
**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 26, 2018

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01. Other Events.

On March 26, 2018, 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 development” 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

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

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 26, 2018

By: /s/ Michael D. Mulholland

Name: Michael D. Mulholland

Title: Chief Financial Officer



PRO 140

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

March 2018

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 known and unknown risks, uncertainties and other factors, many of which are beyond CytoDyn's control and could cause actual results or outcomes 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.

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. In addition, 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 under the caption "Risk Factors" in CytoDyn's Annual Report on Form 10-K and other reports filed with the U.S. Securities and Exchange Commission. 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.

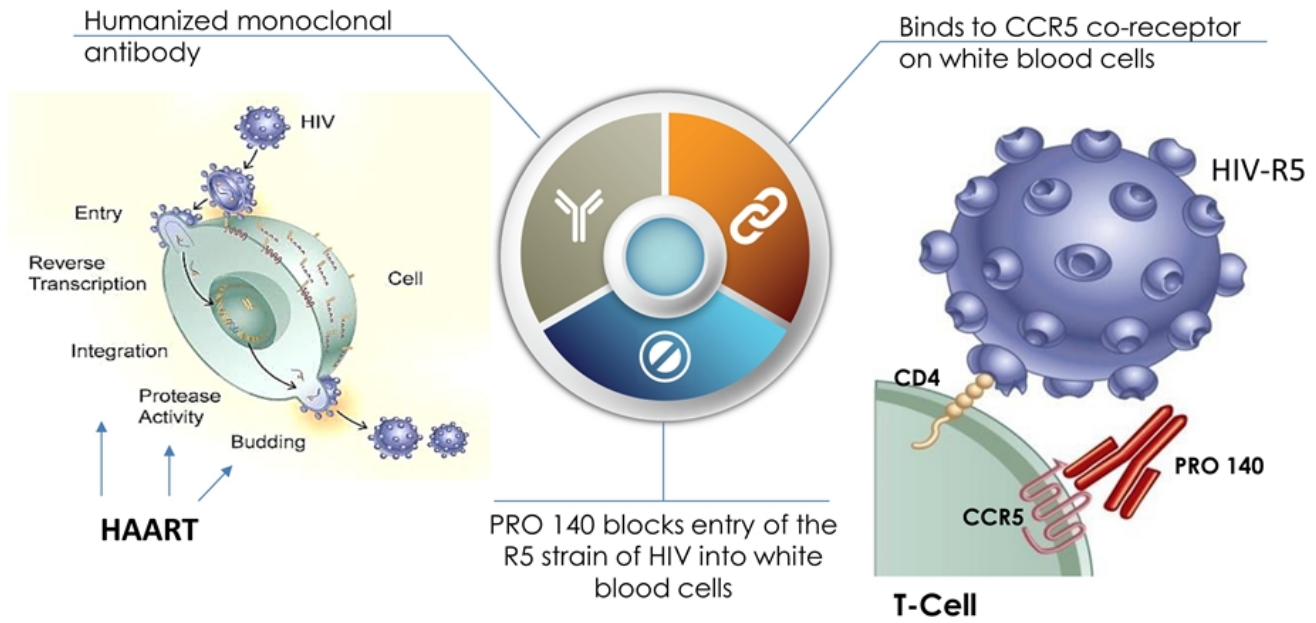
- Large U.S. market (\$20 billion) for HIV therapies
- PRO 140 is currently under development for two different HIV indications:
 - **Combination with HAART** – primary endpoint achieved in February 2018
 - BLA filing in 2018, expected approval in 2019 with BTD
 - Potential market size is estimated at \$1 billion
 - **Monotherapy switch trial** – from HAART to single-drug therapy
 - Potential market size is estimated at \$4 billion
- Pipeline: Multiple opportunities in immunologic indications:
 - Transplantation, GvHD – Phase 2 clinical trial underway
 - Autoimmune disease & oncology – Positive data from preclinical studies
 - Other immunologic indications being explored

