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 12, 2021 (April 6, 2021)

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

Delaware	**000-49908**	**83-1887078**
(State or other jurisdiction of incorporation)	**(Commission 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:

☐ 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 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 6, 2021, CytoDyn Inc. (the "Company") entered into an Exclusive Supply and Distribution Agreement (the "Agreement") with Biomm S.A., a Brazilian pharmaceutical company engaged in the business of manufacturing and distributing pharmaceutical products in Brazil ("Biomm"), pursuant to which Biomm would hold the exclusive right to distribute and sell the Company's product, Vyrologix™ (leronlimab), in Brazil, once regulatory approval has been received. The Agreement provides for the sale of Vyrologix upon approval by the Brazilian National Health Surveillance Agency or Agência Nacional de Vigilância Sanitária ("ANVISA").

Under the Agreement, the Company has appointed Biomm as the exclusive distributor for Vyrologix in Brazil, agreed to supply Vyrologix to Biomm, and agreed not to supply Vyrologix or the rights to import, distribute, resell or market Vyrologix to any other public or private entity in Brazil without Biomm ´s consent and participation. Biomm is responsible for submitting an application for Authorization for Emergency Use for COVID-19 treatment in accordance with the laws and regulations in Brazil following regulatory clearance. Biomm will, at its cost, with the assistance of the Company, prepare the transfer, translation and interpretation of the relevant data and materials submitted by the Company to the U.S. Federal Drug Administration to the extent necessary to complete the relevant filings with ANVISA and all applicable local regulatory agencies, and translate the proposed label and summaries of the clinical information for filing with the local healthcare regulatory authorities and all other applicable regulatory authorities, and take such other actions, at its own cost, as are necessary to obtain and maintain all governmental approvals, authorizations, licenses, permits, registrations and consents that are, or may in the future be, required for the parties to perform under the Agreement.

The term of the Agreement will remain in effect until formal regulatory approval for the sale of Vyrologix in Brazil has been received. For application of formal regulatory approval of Biomm as the marketing authorization holder in Brazil, the Company and Biomm agree to amend the Agreement to describe the specific regulatory and commercial terms of approval. Either Party may terminate the Agreement (i) for cause, if the other party has materially breached any of its obligations and has not cured such breach after being given the reasonable opportunity to do so, (ii) upon the bankruptcy or insolvency of the other party, (iii) upon continuation of a force majeure event that prevents performance of the other party for more than 120 days, (iv) in the event that ANVISA makes a final, non-appealable decision to not approve Vyrologix for emergency use or withdraws approval of its emergency use authorization, or (v) if the other party's license to conduct its business expires, is not renewed, or is revoked or suspended, or such party becomes legally disqualified for any reason from importing, exporting, distributing, promoting or selling Vyrologix in Brazil, or otherwise from performing its obligations under this Agreement.

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, 2021.

Item 7.01 Regulation FD Disclosure

On April 7, 2021, the Company issued a press release announcing its entry into the Exclusive Supply and Distribution Agreement with Biomm 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 Vyrologix, its ability to have positive health outcomes, the ability to obtain regulatory approval for commercial sales, and the market for actual commercial sales once approval has been granted. 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 and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated April 7, 2021
104	Cover Page Interactive Data File (embedded within the inline XBRL document)

SIGNATURE

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 thereunto duly authorized.

CYTODYN INC.

Dated: April 12, 2021

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

CytoDyn Signs Exclusive Supply and Distribution Agreement with Biomm S.A. in Brazil for COVID-19 and All Other Leronlimab Indications

VANCOUVER, Washington, April 7, 2021 (GLOBE NEWSWIRE) — **CytoDyn Inc. (OTC.QB: CYDY)**, ("CytoDyn" or the "Company"), a late-stage biotechnology company developing leronlimab (PRO 140), a CCR5 antagonist with potential multiple therapeutic indications, announced today it has executed an exclusive supply and distribution agreement with Biomm S.A. in Brazil. This commercial agreement will enable Biomm to sell leronlimab in Brazil following regulatory clearance.

CytoDyn has committed to conduct clinical trials in Brazil for all current indications for leronlimab (i.e., Long-Hauler COVID-19, NASH and cancer).

Heraldo Marchezini, Chief Executive Officer of Biomm S.A., commented, "We are very pleased with our recently executed exclusive supply and distribution agreement with CytoDyn. Our urgent goal is to provide leronlimab to Brazilians critically ill with COVID-19."

Nader Pourhassan, Ph.D., President and Chief Executive Officer of CytoDyn, stated, "We are excited to reach this milestone for the potential benefit of Brazilian patients. Mr. Marchezini and his team have worked tirelessly to advance our commercial agreement and we look forward to a long-term relationship with Biomm. I am very grateful to Mr. Marchezini and his team for expediting our efforts to advance the availability of leronlimab for all patients who might benefit from this immune modulator product."

About Biomm S.A.

