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 4, 2019

CytoDyn Inc.
(Exact name of registrant as specified in its charter)

Delaware	**000-49908**	**83-1887078**
(State or other jurisdiction of incorporation)	**(SEC File Number)**	**(I.R.S. Employer Identification No.)**

1111 Main Street, Suite 660 **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 2.03. Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant.

On January 7, 2019 and January 8, 2019, CytoDyn Inc. (the "Company") issued $1.6 million in aggregate principal amount of unsecured convertible promissory notes (the "Notes") and related warrants (the "Warrants") to purchase common stock of the Company (the "Common Stock") in a private placement to various accredited investors (collectively, the "Private Placements"), pursuant to subscription agreements entered into with each (collectively, the "Subscription Agreements"), in exchange for cash in an equal amount. The proceeds are anticipated to be used for general working capital and to fund clinical trials.

The terms of the Private Placements and of the Notes and the Warrants are identical to those of the private placement that occurred on December 28, 2018 (the "Prior Placement"), as described in the Form 8-K filed with the Securities and Exchange Commission on January 3, 2019 (the "Prior 8-K"), which is incorporated herein by reference. Each of the Notes matures nine months from the date of its initial issuance.

Item 3.02. Unregistered Sales of Equity Securities.

In the Private Placements, the Company sold $1.6 million in aggregate principal amount of Notes and related Warrants to various accredited investors. The principal amount of the Notes plus unpaid accrued interest is convertible at the election of the holders into shares of Common Stock at any time prior to maturity at an initial conversion price of $0.50 per share, with an aggregate of 3,200,000 shares of the Company's Common Stock initially underlying the Notes.

As part of the investment in the Notes, the Company also issued Warrants exercisable for 50% of the shares into which the Notes are convertible, with Warrants for an aggregate of 1,600,000 shares of Common Stock issued in the Private Placements. The Warrants are exercisable at a price of $0.30 per share. The Warrants are currently exercisable in full and will expire five years from the date of issuance.

As a result of the issuance of the Notes, pursuant to the terms of the Placement Agent Agreement, dated July 26, 2018, entered into in connection with an earlier private securities offering of common stock and warrants, the placement agent in that offering earned a "tail fee" comprising warrants exercisable for 220,000 shares of Common Stock (the "Placement Agent Warrants") and a cash fee of $132,000. The Placement Agent Warrants are exercisable at a price of $0.50 per share and will expire five years from the date of issuance. The Placement Agent Warrants provide for cashless exercise.

Each of the Notes investors has represented to the Company that it is an "accredited investor" as that term is defined in Rule 501(a) of Regulation D promulgated under the Securities Act of 1933, as amended (the "Securities Act"). The Company relied on the exemption from registration afforded by Section 4(a)(2) of the Securities Act in connection with the issuance of the Notes, the Warrants and the Placement Agent Warrants.

The descriptions contained herein of the Notes, the Warrants, the Subscription Agreement, the Placement Agent Warrants and the offering thereof is qualified in its entirety by reference to the full text of the Notes, the Warrants the Subscription Agreements and the Placement Agent Warrants, the forms of which were filed as Exhibits 4.1, 4.2, 4.3 and 10.1, respectively, to the Prior Form 8-K and are incorporated herein by reference.

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

Appointment of New Director

On January 10, 2019, CytoDyn Inc., a Delaware corporation (the "Company"), announced the appointment of David F. Welch, Ph.D. to its board of directors, effective immediately.

In connection with Dr. Welch's appointment as a director, on January 10, 2019, the Company granted Dr. Welch a non-qualified stock option to purchase up to 38,904 shares of the Company's common stock, representing a pro rata portion of the annual option grant received by each director. The option has an exercise price of $0.50 per share (equal to the closing sale price of the Company's common stock on the grant date) and a ten-year term. The option will vest on March 1, 2019 with respect to 13,904 shares and on June 1, 2019 with respect to 25,000 shares.

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

Resignation of Director

On January 10, 2019, Anthony D. Caracciolo resigned as a member of the Company's board of directors. Mr. Caracciolo informed the Company of his intention to resign at the conclusion of a board meeting on January 4, 2019, and the resignation became effective on January 10, 2019. The resignation was not the result of any disagreement with the Company on any matter relating to the Company's operations, policies or practices.

In connection with the resignation of Mr. Caracciolo, on January 4, 2019, the Company's Board of Directors approved a motion to accelerate all outstanding unvested stock options held by Mr. Caracciolo, to vest immediately upon the effectiveness of his resignation and to retain the stock options' exercise period through their respective expiration date. Stock options covering 1,145,834 shares held by Mr. Caracciolo were subject to acceleration. The other terms of the accelerated stock options remained otherwise unchanged. In addition, the expiration terms of certain of Mr. Caracciolo's other previously awarded stock options covering an aggregate of 150,000 shares of the Company's common stock were extended from five years to 10 years. The other terms of the extended stock options remained otherwise unchanged.

