites have been cleared for enrollment
- Injected the 1st patient in Oct. 2015
- Primary endpoint expected in 1H17: reduction in HIV viral load from baseline (0.5 log in 1 week)
- Secondary endpoints: Tolerability and Safety (24 weeks)
- Safety data to be generated from concurrent Phase 2b/3 Investigative monotherapy trial





Phase 2b/3 Pivotal Combination Therapy
1st patient injected in October 2015
Several patients concluded and are now in a rollover study due to request to receive continued access to PRO 140
Clinical trial for first approval underway

Phase 2b/3 Investigative Monotherapy
1 st patients injected in December 2016
48-week investigative trial
Supported by long-term viral load reductions in ongoing Phase 2b extension study

PRO 140 for Immunologic Indications (Non-HIV)



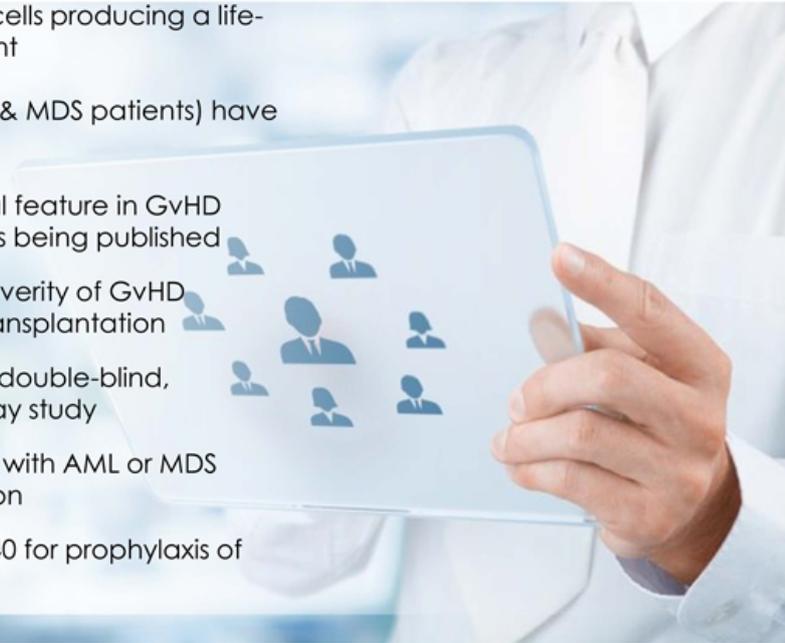
- The target of PRO 140 is CCR5, the receptor for the chemokine responsible for immune cell trafficking, T-cell migration to sites of inflammation
- PRO 140 binds to CCR5 without triggering migration signals and exhibits no agonist activity when it binds (no direct stimulation)
- PRO 140 is a competitive inhibitor of molecules that trigger CCR5 immunologic activity
- CCR5 triggering plays a crucial role in inflammatory responses:
 - Regulation of cancer cell killing
 - Transplantation rejection reactions
 - Autoimmunity
 - Chronic inflammation
- Animal models (mice) for these diseases can be used since PRO 140 recognizes human and mouse CCR5 equivalently
- The transplantation reaction, GvHD, is our first non-HIV indication for clinical investigation



Transplantation Indication – GvHD - Phase 2b



- **GvHD:** Graft versus Host Disease, a rejection reaction by the transplanted bone marrow (BM) stem cells producing a life-threatening reaction against the patient
- Bone marrow transplant patients (AML & MDS patients) have poor survival rate due to GvHD
- CCR5 has been implicated as a central feature in GvHD and positive data in an animal model is being published
- PRO 140 has potential to reduce the severity of GvHD and expand the patient pool for BM transplantation
- FDA approved protocol: randomized, double-blind, placebo-controlled, multicenter 100-day study
- Enrollment of 60 BM transplant patients with AML or MDS undergoing BM stem cell transplantation
- Evaluate safety and efficacy of PRO 140 for prophylaxis of acute GvHD
- 1st patients expected to enroll in 2H17



