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	**000-49908**	**83-1887078**
(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))

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	Press Release dated April 2, 2019.

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

CytoDyn and Samsung BioLogics Enter into Agreement to Manufacture $1 Billion Worth of Leronlimab (PRO 140) to Meet Expected Demand for Future Revenues Post-Approval

Estimated revenue potential of the new leronlimab supply is based upon $120,000 per patient, per year – BLA submission is in process with 1/3 already submitted to FDA

VANCOUVER, Washington, April 2, 2019 – CytoDyn Inc. (OTC.QB: CYDY), ("CytoDyn" or the "Company") a late stage biotechnology company developing leronlimab (PRO 140), a CCR5 antagonist with the potential for multiple therapeutic indications, today announced the execution of a comprehensive strategic agreement with Samsung BioLogics Co., Ltd. for the clinical and commercial manufacturing of leronlimab (PRO 140). The quantity of new leronlimab to be produced under the agreement is anticipated to be sufficient to support potential revenues for CytoDyn of approximately $1 billion based upon $120,000 per patient, per year.

The agreement commences immediately and entails, most notably, technology transfer of the fully validated commercial process andscale-up, large scale commercial production, validation, and regulatory support during the pre- and post- approval process with the U.S. Food and Drug Administration (FDA) and other global regulatory bodies. In the last four years, Samsung BioLogics has secured 8 biologics drugs approvals from the FDA and 22 overall when including other agencies around the world.

It is believed the financial obligation to Samsung will be satisfied predominantly with sales from existing inventory of commercial grade leronlimab and non-dilutive financing. The initial contract period is from April 1, 2019 to December 31, 2027, encompassing the multitude of potential indications for leronlimab (PRO 140) for which CytoDyn anticipates pursuing regulatory approvals.

"We are elated at the distinction of partnering with the world's preeminent biologics manufacturer for our franchise-defining drug," stated Nader Pourhassan, Ph.D, CytoDyn's President, CEO and director. "In the last four years, Samsung BioLogics has been among the most successful, consistent and highest quality biologics manufacturers in the world. We are thrilled beyond measure that Samsung chose to partner with us," continued Dr. Pourhassan. "The validation of Samsung is particularly important as we rapidly advance towards completing the rolling BLA. We are also currently evaluating several potential licensing deals for leronlimab to commercialization companies. We are getting closer to have such agreements in place which will provide CytoDyn non-dilutive funds to execute on our vision," concluded Dr. Pourhassan.

About Leronlimab (PRO 140)

The U.S. Food and Drug Administration (FDA) has granted a "Fast Track" designation to leronlimab (PRO 140) as a combination therapy with HAART for HIV-infected patients. Leronlimab (PRO 140) is an investigational humanized IgG4 mAb that blocks CCR5, a cellular receptor that appears to play multiple roles with implications in HIV infection, tumor metastases and immune signaling. Leronlimab (PRO 140) has successfully completed nine Phase 1/2/3 clinical trials in over 700 people, including a successful pivotal Phase 3 trial in combination with standard anti-retroviral therapies in HIV-infected treatment-experienced patients.

In the setting of HIV/AIDS, leronlimab (PRO 140) belongs to a new class of therapeutics called viral-entry inhibitors; it masks CCR5, thus protecting healthy T cells from viral infection by blocking

the predominant HIV (R5) subtype from entering those cells. Leronlimab (PRO 140) has been the subject of nine clinical trials, each of which demonstrated that leronlimab can significantly reduce or control HIV viral load in humans. The leronlimab (PRO 140) antibody appears to be a powerful antiviral agent leading to potentially fewer side effects and less frequent dosing requirements compared with daily drug therapies currently in use.

In the setting of cancer, research has shown that CCR5 likely plays a central role in tumor invasion and metastasis and that increased CCR5 expression is an indicator of disease status in several cancers. Moreover, research has shown that drugs that block CCR5 can block tumor metastases in laboratory and animal models of aggressive breast and prostate cancer. CytoDyn is conducting additional research with leronlimab (PRO 140) in the cancer setting and plans to initiate additional Phase 2 human clinical trials, in addition to triple-negative breast cancer, when appropriate.

The CCR5 receptor also appears to play a central role in modulating immune cell trafficking to sites of inflammation and may be crucial for the development of acute graft-versus-host disease (GvHD) and other inflammatory conditions. Clinical studies by others further support the concept that blocking CCR5 using a chemical inhibitor can reduce the clinical impact of acute GvHD without significantly affecting the engraftment of transplanted bone marrow stem cells. CytoDyn is currently conducting a Phase 2 clinical study with leronlimab (PRO 140) to further support the concept that the CCR5 receptor on engrafted cells is critical for the development of acute GvHD and that blocking this receptor from recognizing certain immune signaling molecules is a viable approach to mitigating acute GvHD. The FDA has granted “orphan drug” designation to leronlimab (PRO 140) for the prevention of graft-versus-host disease (GvHD).