Item 7.01 Regulation FD Disclosure.

On January 10, 2019, the Company issued a press release to announce the appointment of Dr. Welch as director, which is furnished as Exhibit 99.1 to this Form 8-K.

Item 8.01. Other Events.

On January 9, 2019, the Company posted an updated version of the investor presentation deck titled "Leronlimab (PRO 140) HIV-Cancer" to its website at www.cytodyn.com. A copy of the investor presentation is filed as Exhibit 99.2 to this Form 8-K.

The Company does not intend to incorporate any contents from its website into this Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit No.	Description.
99.1	Press Release, dated January 10, 2019.
99.2	Investor Presentation.

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.

January 10, 2019

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

Exhibit 99.1

CytoDyn Appoints David F. Welch, Ph.D. to Board of Directors

VANCOUVER, Washington (January 10, 2019) – CytoDyn Inc. (OTC.QB: CYDY), a biotechnology company developing a novel humanized CCR5 monoclonal antibody for multiple therapeutic indications, announces that David F. Welch, Ph.D., Founder, Chief Innovation Officer and Director of Infinera Corporation, has joined the CytoDyn Board of Directors. Dr. Welch is an American businessman and research scientist who brings considerable strategic planning expertise and broad capital markets experience to the CytoDyn Board. He is a significant investor in CytoDyn and understands leronlimab's potential for targeting multiple disease processes.

"We are pleased to add Dr. Welch to our Board of Directors. He is a pioneer in the field of optical devices and optical transport with a strong scientific background," said Dr. Nader Pourhassan, President and CEO of CytoDyn. "Dr. Welch has an inventor's heart with over 130 patents and 250 published articles to his name. We anticipate he will be a strong contributor to our strategic planning."

Scott A. Kelly, M.D., CytoDyn's Chairman of the Board noted that, "Dr. Welch has a wealth of experience in technology, intellectual property, biotechnology and is an accomplished business leader with mergers and acquisition experience. We welcome his understanding and support for the opportunities before our company."

"It is very exciting to be part of this team," said Dr. Welch. "Before agreeing to join the board, I had a unique opportunity to meet the team and understand the opportunities driving their excitement. I believe the company is at a unique inflexion point in its trajectory and look forward to helping ensure our success."

Dr. David Welch, Ph.D. co-founded Infinera which is a Nasdaq-listed provider of Intelligent Transport Networks, enabling carriers, cloud operators, governments and enterprises to scale network bandwidth, accelerate service innovation and automate optical network operations. He has been a member of the Infinera Board since October 2010. In November 2017, Dr. Welch transitioned to the role of Chief Strategy and Technology Officer to help guide the long-range technology and product strategy. Dr. Welch also currently serves on the Board of Directors of Rezolute, a biopharmaceutical company. He holds over 130 patents, and has been awarded the Optical Society of America's (OSA) Adolph Lomb Medal, Joseph Fraunhofer Award and John Tyndall Award, as well as the Institute of Engineering Technology's J J Thompson Medal for Electronics. He is a Fellow of OSA and the Institute of Electrical and Electronics Engineers and is a member of the National Academy of Engineering. He previously served as the Chief Technical Officer and Vice President of Corporate Development at SDL and JDS Uniphase. He was responsible for the merger and acquisition strategy that resulted in the $41 billion acquisition of SDL by JDS Uniphase.

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 graft-versus-host disease (GvHD).

About CytoDyn

CytoDyn is a biotechnology company developing innovative treatments for multiple therapeutic indications based on leronlimab (PRO 140), a novel humanized monoclonal antibody targeting the CCR5 receptor. CCR5 plays a key role in the ability of HIV to enter and infect healthy T-cells. The CCR5 receptor is also implicated in tumor metastasis and in immune-mediated illnesses such as graft-vs-host disease (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. The Company plans to seek FDA approval for leronlimab in combination therapy and plans to complete the filing of a Biological License Application (BLA) in the first half of 2019 for that indication. CytoDyn is also conducting a Phase 3 investigative trial with leronlimab 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 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 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 four years. CytoDyn is also conducting a Phase 2 trial to evaluate leronlimab for the prevention of GvHD and initiated a clinical trial with leronlimab in metastatic triple-negative breast cancer in 2018. 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, including statements regarding the Company’s clinical priorities, the Company’s current and proposed trials and the Company’s BLA

