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): July 8, 2020 (July 2, 2020)

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

Not Applicable
(Former name or former address, if changed since last report.)

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
None	**None**	**None**

Indicate by check mark whether the registrant is an emerging growth company as defined in 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 July 2, 2020, CytoDyn Inc. ("CytoDyn" or the "Company") signed an exclusive Distribution and Supply Agreement (the "Agreement") with American Regent, Inc. ("American Regent") with respect to the distribution of the Company's leronlimab (PRO140) drug for the treatment of COVID-19 in the United States.

Under the Agreement, the Company appointed American Regent as the sole and exclusive authorized distributor in the United States of any subcutaneous injectable biopharmaceutical drug product labeled for treating COVID-19 that contains CytoDyn's leronlimab (a humanized monoclonal antibody (also known as PRO 140) targeting against the CCR5 receptor) as the only active pharmaceutical ingredient (the "Product"). The grant of exclusive distribution rights to American Regent does not extend to any intravenous or infusible biopharmaceutical drug product, or any other product of CytoDyn containing leronlimab that is not labeled for treating COVID-19.

Under the Agreement, American Regent shall, at its cost, use commercially reasonable efforts to market the Product in the United States, including, without limitation, directing the methods of sale and distribution, organization and management of sales and marketing and pricing in accordance with the terms and conditions of the Agreement. American Regent shall solely set the resale prices for the Product in accordance with applicable law. Pursuant to the Agreement, the Company remains responsible, at its cost, to pursue, own and maintain the applicable regulatory approvals necessary to market the Product in the United States, and for manufacturing the Product once regulatory approvals have been received.

The Company is currently enrolling a Phase 2b/3 clinical trial for 390 severe and critically illCOVID-19 patients, which is a randomized, placebo-controlled with 2:1 ratio (active drug to placebo ratio). The Company has also completed its enrollment of a Phase 2 randomized clinical trial with 75 patients in the mild-to-moderate COVID-19 population. If results from these trials indicate positive clinical outcomes for theCOVID-19 patients to sufficiently meet the primary endpoints for the trials, the Company will seek approval from the U.S. Food and Drug Administration.

The term of the Agreement extends for three years after the date of the first commercial sale of the Product, and will renew by mutual agreement of the parties for one additional one-year term, unless American Regent notifies the Company of its intention to have the Agreement terminate at the end of the initial term at least six (6) months prior to the end of the initial term. Either party is entitled to terminate the Agreement at any time in the event of material breach by the other party that remains uncured after thirty (30) calendar days following written notice thereof, and either party may terminate the Agreement immediately, at its option, upon written notice in the event that a court of competent jurisdiction declares the other party insolvent or bankrupt, or a bankruptcy proceeding is commenced against the other party or the other party files a proposal, assignment for the benefit of creditors, arrangement, composition or seeks similar relief under any applicable law, or the other party is in receivership. The Company is also entitled to terminate the Agreement at any time after the first Commercial Sale upon six (6) months advance written notice to American Regent, or upon ninety (90) days written notice to American Regent following American Regent's change of control. American Regent is entitled to terminate the Agreement upon six (6) months advance written notice to the Company if, following due diligence and/or a quality inspection of the manufacturing facility associated with the Product, it determines that the distribution of the Product by American Regent should not be pursued, or if there is an unresolved supply interruption as described in the Agreement. In addition, American Regent may terminate the Agreement immediately upon written notice to the Company if (a) American Regent determines there is an unacceptable risk of using American Regent's NDC Number on the Product labeling, (b) if the parties fail to execute a quality agreement and safety data exchange agreement within forty five (45) days of July 2, 2020, (c) if American Regent is named in any patent or trade secret infringement matter filed by a third party (with certain exceptions) resulting from American Regent's marketing of the Product and such matter survives a motion to dismiss or has not been resolved within six (6) months after American Regent first receives written notice of the alleged infringement, (d) if any regulatory authority in the United States requires the cessation of sale or distribution of the Product, (e) if the Company materially impedes American Regent's efforts to implement a recall, market withdrawal or field correction of the Product, or (f) if there is a negative net profit from American Regent's sales of the Product for two (2) consecutive calendar quarters.

The above description of the Agreement does not purport to be complete and is qualified in its entirety by the full text of the Agreement, which the Company intends to file as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended May 31, 2020.

