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): December 17, 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))

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 1.01 Entry into a Material Definitive Agreement.

Commercialization and License Agreement

On December 17, 2019, CytoDyn Inc. (the "Company") entered into a Commercialization and License Agreement (the "License Agreement") and a Supply Agreement (the "Supply Agreement") with Vyera Pharmaceuticals, LLC, a Delaware limited liability company ("Vyera"). Pursuant to the License Agreement, the Company granted Vyera an exclusive royalty-bearing license to commercialize pharmaceutical preparations containing leronlimab (PRO 140) (the "Product") for treatment of HIV in humans (the "Field") in the United States (the "Territory").

Pursuant to the terms of the License Agreement, and subject to the conditions set forth therein, Vyera will bear the cost of, and be responsible for, among other things, commercializing the Product in the Territory and will use commercially reasonable efforts to commercialize the Product in the Field in the Territory. Under the terms of the License Agreement, CytoDyn is permitted to license the Product outside of the Territory for uses in the Field or outside the Field or inside the Territory for uses outside of the Field.

In consideration of the license and other rights granted by the Company, Vyera has agreed to pay the Company, within three business days of the effective date of the License Agreement, a $0.5 million license issue fee, with additional payments totaling up to approximately $87.0 million to be made upon the achievement of certain sales and regulatory milestones. Certain milestones are subject to reduction if not achieved within an agreed-upon timeframe. Vyera may also pay the Company additional potential milestone payments upon the regulatory approval of the Product for certain subsequent indications in the Field. Whether a particular subsequent indication qualifies for an additional milestone payment shall be determined in good faith by the parties. In addition, during the Royalty Term (as defined below), Vyera is obligated to pay the Company a royalty equal to 50% of Vyera's gross profit margin from Product sales (defined in the License Agreement as "Net Sales") in the Territory. The royalty is subject to reduction during the Royalty Term after patent expiry and expiry of regulatory exclusivity. Following expiration of the Royalty Term, Vyera will continue to maintain non-exclusive rights to commercialize the Product.

In addition, as partial consideration for the License Agreement, within seven days of the effective date of the License Agreement, Vyera will make an equity investment of $4.0 million in the Company (the "Equity Investment"), in consideration for which the Company will issue to Vyera 13,114,754 shares of CytoDyn's common stock, $0.001 par value per share ("Common Stock"), and a warrant to purchase 6,557,377 shares of Common Stock with an exercise price of $0.30 per share.

The License Agreement will expire upon the expiration of the Royalty Term. The "Royalty Term" means the period beginning on the date of the first commercial sale of the Product and ends on the latest of (i) the expiration of the last valid claim of the patents covering the Product, (ii) ten years after the first commercial sale of the Product, (iii) the expiration of regulatory exclusivity for the Product and (iv) the Biosimilar Entry Date (as defined in the License Agreement). The License Agreement may be terminated by either party for material breach, upon a party's insolvency or bankruptcy, or for a safety concern or clinical failure.

Vyera has the right to terminate the License Agreement (i) on or after the second anniversary of the effective date of the License Agreement upon written notice to the Company in the event the approval ("Regulatory Approval") by the U.S. Food and Drug Administration of the Biologics License Application for the Product for the manufacture and sale of the Product in the Territory for the Initial Indication (as defined in the License Agreement) has not been received by such second anniversary, (ii) if Vyera fails to achieve certain aggregate Net Sales (as defined in the License Agreement) of the Product during the period beginning on the date of first commercial sale and ending on the date that is two years from the date of the first commercial sale, and (iii) at Vyera's convenience following the second anniversary of the first commercial sale of the Product with 180 days' written notice.

The Company has the right to terminate the License Agreement (i) if Vyera challenges the validity of any patent controlled by the Company, (ii) if Vyera fails to make a first commercial sale within 60 days following the later of Regulatory Approval of the Product and the date the Company supplies (or is ready to supply) Vyera with the Product for sale pursuant to the Supply Agreement, (iii) upon Vyera's breach of certain obligations and covenants contained in the License Agreement, (iv) upon Vyera's failure to meet certain minimum requirements contained in the Commercialization Plan (as defined in the License Agreement), subject to a cure period and (v) upon Vyera's failure to make the Equity Investment (as defined below) within seven days of the effective date of the License Agreement.

The License Agreement also contains customary representations, warranties and covenants by both parties, as well as customary provisions relating to indemnification, confidentiality and other matters.

