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

Date of Report (Date of earliest event reported): September 10, 2021 (September 9, 2021)

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

Delaware	000-49908	83-1887078
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

1111 Main Street, Suite 660
Vancouver, Washington 98660
(Address of principal executive offices, including zip code)

(360) 980-8524
(Registrant's telephone number, including area code)

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 8.01. Other Events.

On September 9, 2021, CytoDyn Inc. (the "Company") issued a press release announcing the treatment of the first patient in the Company's pivotal Phase 3 COVID-19 trial in Brazil for patients with severe symptoms.

A copy of the press release is included as Exhibit 99.1 to this Report and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

99.1	Press Release, dated September 9, 2021
104	Cover Page Interactive Data File (formatted as inline XBRL)

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 hereunto duly authorized.

Date: September 10, 2021

CYTODYN INC.

By: /s/ Antonio Migliarese
Antonio Migliarese
Chief Financial Officer

Exhibit 99.1

CytoDyn Announces Treatment of the First Patient in its Pivotal Phase 3COVID-19 Trial in Brazil for Patients with Severe Symptoms

An interim analysis will be conducted 28 days following enrollment of 245 patients (40% of targeted trial patients)

VANCOUVER, Washington, September 9, 2021 (GLOBE NEWSWIRE) — **CytoDyn Inc. (OTCQB: CYDY)** ("CytoDyn" or the "Company"), a late-stage biotechnology company developing leronlimab, a CCR5 antagonist with the potential for multiple therapeutic indications, announced today the treatment of the first patient in its pivotal Phase 3 COVID-19 trial in Brazil for patients with severe symptoms. An interim analysis will be conducted 28 days following the enrollment of 245 patients, which is 40% of the total number of patients to be enrolled in the trial.

As previously announced, this pivotal Phase 3 trial for severeCOVID-19 patients is being conducted by Academic Research Organization ("ARO") Albert Einstein Israelite Hospital. This trial is intended to provide Brazil's regulatory authority ANVISA (Agência Nacional de Vigilância Sanitária) with the requisite data to consider advancing the availability of leronlimab to Brazilians infected with COVID-19. The trial will be conducted in up to 35 clinical sites with 612 patients who are hospitalized and in need of oxygenation support.

Nader Pourhassan, Ph.D., CytoDyn's President and Chief Executive Officer, commented, "We are very encouraged enrollment for this first trial is underway and look forward to reaching our interim analysis target as soon as possible. We believe our second trial in Brazil will also initiate very soon as ANVISA has cleared the trial with a condition of more information about CMC, which will be provided to ANVISA no later than September 13. Today marks the first day of the much anticipated clinical trial in Brazil that we have been waiting for and we are so grateful to our team who conducted the CD12 trial in U.S. that produced a wealth of information for us to be able to appropriately design and power these two studies. We also give especial thanks to the ARO team for a job well done and look forward to many more trials to be conducted by them in Brazil with leronlimab. We also thank the BIOMM team for exceptional work to finalize this protocol with ANVISA and providing very valuable guidelines to our team."

About Leronlimab

The U.S. Food and Drug Administration (FDA) granted CytoDyn Fast Track designation to explore two potential indications using leronlimab to treat Human Immunodeficiency Virus (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 binds to CCR5, a cellular receptor important in HIV infection, tumor metastases, and other diseases, including nonalcoholic steatohepatitis (NASH). Leronlimab has been studied in 16 clinical trials involving more than 1,200 people and met its primary endpoints in a pivotal Phase 3 trial (leronlimab combined with HIV standard care in patients with multi-drug resistance to current available classes of HIV drugs).

Leronlimab, among various potential applications, is a viral-entry inhibitor in HIV/AIDS. It binds to CCR5, thus protecting healthy T cells from viral infection by blocking the predominant HIV (R5) subtype from entering those cells. Leronlimab does not work on other strains of HIV (for example X4), however, R5 is the most dominant strain of HIV. Five 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 (for example, through angiogenesis). 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 97% in a murine xenograft model. As a result, CytoDyn is conducting two clinical trials, one, a Phase 2 in mTNBC, which was granted Fast Track designation by the FDA in 2019, and a second, a Phase 2, basket trial which encompasses 22 different solid tumor cancers.