Item 7.01 Regulation FD Disclosure

On July 3, 2020, the Company issued a press release announcing its entry into the Distribution and Supply Agreement with American Regent as described above under Item 1.01. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K ("Current Report").

The information in Exhibit 99.1 shall not be deemed as "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of such Section, nor shall it be deemed incorporated by reference in any filing by the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, regardless of any general incorporation language in such filing, unless expressly incorporated by specific reference in such filing.

Forward-Looking Statements

This Current Report on 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," "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. Forward-looking statements specifically include statements about leronlimab, its ability to have positive health outcomes, the possible results of clinical trials, studies or other programs or ability to continue those programs, the ability to obtain regulatory approval for commercial sales, and the market for actual commercial sales. 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 report.

Item 9.01 Financial Statements

(d) Exhibits

Exhibit Number	Description of Exhibit
99.1	Press Release dated July 3, 2020

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.

July 8, 2020

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

CytoDyn Announces Execution of Exclusive Agreement with American Regent for Distribution and Supply of Leronlimab for Treatment of COVID-19 in United States

This Agreement will allow for immediate distribution of leronlimab to patients for the treatment ofCOVID-19 upon successful completion of CytoDyn's ongoing clinical trials and FDA approval

VANCOUVER, Washington, July 3, 2020 (GLOBE NEWSWIRE) — **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, announced today it has signed an exclusive Distribution and Supply Agreement with American Regent, Inc. ("American Regent") for the distribution of leronlimab for the treatment of COVID-19 in the United States.

Under the terms of the agreement, CytoDyn will supply leronlimab for the treatment ofCOVID-19 for distribution by American Regent and receive quarterly payments based on a profit-sharing arrangement.

"Having this distribution agreement in place ahead of the readout from CytoDyn'sCOVID-19 clinical trials further emphasizes CytoDyn's commitment to making leronlimab immediately available to patients based on the successful completion of its ongoing clinical trials," said Nader Pourhassan, Ph.D., President and Chief Executive Officer of CytoDyn. "We are particularly happy to be partnering with a company with the proven expertise, unparalleled commercial reach and stellar reputation of American Regent."

"American Regent is looking forward to partnering with CytoDyn to provideCOVID-19 patients rapid and efficient access to a potentially life-saving drug," said Mr. Harsher Singh, American Regent's Vice President and Chief Commercial Officer.

CytoDyn is currently enrolling a Phase 2b/3 clinical trial for 390 severe and critically illCOVID-19 patients, which is a randomized, placebo-controlled with 2:1 ratio (active drug to placebo ratio). The Company has also completed its enrollment of a Phase 2 randomized clinical trial with 75 patients in the mild-to-moderate COVID-19 population. CytoDyn has been granted more than sixty emergency Investigational New Drug (eIND) authorizations by the U.S. Food and Drug Administration (FDA) and plans to provide clinical updates for this patient population in the coming weeks.

About American Regent

American Regent, Inc., a Daiichi Sankyo Group company, is atop-10 injectable manufacturer. For over 50 years, American Regent has been developing, manufacturing and supplying quality generic and branded injectables for healthcare providers. For nearly 20 years, American Regent have been a leader in IV iron therapy. American Regent is committed to U.S.-based

manufacturing. In 2018, more than 99% of units supplied were manufactured in its U.S.-based facilities making it uniquely positioned to quickly mobilize and respond to shortages or changes in market needs. Speed counts. Flexibility matters. Reliability and quality are paramount. Because patients should never have to wait for the medications they need. For more information, please visit www.americanregent.com.

About Coronavirus Disease 2019

CytoDyn has met its 75-patient enrollment target in its Phase 2 clinical trial for COVID-19, a randomized clinical trial for mild-to-moderate COVID-19 population in the U.S. and enrollment continues in its Phase 2b/3 randomized clinical trial for severe and critically ill COVID-19 population in several hospitals throughout the country.

SARS-CoV-2 was identified as the cause of an outbreak of respiratory illness first detected in Wuhan, China. The origin of SARS-CoV-2 causing the COVID-19 disease is uncertain, and the virus is highly contagious. COVID-19 typically transmits person to person through respiratory droplets, commonly resulting from coughing, sneezing, and close personal contact. Coronaviruses are a large family of viruses, some causing illness in people and others that circulate among animals. For confirmed COVID-19 infections, symptoms have included fever, cough, and shortness of breath. The symptoms of COVID-19 may appear in as few as two days or as long as 14 days after exposure. Clinical manifestations in patients have ranged from non-existent to severe and fatal. At this time, there are minimal treatment options for COVID-19.

