
**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): November 8, 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 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 5.03 Amendments to the Articles of Incorporation or Bylaws; Change in Fiscal Year.

On November 8, 2018, CytoDyn Inc., a Delaware corporation (the “Company”), filed with the Secretary of State of the State of Delaware a Certificate of Amendment (the “**Certificate of Amendment**”) to its Certificate of Incorporation, increasing the total number of authorized shares of Common Stock to 600,000,000. A copy of the Certificate of Amendment is attached hereto as Exhibit 3.1 and incorporated by reference herein. The Company’s stockholders approved the Certificate of Amendment at the Company’s annual meeting of stockholders (the “Annual Meeting”) on November 8, 2018.

Item 5.07 Submission of Matters to a Vote of Security Holders.

Certain matters were submitted to a vote of stockholders at the Annual Meeting. A total of 187,484,542 shares were represented in person or by proxy at the Annual Meeting, out of 248,400,949 shares outstanding and entitled to vote as of the record date. The final results for each of the matters submitted are set forth below. Each of the proposals was approved. A more detailed description of each proposal is set forth in the Company’s Proxy Statement filed with the Securities and Exchange Commission on October 15, 2018 (the “Proxy Statement”).

Proposal No. 1 – Election of Seven Directors. The stockholders elected seven directors, each for a one-year term:

<u>Nominee</u>	<u>Shares Voted For</u>	<u>Shares With held</u>	<u>Broker Non- Votes</u>
Anthony D. Caracciolo	123,994,507	15,020,001	48,470,034
Nader Z. Pourhassan, Ph.D.	132,575,465	6,439,043	48,470,034
Carl C. Dockery	136,609,369	2,405,139	48,470,034
Gregory A. Gould	124,343,094	14,671,414	48,470,034
Scott A. Kelly, M.D.	135,385,236	3,629,272	48,470,034
Michael A. Klump	137,058,574	1,955,934	48,470,034
Jordan G. Naydenov	135,852,703	3,161,805	48,470,034

Proposal No. 2 – Amendment to Certificate of Incorporation to Increase the Number of Authorized Shares. The stockholders approved a proposal to amend the certificate of incorporation of the Company (the “Certificate of Incorporation”) to increase the total number of authorized shares of common stock to 600,000,000, by the votes set forth in the table below:

<u>For</u>	<u>Against</u>	<u>Abstained</u>
164,069,609	22,584,090	830,843

Proposal No. 3 – Ratification of Selection of Independent Registered Public Accounting Firm. The stockholders approved the selection of Warren Averett, LLC as independent registered public accounting firm for the fiscal year ending May 31, 2019, by the votes set forth in the table below:

<u>For</u>	<u>Against</u>	<u>Abstained</u>
182,007,042	4,454,073	1,023,427

Proposal No. 4 –Advisory Vote on Executive Compensation. The stockholders approved the compensation paid to executive officers, by the votes set forth in the table below:

For	Against	Abstained	Broker Non-Vote
107,389,665	27,193,545	4,431,298	48,470,034

Item 8.01. Other Events.

On November 8, 2018, the Company posted an updated version of the investor presentation deck titled “PRO 140- leronlimab” to its website at www.cytodyn.com. A copy of the investor presentation is filed as Exhibit 99.1 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.
	3.1	<u>Certificate of Amendment to the Certificate of Incorporation of CytoDyn Inc.</u>
	99.1	<u>Investor Presentation.</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.

CytoDyn Inc.

November 8, 2018

By: /s/ Michael D. Mulholland

Name: Michael D. Mulholland

Title: Chief Financial Officer

CERTIFICATE OF AMENDMENT
OF
CERTIFICATE OF INCORPORATION
OF
CYTODYN INC.

Pursuant to Section 242 of the General Corporation Law of the State of Delaware, CytoDyn Inc., a corporation organized and existing under the laws of the State of Delaware (the "Corporation"), does hereby certify as follows:

1. The name of the Corporation is CytoDyn Inc. The Corporation was incorporated by the filing of its original Certificate of Incorporation with the Secretary of State of the State of Delaware on January 12, 2015 (as amended, the "Certificate of Incorporation").
2. The Certificate of Incorporation of the Corporation is hereby amended by deleting the first paragraph of Article IV and replacing such paragraph with the following paragraph:
"The total number of shares of capital stock which the Corporation shall have authority to issue is Six Hundred and Five Million (605,000,000), of which (i) Six Hundred Million (600,000,000) shares shall be a class designated as common stock, par value \$0.001 per share (the "**Common Stock**"), and (ii) Five Million (5,000,000) shares shall be a class designated as preferred stock, par value \$0.001 per share (the "**Preferred Stock**")."
3. The Board of Directors of the Corporation has duly adopted a resolution pursuant to Section 242 of the General Corporation Law of the State of Delaware setting forth a proposed amendment to the Certificate of Incorporation of the Corporation and declaring said amendment to be advisable. The requisite stockholders of the Corporation have duly approved said proposed amendment in accordance with Section 242 of the General Corporation Law of the State of Delaware.
4. This Certificate of Amendment and the amendment to the Certificate of Incorporation effected hereby has been duly adopted in accordance with Section 242 of the General Corporation Law of the State of Delaware and shall be effective immediately upon filing.