The CCR5 receptor plays 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 evaluated 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. 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.Pre-clinical studies revealed a significant reduction in NAFLD and a reduction in liver fibrosis using leronlimab. There are currently no FDA approved treatments for NASH, which 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. There have been no strong safety signals identified in patients administered leronlimab in multiple disease spectrums, including patients with HIV, COVID-19, and oncology.

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 plays a critical role in the ability of HIV to enter and infect healthy T-cells and appears to be implicated in tumor metastasis and immune-mediated illnesses, such as NASH.

CytoDyn successfully completed a Phase 3 pivotal trial using leronlimab combined with standard antiretroviral therapies inHIV-infected patients who were heavily treatment-experienced individuals with limited treatment options. CytoDyn is working diligently to resubmit 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. On July 1, 2021, CytoDyn announced that it had submitted a dose justification report to the FDA, an integral step in the resubmission

process for its BLA, which it expects to complete in October 2021. CytoDyn also completed a Phase 2b/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 expansion approval. Clinical results to date from two trials have shown that leronlimab can maintain a suppressed viral load in a sub-population of R5 HIV patients who chose to switch from their daily pills regimen toonce-a-week subcutaneous dose of leronlimab. Several patients on leronlimab's Phase 2b extension arm have remained virally suppressed for almost 7 years and many patients in our Phase 2b/3 investigative trial are passing two and some four years of monotherapy with suppressed viral load.

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 a Phase 2 and Phase 3 trial for mild-to-moderate and severe-to-critical COVID-19 patients, respectively, for which CytoDyn did not meet its primary or secondary endpoints except for the secondary endpoint in the critically ill subpopulation. 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. Forward-looking statements specifically 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 regulatory determinations of leronlimab's efficacy to treat human immunodeficiency virus ("HIV") patients with multiple resistance to current standard of care, COVID-19 patients, and metastatic Triple-Negative Breast Cancer ("mTNBC"), among other cancer indications, by the U.S. Food and Drug Administration and various drug regulatory agencies in other countries; (ii) the Company's ability to raise additional capital to fund its operations; (iii) the Company's ability to meet its debt obligations; (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) legal proceedings, investigations or inquiries affecting the Company or its products; (xiii) general economic and business conditions; (xiv) changes in foreign, political, and social conditions; (xv) stockholder actions or proposals with regard to the Company, its management, or its board of directors; and (xvi) 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.

Important Information

CytoDyn intends to file with the SEC a definitive proxy statement and associated proxy card in connection with the solicitation of proxies for the Company's 2021 Annual Meeting. Details concerning the nominees of the Company's Board of Directors for election at the 2021 Annual Meeting will be included in the proxy statement. BEFORE MAKING ANY VOTING DECISION, INVESTORS AND STOCKHOLDERS OF THE COMPANY ARE URGED TO READ ALL RELEVANT DOCUMENTS FILED WITH OR FURNISHED TO THE SEC, INCLUDING THE COMPANY'S DEFINITIVE PROXY STATEMENT AND ANY SUPPLEMENTS THERETO, BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION.

Investors and stockholders will be able to obtain a copy of the definitive proxy statement and other documents filed by the Company free of charge from the SEC's website, www.sec.gov. The Company's stockholders will also be able to obtain, without charge, a copy of the definitive proxy statement and other relevant filed documents by directing a request by mail to CytoDyn Inc. at 1111 Main Street, Suite 660, Vancouver, Washington 98660.

Participants in the Solicitation

The Company, its directors and certain of its executive officers will be deemed participants in the solicitation of proxies from stockholders in respect of the 2021 Annual Meeting. Information regarding the names of the Company's directors and executive officers and their respective interests in the Company by security holdings or otherwise is set forth in the Company's Annual Report on Form 10-K for the fiscal year ended May 31, 2021, filed with the SEC on July 30, 2021, and the Company's definitive proxy statement for the 2020 annual meeting, filed with the SEC on September 1, 2020. To the extent holdings of such participants in the Company's securities have changed since the amounts described in the proxy statement for the 2020 annual meeting, such changes have been reflected on Initial Statements of Beneficial Ownership on Form 3 or Statements of Change in Ownership on Form 4 filed with the SEC. These documents can be obtained free of charge from the sources indicated above. Additional information regarding the interests of these participants in any proxy solicitation and a description of their direct and indirect interests, by security holdings or otherwise, will also be included in any proxy statement and other relevant materials to be filed with the SEC, if and when they become available.

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