submission. 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, 2018 in the section titled "Risk Factors" in Part I, Item 1A, and in our Form 10-Q for the quarterly period ended August 31, 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 Company's expectations for its leading product candidate leronlimab (PRO 140) to demonstrate efficacy in non-HIV indications, (ii) the sufficiency of the Company's cash position and the Company's ongoing ability to raise additional capital to fund its operations, (iii) the Company's ability to complete its Phase 2b/3 pivotal combination therapy trial for leronlimab (CD02) and to meet the FDA's requirements with respect to safety and efficacy to support the filing of a Biologics License Application, (iv) the Company's ability to obtain FDA approval of PCaTest for use with prostate cancer patients; (v) the Company's ability to meet its debt obligations, if any, (vi) the Company's ability to identify patients to enroll in its clinical trials in a timely fashion, (vii) the Company's ability to achieve approval of a marketable product, (viii) design, implementation and conduct of clinical trials, (ix) the results of the Company's clinical trials, including the possibility of unfavorable clinical trial results, (x) the market for, and marketability of, any product that is approved, (xi) 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, (xii) regulatory initiatives, compliance with governmental regulations and the regulatory approval process, (xiii) general economic and business conditions, (xiv) changes in foreign, political, and social conditions, and (xv) 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 press release 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 press release. 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.

CONTACTS

Investors:
Nader Pourhassan, Ph.D.
President & CEO
(360) 980-8524
npourhassan@cytodyn.com

# # # #

Leronlimab (PRO 140)

CytoDyn

CytoDyn

HIV - Cancer

INVESTOR PRESENTATION
January 2019

Professor Richard G. Pestell
M.D., Ph.D., MB., B.S., F.A.C.P., F.R.A.C.P., F.A.A.A.S., M.B.A.
Vice Chairman and Chief Medical Officer

Nader Pourhassan
Ph.D., President & CEO

Forward-Looking Statements

This presentation contains certain forward-looking statements that involve risks, uncertainties and assumptions that are difficult to predict, including statements regarding Ieronlimab's efficacy in certain cancer indications, the predictive value or benefit from the Company's prostate cancer prognostic test, 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, 2018 in the section titled "Risk Factors" in Part I, Item 1A, and in our Form 10-Q for the quarterly period ended August 31, 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.

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The Company intends that all forward-looking statements made in this presentation 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 presentation. 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.

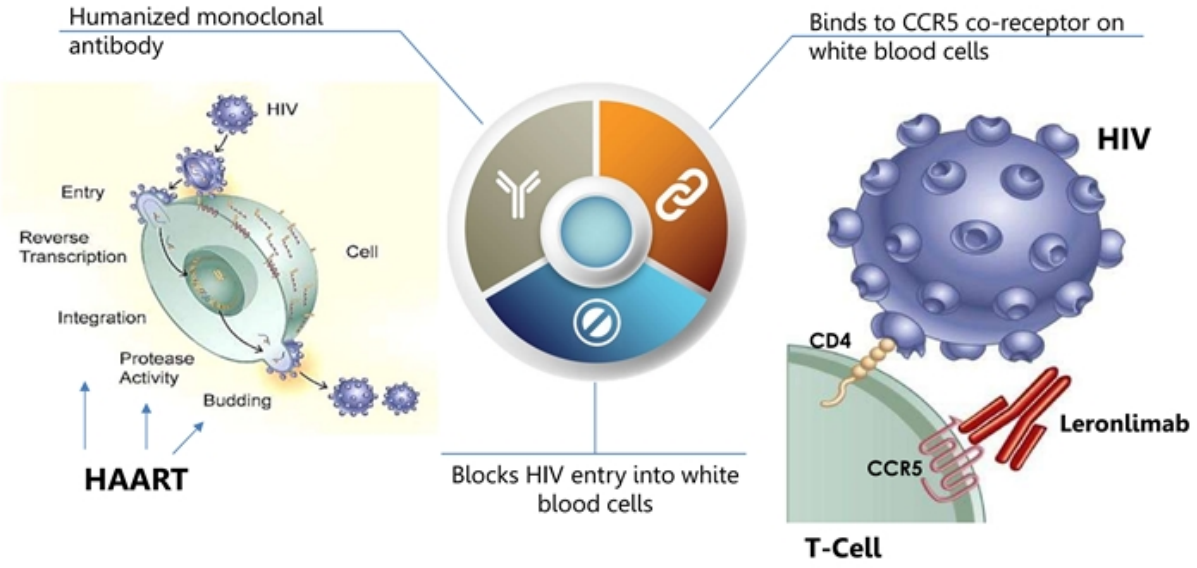
Recent Developments

- **CD02 Phase 3, Pivotal trial** - Combination Therapy
  - Achieved primary endpoint (***p*=0.0032**) – **81%** response rate – BLA in 1Q2019
- **CD03 Phase 3** HIV investigative trial - **360+** enrolled (**60** patients **one year**)
  - About **70%** response rate at 525 mg - About **90%** response rate at 700 mg
- **Phase 1b/2 in Triple Negative Breast Cancer**
  - IND and Protocol has been accepted by the FDA and trial initiated
  - Encouraging preclinical data
- **Phase 2 Graft-versus-Host Disease (GvHD)**
  - Received **Orphan Drug Designation** from FDA
  - Will have interim results in 1H 2019 (mouse model – GvHD eliminated)
- **Prognostic Test for Prostate Cancer**
  - More accurate than current standard of care
  - Licensing agreement could be completed in 1H 2019
- **Licensing and Partnering Discussions**
  - Rights to leronlimab (PRO 140) China – France – Japan – USA are being explored

