CytoDyn Inc.
Form 8-K
September 06, 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): September 6, 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 8.01. Other Events

On September 6, 2017, CytoDyn Inc. (the Company) announced that the Company s previously scheduled telephonic meeting with the U.S. Food and Drug Administration (the FDA) on October 17, 2017 has been rescheduled to an in-person meeting on October 12, 2017. In addition, the Company recently received a memorandum from the FDA and, based on this and subsequent continuing discussions with the FDA, the purpose of the meeting will be to address open issues set forth in the memorandum regarding the adequate number and type of evaluable patients required for efficacy and safety necessary to support the filing of a Biologics License Application. As a result, the Company will continue enrolling patients in the CD02 combination trial until further clarification from the FDA.

A copy of the press release relating to the above is filed as Exhibit 99.1.

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 upcoming meeting with the FDA to discuss the adequate number and type of evaluable patients required for efficacy and safety necessary to support the filing of a Biologic License Application and our intention to continue enrolling patients in our CD02 combination trial. 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 va or the use of future tense, identify forward-looking statements, but their absence does not mean that a statement is not forward-looking. Our 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, we urge you 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 our forward-looking statements.

Our forward-looking statements reflect our 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. You should not place undue reliance on our forward-looking statements, which are subject to risks and uncertainties relating to, among other things: (i) the sufficiency of our cash position and our ongoing ability to raise additional capital to fund our operations, (ii) our ability to complete our 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) our ability to meet our debt obligations, (iv) our ability to identify patients to enroll in our clinical trials in a timely fashion, (v) our ability to achieve approval of a marketable product, (vi) design, implementation and conduct of clinical trials, (vii) the results of our 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 our 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 our 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 our forward-looking statements.

We intend 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, to the extent applicable. Except as required by law, we do 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, we do not undertake any responsibility to update you 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 September 6, 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.

September 6, 2017

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

Exhibit

No.	Description.
99.1	Press Release, dated September 6, 2017.