CytoDyn Inc.
Form 8-K
February 20, 2018

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		**98660**

Vancouver, Washington
(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, pr 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.

	Exhibit No.	Description.
(d)	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