
**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): August 21, 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))

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 7.01 Regulation FD Disclosure.

On August 21, 2017, CytoDyn Inc. (the “Company”) issued a press release relating to the announcement described in Item 8.01 below, a copy of which is furnished as Exhibit 99.1 to this Form 8-K.

Item 8.01. Other Events

On August 21, 2017, the Company announced that it has enrolled 34 patients in its pivotal Phase 2b/3 trial of PRO 140 in combination with antiretroviral therapy (ART) in HIV-infected patients. Thirty-three of the enrolled patients have finished the one-week efficacy endpoint of the study and eleven patients have completed the full 25-week protocol with undetectable viral loads. Ten patients are currently in a rollover study after completing the 25-week trial. The U.S. Food and Drug Administration has set a meeting on October 17, 2017, to discuss the next steps in the Company’s efforts towards the analysis of primary efficacy endpoint and filing of a Biologics License Application for PRO 140.

Item 9.01. Financial Statements and Exhibits.

(d)	<u>Exhibit</u> <u>No.</u>	<u>Description.</u>
	99.1	Press Release, dated August 21, 2017

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.

August 21, 2017

By: /s/ Michael D. Mulholland

Name: Michael D. Mulholland

Title: Chief Financial Officer

Exhibit Index

<u>Exhibit No.</u>	<u>Description.</u>
99.1	Press Release, dated August 21, 2017.



CytoDyn Provides Update on PRO 140 Pivotal Combination Therapy Trial in Patients with HIV

VANCOUVER, Washington (August 21, 2017) – CytoDyn Inc. (OTC.QB: CYDY), a biotechnology company focused on the development of new antibody therapies for combating human immunodeficiency virus (HIV) infection, announces that the Company has enrolled 34 patients in its pivotal Phase 2b/3 trial of PRO 140 in combination with antiretroviral therapy (ART) in HIV-infected patients. Thirty-three of the enrolled patients have finished the one-week efficacy endpoint of the study and eleven patients have completed the full 25-week protocol with undetectable viral loads. Ten patients are currently in a rollover study after completing the 25-week trial. The Company is confident that it has met the enrollment criteria for the trial. The U.S. Food and Drug Administration has set a meeting on October 17 to discuss the next steps in CytoDyn’s efforts towards the analysis of primary efficacy endpoint and filing of a Biologics License Application for PRO 140.

About PRO 140

PRO 140 belongs to a new class of HIV/AIDS therapeutics – viral-entry inhibitors – that are intended to protect healthy cells from viral infection. PRO 140 is a 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. 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 the subject of seven clinical trials, each demonstrating efficacy by significantly reducing or controlling HIV viral load in human test subjects. PRO 140 has been designated a “fast track” product by the FDA. The PRO 140 antibody appears to be a powerful antiviral agent leading to potentially fewer side effects and less frequent dosing requirements compared with daily drug therapies currently in use.

About CytoDyn

CytoDyn is a biotechnology company focused on the clinical development and potential commercialization of humanized monoclonal antibodies for the treatment and prevention of HIV infection. The Company has one of the leading monoclonal antibodies under development for HIV infection, PRO 140, which has completed Phase 2 clinical trials with demonstrated antiviral activity in humans and is currently in Phase 3 development. PRO 140 blocks the HIV co-receptor CCR5 on T cells, which prevents viral entry. Clinical trial results thus far indicate that PRO 140 does not negatively affect the normal immune functions that are mediated by CCR5. Results from seven Phase 1 and Phase 2 human clinical trials have shown that PRO 140 can significantly reduce viral burden in people infected with HIV. A recent Phase 2b clinical trial demonstrated that PRO 140 can prevent viral escape in patients during several months of interruption from conventional drug therapy. CytoDyn intends to continue to develop PRO 140 as a therapeutic anti-viral agent in persons infected with HIV and to pursue non-HIV indications where CCR5 and its ligand CCL5 may be involved. For more information on the Company, please visit <http://www.cytodyn.com>.

Forward-Looking Statements

This press release includes forward-looking statements and forward-looking information within the meaning of United States securities laws, including statements regarding CytoDyn’s current and proposed trials and studies and their enrollment, results, costs and completion. These statements and

information represent CytoDyn’s intentions, plans, expectations, and beliefs and are subject to risks, uncertainties and other factors, many 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 preclinical 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 for the fiscal year ended May 31, 2017 and other reports filed with the U.S. Securities and Exchange Commission.

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