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

Date of Report (Date of earliest event reported): November 24, 2021

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

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

1111 Main Street, Suite 660
Vancouver, Washington 98660
(Address of principal executive offices, including zip code)

(360) 980-8524
(Registrant's telephone number, including area code)

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:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
None	None	None

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

On November 24, 2021, CytoDyn Inc. made an investor presentation during its annual meeting of stockholders. The investor presentation has also been posted on the company's website and a copy of the presentation is furnished as Exhibit 99.1 to this report and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits:

A copy of the investor presentation described in Item 7.01 is furnished with this report as Exhibit 99.1.

EXHIBIT INDEX

Exhibit	Description
99.1	Investor Presentation dated November 24, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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 thereunto duly authorized.

CYTODYN INC.

Date: November 24, 2021

By: /s/ Antonio Migliarese
Antonio Migliarese
Chief Financial Officer

Exhibit 99.1

November 24, 2021

Annual Meeting of Stockholders
CytoDyn's PRESENTATION

Forward-Looking Information and Statements

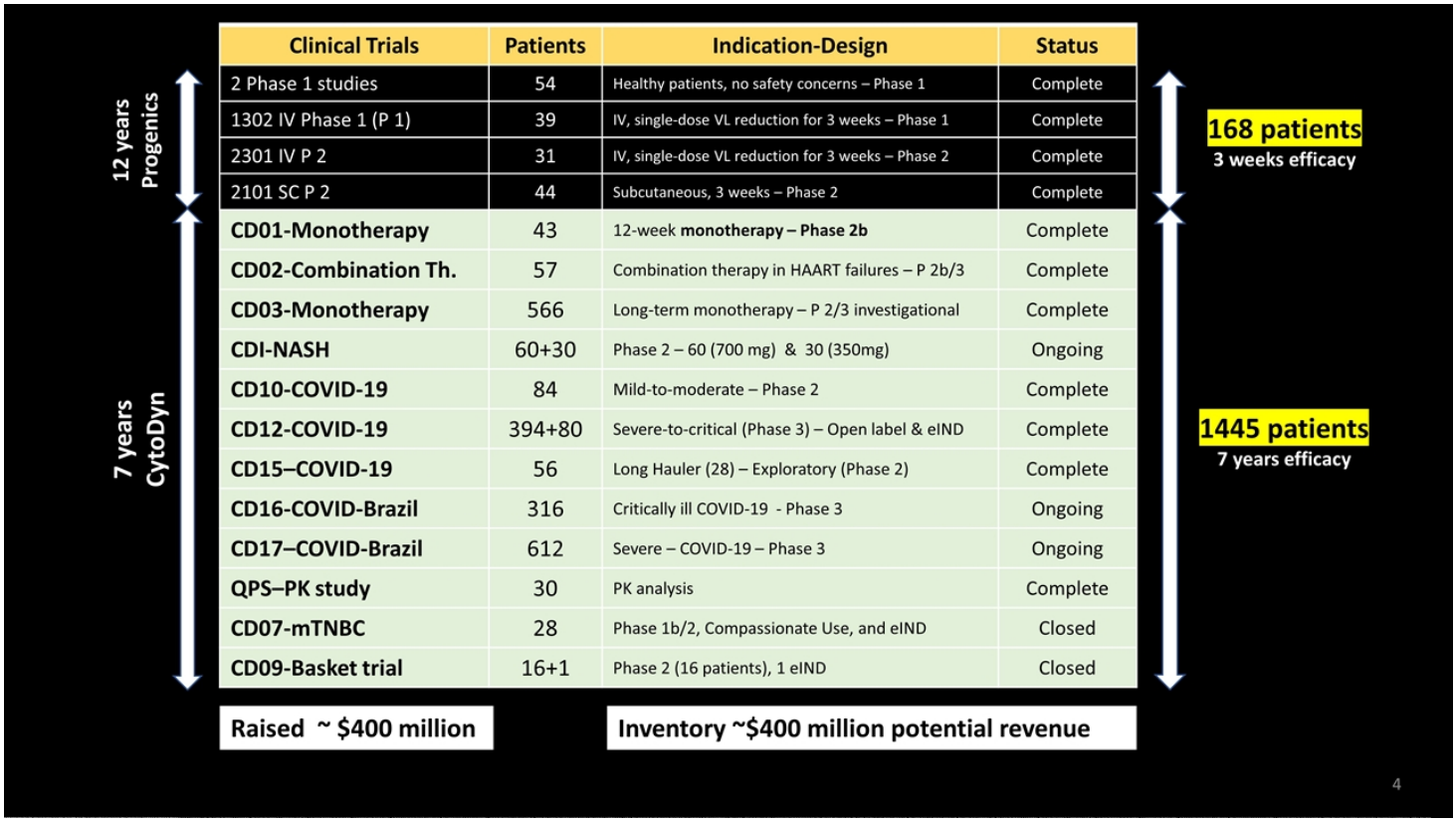
This presentation contains certain forward-looking statements that involve risks, uncertainties and assumptions that are difficult to predict. Words and expressions reflecting optimism, satisfaction or disappointment with current prospects, as well as words such as "believes," "hopes," "intends," "estimates," "expects," "projects," "plans," "anticipates" and variations thereof, or the use of future tense, identify forward-looking statements, but their absence does not mean that a statement is not forward-looking.

