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): February 20, 2018

CytoDyn Inc.
(Exact name of registrant as specified in its charter)

Delaware	**000-49908**	**75-3056237**
(State or other jurisdiction of incorporation)	**(SEC File Number)**	**(I.R.S. Employer Identification No.)**

1111 Main Street, Suite 660 **Vancouver, Washington**	**98660**
(Address of principal executive offices)	**(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 February 20, 2018, CytoDyn Inc., a Delaware corporation (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 February 20, 2018, the Company announced the successful achievement of the primary endpoint in its CD02 Phase 2b/3 pivotal clinical trial with PRO 140 in combination with existing antiretroviral therapy ("ART") in patients failing their current HIV therapy. The trial data show a statistically significant reduction in HIV-1 RNA viral load of greater than 0.5log with PRO 140 versus placebo.

This multicenter clinical trial enrolled 52 patients with CCR5-tropic HIV-1 and documented genotypic or phenotypic resistance to ART drugs within three drug classes or within two or more drug classes with limited treatment options. Enrolled patients all had plasma HIV-1 RNA ³400 copies/mL and documented detectable viral load within three months prior to the screening visit. In the one-week, randomized, double-blind, placebo-controlled portion of the trial, all trial patients received their existing ART therapy, with one-half of the enrolled patients administered a 350mg subcutaneous injection of PRO 140 and the other half receiving a subcutaneous injection of placebo.

The trial's primary endpoint was the proportion of participants with greater than 0.5log reduction in HIV-1 RNA viral load from baseline at the end of the one-week treatment period. At one week, patients in the PRO 140 arm showed a statistically significant reduction in HIV-1 RNA viral load of greater than 0.5log from baseline versus patients in the placebo arm ($p<0.01$). Following this one-week period, all patients continue in the trial for an additional 24 weeks with PRO 140 weekly subcutaneous injections and optimized ART.

Forward-Looking Statements

This Current Report on Form 8-K contains certain forward-looking statements that involve risks, uncertainties and assumptions that are difficult to predict, including statements regarding the Company's current and proposed trials and studies and their enrollment, results, costs and completion. Words and expressions reflecting optimism, satisfaction or disappointment with current prospects, as well as words such as "believes," "hopes," "intends," "estimates," "expects," "projects," "plans," "anticipates" and variations thereof, or the use of future tense, identify forward-looking statements, but their absence does not mean that a statement is not forward-looking. The Company's forward-looking statements are not guarantees of performance and actual results could differ materially from those contained in or expressed by such statements. In evaluating all such statements, the Company urges investors to specifically consider the various risk factors identified in the Company's Form 10-K for the fiscal year ended May 31, 2017 in the section titled "Risk Factors" in Part I, Item 1A, any of which could cause actual results to differ materially from those indicated by the Company's forward-looking statements.

The Company's forward-looking statements reflect its current views with respect to future events and are based on currently available financial, economic, scientific, and competitive data and information on current business plans. Investors should not place undue reliance on the Company's forward-looking statements, which are subject to risks and uncertainties relating to, among other things: (i) the sufficiency of the Company's cash position and the Company's ongoing ability to raise additional capital to fund its operations, (ii) the Company's ability to complete its Phase 2b/3 pivotal combination therapy trial for PRO 140 (CD02) and to meet the FDA's requirements with respect to safety and efficacy to support the filing of a Biologics License Application, (iii) the Company's ability to meet its debt obligations, if any, (iv) the Company's ability to identify patients to enroll in its clinical trials in a timely fashion, (v) the Company's ability to achieve approval of a marketable product, (vi) design, implementation and conduct of clinical trials, (vii) the results of the Company's clinical trials, including the possibility of unfavorable clinical trial results, (viii) the market for, and marketability of, any product that is approved, (ix) the existence or development of vaccines, drugs, or other treatments for infection with the Human Immunodeficiency Virus that are viewed by medical professionals or patients as superior to the Company's products, (x) regulatory initiatives, compliance with governmental regulations and the regulatory approval process, (xi) general economic and business conditions, (xii) changes in foreign, political, and social conditions, and (xiii) various other matters, many of which are beyond the Company's control. Should one or more of these risks or uncertainties develop, or should underlying assumptions prove to be incorrect, actual results may vary materially and adversely from those anticipated, believed, estimated, or otherwise indicated by the Company's forward-looking statements.

The Company intends that all forward-looking statements made in this Current Report on Form 8-K will be subject to the safe harbor protection of the federal securities laws pursuant to Section 27A of the Securities Act of 1933, as amended, to the extent applicable. Except as required by law, the Company does not undertake any responsibility to update these forward-looking statements to take into account events or circumstances that occur after the date of this Current Report on Form 8-K. Additionally, the Company does not undertake any responsibility to update investors upon on the occurrence of any unanticipated events which may cause actual results to differ from those expressed or implied by these forward-looking statements.

Item 9.01. Financial Statements and Exhibits.

(d)	Exhibit No.	Description.
	99.1	Press Release, dated February 20, 2018

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.