Leronlimab (PRO 140) – A Humanized Monoclonal Antibody

CytoDyn

Blocking **HIV** entry receptor (CCR5)
Blocking CCR5/CCL5 interaction with leronlimab for use in **CANCER**



FDA: "fast track designation" – "accelerated approval"
NIH: $28 million grants

BECAUSE

Leronlimab (PRO 140)		HAART
No serious side effects and no serious adverse events (SAEs) in >670 patients in 8 clinical trials	Side Effects	Ranges from mild to severe (Diarrhea, nausea, lethargy, depression)
Negligible toxicity	Toxicity	Problems with short- and long-term toxicity
No drug resistance in patients on monotherapy for over 4 years	Resistance	76% of HIV patients have at least one resistance
Weekly, easy, subcutaneous self administration	Compliance	Daily lifetime dosing with only 35% of patients with complete viral load suppression

CD02 Pivotal Combination Trial with leronlimab (PRO 140)

- **52 patients** prescreened for R5 strain and failing current HAART regimen (3 class resistance or 2 class resistance with limited treatment options)
- **Primary efficacy endpoint**: reduction in viral load after 1 week following single PRO 140 dose
  - All patients continue current HAART; 50% receive PRO 140 / 50% receive placebo
  - PRO 140 patients achieved statistically significant reduction - ***p* =0.0032**
- **24-week open-label** with all patients on weekly PRO 140 with optimized HAART
  - **81%** of patients completing trial achieved HIV viral load suppression of <50 cp/mL Recent approved drugs for this population range from **43%** after 24 weeks to **45%** after 48 weeks with vial load suppression of < 50 cp/mL
- **No reported SAEs** related to PRO 140 – (**670 patients** with zero drug related SAE)
- **40 patients** requested to continue PRO 140 in extension study
- **Regulatory path** – expected first FDA approval for PRO 140 in combination therapy
  - Submission of rolling BLA with full BLA submission expected in 1H2019
  - Safety data from 150 eligible patients from all CytoDyn HIV trials

Potential Approval for leronlimab (PRO 140) in HIV

- **Timeline for submitting rolling BLA**
  - Non-Clinical - Completed
  - Clinical - 1Q19
  - CMC (Manufacturing) - 1Q19
- **Final Complete package: 1Q19**

CD03 leronlimab (PRO 140) Investigative Monotherapy Trial

- All patients prescreened for R5 strain with viral load suppression maintained with HAART
- **Ongoing open-label, 48-week trial** with all patients receiving PRO 140 weekly injections
- Investigative trial with focus on **increasing responder rate** and no harm to non-responders

- **Increasing response rate**
  - With **525 mg** - Responder rate of ~ **70%** so far (4 to 12 months)
  - With **700 mg** - Responder rate of ~ **90%** so far (1 to ~4 months)

- **No reported SAEs** related to leronlimab in any trial to date (over 670 patients)
- **Regulatory path**
  - Conduct pivotal Phase 3 monotherapy trial
  - Submit leronlimab (PRO 140) for approval for label expansion as monotherapy, subject to approval as combination therapy

U.S. Market Size for HIV Indication for leronlimab (PRO 140)

Year	HIV patients	Patients using HAART	1 resistance	2 resistance	3 resistance
2017	1,373,636	712,532	645,646	218,248	28,372
2018	1,400,406	745,167	671,257	232,291	27,875
2019	1,421,563	775,245	694,404	246,842	27,153
2020	1,432,683	799,418	712,153	261,677	26,168
2021	1,450,405	827,477	733,273	276,750	24,907
2022	1,468,530	856,284	754,947	291,950	23,356
2023	1,487,096	885,878	777,208	307,164	21,501
2024	1,506,237	916,377	800,152	338,545	20,313
2025	1,514,925	940,855	817,758	354,548	17,727

