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): January 5, 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 **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 7.01. Regulation FD Disclosure.

On January 5, 2017, CytoDyn Inc. posted to its corporate website a letter to its shareholders. A copy of the letter is furnished with this Form 8-K and is attached as Exhibit 99.1 hereto.

Item 9.01. Financial Statements and Exhibits.

(d)	Exhibit No.	Description.
	99.1	Letter to Shareholders, dated January 5, 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.

January 5, 2017

By: */s/ Michael D. Mulholland*

Name: *Michael D. Mulholland*

Title: *Chief Financial Officer*

Exhibit Index

Exhibit No.	Description.
99.1	Letter to Shareholders, dated January 5, 2017

Exhibit 99.1

January 5, 2017

To our Shareholders and Friends:

I'm proud of our many accomplishments during the past. We are entering 2017 with two Phase 3 trials underway with our antiviral agent PRO 140 and a path toward U.S. approval for this novel approach for treating patients infected with HIV.

I'd like to share several important developments and milestones for the coming year. Among these:

- We are on track to reach a major clinical and business inflection point and expect to report initial efficacy results from our pivotal Phase 3 trial with PRO 140 as a combination therapy during the first half of 2017;
- We are encouraged by the interest shown by clinicians and patients alike in our Phase 3 clinical trial with PRO 140 as a monotherapy and anticipate rapid enrollment in this trial;
- We expect to treat the first patient in our Phase 2 trial with PRO 140 in graft versus host disease (GvHD); and
- We are encouraged by recent developments in evaluating PRO 140 for autoimmune diseases and cancer.

I'm particularly delighted to share another near-term milestone for CytoDyn, which is the presentation of data from our Phase 2b extension study with PRO 140 as a monotherapy next month at the world's premier antiviral event, the Conference on Retroviruses and Opportunistic Infections or CROI. You may recall our announcement in August 2016 that 10 patients in this study were approaching two years of suppressed viral load with weekly subcutaneous injection of PRO 140. Our data at CROI will be featured during a special themed discussion session on February 16 in a panel that includes representatives form Gilead, Merck and the NIH—all key players in HIV therapy.

Now I'd like to review our clinical development programs in greater detail:

Pivotal Phase 3 Combination Trial

In our pivotal Phase 3 trial with PRO 140 administered in combination with standard-of-care HAART, we are enrolling 30 highly treatment-experienced patients who have failed their current HAART. The entry criteria require these patients to screen positive for the R5 strain of HIV, a population in which PRO 140 has proven to be effective. You may recall that our dialogue with the FDA late last year resulted in us reducing the efficacy portion of this trial from 150 to 30 patients. Needless to say, this change vastly reduces costs and time.

Patients enrolled in the trial continue their failing HAART regimen for one week for the efficacy portion of the trial. At the start of that week, half of the patients are treated with PRO 140 and half are injected with a placebo. HIV viral load is then measured at one week post-injection. The primary efficacy endpoint is a viral load reduction of 0.5 log or a three-fold decrease versus

baseline, compared to the primary efficacy endpoint from the prior protocol of 0.7 or a five-fold decrease. PRO 140 achieves the primary efficacy endpoint in this trial if 90% of those injected with PRO 140 and less than 35% of those injected with placebo achieve 0.5 log reduction at one week post-injection. We believe the prospects to reach this endpoint are likely based on our prior clinical experience in which PRO 140 lowered viral load in a broader patient population by approximately seven-fold at one week post-injection.

Following the initial efficacy portion of the trial, patients are placed on optimized HAART along with weekly PRO 140 injections for 24 weeks to complete the safety portion of the study. We believe that we will not need to conduct an additional safety trial in the highly treatment-experienced patient population to obtain sufficient safety data for approval, again significantly reducing our costs.

In another positive development, we are proceeding with a rollover protocol for patients in the pivotal Phase 3 combination trial. This allows those who have completed the trial period to have continued access to PRO 140 if determined beneficial by their treating physicians.

Because PRO 140 has received FDA fast track candidate designation, we plan to submit on a rolling basis various portions of a BLA application for approval of PRO 140 as a combination therapy.

We are often asked about the importance of the Phase 3 combination trial when many HIV-infected patients achieve suppressed viral load with HAART alone. Why add another therapy? The answer is because HAART, which is a combination of three or more drugs in pill form, can cause significant adverse events and the pills must be taken daily at a specific time each day to avoid resistance. This can lead to serious quality-of-life and compliance issues. We believe these reasons provide a compelling advantage for combined therapy, and support our estimate of an annual U.S. market at $1 billion.

We previously announced filing for Orphan Drug designation with PRO 140 as a combination therapy in this patient population and expect to receive a determination from the FDA at any time. This designation has several advantages including multiple years of commercial exclusivity.

Phase 3 Monotherapy Trial

We are delighted to have the 300-patient monotherapy investigative trial underway after receiving clearance from the FDA in December to use the same criteria as our Phase 2b monotherapy trial. Patients in this trial will receive weekly subcutaneous injections of PRO 140 for 48 weeks. As stated before, we expect a rapid enrollment for this monotherapy trial. We believe this indication represents the largest market opportunity for PRO 140.

GvHD Phase 2 Trial

This is a 60-patient randomized, double-blind, placebo-controlled, multicenter trial to evaluate the use of PRO 140 in acute myeloid leukemia or myelodysplastic syndrome patients undergoing bone marrow transplant. These patients have a 60% one-year survival rate with GvHD and relapsed disease is the leading causes of death. In this trial, 30 patients will receive PRO 140 subcutaneous injection prior to and during bone marrow transplant, and then at regular intervals for the following 14 weeks.

This month we expect to have additional animal data that, if positive, we will submit in support of Orphan Drug designation for PRO 140 this indication.

We are excited about the many applications for PRO 140 due to its novel mechanism of action. I'm delighted to share that we have received positive animal data in a colon cancer model and in a well-established model for multiple sclerosis, an autoimmune disease. These results have been slated for publication during the first half of 2017. Given the strength of our results, we will continue to seek opportunities to secure a partner for further development of these indications.

We also enter 2017 with a strengthened balance sheet, having raised $13 million late last year in support of advancing development of PRO 140. We are proud to have raised more than $32 million in all of 2016.

In summary, we are excited about 2017 and have the following expectations:

- Completing enrollment in our Phase 3 PRO 140 combination trial and reporting initial efficacy results during the first half of 2017;
- Advancing recruitment in our Phase 3 monotherapy trial;
- Request a meeting with the FDA in the early part of the second quarter to discuss BLA submission;
- Presenting Phase 2b monotherapy results at CROI on February 15 and participating in a themed discussion session in elite company on February 16;
- Receiving notice from the FDA on Orphan Drug designation for PRO 140 in treatment-experienced HIV patients;
- Injecting the first patient in the Phase 2 GvHD trial;
- Submitting animal data in support of Orphan Drug Designation for GvHD;
- Announcing the publication of new animal data that further validates the effectiveness of PRO 140 in autoimmune disease and cancer; and
- Submitting all three sections of BLA to the FDA and request approval of PRO 140.

We have come a long way very quickly and I'm proud of our progress. We expect an eventful and exciting year ahead that brings us significantly closer to gaining approval for PRO 140 and bringing new treatment options to those with HIV and other underserved diseases and conditions.

I thank you for your continued support.

Sincerely,

Nader Pourhassan, Ph.D.
President and Chief Executive Officer CytoDyn Inc.