[Signature Page Follows]

IN WITNESS WHEREOF, the Corporation has caused this Certificate of Amendment to be signed by its Chief Financial Officer on this 8th day of November, 2018.

CYTODYN INC.

By: /s/ Michael D. Mulholland

Name: Michael D. Mulholland

Title: Chief Financial Officer



PRO 140 - Ieronlimab

First self-administered antibody therapy for **HIV**
in late-stage clinical development

In early-stage development for **cancer** indications
and other **immunological disorders**

CytoDyn Annual Meeting of Stockholders

November 8, 2018

Nader Pourhassan

Ph.D., President & CEO

&

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.

OTCQB: CYDY

www.cytodyn.com

Forward-Looking Statements



This presentation includes forward-looking statements and forward-looking information within the meaning of United States securities laws. These statements and information represent CytoDyn's intentions, plans, expectations and beliefs, and are subject to numerous risks, uncertainties and other factors, of which many are beyond CytoDyn's control. These factors could cause actual results to differ materially from such forward-looking statements or information. The words "believe," "estimate," "expect," "intend," "attempt," "anticipate," "foresee," "plan," and similar expressions and variations thereof, identify certain of such forward-looking statements or forward-looking information, which speak only as of the date on which they are made.

CytoDyn disclaims any intention or obligation to publicly update or revise any forward-looking statements or forward-looking information, whether as a result of new information, future events or otherwise, except as required by applicable law. Readers are cautioned not to place undue reliance on these forward-looking statements or forward-looking information. While it is impossible to identify or predict all such matters, these differences may result from, among other things, the inherent uncertainty of the timing and success of and expense associated with research, development, regulatory approval, and commercialization of CytoDyn's products and product candidates, including the risks that clinical trials will not commence or proceed as planned; products appearing promising in early trials will not demonstrate efficacy or safety in larger-scale trials; future clinical trial data on CytoDyn's products and product candidates will be unfavorable; funding for additional clinical trials may not be available; CytoDyn's products may not receive marketing approval from regulators or, if approved, may fail to gain sufficient market acceptance to justify development and commercialization costs; competing products currently on the market or in development may reduce the commercial potential of CytoDyn's products; CytoDyn, its collaborators or others may identify side effects after the product is on the market; or efficacy or safety concerns regarding marketed products, whether or not scientifically justified, may lead to product recalls, withdrawals of marketing approval, reformulation of the product, additional pre-clinical testing or clinical trials, changes in labeling of the product, the need for additional marketing applications, or other adverse events.

CytoDyn is also subject to additional risks and uncertainties, including risks associated with the actions of its corporate, academic, and other collaborators and government regulatory agencies; risks from market forces and trends; potential product liability; intellectual property litigation; environmental and other risks; and risks that current and pending patent protection for its products may be invalid, unenforceable, or challenged or fail to provide adequate market exclusivity. There are also substantial risks arising out of CytoDyn's need to raise additional capital to develop its products and satisfy its financial obligations; the highly regulated nature of its business, including government cost-containment initiatives and restrictions on third-party payments for its products; the highly competitive nature of its industry; and other factors set forth in CytoDyn's Annual Report on Form 10-K and other reports filed with the U.S. Securities and Exchange Commission.

CytoDyn Past Performance



				~Funds raised
2012	Purchase PRO 140			\$6 million
2013	PRO 140 transfer all process and products to CytoDyn	PRO 140 potential to be a game changer	NIH-funds return Phase 2 abandon	\$16 million

	Combination therapy	Monotherapy	Others trials	~Funds raised
2014		Phase 2b Monotherapy		\$3 million
2015	Phase 3 – Combination therapy Pivotal trial – FDA green light	Mono-label expansion		\$25 million
2016	Phase 3 – with 300 patients Later n=50 patients	Phase 3 – Monotherapy Investigative (n=300)	GvHD – (ODD)	\$33 million
2017	Conduct Phase 3		Colon Cancer	\$23 million
2018	Hit primary endpoint Pre-BLA meeting	40% to 70% to maybe >85%	Cancer metastasis (TNBC)-ProstaGene	\$43 million
2019	Final BLA submission 1st ever in the world	Pivotal trial (Dr Ho -HAART) 1st ever in the world	Cancer - 1st ever in the world	?

