CytoDyn Inc.
Form 8-K
August 19, 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): August 19, 2016

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))

Item 8.01 Other Events.

In connection with recent developments arising from communications between CytoDyn Inc. (the Company) and the U.S. Food and Drug Administration (the FDA), the Company today announced certain updates regarding previously disclosed matters for its clinical trials for PRO 140.

Phase 2b Extension Study for HIV, as Monotherapy. As previously disclosed, there were 11 trial participants in the extension study who successfully passed 29 weeks of therapy and were not discontinued. Currently, 10 out of those 11 trial participants are approaching two years of suppressed viral load with PRO 140 as a single-agent therapy. This extension study remains ongoing.

Phase 2b/3 Trial for HIV, as Combination Therapy. In response to FDA comments, the Company has recently modified its Phase 3 combination therapy protocol to revoke the previously announced change that would have permitted the injection of patients prior to receiving DNA tropism test results. (DNA tropism tests determine whether the strain of HIV present in a patient is exclusively the R5 strain.) The Company also submitted another modified protocol to the FDA. Under this revised protocol, in which the Company previously agreed to inject patients only following the receipt of such tropism test results, the Company also requested a considerably reduced patient population. The Company is currently awaiting the FDA s response.

Phase 3 Trial for HIV, as Long-term Monotherapy. The Company has recently submitted to the FDA an amended trial protocol to add a 100-patient comparator arm to the previously announced study. The trial would now include one arm treated with PRO 140 and a second arm remaining on the patient s baseline HAART regimen. The amendment would bring the total number of patients to be included in the trial to 400. The Company expects to dose its first patient during the fourth quarter of 2016.

Phase 2b Trial for HIV, as a Monotherapy for Treatment-Naïve Patients. Based upon recently expressed concerns by the FDA, among which was the treatment of HIV patients prior to the receipt of tropism tests to determine the strain of each patient s HIV infection, the Company has recently determined to withdraw the trial protocol, as well as the related application for orphan drug designation.

As previously announced, the Company will be hosting an investment community conference call on Friday, August 19, 2016 at 1:30 p.m. PT/4:30 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. The webcast can also be accessed via the following link: http://cytodyn.equisolvewebcast.com/inv-call-8-19-16. A replay of the conference call will be available until October 19, 2016. To access the replay, interested parties may dial 877-660-6853 (U.S./Canada) or 201-612-7415 (international); Conference ID: 13643977.

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.

August 19, 2016

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