# 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 21, 2021 (April 15, 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**<br>**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 15, 2021, CytoDyn Inc. (the "Company") entered into an Exclusive Supply and Distribution Agreement, as amended by Amendment No. 1 dated April 19, 2021 (the "Agreement"), with Chiral Pharma Corporation, a Philippine pharmaceutical company and subsidiary of New Marketlink Pharmaceutical Corporation engaged in the business of importation, sales, and promotion and distribution of a diverse specialty line of pharmaceutical and healthcare products in the Philippines ("Chiral"), pursuant to which the Company granted Chiral the exclusive right to distribute and sell within the next twelve months up to 200,000 vials of the Company's product, Vyrologix™ (leronlimab), to treat critically ill COVID-19 patients in the Philippines under Compassionate Special Permit ("CSP") or Emergency Use Authorization ("EUA") from the Food and Drug Administration of the Philippines.

Under the Agreement, Chiral would hold the exclusive right to distribute Vyrologix in the Philippines for one year in accordance with the treatment protocols approved under the applicable CSPs or EUAs, and purchase all required quantities of Vyrologix in accordance with such CSP or EUA. The parties shall negotiate in good faith and use commercially reasonable efforts to enter into a Quality Agreement upon execution of the Agreement. Either party may terminate the Agreement for a material breach not cured within thirty (30) days of written notice or for convenience upon sixty (60) days-notice.

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 15, 2021, the Company issued a press release announcing its entry into the Exclusive Supply and Distribution Agreement with Chiral 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 15, 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 21, 2021

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

**Exhibit 99.1**

**CytoDyn Executes Exclusive Supply and Distribution Agreement with Chiral Pharma Corporation to Provide Up to 200,000 vials of Leronlimab to Philippines**

*Under Compassionate Special Permit (CSP) in Philippines, CytoDyn is well positioned to generate significant revenues*

VANCOUVER, Washington, April 15, 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 Chiral Pharma Corporation to supply up to 200,000 vials of leronlimab to critically ill COVID-19 patients in the Philippines under CSP authorizations. This agreement will accelerate the delivery of leronlimab upon an expanded authorization under CSP.

Nader Pourhassan, Ph.D., President and Chief Executive Officer of CytoDyn, commented, "We are very pleased how quickly we reached agreement with our commercial partner, Chiral Pharma in the Philippines. Chiral has been working diligently with the Philippine FDA to ensure the regulatory path is cleared so we can provide leronlimab to thousands of critically ill COVID-19 patients under CSP authorization. Upon quick recovery of the first Filipino patient critically ill with COVID-19 treated with leronlimab, Chiral is continuously receiving CSP requests and is hoping to accelerate the availability of leronlimab under CSP to thousands of critically ill COVID-19 patients. In parallel, we are using data generated from our CD12 open-label extension to pursue EUAs in multiple countries experiencing surges in critically ill COVID-19 patients. The Company will accelerate manufacturing of leronlimab at Samsung BioLogics upon such approval."

**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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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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