- **Double Blinded Trial – Gold Standard**
- **Primary efficacy endpoint:** Very positive results - $p = 0.0032$
- **24-week open-label** with all patients on weekly PRO 140 with optimized HAART
 - **81%** with VL < 50cp/mL as compare to **43%** with other antibody approved
- **Regulatory path** – BLA submission to finish by 1Q2019 and starts with clinical and non-clinical package as early as end of 2018

Market Potential - \$1.2 billion

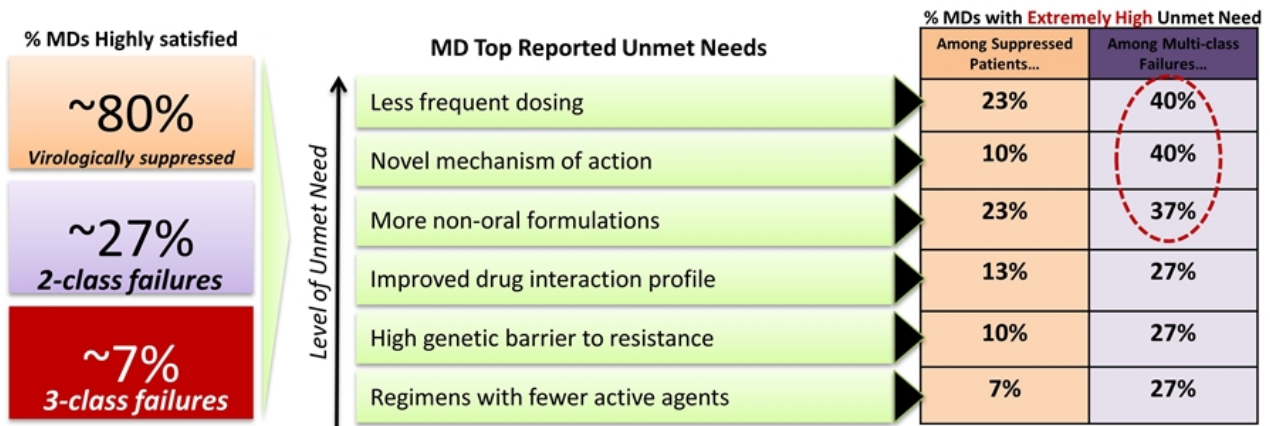
Approval in 2019

**~\$500 million Potential
Revenue 2020**



MDs' unmet needs in HIV treatment align well with PRO 140 strengths

- Unmet need differs based on suppression status. While the **vast majority (80%) of virologically suppressed are highly satisfied** with existing HIV treatment, **patients with multiple failures are much less satisfied**.
- Physicians' top stated **unmet needs align nicely with PRO 140 strengths**.



Base size: Total Physicians (n=30)

Executive Summary



However, patients show a strong 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		
<i>Very little/Moderate effort</i>	85%	95%
<i>A lot of effort</i>	10%	5%
<i>Way too much effort to take on</i>	5%	0%
Level of concern about taking PRO 140 as instructed	5% 15%	5% 10%
	40%	25%
	40%	60%
Level of concern about taking PRO 140 long-term	5% 15%	5% 5%
	35%	35%
	45%	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

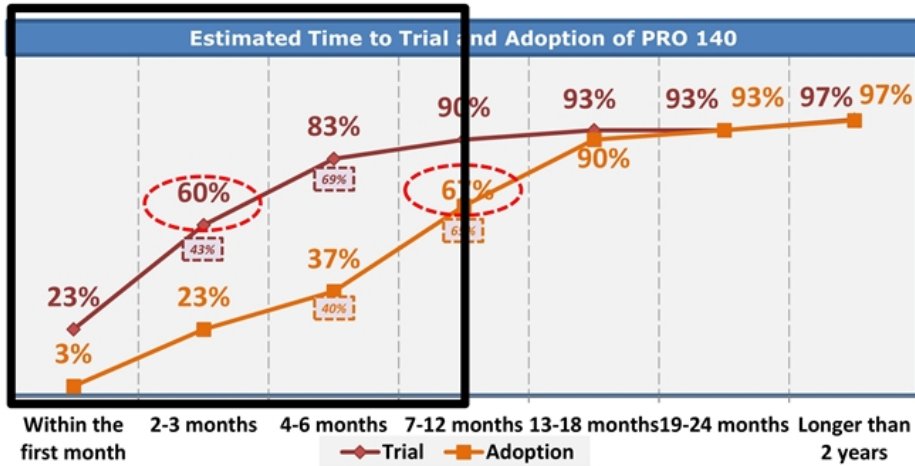


Base Size: Total Patients; Monotherapy Candidates (n=20); Combination Therapy Candidates (n=20)

Executive Summary



Most MDs will trial PRO 140 monotherapy within 3 months of launch, while 2 out of 3 will adopt its use within the 1st year



Base size: Total Physicians (n=30)

