
**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): January 15, 2020

CytoDyn Inc.

(Exact name of registrant as specified in its charter)

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

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.

Appointment of Director

On January 18, 2020, CytoDyn Inc., a Delaware corporation (the “Company”), announced the appointment of Alan P. Timmins to its board of directors (the “Board”), effective immediately.

In connection with Mr. Timmins’ appointment as a director, on January 18, 2020, the Company granted Mr. Timmins a non-qualified stock option to purchase up to 36,986 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 \$1.05 per share, which was the closing sale price of the Company’s Common Stock on the trading day prior to the grant date, and a ten-year term. The option will vest on March 1, 2020 with respect to 11,986 shares of Common Stock and on June 1, 2020 with respect to 25,000 shares of Common Stock.

No arrangement or understanding exists between Mr. Timmins and any other person pursuant to which Mr. Timmins was appointed as a director. Mr. Timmins will be compensated for his services consistent with the Company’s compensation policies for nonemployee directors. The Company’s Board appointed Mr. Timmins to serve as the Chair of the Audit Committee and a member of the Nominating and Corporate Governance Committee.

Resignation of Director

On January 15, 2020, Michael A. Klump resigned as a member of the Board, effective immediately. Mr. Klump’s resignation is not related to any known disagreement with the Company on any matters relating to its operations, policies or practices.

Item 7.01. Regulation FD Disclosure

On January 21, 2020, the Company issued a press release relating to the information set forth above, a copy of which is furnished as Exhibit 99.1 to this Form 8-K.

Item 9.01 Financial Statements and Exhibits.

| <u>(d) Exhibit No.</u> | <u>Description</u> |
|------------------------|--|
| 99.1 | <u>Press Release dated January 21, 2020.</u> |

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.

January 21, 2020

CytoDyn Inc.

By: /s/ Craig S. Eastwood

Name: Craig S. Eastwood

Title: Chief Financial Officer



CytoDyn Appoints Alan Timmins as New Independent Director and Chair of the Audit Committee

VANCOUVER, Washington, Jan. 21, 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 that Alan P. Timmins, former President, Chief Operating Officer, and Board Member of Sarepta Therapeutics, Inc., a Nasdaq-listed company, has joined its board of directors as an independent director and chair of the board’s Audit Committee.

Timmins brings a wealth of financial and operations experience to CytoDyn’s board. He previously served 16 years in various positions including President, Executive Vice President, Chief Operating Officer and Chief Financial Officer of Sarepta Therapeutics, Inc., a publicly traded life sciences technology company focused on precision genetic medicine. His leadership and drive contributed to a period of significant growth and he led several of the company’s strategic, financing, M&A and out-licensing activities. He is currently the Vice President for Financial Affairs at the University of Portland, a position he has served in for over 8 years, focusing on all financial functions and on strategic planning and implementation across the organization. Earlier in his career, Timmins was a Senior Manager at PriceWaterhouseCoopers in the audit practice.

Timmins has also served as a member of boards of directors and as a volunteer for several public, private and not-for-profit companies, providing support in the areas of finance, business development, strategy, operations management and career planning, as well as doing guest lectures and seminars for area graduate and undergraduate students.

“Over the course of his career, Alan has led major growth initiatives – he was a key member of the team that built Sarepta Therapeutics into the company is it today, negotiating major commercial and governmental contracts, raising approximately \$250 million, completing a strategic acquisition, and finalizing two out-licensing transactions,” said Scott Kelly, M.D., CytoDyn’s Chairman of the Board. “Alan has accumulated an impressive array of strategic, financial and commercial achievements and has demonstrated his ability to be a successful and trusted leader. His breadth of experience will be instrumental to the Audit Committee and to CytoDyn as a whole.”

“I am pleased to be joining the CytoDyn board of directors at this important time in the Company’s development,” said Timmins. “Helping the Company reach its considerable potential in the important therapeutic areas of HIV, cancer and immunology will be a worthy and challenging goal, and I look forward to assisting management and the board in reaching that goal.”

Scott Kelly, M.D. added, "I would like to extend my sincerest gratitude to Michael Klump for serving on the board of directors of CytoDyn. Michael provided us with invaluable guidance and vision at a critical time for our company. Michael remains an ardent supporter of the science of CytoDyn and a significant investor. While Michael's increasing business responsibilities drove his decision to step down from our board, I am thrilled that he will remain an advisor to both the CEO and Chairman of the Board."

About Leronlimab (PRO 140)

Leronlimab (PRO 140) is a humanized IgG4 monoclonal antibody that blocks CCR5, a cellular receptor that plays multiple roles with implications in HIV infection, tumor metastasis, and immune signaling.

In the setting of HIV/AIDS, leronlimab belongs to a new class of therapeutics called viral-entry inhibitors; it masks CCR5, thus protecting healthy T cells from viral infection by blocking the predominant HIV (R5) subtype from entering those cells. At the same time, leronlimab does not appear to interfere with the normal function of CCR5 in mediating immune responses. Leronlimab has been the subject of seven clinical trials, each demonstrating efficacy by significantly reducing or controlling HIV viral load in human test subjects. Leronlimab has been designated a "fast track" product by the FDA. 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 plays a central role in tumor invasion and metastasis and that increased CCR5 expression is an indicator of disease status in breast cancer. Moreover, researchers have shown that drugs that block CCR5 can block tumor metastases in laboratory and animal models of aggressive breast and prostate cancer. CytoDyn is conducting additional research with leronlimab in the cancer setting and has initiated a Phase 1b/2 human clinical trial, as recently approved in 2018 by the FDA.

The CCR5 receptor also plays a central role in modulating immune cell trafficking to sites of inflammation and it is crucial for the development of acute graft-versus-host disease (GvHD) and other inflammatory conditions. Clinical studies by others have shown 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 further support the concept that the CCR5 receptor on engrafted cells is critical for the development of acute GvHD and that blocking this receptor from recognizing certain 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 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 key 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 in immune-mediated illnesses, such as GvHD and NASH. CytoDyn has successfully completed a Phase 3 pivotal trial with leronlimab in combination with standard anti-retroviral therapies in HIV-infected treatment-

experienced patients. CytoDyn plans to seek FDA approval for leronlimab in combination therapy and plans to complete the filing of a Biologics License Application (BLA) in the first quarter of 2020 for that indication. CytoDyn is also conducting a Phase 3 investigative trial with leronlimab (PRO 140) as a once-weekly monotherapy for HIV-infected patients and, plans to initiate a registration-directed study of leronlimab monotherapy indication, which if successful, could support a label extension. Clinical results to date from multiple trials have shown that leronlimab (PRO 140) can significantly reduce viral burden in people infected with HIV with no reported drug-related serious adverse events (SAEs). Moreover, results from a Phase 2b/3 clinical trial demonstrated that leronlimab monotherapy can prevent viral escape in HIV-infected patients, with some patients on leronlimab monotherapy remaining 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.

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. 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

Media:

Grace Fotiades
LifeSci Communications
gfortiades@lifescicomms.com
(646) 876-502

Investors:

Nader Pourhassan, Ph.D.
President & CEO
npourhassan@cytodyn.com