# 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** | **000-49908** | **75-3056237** |
|---|---|---|
| **(State or other jurisdiction of incorporation)** | **(SEC File Number)** | **(I.R.S. Employer Identification No.)** |

| **1111 Main Street, Suite 660**<br>**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))

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," "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 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. |
|---|---|---|
| | 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

**Exhibit 99.1**

**CytoDyn to Expand Strategic Focus with PRO 140 to Cancer and Immunologic Disorders**

- **Announces non-binding Letter of Intent to acquire CCR5-focused cancer company ProstaGene LLC**
- **Maintains commitment to advancing PRO 140 clinical programs in HIV and graft-versus-host disease**
- **Advancing plans to submit BLA for PRO 140 in combination therapy for HIV**

**VANCOUVER, Washington (July 12, 2018) –** CytoDyn Inc. (OTC.QB: CYDY), a biotechnology company developing a novel humanized CCR5 monoclonal antibody, announces 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, the Company has signed a non-binding letter of intent regarding the potential acquisition of ProstaGene LLC, a privately held company focused on prostate cancer diagnostics and therapeutics aimed at blocking cancer metastasis by blocking CCR5. At the same time, CytoDyn remains committed to advancing its clinical programs with PRO 140 in human immunodeficiency virus (HIV) and graft-versus-host disease (GvHD), and is continuing with its previously announced plans to submit a Biologics License Application (BLA) for PRO 140 as a combination therapy for HIV.

"We are beginning an exciting new era at CytoDyn that builds upon the scientific promise of PRO 140 and the expansion of our clinical focus," said Anthony Caracciolo, CytoDyn's Chairman. "We believe it is in the best interest of our shareholders, patients and the medical community to advance the evaluation of PRO 140 in these new indications, while pursing partnership opportunities to support all of our development programs. Given our substantial and growing clinical experience with PRO 140, we have confidence in its safety and efficacy profiles. Recent studies indicate potential opportunities for PRO 140 in multiple indications beyond HIV where CCR5 antagonism may be beneficial. These include oncology, immunology, transplant rejection, chronic inflammation, autoimmunity, and nonalcoholic steatohepatitis (NASH), among others."

The scientific rationale underlying this expanded strategic initiative is the ability of PRO 140 to selectively target the CCR5 receptor. Research conducted by CytoDyn, the laboratories of Richard G. Pestell, M.D., Ph.D., Chief Executive Officer of ProstaGene and President of the Pennsylvania Cancer and Regenerative Medicine Research Center and his collaborators, and others has shown that selectively blocking the CCR5 receptor and the interaction of the chemokine CCL5/RANTES is crucial in modulating immune cell trafficking. In addition, the CCR5 receptor is believed to be vital in cancer cell invasion and metastasis.

"When we evaluated PRO 140 last year in our models of metastatic breast cancer, we were excited to see that the monoclonal antibody detected CCR5 on the tumor cells and blocked their invasiveness, suggesting its potential to block certain metastatic cancers," said Dr. Pestell. "I am very excited to have ProstaGene team with CytoDyn to further explore the potential of PRO 140 as an important addition to the therapeutic arsenal against aggressive cancers."

"We are very pleased to be building on our relationship with Dr. Pestell and his team at ProstaGene, who have been focused on understanding the relationship of the CCR5 receptor to cancer metastasis," Mr. Caracciolo commented. "We look forward to working toward the proposed acquisition of the company's intellectual property and other assets over the coming months."

As part of the potential transaction with ProstaGene LLC, it is expected that Dr. Pestell will join the CytoDyn Board of Directors at the closing of the proposed transaction.

Previous clinical and preclinical studies with PRO 140 and other CCR5 antagonists have demonstrated that blocking CCR5 receptors has potential applications in multiple cancer types. Preclinical research has also shown that treatment with CCR5 inhibitors can inhibit metastasis and invasion of prostate, breast and colon cancers, including patients with treatment-resistant colon cancer. Results of a recent preclinical study conducted in collaboration with the laboratory of Dr. Pestell, and announced by CytoDyn, established that PRO 140 was able to detect CCR5 on metastatic human breast cancer cells and block their invasiveness as effectively as small molecule CCR5 inhibitors.