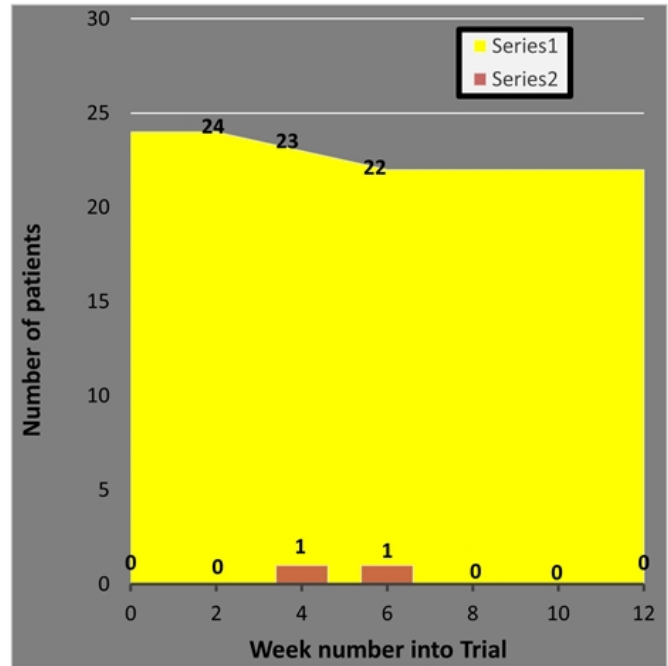
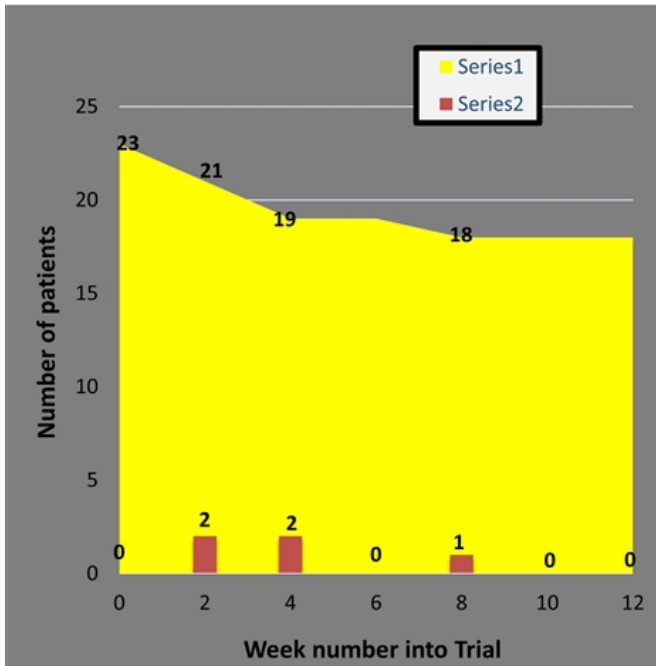
Benchmark data based on BioVid's proprietary Demand database (full database)

Monotherapy – 525 mg vs 700 mg



LOWER DOSE (525 mg) = 78%

HIGHER DOSE (700 mg) = 92%



Monotherapy – 525 mg vs 700 mg - Rescue Arms



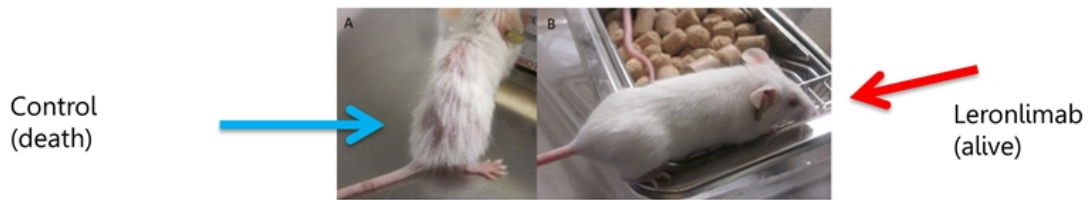
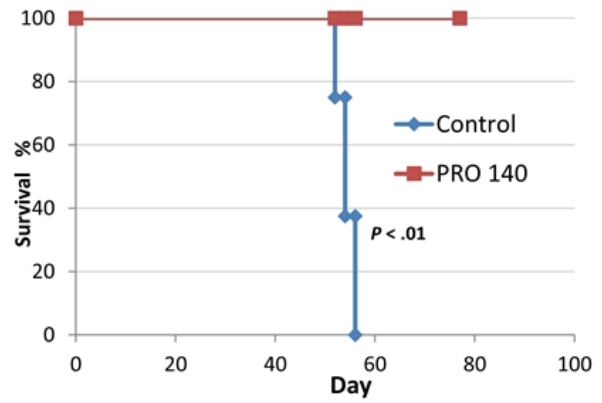
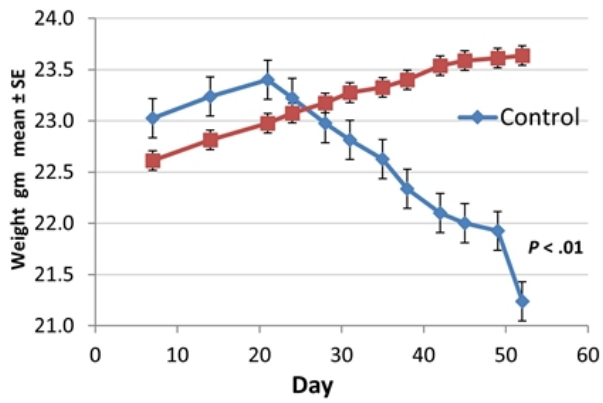
525 mg rescue arm for 350mg patients with VF		
Patients rescued from 350mg (after VF) into 525mg	55	
Patients who achieved complete suppression w/VL of about <50cp/ml	22	40%
Patients who had VF after rescue arm in place	22	40%

