

CytoDyn Inc.
Form 8-K
July 12, 2018

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): July 10, 2018

CytoDyn Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction

of incorporation)

000-49908
(SEC

File Number)

75-3056237
(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))
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 July 12, 2018, CytoDyn Inc., a Delaware corporation (the Company), announced certain leadership changes in connection with the strategic expansion and entry into the letter of intent described in Item 8.01 below.

In connection with such leadership changes, Denis R. Burger, Ph.D. and A. Bruce Montgomery, M.D. have resigned as members of the Company's Board of Directors. Dr. Burger and Dr. Montgomery informed the Company of their intention to resign at the conclusion of a board meeting on July 10, 2018, and the resignations became effective on July 11, 2018. The resignations were not the result of any disagreement with the Company on any matter relating to the Company's operations, policies or practices. Dr. Burger has also resigned as Chief Science Officer of the Company, which is not an executive officer position, but will continue to serve as a scientific consultant to the Company with respect to PRO 140 for human immunodeficiency virus (HIV) and non-HIV development programs.

In connection with the resignations of Dr. Burger and Dr. Montgomery, on July 10, 2018, the Company's Board of Directors approved a motion to accelerate all outstanding unvested stock options held by Dr. Burger and Dr. Montgomery, to vest immediately upon the effectiveness of their resignations and to retain the stock options exercise period through their respective expiration date. Stock options covering 500,000 shares held by Dr. Burger and stock options covering 100,000 shares held by Dr. Montgomery were subject to acceleration. The terms of the stock options remained otherwise unchanged.

Also, effective July 11, 2018, Anthony D. Caracciolo resigned as Executive Chairman of the Company, which is an executive officer position. Mr. Caracciolo will continue to serve as a member and the non-executive Chairman of the Company's Board of Directors.

Item 7.01 Regulation FD Disclosure.

On July 12, 2018, CytoDyn Inc., a Delaware corporation (the Company), issued press releases relating to the announcements described in Item 5.02 above and Item 8.01 below. Copies of the press releases are furnished as Exhibits 99.1 and 99.2 to this Form 8-K.

Item 8.01 Other Events.

On July 12, 2018, the Company announced a strategic expansion of its clinical focus to include the evaluation of PRO 140 in certain cancers and immunological indications where CCR5 antagonism has shown initial promise.

In connection with such expansion, on July 12, 2018, the Company signed a non-binding letter of intent regarding a proposed acquisition of intellectual property and other assets of ProstaGene LLC (ProstaGene), a privately held company focused on prostate cancer diagnostics and therapeutics aimed at blocking cancer metastasis by blocking CCR5. At the same time, the Company remains committed to advancing its clinical programs with PRO 140 in HIV and graft-versus-host disease (GvHD), and is continuing with its previously announced plans to submit a Biologics License Application to the U.S. Food and Drug Administration (the FDA) for PRO 140 as a combination therapy for HIV.

As part of the proposed transaction with ProstaGene, Richard G. Pestell, M.D., Ph.D., M.B.A., F.A.C.P., F.R.A.C.P., the Chief Executive Officer of ProstaGene and President of the Pennsylvania Cancer and Regenerative Medicine Research Center, will join the Company as Chief Medical Officer. It is also expected that Dr. Pestell will join the Company's Board of Directors at the closing of the transaction. The transaction is subject to completion of due diligence review, customary definitive documentation, deal structure and requisite corporate and regulatory approvals. The final terms of the transaction will be available upon the execution of definitive documentation.

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, including statements regarding the proposed transaction with ProstaGene, the likelihood of closing the proposed transaction with ProstaGene, the Company's clinical focus, and the Company's current and proposed trials. Words and expressions reflecting optimism, satisfaction or disappointment with current prospects, as well as words such as believes, hopes, intends, estimates, expects, projects, plans, anticipate, 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 differ materially from those contained in or expressed by such statements. In evaluating all such statements, the Company urges investors to specifically consider the various risk factors identified in the Company's Form 10-K for the fiscal year ended May 31, 2017 in the section titled "Risk Factors" in Part I, Item 1A, as supplemented by its Form 10-Q for the quarterly period ended February 28, 2018 in the section titled "Risk Factors" in Part II, Item 1A, any of which could cause actual results to differ materially from those indicated by the Company's forward-looking statements.

The Company's forward-looking statements reflect its current views with respect to future events and are based on currently available financial, economic, scientific, and competitive data and information on current business plans. Investors should not place undue reliance on the Company's forward-looking statements, which are subject to risks and uncertainties relating to, among other things: (i) the sufficiency of the Company's cash position and the Company's ongoing ability to raise additional capital to fund its operations, (ii) the Company's ability to complete its Phase 2b/3 pivotal combination therapy trial for PRO 140 (CD02) and to meet the FDA's requirements with respect to safety and efficacy to support the filing of a Biologics License Application, (iii) the Company's ability to meet its debt obligations, if any, (iv) the Company's ability to identify patients to enroll in its clinical trials in a timely fashion, (v) the Company's ability to achieve approval of a marketable product, (vi) design, implementation and conduct of clinical trials, (vii) the results of the Company's clinical trials, including the possibility of unfavorable clinical trial results, (viii) the market for, and marketability of, any product that is approved, (ix) the existence or development of vaccines, drugs, or other treatments for infection with HIV that are viewed by medical professionals or patients as superior to the Company's products, (x) regulatory initiatives, compliance with governmental regulations and the regulatory approval process, (xi) general economic and business conditions, (xii) changes in foreign, political, and social conditions, and (xiii) various other matters, many of which are beyond the Company's control. Should one or more of these risks or uncertainties develop, or should underlying assumptions prove to be incorrect, actual results may vary materially and adversely from those anticipated, believed, estimated, or otherwise indicated by the Company's forward-looking statements.

The Company intends that all forward-looking statements made in this Current Report on Form 8-K will be subject to the safe harbor protection of the federal securities laws pursuant to Section 27A of the Securities Act of 1933, as amended, to the extent applicable. Except as required by law, the Company does not undertake any responsibility to update these forward-looking statements to take into account events or circumstances that occur after the date of this Current Report on Form 8-K. Additionally, the Company does not undertake any responsibility to update investors upon the occurrence of any unanticipated events which may cause actual results to differ from those expressed or implied by these forward-looking statements.

Item 9.01 Financial Statements and Exhibits.

(d)	Exhibit No.	Description.
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99.1 Press Release, dated July 12, 2018

99.2 Press Release, dated July 12, 2018

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.

July 12, 2018

By: */s/ Michael D. Mulholland*
Name: Michael D. Mulholland
Title: Chief Financial Officer