
**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): May 20, 2021 (May 18, 2021)

CytoDyn Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

000-49908
(Commission
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

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.

On May 18, 2021, the Board of Directors of CytoDyn Inc. (the “Company”) appointed Antonio Migliarese, the Company’s current Vice President, Corporate Controller, as Chief Financial Officer and Treasurer of the Company. Mr. Migliarese succeeds Michael D. Mulholland who will be assuming the role of Senior Vice President of Finance and will continue to support the Company in an advisory role.

Mr. Migliarese is currently employed by the Company on an at-will basis at an annual base salary of \$225,000. The Compensation Committee will be meeting to finalize an employment agreement with Mr. Migliarese and formalize his compensation to be consistent with the compensation structure of other executive officers of the Company.

Mr. Migliarese, 37, has had various positions with increasing responsibilities since joining the Company on January 16, 2020. Prior to joining the Company, Mr. Migliarese was the Controller for Domaine Serene Vineyards and Winery, Inc. from 2018 to 2020, Corporate Controller for Lightspeed Technologies, Inc. from 2015 to 2018, and CFO of Hollister & Blacksmith, Inc. from 2014 to 2016. Mr. Migliarese is a Certified Public Accountant and began his career in the assurance group of PricewaterhouseCoopers (PwC).

There are no family relationships, as defined in Item 401 of Regulation S-K, between Mr. Migliarese 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 Mr. Migliarese and any other persons pursuant to which he was selected as Chief Financial Officer and he has no direct or indirect material interest in any transaction required to be disclosed pursuant to Item 404(a) of Regulation S-K.

On May 20, 2021, the Company issued a press release announcing the promotion of Antonio Migliarese to Chief Financial Officer of CytoDyn. A copy of the press release is furnished as Exhibit 99.1 to this current report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated May 20, 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: May 20, 2021

By: /s/ Arian Colachis
Arian Colachis
Senior Vice President, General Counsel and Corporate Secretary



Antonio Migliarese Promoted to Chief Financial Officer of CytoDyn

VANCOUVER, Washington, May 20, 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 promotion of Antonio Migliarese to Chief Financial Officer of the Company. Mr. Migliarese joined CytoDyn in January 2020, and previously served as Vice President, Corporate Controller.

Former Chief Financial Officer Michael D. Mulholland will assume the role of Senior Vice President of Finance and continue to support the Company in an advisory role. “Unfortunately, for unexpected personal reasons I have had to make the difficult decision to assume a less demanding role to allow for more personal time for my family and myself. I fully support Antonio’s appointment as the Company’s next CFO, which is in-line with the Company’s succession plan. I am very proud of what our team has achieved over the past several years and am delighted to continue to support Nader and Antonio in an advisory capacity as Senior Vice President of Finance,” commented Mr. Mulholland.

“We are pleased to announce the promotion of Antonio to the CFO role. Since joining CytoDyn, Antonio has made significant contributions to the Company, taking on increasing scope and responsibilities and leading the charge of the financial organization as we transition from being a pre-revenue research and development-driven biotech company, to a fully functional commercial organization,” said Dr. Nader Pourhassan, Ph.D., President and CEO of CytoDyn. “We are excited to have Antonio join our executive team. Michael Mulholland has helped prepare Antonio for this role and is equally pleased about this move. Under the financial leadership of Michael, CytoDyn successfully raised nearly half a billion dollars of capital propelling the Company to where it is today. I am personally grateful for Michael and for his dedication, hard work and willingness to continue to support the Company in his new role.”

“I am thrilled to continue to take on increased responsibilities and move into the role of CFO at CytoDyn,” said Migliarese. “I look forward to contributing to the CytoDyn executive team, and continuing to create, drive and execute on the vision of CytoDyn’s financial organization, ensuring the Company is properly equipped for its next phase of growth and successful in doing so. I am even more excited Michael has gratefully chosen to continue to serve and provide us with his wealth of knowledge and experience.”

Mr. Migliarese will lead CytoDyn's financial organization. Mr. Migliarese is a Certified Public Accountant and a graduate of Oregon State University, with a BS in Accounting. Mr. Migliarese has held various senior financial leadership positions at both public and private companies since 2014. He has a wide array of experience including strategic planning, FP&A, SEC reporting, internal controls, process improvement, IT, preparing companies to go public, treasury, and debt, equity and M&A transactions. Prior to CytoDyn Mr. Migliarese was the Controller for Domaine Serene Winery and Vineyards, Inc. from 2018 to 2020, Corporate Controller for Lightspeed Technologies Inc. from 2015 to 2018, and CFO of Hollister & Blacksmith, Inc. from 2014 to 2016. Prior to this time, Mr. Migliarese provided outsourced Controller and CFO services to a variety of companies and served as the Financial Reporting Manager for a technology company. Mr. Migliarese began his career in the assurance group of PricewaterhouseCoopers (PwC).

About Vyologix™ (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 SARS-CoV-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. 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 appears to play 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 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 2/b3 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. Several patients on leronlimab’s Phase 2b/3 monotherapy extension arm have remained virally suppressed for more than six years.

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). 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 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

Investors:

Cristina De Leon

Office: 360.980.8524

cdeleon@cytodyn.com