700 mg rescue arm for 525mg patients with VF		
Patients rescued from 525mg (after VF) into 700mg	23	
Patients who achieved complete suppression w/VL of about <50cp/ml	12	52%
Patients who had VF after rescue arm in place	5	22%

	525 mg (n=55)	700 mg (n=23)
Failures	40%	22%
Passing - suppressed	40%	52%

Leronlimab on Xeno-GvHD

Human BM Transplanted Into Immuno-Deficient Mice



- **2. GVHD**
 - **Phase 2** graft-versus-host disease (**GvHD**)
 - Modified protocol to improve enrollment and reflect positive preclinical findings

3 Expansion into Cancer Indications



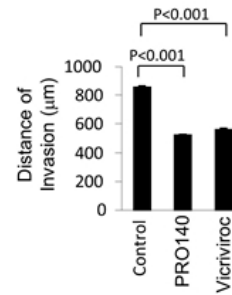
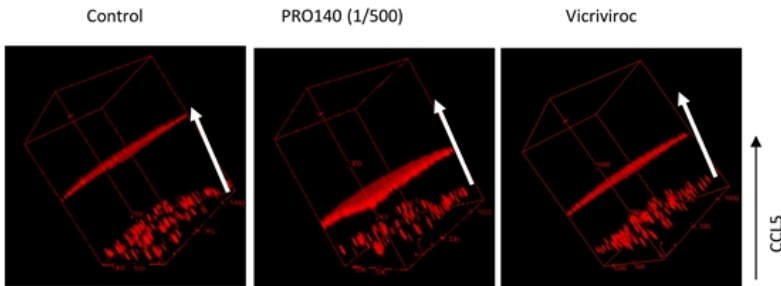
- Dr. Richard Pestell (Chief Medical Officer)
 - Lead leronlimab in non-HIV development programs
 - Led 2 National Cancer Institute-designated cancer centers
 - Lombardi Comprehensive Cancer Center at Georgetown University
 - Sidney Kimmel Cancer Center at Thomas Jefferson University
 - EVP Thomas Jefferson University (22,000 employees, \$5.6B)
- 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 dramatically blocked breast and colon cancer spread; blocked prostate cancer metastasis to bones and brain

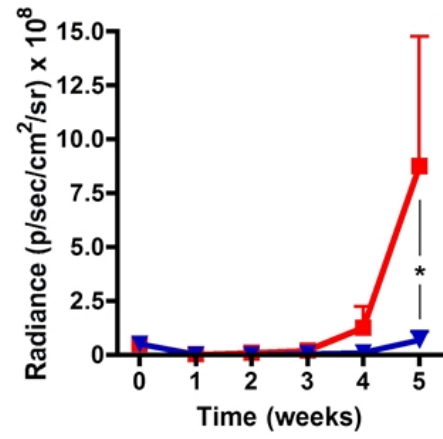
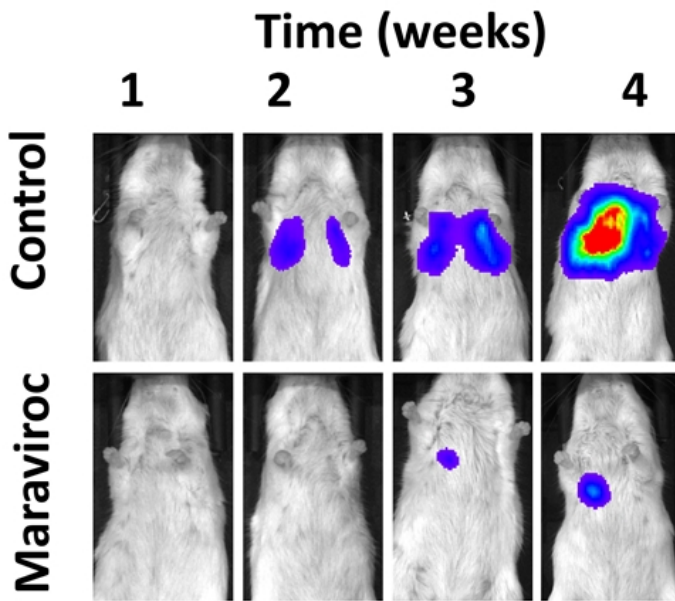
CCR5 is Expressed in >50% of Breast Cancer