The contemplated transaction is subject to completion of due diligence review, customary definitive documentation, deal structure and requisite corporate and regulatory approval. The final terms of the proposed acquisition will be available upon the execution of the definitive documents.

**About ProstaGene**

ProstaGene is a biotechnology start-up company that is developing technology based on issued patents of the Founder, Dr. Richard G. Pestell. ProstaGene integrates proprietary molecular diagnostics with novel therapeutic screening and commercial experience in order to develop novel treatments for cancer utilizing its gene-based prostate cancer testing technology and its cancer metastasis prevention and treatment technology. It has issued patents in the U.S.A. and Australia and is prosecuting patents covering its technologies in the United States and major countries around the world. ProstaGene also maintains its gene signature test details as trade secrets. For more information on ProstaGene, please visit http://prostagene.com.

**About PRO 140**

PRO 140 belongs to a new class of HIV/AIDS therapeutics – viral-entry inhibitors – that is intended to protect healthy cells from viral infection. PRO 140 is a humanized IgG4 monoclonal antibody directed against CCR5, a molecular portal that HIV uses to enter T cells. PRO 140 blocks the predominant HIV (R5) subtype entry into T cells by masking this required co-receptor, CCR5. Importantly, PRO 140 does not appear to interfere with the normal function of CCR5 in mediating immune responses. PRO 140 does not have agonist activity toward CCR5 but does have antagonist activity to CCL5, which is a central mediator in inflammatory diseases. PRO 140 has been the subject of seven clinical trials, each demonstrating efficacy by significantly reducing or controlling HIV viral load in human test subjects. PRO 140 has been designated a “fast track” product by the FDA. The FDA also granted orphan drug designation to PRO 140 for the prevention of graft-versus-host disease (GvHD). The PRO 140 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**.**

**About CytoDyn**

CytoDyn is a biotechnology company focused on the clinical development and potential commercialization of humanized monoclonal antibodies for the treatment and prevention of HIV infection, cancer and inflammatory diseases. The Company has one of the leading monoclonal antibodies under development for HIV infection, PRO 140, which has completed Phase 2 clinical trials with demonstrated antiviral activity in humans and is currently in Phase 3 development. PRO 140 blocks the HIV co-receptor CCR5 on T cells, which prevents viral entry. Clinical trial results thus far indicate that PRO 140 does not negatively affect the normal immune functions that are mediated by CCR5. Results from seven Phase 1 and Phase 2 human clinical trials have shown that PRO 140 can significantly reduce viral burden in people infected with HIV. A recent Phase 2b clinical trial demonstrated that PRO 140 can prevent viral escape in patients during several months of interruption from conventional drug therapy. CytoDyn intends to continue to develop PRO 140 as a therapeutic anti-viral agent in persons infected with HIV and to pursue cancer, inflammatory and other non-HIV indications where CCR5 and its ligand CCL5 may be involved. For more information on the Company, please visit http://www.cytodyn.com.

**Forward-Looking Statements**

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**Exhibit 99.2**

**CytoDyn Announces Leadership Changes to Align with Expanded Focus of PRO 140 to Cancer and Immunological Disorders**

**VANCOUVER, Washington (July 12, 2018) –** CytoDyn Inc. (OTC.QB: CYDY), a biotechnology company developing a novel humanized CCR5 monoclonal antibody, announces leadership changes that align with the strategic expansion of its focus with PRO 140 to cancer and immunological disorders, separately announced today.

Richard G. Pestell, M.D., Ph.D., M.B.A., F.A.C.P., F.R.A.C.P., Founder and Chief Executive Officer of ProstaGene LLC and President of the Pennsylvania Cancer and Regenerative Medicine Research Center, part of the Baruch S. Blumberg Institute, will join CytoDyn as Chief Medical Officer.