About Leronlimab (PRO 140) and BLA Submission for the HIV Combination Therapy

The FDA has granted a Fast Track designation to CytoDyn for two potential indications of leronlimab for deadly diseases. The first as a combination therapy with HAART for HIV-infected patients and the second is for metastatic triple-negative breast cancer. Leronlimab is an investigational humanized IgG4 mAb that blocks CCR5, a cellular receptor that is important in HIV infection, tumor metastases, and other diseases, including NASH. Leronlimab has completed nine clinical trials in over 800 people, including meeting its primary endpoints in a pivotal Phase 3 trial (leronlimab in combination with standard antiretroviral therapies in HIV-infected treatment-experienced patients).

In the setting of HIV/AIDS, leronlimab is a viral-entry inhibitor; it masks CCR5, thus protecting healthy T cells from viral infection by blocking the predominant HIV (R5) subtype from entering those cells. Leronlimab has been the subject of nine clinical trials, each of which demonstrated that leronlimab could significantly reduce or control HIV viral load in humans. The leronlimab 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.

The Company filed its BLA for Leronlimab as a Combination Therapy for Highly Treatment Experienced HIV Patients with the FDA on April 27, 2020, and submitted additional FDA requested clinical datasets on May 11, 2020. After the FDA deems a BLA submission complete, it sets a PDUFA goal date. CytoDyn has Fast Track designation for leronlimab and a rolling review for its BLA, as previously assigned by the FDA. The Company filed a request for Priority Review designation for its BLA to shorten the FDA’s review time from 10 to 6 months, an FDA goal for BLA applications given Priority Review designation.

In the setting of cancer, research has shown that CCR5 may play a role in tumor invasion, metastases, and tumor microenvironment control. Increased CCR5 expression is an indicator of disease status in several cancers. Published studies have shown that blocking CCR5 can reduce tumor metastases in laboratory and animal models of aggressive breast and prostate cancer. Leronlimab reduced human breast cancer metastasis by more than 98% in a murine xenograft model. CytoDyn is, therefore, conducting a Phase 1b/2 human clinical trial in metastatic triple-negative breast cancer and was granted Fast Track designation in May 2019.

The CCR5 receptor appears to play a central role in modulating immune cell trafficking to sites of inflammation. It may be crucial in 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 to support further the concept that the CCR5 receptor on engrafted cells is critical for the development of acute GvHD, blocking the CCR5 receptor from recognizing specific immune signaling molecules is a viable approach to mitigating acute GvHD. The FDA has granted “orphan drug” designation to leronlimab for the prevention of GvHD.

About CytoDyn

CytoDyn is a late-stage biotechnology company developing innovative treatments for multiple therapeutic indications based on leronlimab, a novel humanized monoclonal antibody targeting the CCR5 receptor. CCR5 appears to play a critical 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 immune-mediated illnesses, such as GvHD and NASH. CytoDyn has successfully completed a Phase 3 pivotal trial with leronlimab in combination with standard antiretroviral therapies in HIV-infected treatment-experienced patients. CytoDyn filed its BLA in April 2020 to seek FDA approval for leronlimab as a combination therapy for highly treatment experienced HIV patients, and submitted additional FDA requested clinical datasets on May 11, 2020. CytoDyn is also conducting a Phase 3 investigative trial with leronlimab as a once-weekly monotherapy for HIV-infected patients. CytoDyn plans to initiate a registration-directed study of leronlimab monotherapy indication. If successful, it could support a label extension. Clinical results to date from multiple trials have shown that leronlimab can significantly reduce viral burden in people infected with HIV. No drug-related serious site injection reactions reported in about 800 patients treated with leronlimab and no drug-related SAEs reported in patients treated with 700 mg dose of leronlimab. Moreover, a Phase 2b clinical trial demonstrated that leronlimab monotherapy can prevent viral escape in HIV-infected patients; some patients on leronlimab monotherapy have remained virally suppressed for more than five years. CytoDyn is also conducting a Phase 2 trial to evaluate leronlimab for the prevention of GvHD and a Phase 1b/2 clinical trial with leronlimab in metastatic triple-negative breast cancer. More information is at www.cytodyn.com.

Forward-Looking Statements

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CYTODYN CONTACTS

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