Forward-looking statements specifically include statements about leronlimab, its ability to provide positive health outcomes, the possible results of clinical trials, studies or other programs or ability to continue those programs, the ability to obtain regulatory approval for commercial sales, and the market for actual commercial sales. The Company's forward-looking statements are not guarantees of performance, and actual results could vary materially from those contained in or expressed by such statements due to risks and uncertainties including: (i) the regulatory determinations of leronlimab's efficacy to treat human immunodeficiency virus ("HIV") patients with multiple resistance to current standard of care, COVID-19 patients, and metastatic Triple-Negative Breast Cancer ("mTNBC"), among other indications, by the U.S. Food and Drug Administration and various drug regulatory agencies in other countries; (ii) the Company's ability to raise additional capital to fund its operations; (iii) the Company's ability to meet its debt obligations; (iv) the Company's ability to enter into partnership or licensing arrangements with third-parties; (v) the Company's ability to identify patients to enroll in its clinical trials in a timely fashion; (vi) the Company's ability to achieve approval of a marketable product; (vii) the design, implementation and conduct of the Company's clinical trials; (viii) the results of the Company's clinical trials, including the possibility of unfavorable clinical trial results; (ix) the market for, and marketability of, any product that is approved; (x) the existence or development of vaccines, drugs, or other treatments that are viewed by medical professionals or patients as superior to the Company's products; (xi) regulatory initiatives, compliance with governmental regulations and the regulatory approval process; (xii) legal proceedings, investigations or inquiries affecting the Company or its products; (xiii) general economic and business conditions; (xiv) changes in foreign, political, and social conditions; (xv) stockholder actions or proposals with regard to the Company, its management, or its board of directors; and (xvi) various other matters, many of which are beyond the Company's control.

The Company urges investors to consider specifically the various risk factors identified in its most recent Form 10-K, and any risk factors or cautionary statements included in any subsequent Form 10-Q or Form 8-K, filed with the Securities and Exchange Commission. Except as required by law, the Company does not undertake any responsibility to update any forward-looking statements to take into account events or circumstances that occur after the date of this presentation.

OVERVIEW of Last 13 Years of CYTODYN

Year	Total trading ($)	CytoDyn's CEO	Accomplishment
2008	495,725	Allen D. Allen	Cytolin Clinical Hold No Trials
2009	1,303,837		
2010	3,997,954		
2011	14,358,161	Kenneth Van Ness	CytoFelin No Trials
2012	13,992,695	Nader Pourhassan & Current management team	Purchased PRO 140 CD01-Phase 2b HIV CD02- Phase 2/3 piv. HIV CD03-Phase 2/3 inv. HIV CD07-Phase 1b/2 Cancer CD08-Phase 2 Cancer CD10-Phase 2 COVID-19 CD12-Phase 3 COVID-19 CD15-Explaratory Long-Hauler's CD16-Phase 3 COVID-19 CD17-Phase 3 COVID-19 CDI-NASH-Phase 2 NASH
2013	6,101,525		
2014	13,258,855		
2015	18,005,475		
2016	65,431,355		
2017	32,031,997		
2018	40,384,985		
2019	91,965,299		
2020	5,085,168,017		
2021	2,063,332,851		


12 years Progenics
7 years CytoDyn
Clinical Trials | Patients | Indication-Design | Status
2 Phase 1 studies | 54 | Healthy patients, no safety concerns – Phase 1 | Complete
1302 IV Phase 1 (P 1) | 39 | IV, single-dose VL reduction for 3 weeks – Phase 1 | Complete
2301 IV P 2 | 31 | IV, single-dose VL reduction for 3 weeks – Phase 2 | Complete
2101 SC P 2 | 44 | Subcutaneous, 3 weeks – Phase 2 | Complete
CD01-Monotherapy | 43 | 12-week monotherapy – Phase 2b | Complete
CD02-Combination Th. | 57 | Combination therapy in HAART failures – P 2b/3 | Complete
CD03-Monotherapy | 566 | Long-term monotherapy – P 2/3 investigational | Complete
CDI-NASH | 60+30 | Phase 2 – 60 (700 mg) & 30 (350mg) | Ongoing
CD10-COVID-19 | 84 | Mild-to-moderate – Phase 2 | Complete
CD12-COVID-19 | 394+80 | Severe-to-critical (Phase 3) – Open label & eIND | Complete
CD15–COVID-19 | 56 | Long Hauler (28) – Exploratory (Phase 2) | Complete
CD16-COVID-Brazil | 316 | Critically ill COVID-19 - Phase 3 | Ongoing
CD17–COVID-Brazil | 612 | Severe – COVID-19 – Phase 3 | Ongoing
QPS–PK study | 30 | PK analysis | Complete
CD07-mTNBC | 28 | Phase 1b/2, Compassionate Use, and eIND | Closed
CD09-Basket trial | 16+1 | Phase 2 (16 patients), 1 eIND | Closed
168 patients
3 weeks efficacy
1445 patients
7 years efficacy
Raised ~ $400 million
Inventory ~$400 million potential revenue
4

LERONLIMAB – HIV

PROGENICS gave up development of leronlimab (PRO 140) – WHY?

Progenics' Question to the FDA | April 21, 2008

15. Does the Agency agree that the phase 2a studies (PRO 140 2301, PRO 140 2101 and PRO 140 2401) are adequate, assuming results are favorable, to initiate the phase 2b/3 study (PRO 140 3X01)?

