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 22, 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 22, 2021, CytoDyn Inc. (the "Company") issued a press release announcing that the Company has received clearance from Brazil's regulatory authority, ANVISA (Agência Nacional de Vigilância Sanitária), to commence a pivotal Phase 3 trial in critically ill COVID-19 patients with IV administration of four doses (700 mg/week).

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 22, 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 22, 2021

CYTODYN INC.

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

Exhibit 99.1

CytoDyn Receives Clearance from Brazil's FDA (ANVISA) to Commence a Pivotal Phase 3 Trial in Critically Ill COVID-19 Patients with IV Administration of Four Doses (700mg/week)

VANCOUVER, Washington – September 22, 2021 – 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, today announced that Brazil's regulatory authority, ANVISA (Agência Nacional de Vigilância Sanitária), has approved the start of an additional Phase 3 CD16 clinical trial of leronlimab.

The new clinical trial will focus on hospitalized COVID-19 patients in critical condition who require mechanical and invasive ventilation or Extracorporeal Membrane Oxygenation (ECMO). The trial will be carried out across 22 research centers with a total of 316 patients. An interim analysis will be conducted after 40% of the patients have been enrolled and have completed a 28-day trial. The first goal for this trial is to enroll 127 patients as soon as possible.

The Academic Research Organization (ARO) Albert Einstein Israelite Hospital (AEIH) in Brazil will conduct the trial in coordination with CytoDyn and BIOMM, the Company's exclusive partner for the commercialization of leronlimab in Brazil.

Nader Pourhassan, Ph.D., CytoDyn's President and Chief Executive Officer, commented:

"We are excited about this news and what it means for leronlimab's potential ability to successfully treat critically ill COVID-19 patients in the future all over the world. We believe the IV treatment in this trial will have an enormous advantage over treatment via subcutaneous (SQ) injections, which was the route of administration in our last COVID-19 trial (CD12) in the US.

Absorption of leronlimab into the body occurs within one to two hours post IV administration. In contrast, SQ injection could be two to three days before leronlimab is completely absorbed. With a critically ill population, time is of the essence. In the previous trial (CD12), we believe that the 30% survival benefit (after 28 days) in the leronlimab arm versus placebo could have been much higher if IV administration had been used instead of SQ and if the treatment was with four dosages instead of only two.

Furthermore, in our CD12 study, the survival benefit in the critically ill population was 78% after the first-week post the first dose of leronlimab and 82% after the second week. The treatment with leronlimab was only for two doses (day 0 and day 7); from day 14 to 28, the survival rate declined from 82% to 30%, respectively in the absence of additional doses of leronlimab. In this trial (CD16), there will be four doses during the first four weeks of treatment, and with IV administration, we believe our chance of success is much improved. Furthermore, the primary endpoint in this study (CD16) is time to recovery. This similar endpoint in the previous study (CD12) showed the time to discharge from hospital to be 166% better than placebo in the critically ill population. This is why we are very excited to see the results of the interim analysis. We continue to be grateful to the ARO and BIOMM teams for their work in getting us to this point."

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 in HIV-infected patients who were heavily treatment-experienced individuals with limited treatment options. CytoDyn is working diligently to resubmit its 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. 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 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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