February 20, 2018

By: */s/ Michael D. Mulholland*
Name: Michael D. Mulholland
Title: Chief Financial Officer

Exhibit 99.1

CytoDyn Reports Primary Endpoint Achieved in PRO 140 Pivotal Combination Therapy Trial in HIV Infection

Results demonstrate statistically significant reduction in HIV-1 RNA viral load with PRO 140 versus placebo

VANCOUVER, Washington (February 20, 2018) – CytoDyn Inc. (OTC.QB: CYDY) reports the successful achievement of the primary endpoint in its CD02 Phase 2b/3 pivotal clinical trial with PRO 140 in combination with existing antiretroviral therapy (ART) in patients failing their current HIV therapy. The trial data show a statistically significant reduction in HIV-1 RNA viral load of greater than 0.5log with PRO 140 versus placebo. CytoDyn is developing PRO 140, a humanized CCR5 monoclonal antibody, to combat human immunodeficiency virus (HIV) infection and certain immunologic disorders.

"These data clearly demonstrate the anti-HIV-1 activity of PRO 140 in antiretroviral treatment-experienced individuals who were documented to have ongoing virus replication in the face of therapy with currently approved drugs," said Scott M. Hammer, MD, Harold C. Neu Professor and Chief of the Division of Infectious Diseases, Columbia University Medical Center/New York-Presbyterian Hospital. "Antiviral drug resistance is an ongoing threat to HIV infected persons. Despite the dramatic progress in treatment success over the course of the epidemic, we cannot be complacent. Agents with different mechanisms of action, modes of delivery, and frequencies of administration are needed to provide patients with the options necessary to achieve and sustain virologic suppression. PRO 140 is a clear example of the advances in HIV therapeutics that can result from the dedication of developers, patients and providers to this principle."

"The standard approach to ART therapy has been to administer combinations of oral medications that must be taken daily," said Robert T. Schooley, MD, Professor of Medicine, Department of Infectious Diseases and Global Public Health, University of California, San Diego. "Recently, there has been increasing interest in the development of drugs that do not require daily administration. I believe that PRO 140 is a step in that direction. These PRO 140 trial findings support the potential of managing HIV by blocking its entry into T cells through a novel humanized monoclonal antibody administered in weekly subcutaneous injections. PRO 140 could provide an important new therapeutic option in suppressing a patient's viral load as well as deterring the spread of this disease."

Trial Design and Efficacy Endpoint Results

This multicenter clinical trial enrolled 52 patients with CCR5-tropic HIV-1 and documented genotypic or phenotypic resistance to ART drugs within three drug classes or within two or more drug classes with limited treatment options. Enrolled patients all had plasma HIV-1 RNA ³400 copies/mL and documented detectable viral load within three months prior to the screening visit.

In the one-week, randomized, double-blind, placebo-controlled portion of the trial, all trial patients received their existing ART therapy, with one-half of the enrolled patients administered a 350mg subcutaneous injection of PRO 140 and the other half receiving a subcutaneous injection of placebo. The trial's primary endpoint was the proportion of participants with greater than 0.5log reduction in HIV-1 RNA viral load from baseline at the end of the one-week treatment period. At one week, patients in the PRO 140 arm showed a statistically significant reduction in HIV-1 RNA viral load of greater than 0.5log from baseline versus patients in the placebo arm, ($p<0.01$). Following this one-week period, all patients continue in the trial for an additional 24 weeks with PRO 140 weekly subcutaneous injections and optimized ART.

"The high virologic response rate seen following a single PRO 140 injection in this study is exciting given the status of these treatment-experienced patients who were failing their antiretroviral therapies," said Paul J. Maddon, MD, Ph.D., Senior Science Advisor to CytoDyn, an inventor of PRO 140 and retired founder, Chairman, CEO and CSO of Progenics Pharmaceuticals, Inc. "These data suggest that PRO 140 could provide a vital treatment option for patients and physicians and a potent evolution in HIV therapy."

“It is truly exciting that PRO 140 surpassed the one-week viral load reduction endpoint in what is certainly our most significant clinical trial result to date for this therapeutic candidate,” said Nader Pourhassan, Ph.D., CytoDyn’s President and Chief Executive Officer. “Given these positive results in the combination treatment setting with PRO 140 in HIV, we look forward to completing enrollment in our ongoing monotherapy trial in HIV infection.”

The target for PRO 140, CCR5, is the trafficking receptor on immune cells that is responsible for directing them to the sites where they produce inflammatory reactions. CytoDyn is currently evaluating PRO 140 in transplantation, autoimmune, inflammatory and cancer indications where CCR5 has been implicated to play a critical role. The Company’s first human evaluation of PRO 140 in this area is an ongoing Phase 2 trial in graft-versus-host disease (GvHD) for leukemia and lymphoma patients requiring a bone marrow stem cell transplant. To date, PRO 140 has been generally well tolerated with no drug-related major adverse events or treatment discontinuation reported.

About PRO 140

PRO 140 belongs to a new class of HIV/AIDS therapeutics – viral-entry inhibitors – that is 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 FDA also granted orphan drug designation to PRO 140 for the prevention of graft-versus-host disease (GvHD). 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, inflammatory indications where CCR5 and its ligand CCL5 may be involved. For more information on the Company, please visit http://www.cytodyn.com.

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