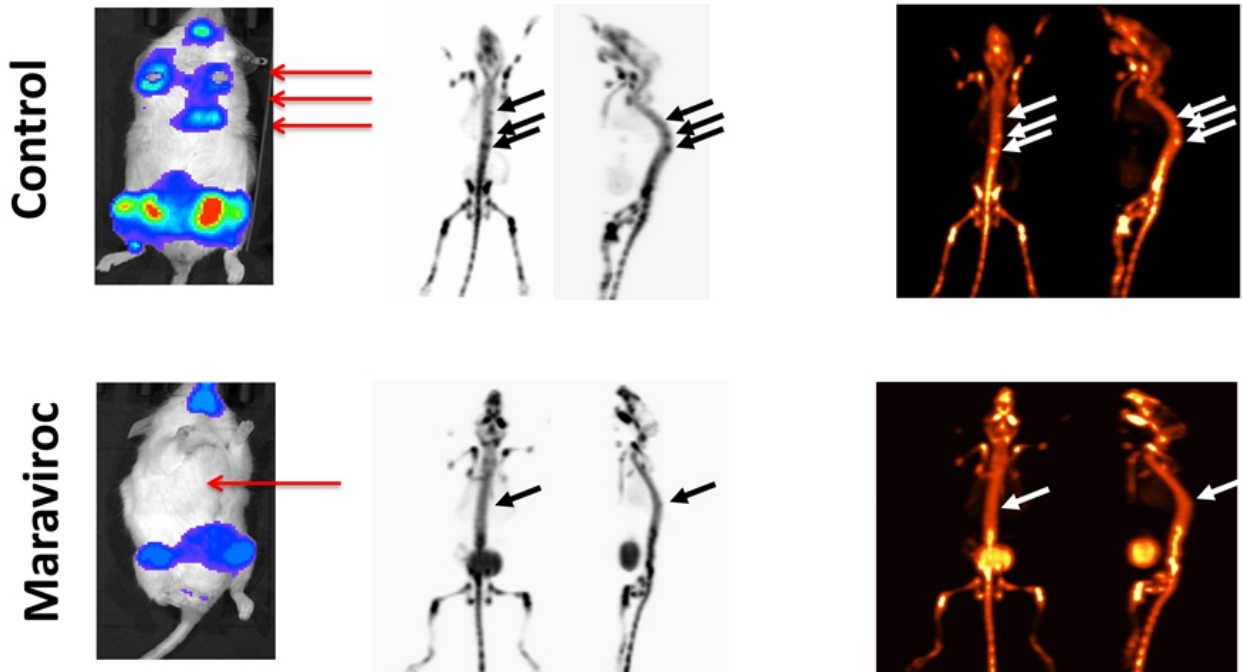
– Metastatic cancer

- 50% of breast cancers CCR5+
- Leronlimab reduces breast cancer invasion



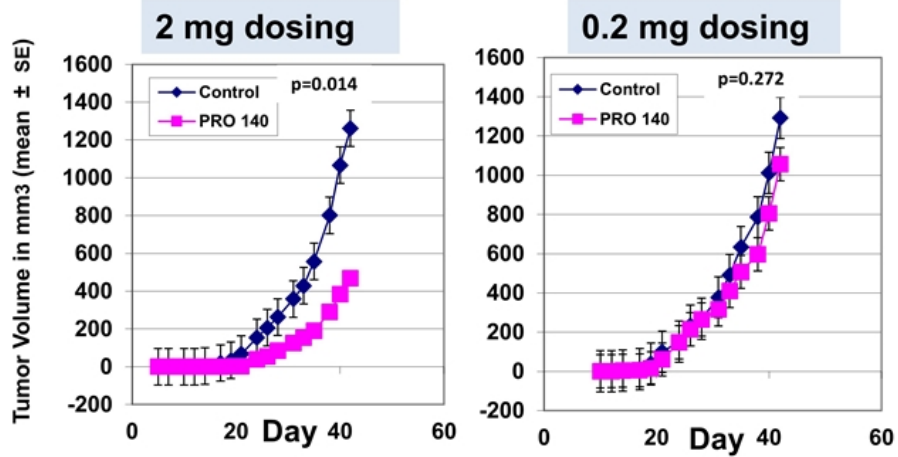


CCR5 Antagonists Block Prostate Cancer Metastasis



SW480 Human Colon Carcinoma Xenografts in NCr Nude Mice

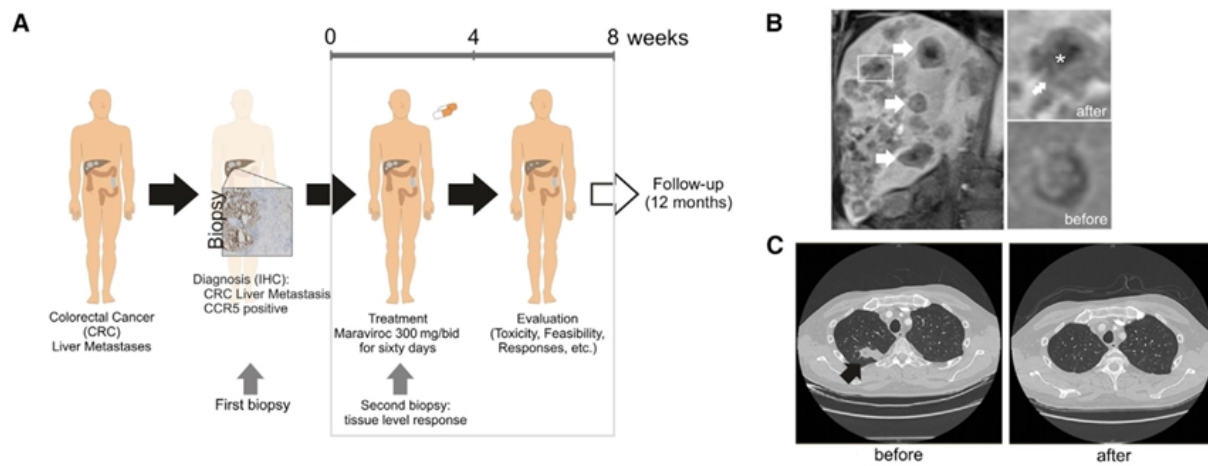
PRO 140, 2 mg i.p. twice/week, started day 1, n=16 tumors/group