FDA response:

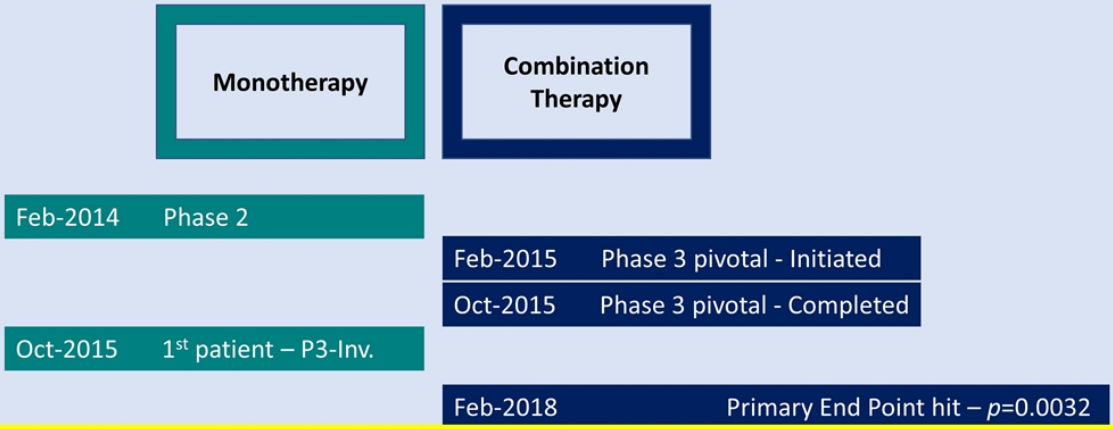
Based on the preliminary data provided to date, the proposed phase 2 development plan does not appear adequate. The primary objective of phase 2 trials is to determine the appropriate dose or doses(s) and dosing frequency for phase 3 trials. At this time the longest study duration for your phase 2 studies is one month of treatment. Longer-term data to assess safety and activity beyond one month are needed prior to initiating phase 3 studies.

LERONLIMAB–HIV: Our Record of Overcoming Adversity

Monotherapy	Combination Therapy
Feb-2014 Phase 2	
	Feb-2015 Phase 3 pivotal - Initiated
	Oct-2015 Phase 3 pivotal – injected 1st patient
Oct-2015 1st patient – P3-Inv.	
	Feb-2018 Primary End Point hit – *p*=0.0032

TOTAL VICTORY FOR CYTODYN

LERONLIMAB–HIV: Our Record of Overcoming Adversity



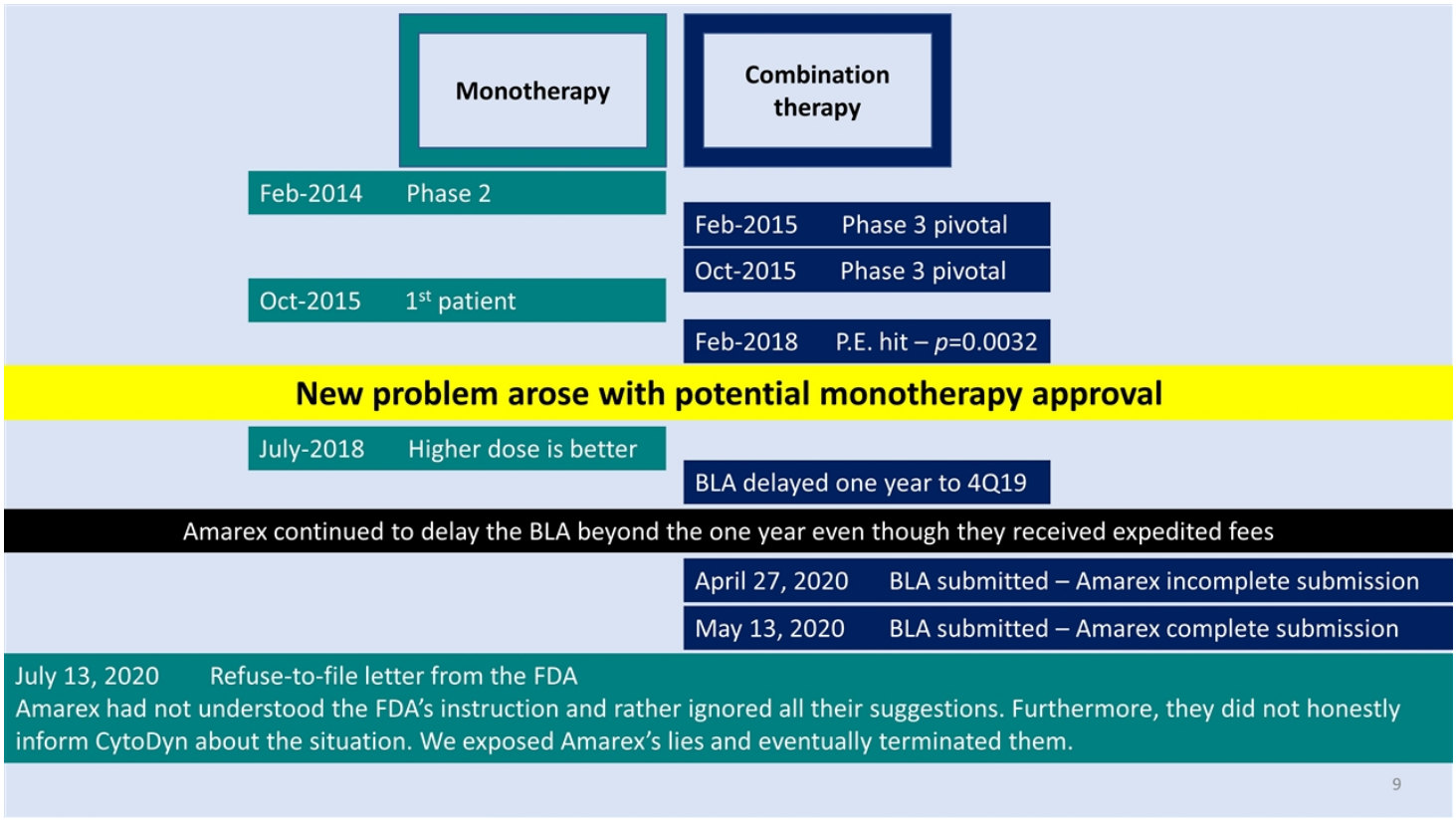
New problem arose with potential monotherapy approval

Monotherapy

Combination Therapy

Minutes from Past FDA meeting (Oct 5, 2016)