*HAART - Highly Active Antiretroviral Therapy

PRO 140 – A Humanized Monoclonal Antibody



CCR5 is the Entry Receptor for R5 Strain of HIV



- Viral Load (VL) of an HIV patient = HIV particles per milliliter of the blood (copies/mL)
- A major goal of current therapy is to reduce transmission:
 - If VL < 50 copies/mL, then transmission rate about zero
- Transmission of HIV remains high due to liabilities of HAART
- Major issues with current standard-of-care (HAART):
 - Side effects
 - Toxicity
 - Resistance
 - Compliance
- As a result, currently only about 35% of HIV patients in the U.S. have a suppressed viral load

Year	New HIV
2012	46,671
2013	46,770
2014	46,947
2015	47,092
2016	47,252
2017	47,420

PRO 140 Advantages Over HAART



PRO 140



HAART

<p>No serious side effects and no serious adverse events (SAEs) in >400 patients in 8 clinical trials</p>	<p>Side Effects</p>	<p>Ranges from mild to severe (Diarrhea, nausea, lethargy, depression)</p>
<p>Negligible toxicity</p>	<p>Toxicity</p>	<p>Problems with short- and long-term toxicity (hepatic toxicity, myelosuppression)</p>
<p>No drug resistance in patients on monotherapy for over 3 years</p>	<p>Resistance</p>	<p>76% of patients develop resistance</p>
<p>Weekly, easy, subcutaneous self administration</p>	<p>Compliance</p>	<p>Daily lifetime dosing with only 35% of patients with complete VL suppression</p>

PRO 140 may help reduce resistance to HAART and improve patient 'Quality of Life'

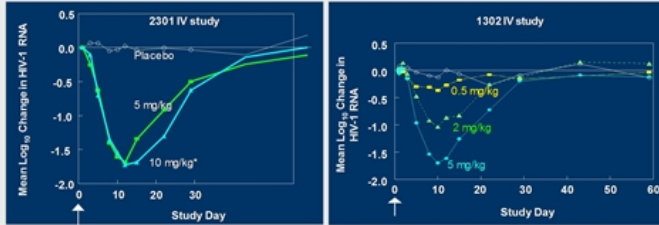
PRO 140 Viral Load Reduction

>400 HIV Patients (8 clinical trials)



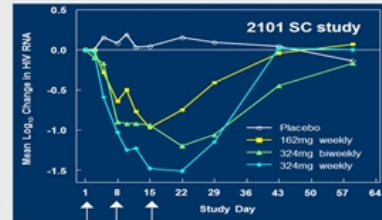
Intravenous Administration

Significant single-dose viral load reductions over 3-week period



Subcutaneous Administration

First proof of concept for a long-acting, self-administrable HIV drug administered weekly or bi-monthly



Mean Log₁₀ Change in HIV RNA

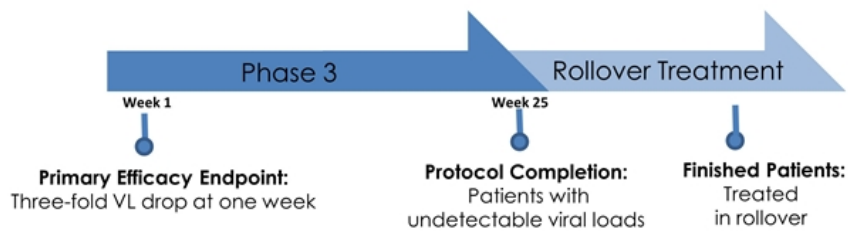
Study	Route	Treatment Groups	Reference
PRO 140 1302	IV	<ul style="list-style-type: none"> Placebo (n=9) 0.5 mg/kg single dose (n=10) 2 mg/kg single dose (n=10) 5 mg/kg single dose (n=10) 	Jacobson et al., J. Infect. Dis. 198:1345, 2008
PRO 140 2301	IV	<ul style="list-style-type: none"> Placebo (n=11) 5 mg/kg single dose (n=10) 10 mg/kg single dose (n=10) 	Jacobson et al., AAC, 54:4137, 2010
PRO 140 2101	SC	<ul style="list-style-type: none"> Placebo (n=10) 162 mg Days 1, 8, 15 (n=11) 324 mg Days 1, 15 (n=12) 324 mg Days 1, 8, 15 (n=11) 	Jacobson et al., J. Inf. Dis. 201:1481, 2010