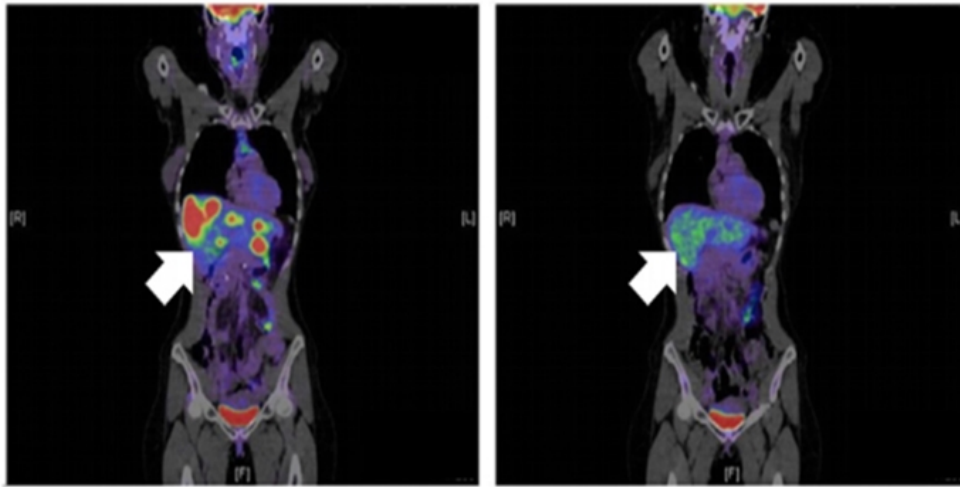
Objective Tumor Response, Phase 1 Trial



Advanced-stage metastatic colorectal cancer who are refractory to standard chemotherapy, including regorafenib



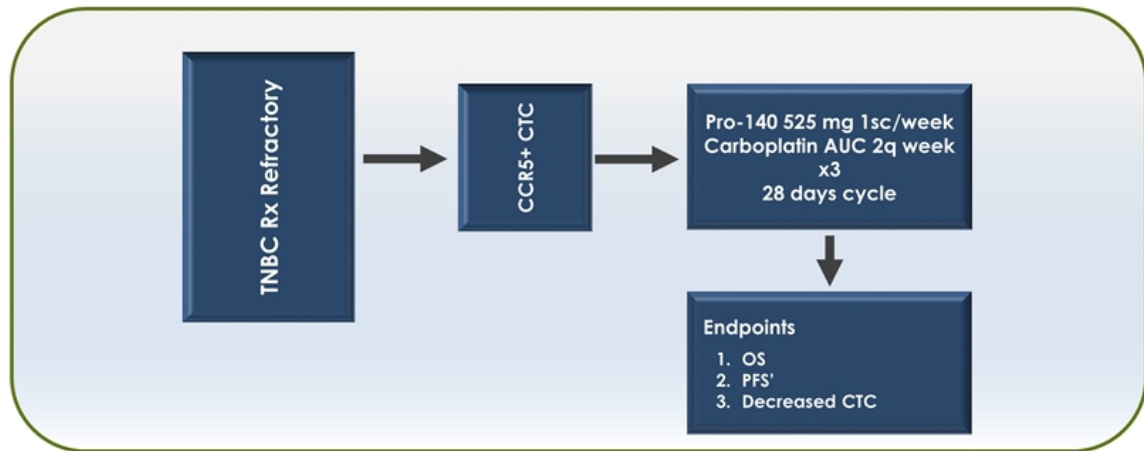
F



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

[Tumoral Immune Cell Exploitation in Colorectal Cancer Metastases Can Be Targeted Effectively by Anti-CCR5 Therapy in Cancer Patients](#)
Cancer Cell. 2016 587-601

Pro 140 Breast Cancer Study



CytoDyn Prostate Cancer Prognostic Test

CytoDyn Prognostic Test

Clinical Problem:

- 220,800 new cases of prostate cancer will be diagnosed in the USA in 2015*
- Current standard for risk assessment is Gleason score combined with serum PSA and tumor stage/grade
 - Gleason score intermediate - is a weak predictor of outcome
- Recommendation to add gene based test
- Reimbursement from many health care providers (>\$3,500 /test).
- Current gene tests warrant improvement