PRO140_CD3, which studies use of PRO 140 as monotherapy viral suppression maintenance, will no longer be intended as pivotal. Instead, PRO140_CD03 will be exploratory and seek to better define the mechanisms underlying the efficacy disparity noted in PRO140-CD01, wherein 25% of enrollees remain virologically suppressed at more than 2 years, but the remaining 75% experienced virologic failure. The new objectives of PRO 140_CD03 are to understand what factors differentiate the subjects experiencing long term suppression from those who experienced virologic failure. The ultimate goal would be to identify those subjects who are best suited to PRO140 monotherapy. The change in objectives necessitates a major change in subject population. The proposed new population would now replicate that which participated in PRO 140_CD01: HIV-1 infected subjects fully virally suppressed on HAART without regard to any viral resistance history. A battery of testing modalities will be developed to try and answer the question of what factors are associated with viral suppression maintenance. Consultants for CytoDyn suggested that the most productive investigation is to examine the immunologic aspects that may differ between the successes and the failures. If suspected factors are identified then additional studies can be conducted to further refine the hypothesis. If successful, this may lead to additional BLA submissions in the future.


Monotherapy
Combination therapy
Feb-2014 Phase 2
Feb-2015 Phase 3 pivotal
Oct-2015 Phase 3 pivotal
Oct-2015 1st patient
Feb-2018 P.E. hit – p=0.0032
New problem arose with potential monotherapy approval
July-2018 Higher dose is better
BLA delayed one year to 4Q19
Amarex continued to delay the BLA beyond the one year even though they received expedited fees
April 27, 2020 BLA submitted – Amarex incomplete submission
May 13, 2020 BLA submitted – Amarex complete submission
July 13, 2020 Refuse-to-file letter from the FDA
Amarex had not understood the FDA's instruction and rather ignored all their suggestions. Furthermore, they did not honestly inform CytoDyn about the situation. We exposed Amarex's lies and eventually terminated them.
9

Demonstrating That We Can Solve Problems

Overcame inherited problem from Progenics of not enough efficacy data

Overcame problems of needing higher responder's rate in our monotherapy

Overcame problems with manufacturing new vials and new stability data requirement

Overcame Amarex's poor performance in most crucial times

Now we must overcome RTF

July-2021	Dose justification submitted to the FDA to avoid RTF again-This was a gift from the FDA
Aug-2021	FDA guidance was received, and right team is working on it. Dr. Nitya Ray (also CMC section in the past) & Dr. Chris Recknor (Moving away from Amarex)
Oct-2021	HIV BLA rolling review granted again – Back on track
Nov-16-2021	1st BLA section completed and submitted to the FDA under rolling review – Back on track
Next 2 weeks	2nd section of BLA (CMC) will be filed shortly
In a week or two	Request for a type B meeting?

Demonstrating That We Can Solve Problems

How about MANUFACTURING				
April 2, 2019	**Samsung agreement**	**-**	**Side note: On 4/2/2019**	**CYDY=$0.52**
	Signed a deal that had $20-30 million due very quickly – Our board members pushed back			
	The next 8 months CYDY decreased from $0.52 to $0.28			**on 12/12/2019 CYDY=0.28**
	RECKLESS or GENIUS ?			

Scientific Community Begin to Notice Leronlimab Success in HIV

Multiple presentations in ASM Microbe

Multiple presentations at CROI (one of largest gatherings of top scientists in the world)

Usually, we share our data with scientific community as soon as possible

Many publications of leronlimab in the past 18 months

PRO 140 Single-Agent Maintenance Therapy for HIV-1 Infection: A 2-Year Update

#437

Jay Lalezari[1], Kush Dhody[2], Ula Kowalczyk[1], Kazem Kazempour[2], Nader Pourhassan[3] and Paul J. Maddon[4]

[1]Quest Clinical Research, San Francisco, CA, [2]Amarex Clinical Research, LLC, Germantown, MD [3]CytoDyn Inc., Vancouver, WA, [4]Maddon Advisors LLC, Scarsdale, NY

Introduction

- PRO 140 is a humanized IgG4 monoclonal antibody that blocks HIV-1 from entering and infecting immune cells by binding to CCR5 with high affinity
- Potently inhibits CCR5-mediated HIV-1 entry without blocking the natural activity of CCR5 *in vitro*
  - High genetic barrier to virus resistance
- PRO 140 broadly inhibits genotypically diverse viruses *in vitro*
  - Wild-type and multidrug-resistant HIV-1
  - viruses resistant to maraviroc (SELZENTRY®)
  - Both laboratory and low-passage clinical strains
- No dose-limiting toxicity in animals and generally well tolerated in clinical studies
- Potent, long-term antiviral activity in clinical studies
- Designated FDA Fast Track drug candidate

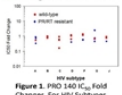


Figure 1. PRO 140 IC_{50} Fold Changes For HIV Subtypes

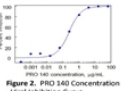


Figure 2. PRO 140 Concentration - Viral Inhibition Curve

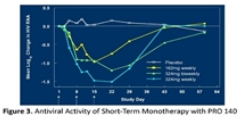


Figure 3. Antiviral Activity of Short-Term Monotherapy with PRO 140

Methods and Materials

- The Extension of CD01 study was designed to evaluate efficacy, safety, and tolerability of long-term PRO 140 monotherapy regimen (Weekly 350 mg SC injection) for the maintenance of viral suppression in subjects who were stable on effective combination ART
- Subjects were shifted from daily oral ART to weekly PRO 140 monotherapy for up to 12 weeks (with 1 week overlap of ART+PRO140) under CD01 study

Key Inclusion Criteria for CD01 study:

- age ≥18 years
- on stable ART regimen for 12 months and no change in last 4 wks prior to Screening
- Exclusive R5-tropic virus (Trofile™ DNA Assay)
- Plasma HIV-1 RNA <100 c/mL at Screening and no documented detectable viral loads (<50 c/mL) within the last 12 months prior to Screening
- Nadir CD4 count >200 cells/mm³
- CD4 count >350 cells/mm³ at Screening

Key Exclusion Criteria for CD01 study:

- Hepatitis B
- A history of an AIDS-defining illness
- ≥ Gr 4 DAIDS lab abnormality
- Subjects who maintained viral suppression for 12 weeks were allowed to continue PRO 140 monotherapy for up to an additional 160 wks (3 yrs)

Study Design Schematic

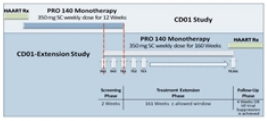


Figure 4. Study Design Schematic

Study Subject Disposition

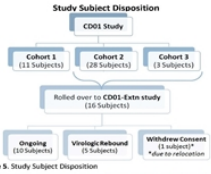


Figure 5. Study Subject Disposition

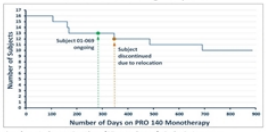
Results

Baseline Characteristics

Characteristic	Statistic	N = 16
Age (years)	Median	54.9
	Min - Max	26-68
Time since HIV Diagnosis (yrs)	Median	12.5
	Min - Max	2-37
Baseline CD4 cell count	Median	593
	Min - Max	365-1059
Gender	Male, n (%)	14 (87.5)
Race	Non-Caucasian, n (%)	3 (18.8)
Ethnicity	Hispanic or Latino, n (%)	4 (25.0)

N = number of eligible subjects within the population and the denominator for percentages
n = number of subjects within the group and the numerator for percentages

Time to Loss of Virologic Response



Graph 1. Kaplan-Meier Plot of Time to loss of Virologic Response

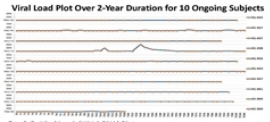
PRO 140 SC provides Long-term, Virologic Suppression in HIV infected Patients

Single Copy HIV-1 RNA Results

Subject ID	Current Status: Number of Weeks on PRO 140 monotherapy	At the time of Abstract Submission: Number of Weeks on PRO 140 monotherapy	Standard HIV-1 RNA Assay (Abbott RealTime) [LabCorp/Covance]	Single-Copy HIV-1 RNA Assay [bioMONTR Lab]
01-025	115	99	TND	**<1**
01-027	123	103	<40	**19**
01-037	105	91	TND	**<1**
01-038	121	103	TND	**<1**
01-052	115	99	<40	**10**
01-053	119	103	TND	**<1**
01-057	107	91	TND	**<1**
01-061	109	91	TND	**<1**
01-064	115	95	<40	**<1**
01-069	41	21	<40	**4**

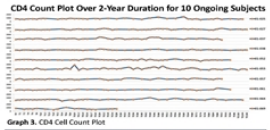
Single copy HIV-1 RNA results from ongoing subjects provides evidence of potent antiviral activity of PRO 140

Viral Load Plot Over 2-Year Duration for 10 Ongoing Subjects



Graph 2. Viral Load (HIV-1 RNA) Plot

CD4 Count Plot Over 2-Year Duration for 10 Ongoing Subjects



Graph 3. CD4 Cell Count Plot

CD4 cell counts maintained at stable levels throughout study

Additional Key Endpoints

- Anti-PRO 140 antibodies were not detected in any subject
- Favorable PRO 140 PK profile that allows once-weekly dosing
- No change in co-receptor tropism at virologic rebound

Safety Summary

- Generally well-tolerated
- No drug-related SAEs
- No discontinuation due to AEs
- No pattern of toxicity
- Administration-site reactions were infrequent, mild, transient, and self-resolving (in <10% of subjects)
- No dose-limiting toxicity in preclinical or clinical studies

Summary of Serious Adverse Events (SAEs)

Parameters	CD01 and CD01-Extn Study (N = 16)
Number of subjects with any reported SAE, n(%)	1 (6.3%)
Incidence of all SAEs	1
SAE, Preferred Term	Bile duct stone
Relationship to Study Drug	Unrelated

Summary of all AEs by Severity

Severity Grading	CD01 and CD01-Extn Study (N = 16) Events	n (%)
Total	122	16 (100%)
Mild	94	7 (43.8%)
Moderate	25	9 (56.3%)
Severe*	0	0 (0.0%)

Note: Severity grading assessment missing for three AEs in the CD01 Extn study
*Severe AEs are those adverse events that were considered severe or life-threatening or causing death.

Summary of all AEs by Relationship to Study Treatment

Relationship to Study Drug	CD01 and CD01-Extn Study (N = 16) Events	n (%)
Total	122	16 (100%)
Definitely Related	2	1 (6.3%)
Probably Related	2	2 (12.5%)
Possibly Related	8	5 (31.3%)
Unlikely	43	5 (31.3%)
Unrelated	65	3 (18.8%)

Note: Relationship to Study Drug assessment missing for two AEs in the CD01 Extension study
N = number of eligible subjects within the population and the denominator for percentages
n = number of subjects within the group and the numerator for percentages

Conclusions and Path Forward

- **PRO 140 CD01-Extension Phase 2b Study**
  - Weekly PRO 140 SC 350 mg was well tolerated and suppressed HIV-1 RNA levels below 40 copies/mL
    - For >40 weeks: in **81.3%** (13/16) of subjects
    - For >2 years: in **62.5%** (10/16) of subjects
  - These results support further development of PRO 140 as a simple, long-acting, single-agent maintenance therapy in selected HIV-1 patients who are experiencing antiretroviral toxicity, intolerance or suboptimal adherence to a daily oral combination regimen.
  - We are currently identifying factors that may predict PRO 140 treatment success.
- **Two Other Phase 2b/3 studies are ongoing:**
  - **Monotherapy Study** (PRO140_CD03): 300 subjects
    PRO 140 as long-acting, single-agent maintenance therapy for 48 weeks in virologically suppressed subjects with CCR5-tropic HIV-1 infection
  - **Pivotal Combination Study** (PRO140_CD02): 30 subjects
    PRO 140 in combination with other antiretroviral agents, in treatment-experienced adult patients infected with CCR5-tropic virus who have documented multi-antiretroviral class resistance and evidence of HIV-1 replication despite ongoing antiretroviral therapy

