

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549**

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**FORM 8-K**

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**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 17 2020**

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**CytoDyn Inc.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction  
of incorporation)

**000-49908**  
(SEC  
File Number)

**83-1887078**  
(I.R.S. Employer  
Identification No.)

**1111 Main Street, Suite 660**  
**Vancouver, Washington**  
(Address of principal executive offices)

**98660**  
(Zip Code)

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

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

*Director Appointment*

On April 17, 2020, the Board of Directors (the “Board”) of CytoDyn Inc. (the “Company”) appointed Samir R. Patel, M.D. as a director of the Company.

In connection with Dr. Patel’s appointment as a director, on April 17, 2020, the Board approved a grant of a Non-qualified Stock Option to purchase 12,329 shares of the Company’s common stock, \$0.001 par value per share (the “Common Stock”), representing a pro rata portion of the annual option grant received by each director. The option has an exercise price of \$2.25 per share, which was the closing sale price of the Company’s Common Stock on the grant date, and a ten-year term. The option will fully vest on May 31, 2020.

No arrangement or understanding exists between Dr. Patel and any other person pursuant to which Dr. Patel was appointed as a director. Dr. Patel will be compensated for his services as a director consistent with the Company’s compensation policies for nonemployee directors. The Board has not yet determined the committees of the Board to which Dr. Patel will be appointed.

**Item 7.01. Regulation FD Disclosure.**

On April 20, 2020, the Company issued a press release to announce the appointment of Dr. Patel as director, which is furnished as Exhibit 99.1 to this Form 8-K.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits. The following exhibits are filed herewith:

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press release dated April 20, 2020</a>

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**SIGNATURES**

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.

CytoDyn Inc.

April 23, 2020

By: /s/ Craig S. Eastwood

Name: Craig S. Eastwood

Title: Chief Financial Officer



### CytoDyn Appoints Samir Patel, M.D., to its Board of Directors

VANCOUVER, Washington, April 20, 2020 (GLOBE NEWSWIRE) -- **CytoDyn Inc. (OTC:QB: CYDY)**, (“CytoDyn” or the “Company”), a late-stage biotechnology company developing leronlimab (PRO 140), a CCR5 antagonist with the potential for multiple therapeutic indications, announced today Samir R. Patel, M.D., has joined its Board of Directors (the “Board”).

Dr. Patel is an active entrepreneur serving as co-founder and CEO of Digital Therapeutics, LLC, co-founder of SPEC Pharma, LLC, consultant for GE Global Research, and principal in PranaBio Investments, LLC, which provides strategic advisory services for small cap biotechnology companies. Previously he was Medical Director at Centocor, Inc., (now Janssen Biotech, Inc.) a Johnson & Johnson Company. Dr. Patel is board certified in rheumatology and was in medical practice in Austin, Texas. He has published several papers from his clinical research studies. Dr. Patel received his BS in Biology from University of Cincinnati, Doctor of Medicine from Medical College of Ohio, and completed his internal medicine internship and residency, as well as rheumatology fellowship at University of New Mexico School of Medicine Affiliated Hospitals.

Dr. Patel commented, “I am honored to have the opportunity to join CytoDyn’s Board at this important time. The Company is in a very unique position to have such a broad array of potential clinical indications to explore with leronlimab. I look forward to working closely with the entire CytoDyn team to advance the Company’s drug for the benefit of patients and our shareholders.”

Dr. Scott Kelly, Chairman of the Board, Chief Medical Officer and Head of Business Development, added, “We are very pleased Dr. Patel has joined our Board. He brings a wealth of experience, which uniquely combines his medical training, inventorship, clinical research and broad business experience in the biotechnology space. We are excited to have Dr. Patel on our team.”

#### **About Coronavirus Disease 2019**

CytoDyn is currently enrolling patients in two clinical trials for COVID-19, a Phase 2 randomized clinical trial for mild-to-moderate COVID-19 population in the U.S. and a Phase 2b/3 randomized clinical trial for severe and critically ill COVID-19 population.

SARS-CoV-2 was identified as the cause of an outbreak of respiratory illness first detected in Wuhan, China. The origin of SARS-CoV-2 causing the COVID-19 disease is uncertain, and the virus is highly contagious. COVID-19 typically transmits person to person through respiratory droplets, commonly resulting from coughing, sneezing, and close personal contact. Coronaviruses are a large family of viruses, some causing illness in people and others that circulate among animals. For confirmed COVID-19 infections, symptoms have included fever, cough, and shortness of breath. The symptoms of COVID-19 may appear in as few as two days

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or as long as 14 days after exposure. Clinical manifestations in patients have ranged from non-existent to severe and fatal. At this time, there are minimal treatment options for COVID-19.

#### **About Leronlimab (PRO 140)**

The FDA has granted a “Fast Track” designation to CytoDyn for two potential indications of leronlimab for deadly diseases. The first is a 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 that is important in HIV infection, tumor metastases, and other diseases, including NASH. Leronlimab has completed nine clinical trials in over 800 people, including meeting its primary endpoints in a pivotal Phase 3 trial (leronlimab in combination 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.

In the setting of cancer, research has shown that 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 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 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 the engraftment of transplanted bone marrow stem cells. CytoDyn is currently 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 has granted “orphan drug” designation to leronlimab for the prevention of 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 in combination with standard antiretroviral therapies in HIV-infected treatment-experienced patients. CytoDyn plans to seek FDA approval for

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leronlimab in combination therapy and plans to complete the filing of a Biologics License Application (BLA) in April of 2020 for that indication. CytoDyn is also conducting 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 viral burden in people infected with HIV with no reported drug-related serious adverse events (SAEs). Moreover, a Phase 2b clinical trial demonstrated that leronlimab monotherapy can prevent viral escape in HIV-infected patients; some patients on leronlimab monotherapy have remained virally suppressed for more than five years. CytoDyn is also conducting a Phase 2 trial to evaluate leronlimab for the prevention of GvHD and a Phase 1b/2 clinical trial with leronlimab in metastatic triple-negative breast cancer. More information is at [www.cytodyn.com](http://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 have 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.

#### **CYTODYN CONTACTS**

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**Investors:**

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