ANSWER – CYTODYN PROGNOSTIC TEST

*American Cancer Society, Cancer Facts and Figures, 2015

CytoDyn Prognostic Test

Superior Prognostic Test Discrimination Proven in Three Independent Data Sets

	Accuracy			
	AUC	Hazard Ratio*	P value	Group size
CytoDyn **Distant metastasis. (16 gene #)	0.8, 0.88 #	11.6**	2.5x10 ⁻²	130
<i>*Biochemical Recurrence</i>	0.64	4.1*	3x10 ⁻⁴	79
<i>*Biochemical Recurrence</i>	0.69	9.2*	9x10⁻¹⁵	139
4Kscore ® 4 proteins/blood, <i>OPKO Health, Inc.</i>	0.68 -0.83	1.2	5x10 ⁻⁴	740
Genome Dx Decipher ® 22 genes, biopsy, <i>GenomeDx Biosciences Corporation</i>	0.66	1.9	1x10 ⁻²	198
Oncotype Dx ® 12 genes, biopsy, covered by Medicare/ <i>Genomic Health Inc.</i>	0.53 -0.62	2.3	3x10 ⁻³	395
ProMark ® 8 proteins/biopsy, <i>Metamark Genetics, Inc.</i>	0.69	1.3-2.6	1x10 ⁻⁴	274
Prolaris score ® 31 genes, biopsy/prostatectomy tissue, FDA Approved, <i>Myriad Genetic Laboratories, Inc.</i>	0.69	1.6-2.9	8.6x10 ⁻¹⁰	337
Gleason Score (7) cytopathology procedure, standard of care	0.65	1.7		222

*Biochemical Recurrence
**Distant metastasis

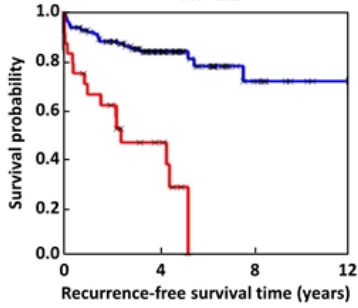
Prognostic Test

Competitive Environment

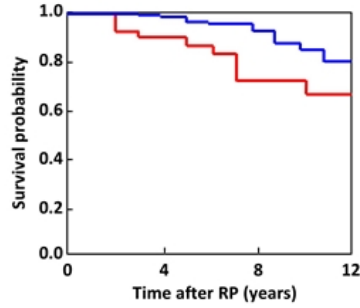
High hazard ratio indicates a better discrimination between good vs. poor outcome

Cytodyn

HR= 9.2

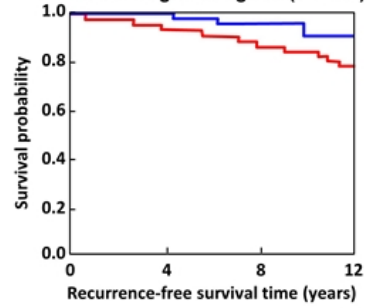


GenomeDx Decipher



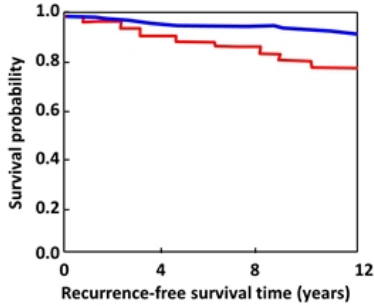
4Kscore test-OPKO Lab

PSA>3.0 ng/ml at age 60 (n=2432)



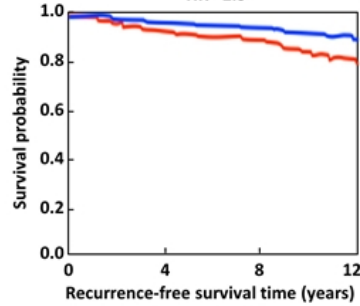
MetaMark

HR= 1.3 - 2.6



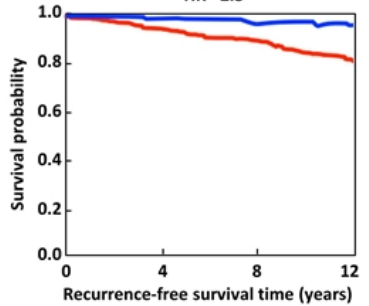
OncotypeDx

HR= 2.3



OncotypeDx

HR= 2.3



ProstaGene

• 3. Cancer- CCR5 Targeted Therapeutics

- New, broader focus with PRO 140 to include **cancer**
- Promising preclinical (in vitro) results in **BREAST CANCER**
- Great preclinical (animal) results in **COLON CANCER**

Cancer- Diagnostics

- Prostate Cancer Prognostic test- current data indicates superior precision
- **2200 new cancer patients per year**

- ❖ **BLA – Combination therapy** - CROI - Publication
- ❖ **Commercialization – PRO 140** - \$1.2 Billion and Monotherapy \$4 Billion
- ❖ **Monotherapy pivotal** - CROI – Pivotal Trial
- ❖ **TNBC** - Publication
- ❖ **ProstaGene Closing (Dec. 7)**
- ❖ **Prognostic test** – Publication

2018 Annual Meeting of Stockholders

Questions