Contact: Nader Pourhassan, President & CEO, CytoDyn Inc. Email: npourhassan@cytodyn.com, Phone: 503-348-4173

Kush Dhody, Senior Director, Clinical Operations, Amarex Clinical Research, LLC, Email: kushd@amarexcro.com, Phone:301-956-2536

PRO 140 (leronlimab) SC: Long-Acting Single-Agent Maintenance Therapy (SAMT) for HIV-1 Infection

Kush Dhody[1], Kazem Kazempour[1], Nader Pourhassan[2] and Paul J. Maddon[3]
[1]Amarex Clinical Research, LLC, Germantown, MD [2]CytoDyn Inc., Vancouver, WA, [3]Maddon Advisors LLC, Scarsdale, NY

Introduction

- PRO 140 (leronlimab) is a humanized IgG4 monoclonal antibody that blocks HIV-1 from entering and infecting immune cells by binding to CCR5 with high affinity
- Potently inhibits CCR5-mediated HIV-1 entry without blocking the natural activity of CCR5 *in vitro*
  - High genetic barrier to virus resistance
- PRO 140 (leronlimab) broadly inhibits genotypically diverse viruses *in vitro*
  - Wild-type and multidrug-resistant HIV-1
  - Viruses resistant to maraviroc (SELZENTRY®)
  - Both laboratory and low-passage clinical strains
- PRO 140 has been administered intravenously or subcutaneously to more than 650 healthy and HIV-1 infected individuals in Phase I/II/III studies showing potent, long-term antiviral activity in clinical studies.
- No dose-limiting toxicity in animals and generally well tolerated following intravenous administration of single doses of 0.5 to 10 mg/kg or up to 700 mg weekly doses as subcutaneous (SC) injection in clinical studies. The longest duration of exposure lasting more than 4 years at 350 mg SC weekly dose.
- Designated FDA Fast Track drug candidate

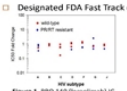


Figure 1. PRO 140 (leronlimab) IC_{50} Fold Changes For HIV Subtypes

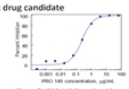


Figure 2. PRO 140 (leronlimab) Concentration - Viral Inhibition Curve

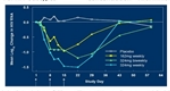


Figure 3. Antiviral Activity of Short-Term Monotherapy with PRO 140

Objectives

- The CD03 study was designed to assess the clinical safety and treatment strategy of PRO 140 (leronlimab) SC as a long-acting, single-agent, maintenance therapy in virally suppressed HIV-1 patients with CCR5-tropic HIV-1 receiving combination antiretroviral therapy.

Methods and Materials

- Patients were shifted from combination antiretroviral regimen to weekly PRO 140 (leronlimab) monotherapy for 48 weeks during the Treatment Phase with the one week overlap of existing retroviral regimen and PRO 140 (leronlimab) at the beginning of the study treatment.
- Patients who experienced virologic failure were given the option of receiving a higher dose of PRO 140 under rescue arm or returning to their prior ART regimen .
- The first ~150 eligible subjects were enrolled to receive PRO 140 (leronlimab) 350mg SC weekly injection in a single-arm study. Subsequently, next ~150 subjects were randomized 1:1 to PRO 140 (leronlimab) 350mg (Group A) or PRO 140 (leronlimab) 525mg (Group B). An additional ~200 subjects will be randomized 1:1 to PRO 140 (leronlimab) 525mg (Group B) or PRO 140 (leronlimab) 700mg (Group C).

Key Inclusion Criteria

- Age ≥18 years
- Receiving combination antiretroviral therapy for last 24 weeks
- Exclusive R5-tropic virus (Trofile™ DNA Assay)
- Plasma HIV-1 RNA <50 c/mL at Screening and no documented detectable viral loads (>50 c/mL) within the last 24 weeks prior to Screening
- Nadir CD4 count >200 cells/mm³
- CD4 count >350 cells/mm³ at in preceding 24 weeks and at Screening

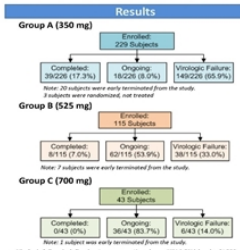
Key Exclusion Criteria

- Hepatitis B
- A history of an AIDS-defining illness
- ≥ Grade 4 DAIDS lab abnormality

Baseline Characteristics

		PRO 140 (leronlimab)		
Parameter	Statistic	350 mg N=227	525 mg N=115	700 mg N=43
Age	Mean (SD)	49.9 (12.5)	49.3 (12.0)	49.4 (11.7)
Gender	Male, n(%)	183 (81.0%)	87 (75.7%)	34 (79.1%)
Race	Caucasian, n(%)	149 (65.9%)	59 (51.3%)	31 (72.1%)
Time since HIV Diagnosis (yrs)	Mean (SD)	17.1 (9.57)	15.1 (10.3)	14.6 (10.0)
Years of HAART	Mean (SD)	15.1 (8.93)	12.7 (8.26)	12.3 (9.10)

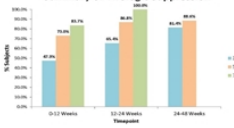
Results



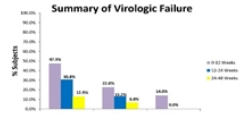
Virologic failure is defined as two consecutive plasma HIV-1 RNA levels of ≥200 c/mL.