Source: GlobalData & https://doi.org/10.1086/597352

U.S. Market Potential for leronlimab (PRO 140) in HIV Alone

CytoDyn

Initial approval **Combination Therapy**

- HAART failures: ~ 70,000* patients with 2 or more drug class resistances
- 70,000 patients x 70% (R5-HIV strain) = 49,000 HIV patient R5 eligible
- 49,000 patients x **$24,000** (current market pricing) = **~ $1.2 billion**
- 49,000 patients x **$75,000** (current market pricing) = **~ $3.7 billion**

Label Expansion **Switch to Monotherapy Maintenance**

- Target population (suppressed viral load) = 17.5% of 1.3 million HIV+ = 227,500**
- 227,500 patients x 70% (R5-HIV) = 159,250 patients
- 159,250 patients x **$24,000** (current market pricing) = **~ $3.8 billion**
- 159,250 patients x **$75,000** (current market pricing) = **~ $12 billion**

* Market size – BioVid Market Research: 2 class resistance ~ 5% to 20% ~ **70,000 to 280,000** patients

** Market size – BioVid Market Research: Monotherapy ~ 60% to 100% suppressed viral load among ~ **480,000 to 770,000**

U.S. Market Size - Research Report From BIOVID

Executive Summary

However, patients show a strong leronlimab (PRO 140) call to action

Patient Reactions to PRO 140 *(pre-video review)*	Monotherapy Patients	Combo Therapy Patients
PRO 140 is a **significant improvement** vs. current options	55%	55%
Highly likely to start a conversation with my doctor	70%	60%
Highly likely to try to find more information about PRO 140	65%	60%
Would schedule an appointment **within 3 months** to discuss PRO 140	70%	65%
Effort needed to make PRO 140 part of daily routine		
Very little/Moderate effort	**85%**	**95%**
A lot of effort	10%	5%
Way too much effort to take on	5%	0%
Level of concern about taking PRO 140 as instructed	5% 15% 40% 40%	5% 10% 25% 60%
Level of concern about taking PRO 140 long-term	15% 35% 45%	5% 35% 35% 25%

- Monotherapy patients are slightly more likely to act upon their interest in PRO 140 by talking to their MD and/or searching for more product details on their own
- Both patient types see PRO 140 as requiring minimal effort to implement in their daily routine, and the majority do not have significant concerns with self-injecting PRO 140 once/weekly long-term

Very concerned
Somewhat concerned
A little bit concerned
Not concerned

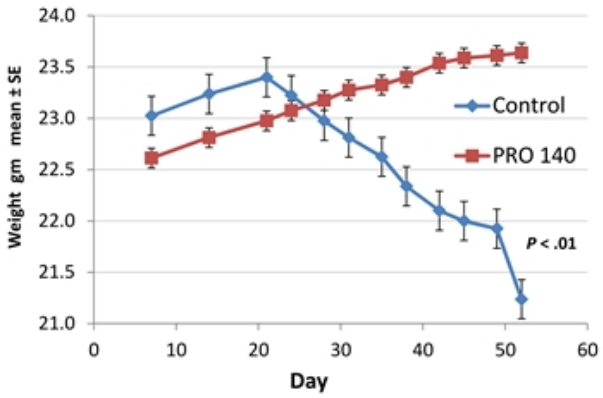
Base Size: Total Patients; Monotherapy Candidates (n=20); Combination Therapy Candidates (n=20)

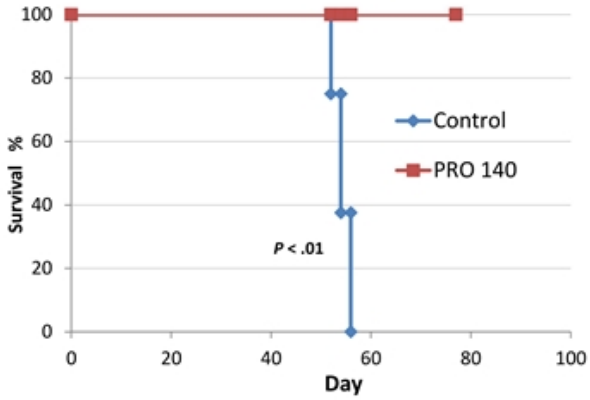
Leronlimab (PRO 140) Immunologic Indications

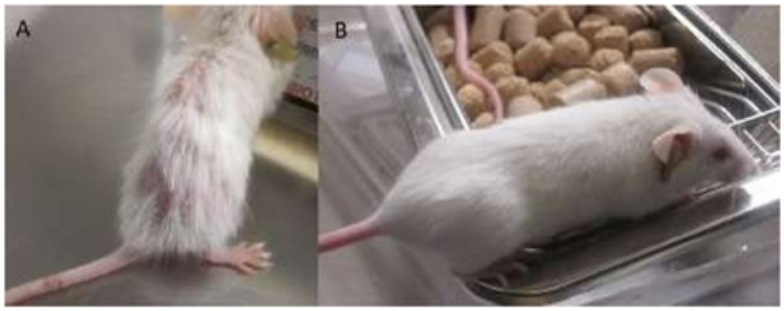
Additional potential leronlimab (PRO 140) applications

