CytoDyn Inc. Form 8-K May 11, 2016

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): May 10, 2016

CytoDyn Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction

000-49908 (SEC 75-3056237 (I.R.S. Employer

of incorporation)

File Number)

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))

Item 1.01 Entry into a Material Definitive Agreement.

Between April 26, 2016 and May 10, 2016, CytoDyn Inc., a Delaware corporation (the Company), issued in private placements to accredited investors an aggregate of 4,301,500 shares of its common stock, par value \$0.001 per share (the Common Stock), together with warrants to purchase an aggregate of 1,075,375 shares of Common Stock at an exercise price of \$1.35 per share. The securities were issued at a combined purchase price of \$1.00 per share of Common Stock and a warrant covering 25% of the number of common shares purchased, for aggregate gross proceeds to the Company of approximately \$4.3 million. The warrants have a five-year term, running from their respective dates of issuance, and are immediately exercisable. A copy of the form of subscription agreement in the offering, including the form of warrant, is filed as Exhibit 10.1 to this Form 8-K and is incorporated into this Item 1.01 by reference.

As a fee to the placement agent utilized for part of the offering, in addition to a cash payment of approximately \$0.2 million, the Company became obligated to issue additional warrants to purchase an aggregate of 132,050 shares of Common Stock on terms similar to the investor warrants described above.

As part of the offering, Jordan G. Naydenov, a director and existing stockholder of the Company, purchased \$1.0 million of Common Stock and warrants on terms identical to those applicable to the other investors in the offering.

The Company relied on the exemption provided by Rule 506 of Regulation D and Section 4(a)(2) of the Securities Act of 1933, as amended, in connection with the foregoing transactions.

After giving effect to the foregoing transactions, the number of shares of Common Stock outstanding as of May 10, 2016 was 123,258,711.

Item 3.02 Unregistered Sales of Equity Securities.

The disclosure in Item 1.01 of this Form 8-K is incorporated by reference into this Item 3.02.

Item 8.01 Other Events.

The Company recently received a letter from the Office of Orphan Products Development at the Food and Drug Administration (the FDA) in response to the Company s previously disclosed request for orphan-drug designation with respect to PRO 140 for the treatment of graft versus host disease (GvHD). Pursuant to the letter, the FDA has requested (a) additional population data to support that the prevalence of patients with acute and chronic GvHD is less than 200,000 in the United States and (b) additional scientific rationale to support orphan drug designation for PRO 140 for the treatment of GvHD, which the Company intends to provide through either (i) the clinical data derived from its current Phase 2 GvHD trial or (ii) a pre-clinical study of the use of PRO 140 in an *in vivo* animal model of GvHD. The FDA requested that such information be provided to the FDA by May 2017. The Company has not yet determined which alternative to pursue to provide the requested data. In the interim, the Company intends to gather the additional population data.

As previously announced, the Company will be hosting an investment community conference call on Wednesday, May 11, 2016 at 1:00 p.m. PT/4:00 p.m. ET to provide an update on clinical and regulatory developments. Interested participants and investors may access this conference call by dialing 877-407-2986 (U.S./Canada) or 201-378-4916 (international).

A live audio webcast may also be accessed via the Investors section of CytoDyn s corporate web site at www.cytodyn.com, and will be archived for 60 days. A replay of the conference call will be available until July 11,

2016. To access the replay, interested parties may dial 877-660-6853 (U.S./Canada) or 201-612-7415 (international); Conference ID: 13578723.

Forward-Looking Statements

This Form 8-K contains certain forward-looking statements that involve risks, uncertainties and assumptions that are difficult to predict. Words and expressions reflecting optimism, satisfaction or disappointment with current prospects, as well as words such as believes, hopes. intends. estimates. expects. anticipates projects. plans. 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. Such 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 readers should specifically consider the various risk factors identified in the Company s Form 10-K for the fiscal year ended May 31, 2015 (filed July 10, 2015), Forms 10-Q for the fiscal quarters ended August 31, 2015 (filed October 9, 2015), November 30, 2015 (filed January 11, 2016) and February 29, 2016 (filed April 13, 2016), and other reports filed with the U.S. Securities and Exchange Commission, including the matters set forth under the heading Risk Factors therein, any of which could cause actual results to differ materially from those indicated by these forward-looking statements.

These forward-looking statements reflect the Company s 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. Readers should not place undue reliance on these forward-looking statements, which are subject to risks and uncertainties relating to, among other things: (i) the sufficiency of the Company s cash position, (ii) the Company s ability to achieve approval of a marketable product, (iii) design, implementation and conduct of clinical trials, (iv) the results of the Company s clinical trials, including the possibility of unfavorable clinical trial results, (v) the market for, and marketability of, any product that is approved, (vi) 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, (vii) regulatory initiatives, compliance with governmental regulations and the regulatory approval process, (viii) general economic and business conditions, (ix) changes in foreign, political, and social conditions, and (x) 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 these forward-looking statements.

The Company intends that all forward-looking statements made herein 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 filing. Additionally, the Company does not undertake any responsibility to update these forward-looking statements 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) Exhibits. The following exhibits are filed herewith:

Exhibit

Description No.

4.1 Form of Investor Warrant (included as Exhibit A to the Form of Subscription Agreement filed as Exhibit 10.1 herewith)

10.1 Form of Subscription Agreement

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.

May 11, 2016 By: /s/ Michael D. Mulholland

Name: Michael D. Mulholland Title: Chief Financial Officer

EXHIBIT INDEX

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