Efficacy

Summary of Virologic Suppression



Summary of Virologic Failure



* There are no enrolled subjects in the study beyond 24 weeks as of 1 Jan 2019. Subjects are currently ongoing.

Safety Summary

Summary of Adverse Events (AEs) by Severity

	PRO 140 (leronlimab)		
Parameter	350 mg N=226	525 mg N=115	700 mg N=43
Total # of subjects with ≥1 AE	170 (75.2%)	65 (56.5%)	21 (48.8%)
Total Number of AEs	983	314	69
Mild	62 (27.4%)	33 (28.7%)	16 (37.2%)
Moderate	90 (39.8%)	28 (24.3%)	4 (9.3%)
Severe	18 (8.0%)	3 (2.6%)	1 (2.3%)
Missing	0 (0.0%)	1 (0.9%)	0 (0.0%)

All percentages are based on the number of subjects in the treatment group(N).
A subject is counted only once within each category.

Summary of AEs by Relationship

	PRO 140 (leronlimab)		
Parameter	350 mg N=226	525 mg N=115	700 mg N=43
Total Number of Subjects with ≥1 AE	170 (75.2%)	65 (56.5%)	21 (48.8%)
Total Number of AEs	983	314	69
Definitely Related	42 (18.6%)	21 (18.3%)	5 (11.6%)
Probably Related	14 (6.2%)	0 (0.0%)	1 (2.3%)
Possibly Related	35 (15.5%)	2 (1.7%)	1 (2.3%)
Unlikely	22 (9.7%)	12 (10.4%)	7 (16.3%)
Unrelated	57 (25.2%)	30 (26.1%)	7 (16.3%)

All percentages are based on the number of subjects in the treatment group (N).
A subject is counted only once within each category.

Summary of Serious Adverse Events (SAEs)

	PRO 140 (leronlimab)		
Parameter	350 mg N=226	525 mg N=115	700 mg N=43
Number of subjects with any reported SAE, n(%)	19 (8.4%)	4(3.5%)	2 (4.7%)
Incidence of all SAEs	23	5	2

All percentages are based on the number of subjects in the treatment group (N).
A subject is counted only once within each category.

Injection Site Reactions (ISR)

	PRO 140 (leronlimab)		
Parameter	350 mg N=226	525 mg N=115	700 mg N=43
Total Number of Subjects with ≥ Injection Site Reaction	59 (26.1%)	19 (16.5%)	1 (2.3%)
Total Number of Injection Site Reactions	164	78	1

All percentages are based on the number of subjects in the treatment group (N).
A subject is counted only once within each category.

- None of the reported SAEs were definitely or probably related to PRO 140 (leronlimab).
- Overall, the majority of AEs were considered mild in nature.
- Approximately 95% of injection site reactions were mild in intensity and considered to be self-resolving.
- There were no patterns of drug-related toxicities observed.
- No dose-proportional increase in incidence and severity of AEs were reported with higher doses of PRO 140.

Conclusions and Path Forward

- Based on preliminary results, the majority of patients receiving higher doses of PRO 140 (leronlimab) (525 or 700 mg) as single-agent maintenance therapy (SAMT) were able to maintain virologic suppression.
- Pharmacokinetic parameters demonstrated dose-proportionality over the range of three doses tested in this study.
- Additionally, there were no significant anti-drug antibodies to PRO 140 (leronlimab) detected in subjects.
- Now that response rates for higher doses are more closely aligned with standard of care, in combination with its excellent safety profile, PRO 140 (leronlimab) could be a paradigm shift in the treatment of HIV as a single-agent maintenance therapy.
- In 2019, CytoDyn is targeting a BLA submission for PRO 140 (leronlimab) in treatment of HIV-1 in treatment-experienced patients with CCR5-tropic virus and demonstrated evidence of HIV-1 replication despite ongoing antiretroviral therapy with documented genotypic or phenotypic multi-drug resistance. As the results from the recently completed CD02 study demonstrated that the proportion of subjects in the PRO 140 (leronlimab) group with reductions ≥ 0.5 log10 copies/mL was significantly higher than subjects in the placebo group (p=0.0032).
- The safety of PRO 140 (leronlimab) has been tested in over 650 subjects, providing a strong foundation for upcoming clinical trials for cancer and graft vs. host disease (GvHD) indications.

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Published Paper (8 Paper in ~13 Months)

Publications	Date
International Journal of Infectious Diseases – CCR5 inhibition in critical COVID-19 patients decreases inflammatory cytokines, increases CD8 T0cells, and decreases SARS-CoV2 RNA in plasma by day 14	Oct. 2020
Infectious Diseases Society of America – Clinical Characteristics and Outcomes of Coronavirus Disease 2019 Patients Who Received Compassionate-Use Leronlimab	Oct. 2020
Frontiers – CCR5 Receptor Occupancy Analysis Reveals Increased Peripheral Blood CCR5+CD4+ T Cells Following Treatment With the Anti-CCR5 Antibody Leronlimab	Nov. 2021
Nature Communications – Antibody-based CCR5 blockade protects Macaques from mucosal SHIV transmission	June 2021
Journal of Translational Autoimmunity – Case study of a critically ill person with COVID-19 on ECMO successfully treated with leronlimab	2021
Journal of Translational Autoimmunity – Disruption of CCR5 Signaling to Treat COVID-19-Associated Cytokine Storm: Case Series of Four Critically Ill Patients Treated with Leronlimab	2021
International Journal of Molecular Sciences – Update on Glioblastoma Biology, Genetics, and Current Therapies: Novel Inhibitors of the G Protein-Coupled Receptor CCR5	April 2021
Breast Cancer Research – Leronlimab, a humanized monoclonal antibody to CCR5, blocks breast cancer cellular metastasis and enhances cell death induced by DNA damaging chemotherapy	Jan. 2021