Initial Approval and Label Expansion		
Study	Design / Findings	Status
Phase 2b/3 Pivotal HIV Trial Initial Approval	Combination Trial Patients failing on HAART 1 week efficacy + 24 weeks safety	Primary endpoint achieved (p<0.01)
Phase 2b/3 Investigative HIV Trial Label Expansion	Monotherapy Switch Trial Long-term single agent therapy 48 weeks of monotherapy	Data in 2018

Heavily Treatment-Experienced HIV-Infected Patients

- PRO 140 + HAART
- Path to 1st FDA approval of PRO 140
- Potential for Breakthrough Therapy Designation by FDA
- Patient enrollment completed
- Primary endpoint achieved and announced in February 2018



HIV Patients Managed with HAART

- Long-term efficacy from CD01 Phase 2b study which has patients in a Monotherapy extension study for over 3 years

48 Weeks | N = 300

Primary Endpoint:

Proportion of patients who remain on PRO 140 without experiencing virologic failure

Secondary Endpoint:

Efficacy, safety and tolerability data

Safety results to support BLA submission for PRO 140 in combination with HAART

Primary Objective:

Identify PRO 140 responders and achieve responder rate **above 70%**

Secondary Objective:

Non-responders can resume their original HAART therapy without resistance

Current HAART and the Role of Entry Inhibitors



Four Classes of Drugs
Interference with HIV Life Cycle Inside of T-cells

Entry Inhibitors

NRTI

NNRTI

INTI

PI

EI

AZT
ddI
ddC
d4T
3TC
ABC
TDF
FTC

NVP
DLV
EFV
ETV

RTG
EVG
DTG

SQV
RTV
IDV
NFV
APV
LPV/r
FPV
ATV
TPV
DRV

Maraviroc
Ibalizumab
PRO 140

HAART
3 Drugs from
2 Different
Classes



Most Commonly Prescribed HAART Drugs

STR (Single Tablet Regimen)	<ul style="list-style-type: none"> • Atripla • Stribild • Complera 	<ul style="list-style-type: none"> • Triumeq* • Quad*
Nucleoside reverse transcriptase inhibitors (NRTI)	<ul style="list-style-type: none"> • Truvada • Epzicom • Viread 	
Non-Nucleoside reverse transcriptase inhibitors (NNRTI)	<ul style="list-style-type: none"> • Sustiva • Intelence • Edurant 	
Protease inhibitors (PI)	<ul style="list-style-type: none"> • Prezista • Reyataz • Kaletra 	
Integrase inhibitors (INI)	<ul style="list-style-type: none"> • Isentress • Tivicay 	
<small>Source: GlobalData, based on primary research interviews and surveys conducted with KOLs and high-prescribing physicians in the countries included in this report; AIDSinfo, 2014c; CDC, 2014c; DHHS, 2014</small>		
<small>*Recent</small>		

Entry Inhibitors *versus* HAART Combinations in Daily Single Pill Formulations



Entry Inhibitors - Heavily Treatment-Experienced (HTE) Patients	
Dosing Schedule	Suppressed viral load
Maraviroc, oral, twice daily	39% at 96 weeks
Ibalizumab, IV, biweekly	43% at 24 weeks
PRO 140 (Ieronlimab), SC self injection, weekly	ongoing trial *

HAART-Viral Life Cycle Inhibitors First-line Treatment Patients	
Daily Single Pill	Suppressed viral load (48-week trial)
Combivir	73%
Atripla	82%
Complera	86%
Stribild	87%
Triumeq	88%

*majority of patients have maintained viral suppression at end of trial

Current HIV Status in U.S.