"We are very pleased to expand and strengthen our relationship with Dr. Pestell, a world leading cancer researcher, whose work has focused on the relationship between CCR5 and metastasis in breast, prostate and other cancers," said Anthony Caracciolo, CytoDyn's Chairman. "As we separately announced today, we have signed a non-binding letter of intent for the proposed acquisition of ProstaGene, which will form an important part of our strategic expansion of PRO 140 development into the cancer and inflammatory space."

"Research has shown CCR5 to be an important receptor involved in tumor cell metastasis and immune cell trafficking, thus making it an interesting therapeutic target for a variety of important disease indications," said Dr. Pestell. "Preclinical research with PRO 140, which blocks the CCR5 receptor, has shown its ability to effectively inhibit cancer cell invasiveness, and CytoDyn's clinical studies of PRO 140 in HIV have shown the antibody to have an excellent safety and tolerability profile in humans. I am very excited to be joining the CytoDyn team to help realize the full therapeutic potential of PRO 140, in the cancer and inflammatory disease setting, as well as HIV treatment and the prevention of graft-vs-host disease."

Other changes, also effective immediately, include the resignation of Denis R. Burger, Ph.D. as Vice Chairman and A. Bruce Montgomery, M.D. as director of the Company's Board of Directors. Dr. Burger has also resigned as Chief Science Officer, but will continue to serve as a scientific consultant to the Company for PRO 140 HIV and non-HIV development programs. Anthony Caracciolo has resigned his operating position as Executive Chairman and will continue to serve as Chairman of the Board.

"On behalf of the CytoDyn Board and our entire organization, I'd like to express our deepest appreciation to our long-serving directors Denis Burger and Bruce Montgomery for their leadership and dedication to advancing the development of PRO 140," said Mr. Caracciolo. "Among their many contributions, Bruce was first to recognize the significant potential value of PRO 140 in GvHD and was instrumental in advancing that program. We give special thanks to Denis for spearheading our non-HIV programs both as Vice Chair of our Board and as a member of senior management, as well as organizing our scientific advisory board."

**About Richard G. Pestell, M.D., Ph.D., FRS of Medicine, M.B.A., F.A.C.P., F.R.A.C.P.**

Dr. Richard G. Pestell is the CEO of ProstaGene, a company he founded to rapidly bring to cancer patients the benefits of novel cancer metastasis therapeutics based on targeting CCR5, and novel prostate cancer diagnostic and prognostic tests. These technologies were discovered while he was Professor and Director of the Sidney Kimmel Cancer Center at Thomas Jefferson University in Philadelphia (2005-2015). Dr. Pestell is an internationally acclaimed clinician and cancer researcher. With more than 600 published works, he is ranked by Google Scholar among the top 10 in the world for oncology, breast cancer and prostate cancer research publication citations. He has received significant national and international awards for both clinical care and cancer research, has directed two National Cancer Institute (NCI)-Designated Cancer Centers (2002-2015), and has served on the advisory board of seven NCI cancer centers, and several international research centers. Since December 2016, he has been President of the Pennsylvania Cancer and Regenerative Medicine Research Center (PCARM) and Distinguished Professor, Translational Medical Research at the Baruch S. Blumberg Institute. Dr. Pestell received his M.B.B.S. from the University of Western Australia, his M.D. and Ph.D. from the University of Melbourne and completed postdoctoral clinical and research fellowships at the Massachusetts General Hospital and Harvard Medical School. He received his Executive MBA from the Stern School of Business of New York University. From 2005 to January 2015, he was Director of the Sidney Kimmel Cancer Center and was an Executive Vice President of Thomas Jefferson University, Philadelphia. He previously served as Chairman of the Department of Oncology, Director of the Lombardi Comprehensive Cancer Center and tenured Professor at Georgetown University, Washington DC.

**About PRO 140**

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