Touching Human Lives

Monotherapy	Video interviews of patients on Monotherapy after 2.5 years. Now 5 more than 7 years
Combination therapy	Doctors requesting extension for their patients in CD02 due to continuous need for leronlimab to suppress viral load (HIV level)

CD02 – Combination therapy 21 patients are 4-5 years in extension arm	
Ongoing Patient Count	
350mg	12
700mg	12
Total Active	**24**

CD01 – Monotherapy More than 7 years	
Ongoing Patient Count	
350mg	2
700mg	3
Total Active	**5**

CD03 – Monotherapy 3 to 5 years	
Ongoing Patient Count	
350mg	6
525mg	14
700mg	17
Total Active	**37**

Touching Human Lives

CD02 – Combination therapy 21 patients are 4-5 years in extension arm	
Ongoing Patient Count	
350mg	12
700mg	12
Total Active	**24**

CD01 – Monotherapy More than 7 years	
Ongoing Patient Count	
350mg	2
700mg	3
Total Active	**5**

CD03 – Monotherapy 3 to 5 years	
Ongoing Patient Count	
350mg	6
525mg	14
700mg	17
Total Active	**37**

Cancer	
Compassionate use	~20
eIND/Basket/Phase1b/2	~20
Total	**~40**

COVID-19	
eIND	Over 80
Open label	~10
Philippines	>200
Total	**>290**

Long-Hauler/NASH	
Long-Hauler	?
NASH	?
Total	**?**

LERONLIMAB – Update, Future Expectations & Timelines

HIV

Approval 2022 very possible

Filing for expanded access for a fee for MDR population

BTD

(Breakthrough Therapy Designation)

FDA response ~6 weeks

Expanded access to be filed

Canada and other countries

1) Brazil trials
2) Philippines
3) US-FDA protocol filed
4) Long-Hauler's trial – setup initiated

NASH & NAFLD

FTD – Phase 3

Autoimmune

New trials

LERONLIMAB – From 1 Indication to 32 X Indications in Just 7 years

Potential Market Size From $50 Million to More Than $100 Billion

Potential Partnership

1	Combination Therapy PrEP HIV CURE Monotherapy	Combination therapy for MDR ~ $30 million Combination therapy for 2 class resistance ~ $1 billion Monotherapy ~ $5 billion PrEP ~ $3 billion	From potential **$30 million** to $1 billion (2 class resistance) Then to **$9 billion** (MDR-Mono-PrEP)
2	mTNBC Cancer BASKET TRIAL	The global cancer therapy market was valued at approximately $158 billion in 2020, and it is expected to witness a revenue of USD $268 billion in 2026. Worldwide cancer data | World Cancer Research Fund International (wcrf.org)	Potential **$50 billion**
3	Severe COVID Critically ill Long Hauler	Potential market size for critical ill COVID-19 population maybe a few billion, however, long-hauler's COVID-19 market size could be much larger than that.	Potential **$5 billion**
4	NASH	About $21 billions by 2023 https://www.reportsanddata.com/report-detail/non-alcoholic-steatohepatitis-nash-market The global NASH market was valued at USD 4.57 billion in 2020 and is projected to reach USD 180.09 billion by 2028, growing at a CAGR of 58.64%from 2020 to 2028	Potential **$10 billion**
5	AUTOIMMUNE DISEASES •Crohn's disease •Polymyositis •IBD (inflammatory bowel disease) •SLE •Graves' disease •Vasculitis •Hashimoto's thyroiditis •Psoriasis •Autoimmune hepatitis •Sjogren's syndrome •Myasthenia gravis	The Global Autoimmune Disease Therapeutics Market size is expected to reach $149.4 billion by 2025, rising at a market growth of 4.34% CAGR during the forecast period	Potential **$50 billion**

Leronlimab - $3.5 Million Down Payment

PRO 140 (leronlimab) was purchased for $3.5 million down payment

Today CytoDyn has one molecule, leronlimab (potential 32 indications)

And our Market cap is ~ $1 Billion (~300 times the down payment for leronlimab)

And this is just the beginning

OVERVIEW of Short- and Long-Term Goals

Dec-2021	File for expanded access for HIV MDR patients in US
Dec-2021	File for expanded access for mTNBC patients in US The FDA has reminded us that if we do receive BTD for our mTNBC, then we have 15 days to file for expanded access program. This also must be posted to our website
Dec-2021	File for FTD for NASH and NAFLD
Dec-2021	File for BTD for both NASH and NAFLD for 350 mg weekly leronlimab dose **or** file for Phase 3
Dec-2021	File with the FDA to allow us to charge for leronlimab for all its expanded access and currently approved compassionate use programs (and RTT programs)
Dec-2021	Long-Hauler trial is being setup and the protocol is being finalized with the FDA
Dec-2021	Health Canada authorized first emergency use for one patient, and we now are in discussions with a Canadian pharmaceutical to provide leronlimab to more mTNBC patients under the same situation and proceed for potential registration of leronlimab in Canada for mTNBC
Jan-2022	Results of our mTNBC BTD filing
1Q-2022	BLA resubmission for HIV
2022	Potential approval of leronlimab for HIV (MDR and two class resistance with limited options)

Executive Management Team

Nader Z. Pourhassan, Ph.D.
President, CEO and Director

Scott A. Kelly, M.D.
Chief Medical Officer, Head of Business Development and Chairman of the Board

Nitya G. Ray, Ph.D.
Chief Operating and Technology Officer

Antonio Migliarese, C.P.A.
Chief Financial Officer

Christopher P. Recknor, M.D.
Senior Executive VP of Clinical Operations