- **GvHD**
- **Cancer including tumor metastasis (Dr. Richard Pestell)**

Effect of leronlimab (PRO 140) on Xeno-GvHD
Human BM Transplanted Into Immuno-Deficient Mice





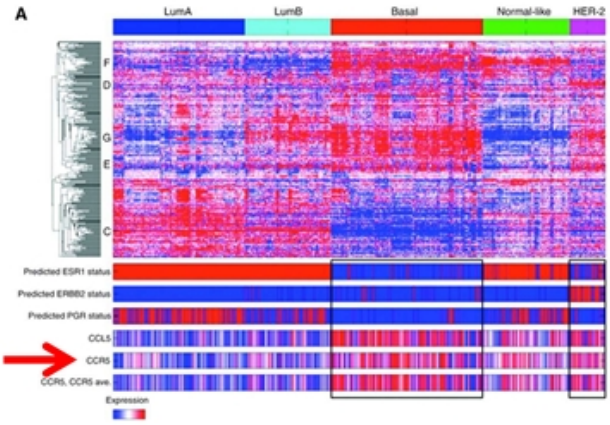


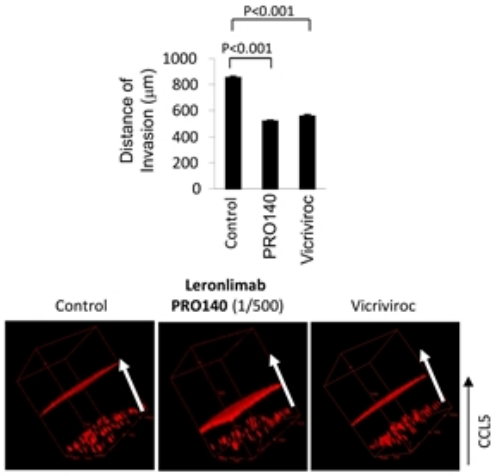
Expansion into Cancer Indications

- Named world-renowned oncologist Dr. Richard Pestell Chief Medical Officer and Vice Chairman
  - Lead leronlimab (PRO 140) non-HIV development programs
  - Led 2 National Cancer Institute-designated cancer centers
    - Lombardi Comprehensive Cancer Center at Georgetown University
    - Sidney Kimmel Cancer Center at Thomas Jefferson University
- Founded ProstaGene to develop CCR5 technology in cancer
  - Important focus on metastasis of many types of cancer
  - Research showed nearly 50% of 2,200 patients with breast cancer had overexpressed CCR5
- Published preclinical studies provide support
  - CCR5 inhibitors effectively blocked breast and colon cancer spread; blocked prostate cancer metastasis to bones and brain

CCR5 is Expressed in >50% of Breast Cancer

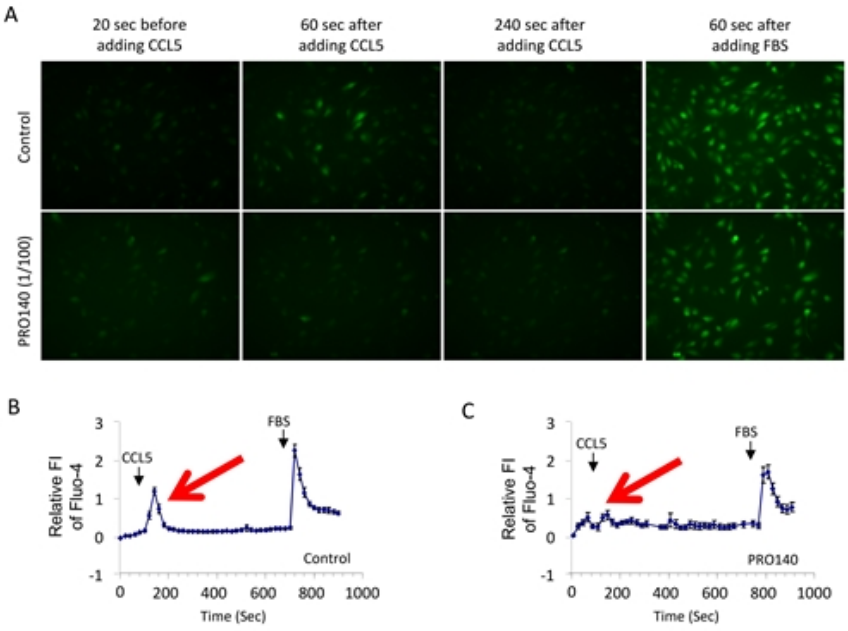
- **Metastatic cancer.**
  - 50% of breast cancers CCR5+
  - Leronlimab(PRO 140) reduces breast cancer invasion





