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): March 16, 2021 (March 11, 2021)

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

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 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 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers

Effective March 11, 2021, CytoDyn Inc. (the "Company") appointed Dr. Christopher P. Recknor, M.D. as Chief Operating Officer.

Dr. Recknor, 56, joined the Company in August 2020 as Vice President, Clinical Development. Prior to joining the Company, Dr. Recknor served as a principal investigator in over 100 clinical trials for numerous global pharmaceutical companies. He is also the founder of IONmed Systems, a software technology company formed in 2006 with a focus on clinical trial recruitment and management, and owner of the Center for Advanced Research & Education (CARE), a private research facility formed in 2002. Dr. Recknor was an Adjunct Assistant Professor at Clemson University from 2002 to 2004, a medical director at United Osteoporosis Centers from 1998 to 2013 and was in private practice from 1998 to 2015. Dr. Recknor has a deep background in clinical research, with over 40 published research studies and co-authored several research abstracts. Dr. Recknor holds a B.A. from Furman University and received his M.D. from Medical University of South Carolina. He is a former Diplomate of the American Board of Internal Medicine and is a Certified Clinical Densitometrist.

The Company has entered into an employment agreement with Dr. Recknor under which he will be employed by us at an at-will basis, and which contains the following terms regarding his compensation: Dr. Recknor will receive an annual base salary of $400,000. He is eligible to participate in our short- and long-term incentive plans in which other executive officers may participate, with a short term target annual bonus equal to 50% of his base salary, and other customary benefits for which he is qualified as an executive officer of the Company and which will be described in his employment agreement. Dr. Recknor is also entitled to severance in the event his employment is terminated by the Company without cause, equal to 12 months of his base salary (or a prorated amount if his employment is terminated prior to the one year anniversary), or, in the event the Company experiences a change of control during his employment, and there is a termination of his employment without cause during the 12 months following the change of control, Dr. Recknor will receive severance equal to 18 months of his base salary in effect in the year in which his termination occurs, plus the Company will accelerate the vesting on any equity grant previously made to him under the Company's Amended and Restated 2012 Stock Incentive Plan.

The foregoing description of Dr. Recknor's Employment Agreement is not complete and will be qualified in its entirety by reference to the complete text of the Employment Agreement, a copy of which will be filed as an exhibit to the Company's next Form 10-Q.

There are no family relationships, as defined in Item 401 of Regulation S-K, between Dr. Recknor and any of the Company's executive officers or directors or persons nominated or chosen to become a director or executive officer. There are no arrangements or understandings between Dr. Recknor and any other persons pursuant to which he was selected as an officer. Dr. Recknor has no direct or indirect material interest in any transaction required to be disclosed pursuant to Item 404(a) of Regulation S-K, other than as described below.

The Center for Advanced Research & Education, LLC ("CARE"), owned by Dr. Recknor's spouse, Julie Recknor, Ph.D., is one of several clinical locations for the Company's ongoing NASH and COVID-19 long-hauler clinical trials, and was a clinical location for the Company's completed Phase 2b/3 mild-to-moderate and severe-to-critical COVID-19 clinical trials. Dr. Julie Recknor serves as the Site Director of CARE and manages its day-to-day operations. The Company entered into a Clinical Trial Agreement ("CTA") with CARE for each of these clinical trials. Each CTA was negotiated in the ordinary course of business by Amarex, the Company's Clinical Research Organization, prior to Dr. Chris Recknor's appointment as COO, and the operational and financial terms of the CTA with CARE are comparable to the terms available to unrelated clinical locations. Dr. Recknor was not involved in the Company's decision to choose CARE as a clinical location for its ongoing trials, and he is not involved in patient recruitment at the CARE site. During the fiscal year ended May 31, 2020, the Company made no payments to CARE as it had not yet received any services under the one CTA in effect prior to this time. The Company expects to make payments to CARE during the fiscal year ending May 31, 2021 and thereafter of approximately $2.5 million, which is based upon the total number of patients that enrolled in the Company's previously completed trials and the number of patients that may enroll in the Company's current clinical trials. On November 17, 2020, the Company and Dr. Chris Recknor entered into a subscription agreement pursuant to which Dr. Chris Recknor purchased approximately 0.67 million shares of Company common stock for a purchase price of $1.0 million.

Item 7.01. Regulation FD Disclosure.

On March 16, 2021, the Company issued a press release relating to the announcement described above, a copy of which is furnished as Exhibit 99.1 to this report.

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. 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 affecting the Company, 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 Current Report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated March 16, 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: March 16, 2021

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

CytoDyn Appoints Christopher Recknor, M.D., as Chief Operating Officer

Dr. Recknor will continue to oversee the Company's COVID-19 long-haulers and Phase 2 NASH trials

VANCOUVER, Washington, March 16, 2021 (GLOBE NEWSWIRE) —**CytoDyn Inc. (OTC.QB: CYDY)**, ("CytoDyn" or the "Company"), a late-stage biotechnology company developing Vyrologix™ (leronlimab-PRO 140), a CCR5 antagonist with the potential for multiple therapeutic indications, announced today the appointment of Christopher P. Recknor, M.D. to the executive position of Chief Operating Officer. In his role as COO, Dr. Recknor will assist the senior management team to define and implement the overall business strategy and clinical development priorities, along with the requisite timelines.

Dr. Recknor joined CytoDyn in August 2020 as Vice President, Clinical Development. Before joining CytoDyn, Dr. Recknor served as a principal investigator in over 100 clinical trials for numerous global pharmaceutical companies including Amgen, AstraZeneca, Eli Lilly, Glaxo SmithKline, Merck, Novartis and Pfizer. He has a deep background in clinical research with over 40 published research studies and co-authored several research abstracts. Dr. Recknor holds a B.A. from Furman University and received his M.D. from the Medical University of South Carolina. He completed his residency in internal medicine at the Medical University of South Carolina. He is a former Diplomate of the American Board of Internal Medicine.

Nader Pourhassan, Ph.D., President and Chief Executive Officer of CytoDyn, commented, "We are very pleased Dr. Recknor is joining our executive team. Dr. Recknor has demonstrated exemplary clinical trial management skills coupled with strong business acumen. With his broad experience in clinical operations, Dr. Recknor will effectively accelerate the evaluation of several indications in our pipeline."

About Leronlimab (PRO 140)

The FDA has granted a Fast Track designation to CytoDyn for two potential indications of leronlimab for critical illnesses. The first indication is 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 important in HIV infection, tumor metastases, and other diseases, including NASH. Leronlimab has completed 11 clinical trials in over 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).

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.

Research has shown that CCR5 may play a role in tumor invasion, metastases, and tumor microenvironment control in the setting of cancer. 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 by the FDA 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 transplanted bone marrow stem cells' engraftment. CytoDyn was 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 granted orphan drug designation to leronlimab for the prevention of GvHD. Due to the lack of patients during the COVID-19 pandemic, the Company suspended its Phase 2 trial for acute 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 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 calendar year 2021.

CytoDyn has completed 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 the viral burden in people infected with HIV. No severe drug-related site injection reactions were reported in about 800 patients treated with leronlimab, and no drug-related SAEs were reported in patients treated with 700 mg of leronlimab. Moreover, a Phase 2b clinical trial demonstrated that leronlimab monotherapy could prevent viral escape in HIV-infected patients; some patients on leronlimab monotherapy have remained virally suppressed for more than six years.

CytoDyn is also conducting a Phase 1b/2 clinical trial with leronlimab in metastatic triple-negative breast cancer. 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 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 Form10-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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