About Samsung BioLogics

Samsung BioLogics is a global full-service provider of quality-driven contract process development and cGMP manufacturing to the global biopharmaceutical industry. Its facilities are custom designed for monoclonal & recombinant production with maximum flexibility. Its one-stop services include cell line generation, process and analytical method development, analytical services, clinical and commercial bulk cGMP manufacturing of drug substance and drug product including quality assurance, quality control, regulatory compliance standards & support for its customers. Samsung BioLogics recently won the CMO Leadership Award in all six core categories (capabilities, compatibility, expertise, quality, reliability and service) three years in a row, the first company ever to do so. The CMO Leadership Award is presented by *Life Science Leader* and Industry Standard Research every year. Samsung BioLogics was also recognized globally for its competitiveness when it was named by *Fortune* magazine as one of the “Future 50” companies last October. For additional information about the company, please visit http://www.samsungbiologics.com.

About CytoDyn

CytoDyn is a biotechnology company developing innovative treatments for multiple therapeutic indications based on leronlimab (PRO 140), a novel humanized monoclonal antibody targeting the CCR5 receptor. CCR5 appears to play a key role in the ability of HIV to enter and infect healthy T-cells. The CCR5 receptor also appears to be implicated in tumor metastasis and in immune-mediated illnesses, such as graft-vs-host disease (GvHD) and NASH. CytoDyn has successfully completed a Phase 3 pivotal trial with leronlimab (PRO 140) in combination with standard anti-retroviral therapies in HIV-infected treatment-experienced patients. CytoDyn plans to seek FDA approval for leronlimab (PRO 140) in combination therapy and plans to complete the filing of a Biologics License Application (BLA) in 2019 for that indication. CytoDyn is also conducting a Phase 3 investigative trial with leronlimab (PRO 140) as a once-weekly monotherapy for HIV-infected patients and, plans to initiate a registration-directed study of leronlimab monotherapy indication, which if successful, could support a label extension. Clinical results to date from multiple trials have shown that leronlimab (PRO 140) can significantly reduce viral burden in

people infected with HIV with no reported drug-related serious adverse events (SAEs). Moreover, results from a Phase 2b clinical trial demonstrated that leronlimab (PRO 140) monotherapy can prevent viral escape in HIV-infected patients, with some patients on leronlimab monotherapy remaining virally suppressed for more than four years. CytoDyn is also conducting a Phase 2 trial to evaluate leronlimab (PRO 140) for the prevention of GvHD and has received clearance to initiate a clinical trial with leronlimab (PRO 140) in metastatic triple-negative breast cancer. More information is at www.cytodyn.com.

Forward-Looking Statements

This press release 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," "projects," "plans," "anticipates" and variations thereof, or the use of future tense, identify forward-looking statements, but their absence does not mean that a statement is not forward-looking. The Company's forward-looking statements are not guarantees of performance, and actual results could vary materially from those contained in or expressed by such statements due to risks and uncertainties including: (i) the sufficiency of the Company's cash position, (ii) the Company's ability to raise additional capital to fund its operations, (iii) the Company's ability to meet its debt obligations, if any, (iv) the Company's ability to enter into partnership or licensing arrangements with third parties, (v) the Company's ability to identify patients to enroll in its clinical trials in a timely fashion, (vi) the Company's ability to achieve approval of a marketable product, (vii) the design, implementation and conduct of the Company's clinical trials, (viii) the results of the Company's clinical trials, including the possibility of unfavorable clinical trial results, (ix) the market for, and marketability of, any product that is approved, (x) the existence or development of vaccines, drugs, or other treatments that are viewed by medical professionals or patients as superior to the Company's products, (xi) regulatory initiatives, compliance with governmental regulations and the regulatory approval process, (xii) general economic and business conditions, (xiii) changes in foreign, political, and social conditions, and (xiv) various other matters, many of which are beyond the Company's control. The Company urges investors to consider specifically the various risk factors identified in its most recent Form 10-K, and any risk factors or cautionary statements included in any subsequent Form 10-Q or Form 8-K, filed with the Securities and Exchange Commission. Except as required by law, the Company does not undertake any responsibility to update any forward-looking statements to take into account events or circumstances that occur after the date of this press release.

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