

CytoDyn Inc.
Form 8-K
April 03, 2019

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): April 1, 2019

CytoDyn Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction

of incorporation)

000-49908
(SEC

File Number)

83-1887078
(I.R.S. Employer

Identification No.)

1111 Main Street, Suite 660

Vancouver, Washington
(Address of principal executive offices)

98660
(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 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 1.01. Entry into a Material Definitive Agreement

On April 1, 2019, CytoDyn Inc., a Delaware corporation (the "Company"), entered into a Master Services Agreement and Product Specific Agreement (together, the "Agreement") with Samsung BioLogics Co., Ltd. ("Samsung"), pursuant to which Samsung will perform technology transfer, process validation, manufacturing and supply services for the commercial supply of the Company's leronlimab (PRO140) drug substance ("Product").

Under the terms of the Agreement, the Company is obligated to make specified minimum purchases of Product from Samsung pursuant to the Company's forecasted requirements. The first forecast for Product will be delivered to Samsung by March 31, 2020. The Company must provide Samsung with a rolling forecast on a quarterly basis setting forth the total quantity of Product that it expects to require in the following years. The Company estimates that initial ramp-up costs to manufacture commercial Product at scale could aggregate approximately \$60 million, with approximately \$30 million payable over the course of calendar 2020 and approximately \$30 million more payable in the first quarter of 2021. Thereafter, the Company will pay Samsung per 15,000L batch according to the pricing terms specified in the Agreement.

The Company's agreement with Samsung has an initial term ending in December 2027 and shall be automatically extended for additional two year periods unless either party gives notice of termination at least six months prior to the then current term. Either party may terminate the Agreement in the event of the other party's insolvency or uncured material breach, and the Company may terminate the Agreement in the event of a voluntary or involuntary complete market withdrawal of Product, with one and half year's prior notice. Neither party may assign the Agreement without the consent of the other, except in the event of a sale of all or substantially all of the assets of a party to which the Agreement relates. The Agreement contains indemnification and limitation of liability provisions.

A copy of the Agreement will be filed as an exhibit in an amendment to this Current Report on Form 8-K or in our next annual report due to be filed under the Securities Exchange Act of 1934.

Item 7.01. Regulation FD Disclosure

On April 2, 2019, the Company issued a press release relating to the announcements described in Item 1.01 above, a copy of which is furnished as Exhibit 99.1 to this Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibit

No.	Description
99.1	<u>Press Release dated April 2, 2019.</u>

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.

April 3, 2019

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