Experienced Management Team



- **Anthony Caracciolo, Executive Chairman:** Former Gilead Senior Vice President of Manufacturing and Operations, member of Gilead executive committee, over 30 years of executive and senior leadership in the pharmaceutical sciences industry.
- **Nader Pourhassan, Ph.D., CEO:** Led the development pathway for PRO 140 and was instrumental in leading the Company through several rounds of financing.
- **Michael Mulholland, CFO:** Financial executive with 30 years of senior financial leadership with public companies in several industries. Experienced in strategic planning, corporate finance and M&A.
- **Denis Burger, Ph.D., Vice Chairman, CSO:** Former academic Immunologist, successful biotech CEO, experienced with public company financing
- **Tom Boyd, Ph.D., BLA Team Leader:** Formerly SVP Product Development, Progenics Pharmaceuticals Inc.; ex-Boehringer Ingelheim, Wyeth and Alteon. Experienced in project leadership and nonclinical drug development of small molecules and biologics from discovery through registration.
- **Nitya Ray, Ph.D., SVP-Manufacturing & CMC Team Leader:** Formerly SVP Manufacturing, Progenics Pharmaceuticals Inc.; ex-Hoffmann-La Roche and Ortec International. Experienced in process development, manufacturing and quality control of biopharmaceutical, small molecule and radiopharmaceutical drugs.



Robert Schooley, MD

Professor of Medicine,
Chief of Division of
Infectious Diseases,
Academic Vice Chair
Department of Medicine,
University of California,
San Diego

Paul Maddon, MD, PhD

An inventor of PRO 140;
discovered CD4 and
CCR5 interaction with
HIV, Trustee of Columbia
University

Daniel Kuritzkes, MD

Professor of Medicine at
Brigham & Women's
Hospital, Infectious
Disease/Partners AIDS
Research Center, Infectious
Diseases Professor at
Harvard Medical School,
Principal Investigator and
Chair of AIDS Clinical Trials
Group (ACTG), Associate
Editor for Journal of
Infectious Diseases



Projections for 2018			
Combination Therapy population size		Monotherapy population size	
2 nd line therapy*	350,000	Patients with VL< 40 cp/mL	411,380
3 classes of resistance	20,000 to 25,000		
* 2 nd line therapy is for patients who are on second HIV drug regime and primarily have one drug resistance.			
Sources: (GlobalData.com – CDC.gov – AIDS.gov)			
Assumes that the total HIV population in US (2018) ~ 1.365 million patients Assumes 67% of patients with R5 strain			
Combination Therapy: Assumes that 20,000 – 25,000 patients have at least 3 drug classes of resistance Total number of patients on HAART = 1.365 million x 0.57 ~ 778,100 patients Assumes 45% as 2 nd -line or higher which yields: ~ 778,100 patients x 0.45 ~ 350,000 patients			
Monotherapy: Assumes that patients with VL<40 cp/mL = 40% x 1.365 million = 614,000 patients Patients for monotherapy population = 67% x 614,000 = 411,380 patients Source: https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2000-vol-12-1.pdf			

Upcoming Milestones

Events	1H 2017	2H 2017	2018
Phase 2b/3 Combination Therapy PIVOTAL Trial	Primary Endpoint	BTB ODD	Submit BLA
Phase 2b/3 Monotherapy Investigative Trial	100 patients enrolled for safety arm of Combination Trial for BLA	300 patient enrollment completed	Pre-BLA meeting with FDA for label expansion
Phase 2b Monotherapy extension arm	2 publications Presentation at ASM		
Phase 2 GvHD		1st patient treated ODD	
Non-HIV indications		3 publications	

ODD: Orphan Drug Designation
 BTB: Breakthrough Therapy Designation

Investment Highlights



- U.S. market size for HIV therapies is about **\$20 billion** ⁽¹⁾
Only 56% on HAART (US only)
- PRO 140 addresses HAART shortcomings:
 - No serious side effects or toxicities
 - No drug resistance,
 - Once-weekly, self-administered subcutaneous injection addresses compliance issues
- **Phase 2b/3 Pivotal** combination therapy trial underway – Primary Endpoint results expected in 1H17 – several patients successfully completed and now in rollover study due to their request to receive continued access to PRO 140
- **Phase 2b/3 Investigative** monotherapy trial – first several patients treated in Dec. 2016
- Pipeline opportunities for Non-HIV indications: transplantation, autoimmunity, cancer and chronic inflammation
 - Phase 2 clinical trial underway for GvHD

Source: (1) <http://www.transparencymarketresearch.com/hiv-market.html>