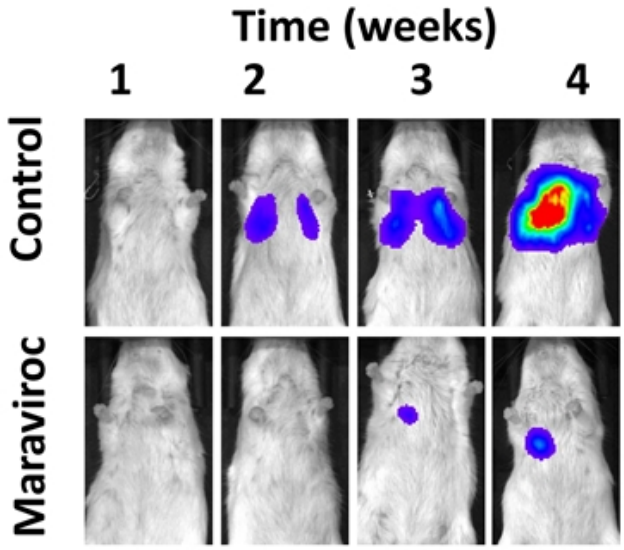
Professor Richard Pestell, PhD, MD

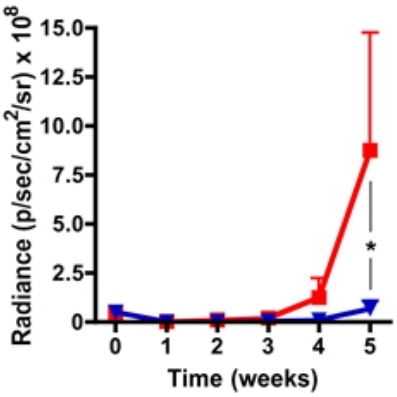
Leronlimab (PRO 140) Blocks Breast Cancer Ca^{+2} signaling



Professor Richard Pestell, PhD, MD

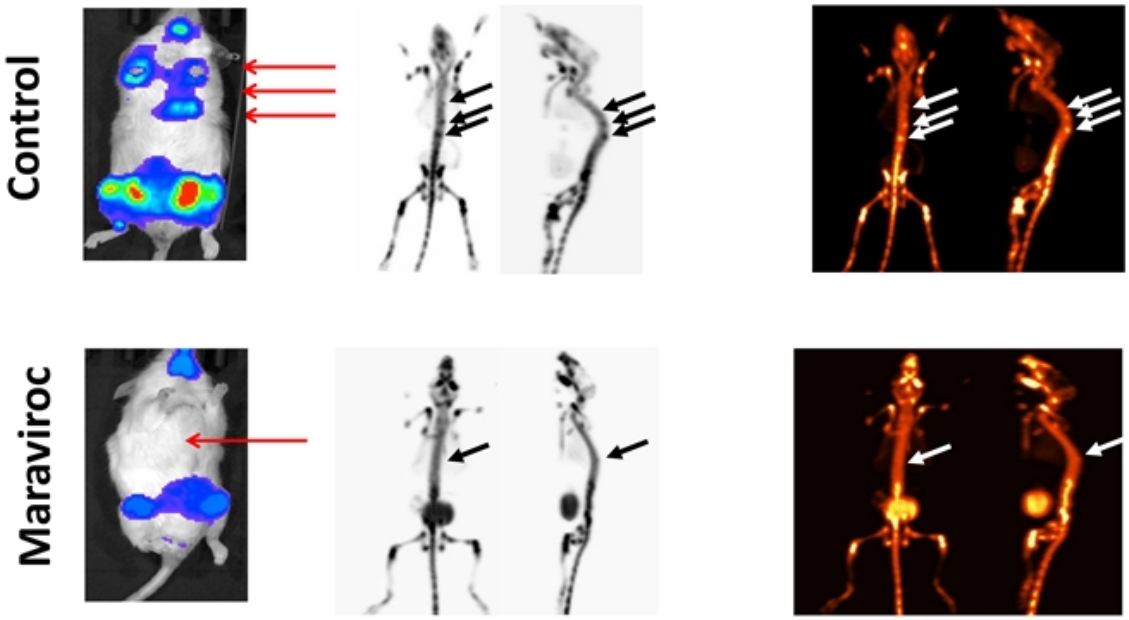
CCR5 Antagonists Block Breast Cancer Metastasis