(Source: GlobalData)



PRO 140
market
launch

Year	Number of HIV patients in US	HIV Patients using ART	New cases in US
2003	1,021,840	575,883	51,818
2004	1,030,428	580,723	52,076
2005	1,039,791	586,000	52,169
2006	1,049,343	591,383	52,360
2007	1,081,789	609,669	52,510
2008	1,102,634	621,416	46,724
2009	1,123,727	633,304	43,994
2010	1,145,461	645,553	46,428
2011	1,174,049	661,664	46,582
2012	1,195,885	673,970	46,671
2013	1,218,323	686,616	46,770
2014	1,242,667	700,335	46,947
2015	1,268,852	715,093	47,092
2016	1,295,157	729,917	47,252
2017	1,320,244	744,056	47,420
2018	1,343,633	757,237	47,651
2019	1,365,882	769,776	47,907
2020	1,388,425	782,481	48,144
2021	1,410,694	795,031	48,424
2022	1,433,380	807,816	48,716
2023	1,456,102	820,622	49,003

Initial approval **Combination Therapy**

U.S. Market Potential

- HAART failures: ~ 70,000 pts with two or more drug class resistances
- 70,000 pts x 70% (R5-HIV strain) = 49,000 HIV pts R5 eligible
- 49,000 pts x \$24,000 (current market pricing) = ~ **\$1.2 billion**

Label Expansion **Switch to Monotherapy Maintenance**

U.S. Market Potential

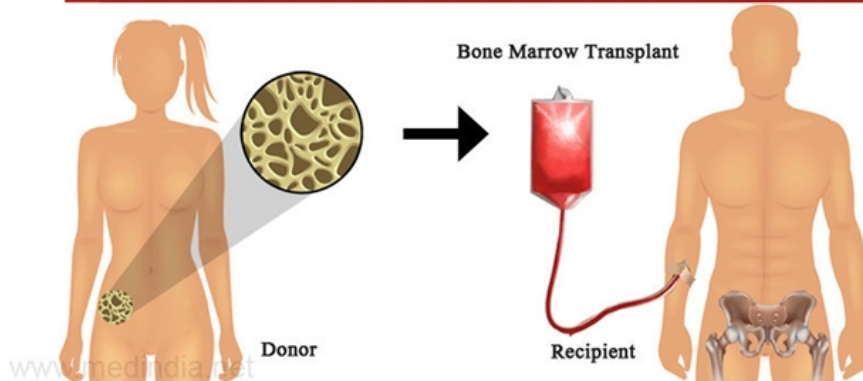
- Target population (suppressed VL) = 17.5% of 1.3 million HIV+ = 227,500
- 227,500 pts x 70% (R5-HIV) = 159,250 pts
- 159,250 pts x \$24,000 (current market pricing) = ~ **\$3.8 billion**

PRO 140 for Immunologic Indications (Non-HIV)



- CCR5 – responsible for T-cell migration to sites of inflammation
- T-cell migration plays a crucial role in inflammatory responses
 - Transplantation rejection reactions
 - Autoimmunity
 - Chronic inflammation
 - Tumor metastases
- Transplantation reaction, GvHD, is the first immunologic indication for PRO 140
 - Phase 2 trial enrollment underway
 - 60 patients to be enrolled
 - 100-day trial period
 - Orphan Drug Designation granted by FDA

BONE MARROW TRANSPLANT IS A MAJOR CAUSE OF GvHD.