Biomm's mission is to develop, produce and market global competitive biomedicines with quality and accessibility. The company's focus is developing biological products, aiming to guarantee national self-sufficiency. Due to its innovator DNA, the company is pioneer in biotechnological drugs in Brazil. Founded in 2002, Biomm's headquarters and factory are in Nova Lima (MG), with capacity to produce 20 million of insulin per year, based on advanced and innovative technologies that guarantee the medicines quality. The company is listed on the Brazilian stock exchange (BVMF: BIOM3). For further information access www.biomm.com

About Leronlimab (PRO 140)

The U.S. Food and Drug Administration (FDA) granted CytoDyn Fast Track designation to explore two potential indications using leronlimab to treat HIV and metastatic cancer. The first indication is combination therapy with HAART for HIV-infected patients, and the second is for metastatic triple-negative breast cancer (mTNBC). Leronlimab is an investigational humanized

IgG4 mAb that blocks CCR5, a cellular receptor important in HIV infection, tumor metastases, and other diseases, including NASH (Nonalcoholic Steatohepatitis). Leronlimab has been studied in 11 clinical trials involving more than 1,200 people and met its primary endpoints in a pivotal Phase 3 trial (leronlimab combined with standard antiretroviral therapies in HIV-infected treatment-experienced patients).

Leronlimab is a viral-entry inhibitor in HIV/AIDS. It masks CCR5, thus protecting healthy T cells from viral infection by blocking the predominant HIV (R5) subtype from entering those cells. Nine clinical trials have demonstrated leronlimab could significantly reduce or control HIV viral load in humans. The leronlimab antibody appears to be a powerful antiviral agent with fewer side effects and less frequent dosing requirements than currently used daily drug therapies.

Cancer research has shown 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 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. As a result, CytoDyn is conducting two Phase 2 human clinical trials, one in mTNBC, which was granted Fast Track designation by the FDA in 2019, and a second in a basket trial which encompasses 22 different solid tumor cancers.

The CCR5 receptor appears to play a central role in modulating immune cell trafficking to sites of inflammation. After completing two clinical trials with COVID-19 patients (a Phase 2 and a Phase 3), CytoDyn initiated a Phase 2 investigative trial for post-acute sequelae of SARSCOV-2 (PASC), also known as COVID-19 Long-Haulers. This trial will evaluate the effect of leronlimab on clinical symptoms and laboratory biomarkers to further understand the pathophysiology of PASC. It is currently estimated that between 10-30% of those infected with COVID-19 develop long-term sequelae. Common symptoms include fatigue, cognitive impairment, sleep disorders, and shortness of breath. If this trial is successful, CytoDyn plans to pursue clinical trials to evaluate leronlimab's effect on immunological dysregulation in other post-viral syndromes, including myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS).

CytoDyn is also conducting a Phase 2 clinical trial for NASH to evaluate the effect of leronlimab on liver steatosis and fibrosis. Preclinical studies revealed a significant reduction in NAFLD and a reduction in liver fibrosis using leronlimab. There are currently no FDA approved treatments for NASH. NASH is a leading cause of liver transplant. About 30 to 40 percent of adults in the U.S. live with NAFLD, and 3 to 12 percent of adults in the U.S. live with NASH.

About CytoDyn

CytoDyn is a late-stage biotechnology company developing innovative treatments for multiple therapeutic indications using 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 using leronlimab combined with standard antiretroviral therapies in HIV-infected treatment-experienced patients. CytoDyn has been working diligently to refile its Biologics License Application ("BLA") for this HIV combination therapy since receiving a Refusal to File in July 2020 and subsequently meeting with the FDA telephonically to address their written guidance concerning the filing. CytoDyn expects to refile its BLA in the first half of the calendar year 2021 or shortly thereafter.

CytoDyn also completed a Phase 3 investigative trial with leronlimab used 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 approval. Clinical results to date from multiple trials have shown that leronlimab can significantly reduce the viral burden in people infected with HIV. Moreover, a Phase 2 clinical trial demonstrated that leronlimab monotherapy could prevent viral escape in HIV-infected patients; several patients on leronlimab's Phase 2 monotherapy extension arm have remained virally suppressed for more than six years. There have been no strong safety signals identified in patients administered leronlimab in multiple disease spectrums, including patients with HIV, COVID-19 and Oncology.

CytoDyn is also conducting a Phase 2 clinical trial with leronlimab in mTNBC, a Phase 2 basket trial in solid tumor cancers (22 different cancer indications), Phase 2 investigative trial for post-acute sequelae of SARS COV-2, also known as COVID-19 Long-Haulers, and a Phase 2 clinical trial for NASH. CytoDyn has already completed two trial in COVID-19 patients (a Phase 2 and a Phase 3) and is in the process of conducting an additional COVID-19 Phase 3 trial for mechanically ventilated critically ill COVID-19 patients. More information is at www.cytodyn.com.

Forward-Looking Statements

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include statements about leronlimab, its ability to provide 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 press release.

CONTACTS

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