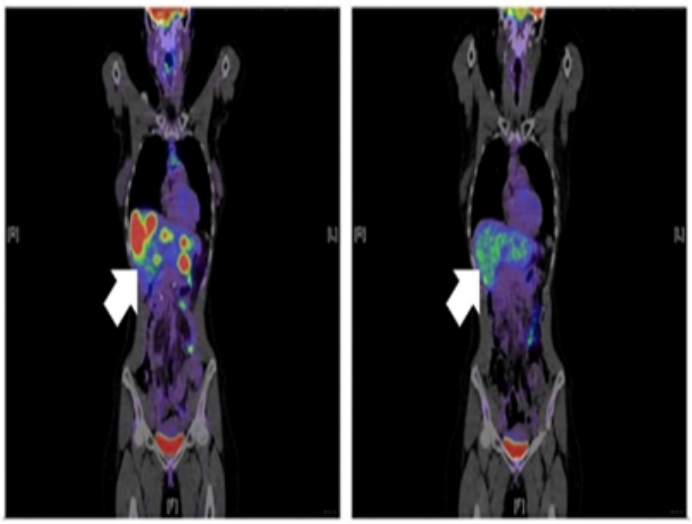


Professor Richard Pestell, PhD, MD

CCR5 Antagonists Block Prostate Cancer Metastasis

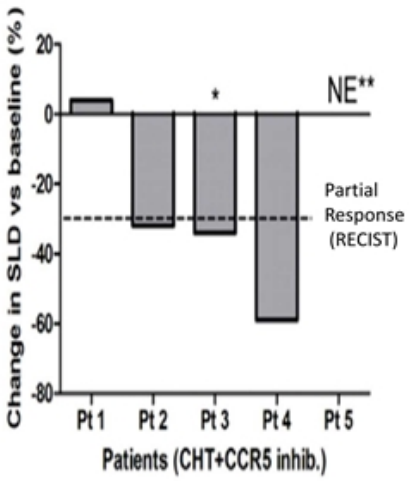


Objective Tumor Response, Phase 1 Trial

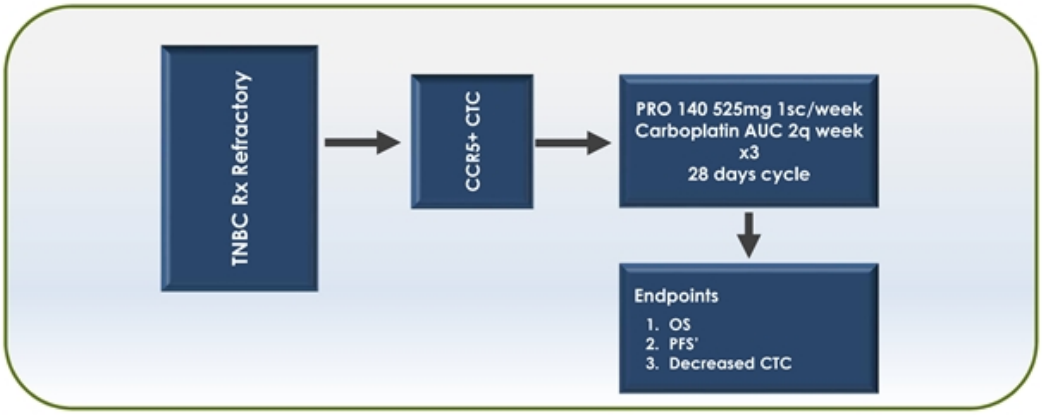


before CHT+CCR5 inh. after CHT+CCR5 inh.

G



Leronlimab (PRO 140) Breast Cancer Study



November 2018-March 2019
Phase II

Breakthrough (unmet need)
April 2019-July 2021 (Phase III)

Potential Market Size for CCR5 Antagonist for Breast Cancer

CytoDyn

Trastuzumab for breast cancer with HER-2+ patients
Annual sales = $15 billion

HER-2+ is about 12% of breast cancer population

CCR5 + is about 50% breast cancer population

Market potential ~ 4 x $15 billion = $60 billion

Other Potential Non-Dilutive Capital Raise

- **Prognostic Test**
  Potential licensing in 2019

- **Potential use of leronlimab**
  - Already sent product to interested EU collaborators
  - Already testing for CCR5 staining purposes

- **Several abstracts**
  - At least 5 abstract are ready or will be submitted for publishing in 2019
  - Presenting in many Prostate and other oncology conferences in 2019

PRO 140 Important Milestones for HIV and Cancer 2019

Milestones	Target Dates
BLA submission	1H2019
Revenue potential of about $480 million	2020
Large Pharma discussion for potential licensing or partnering	1H2019
Triple Negative Breast Cancer study first patient injected	1Q2019
Triple Negative Breast Cancer study Interim results	1H2019
Late Breaker at CROI – Combination therapy – Monotherapy	Will apply
Prognostic test licensed	2019
IND-Protocol for colon cancer Phase 2	1H2019