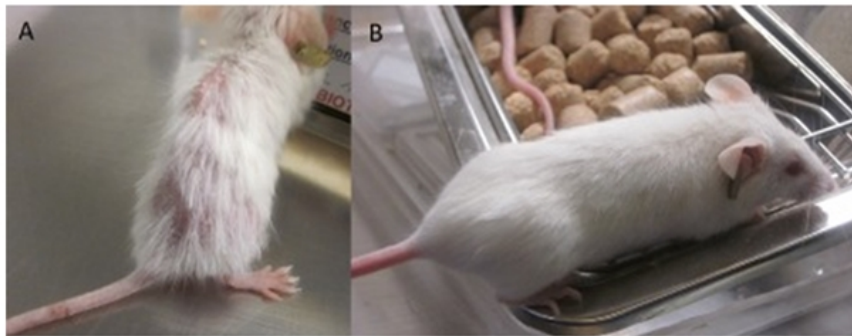
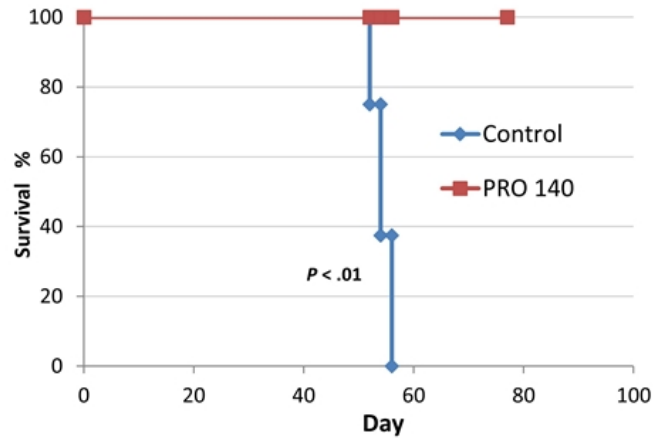
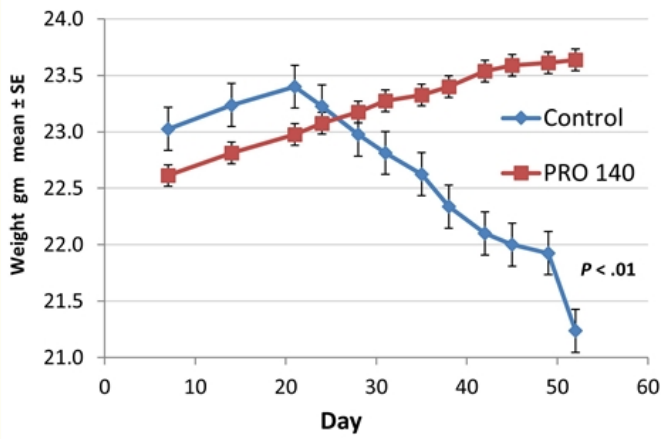


- Bone marrow transplant required due to aggressive cancer therapy
- GvHD occurs due to imperfect tissue match
- Mild: Cutaneous
Severe: Liver & gut involvement

Examples of Mild GvHD



Effect of PRO 140 on Xeno-GvHD Human BM transplanted into immuno-deficient mice



PRO 140 Important Milestones 2018/2019



Milestones	Target Dates
Phase 2b/3, Pivotal HIV Combination Trial Primary Endpoint	Completed
Medical Conference Presentations (CROI and ASM Microbe)	Completed
Published studies – GvHD (Preclinical study)	Completed
Orphan Drug Designation for GvHD	FDA Granted
Publication of Monotherapy (Phase 2b)	2Q2018
Publication Studies – HIV Combination Trial Primary Endpoint Study	2Q2018
Pivotal Phase 3 Endpoint Achieved (ASM Microbe late breaker)	June 2018
BLA Submission for HIV Combination Therapy	3Q2018
Phase 2b/3 Monotherapy Investigative Trial Readout	4Q2018
HIV Breakthrough Therapy Designation (BTD)	2018
HIV Combination Therapy Approval	2019w/BTD