CytoDyn Inc.
Form 8-K
October 13, 2017

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): October 13, 2017

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 October 13, 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 October 13, 2017, the Company announced that, in a meeting held on October 12, 2017, the U.S. Food and Drug Administration (the FDA) confirmed the number and type of evaluable patients required for submission of a Biologics License Application (BLA) for PRO 140 as a combination therapy.

The FDA accepted the 40 patients currently enrolled in the Company s Phase 2b/3 pivotal combination trial as evaluable and further agreed that the trial s Data Monitoring Committee can conduct an interim efficacy analysis of primary endpoint. The FDA also confirmed that 50 patients will be required for the completion of this trial and agreed to allow more flexibility in the enrollment criteria for the remaining 10 patients. As a result, the Company expects to complete enrollment within the near future. The FDA also confirmed that 300 patients will be required for the safety analysis in a BLA, which can be provided by all of the Company s HIV trials, providing that those patients have been on a PRO 140 therapy for 24 weeks.

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 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 CD02 combination trial 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, (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 October 13, 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.

October 13, 2017

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