Supply Agreement

Pursuant to the Supply Agreement, the Company has agreed to supply to Vyera and Vyera has agreed to purchase from the Company its requirements of Product for commercialization under the License Agreement. The price that Vyera will pay for purchases of Product is capped at an agreed upon amount that will rise over time in accordance with the Producer Price Index for Pharmaceutical Preparation Manufacturing published by the United States Department of Labor, Bureau of Labor Statistics. Under the terms of the Supply Agreement, Vyera is obligated to make purchases of the Product from the Company pursuant to Vyera's forecasted requirements, updated monthly, which will contain a binding period that will increase over the course of the first two years following receipt of Regulatory Approval of the Product for the Initial Indication. The Supply Agreement contains customary representations, warranties and covenants, including representations and warranties relating to compliance of the Product with specifications and applicable governmental rules and covenants with respect to the rejection of delivered Product and non-conforming Product, product recalls and regulatory communications.

The Supply Agreement will expire at the expiration of the Royalty Term, provided that Vyera shall have the right, in its sole discretion, to extend the term of the Supply Agreement for so long as Vyera agrees to continue to pay the Company an agreed-upon royalty payment. The Supply Agreement will automatically terminate upon the termination of the License Agreement in the event that the termination of the License Agreement occurs prior to the expiration of the Royalty Term. The Supply Agreement may be terminated by either party for material breach or upon a party's insolvency or bankruptcy.

Copies of the License Agreement and the Supply Agreement will be filed as exhibits in an amendment to this Current Report on Form 8-K or in a subsequent periodic report to be filed under the Securities Exchange Act of 1934.

Item 7.01. Regulation FD Disclosure

On December 17, 2019, the Company issued a press release relating to the announcements described in Item 1.01 above, a copy of which is furnished as Exhibit 99.1 to this Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibit No.	Description
99.1	Press Release dated December 17, 2019.

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.

December 18, 2019

By: /s/ Craig Eastwood
Name: Craig Eastwood
Title: Chief Financial Officer

CytoDyn Signs Definitive Agreements with Vyera Pharmaceuticals to Commercialize Leronlimab in the U.S. for the Treatment of HIV

In exchange for the exclusive right to market and distribute leronlimab in the U.S. forHIV-related indications, Vyera will pay upfront and regulatory and sales-based milestone payments of up to $87.5 million, as well as a royalty of 50 percent on net sales. Vyera will also make an investment in CytoDyn of $4 million in the form of registered CytoDyn common stock

CytoDyn will maintain responsibility for the development and FDA approval of leronlimab for allHIV-related and other indications

VANCOUVER, Washington and NEW YORK, New York (December 17, 2019) – **CytoDyn Inc. (OTC.QB: CYDY), ("CytoDyn") and Vyera Pharmaceuticals, LLC ("Vyera"),** today announced that they have entered into a Commercialization and License Agreement (CLA) and a related Supply Agreement to commercialize leronlimab (PRO 140) in the U.S. for the treatment of HIV.

Under the terms of the CLA, CytoDyn will maintain responsibility for the development and FDA approval of leronlimab for allHIV-related and other indications, while Vyera has been granted an exclusive license to market and distribute leronlimab in the U.S. for the treatment of HIV. In exchange for such exclusive license, Vyera has agreed to pay upfront and regulatory and sales-based milestone payments of up to $87.5 million, as well as a royalty of 50 percent on net sales. Vyera also agreed to make an investment in CytoDyn of $4 million in the form of registered CytoDyn common stock.

It is anticipated that these agreements will enable CytoDyn to leverage Vyera's well-established commercial infrastructure and highly-experienced sales team for the launch and commercialization of leronlimab and provide Vyera with a complimentary and novel product to bolster its pipeline of therapies for the treatment of infectious diseases.

"This agreement helps complete the strategic objective to further establish CytoDyn as a leader in efforts to enhance the lives of patients through target-specific medicine," said Nader Pourhassan, Ph.D., CytoDyn's President and Chief Executive Officer. "Vyera's focus on developing therapies for patients living with serious and neglected diseases make them an ideal partner for this collaboration. We are excited to work with Vyera to leverage their platforms and capabilities to potentially offer a more effective treatment option for this HIV population."

Averill L. Powers, Chief Executive Officer of Phoenixus AG, Vyera's parent company, noted: "Vyera's collaboration with CytoDyn demonstrates our commitment to address the needs of significant patient populations across our group companies generally and, in particular, a new level of our commitment to supporting patients living with HIV. "

About Leronlimab (PRO 140)

The U.S. Food and Drug Administration (FDA) has granted a “Fast Track” designation to CytoDyn for two potential indications of leronlimab for deadly diseases. The first as a combination therapy with HAART for HIV-infected patients, and the second is for metastatic triple-negative breast cancer (mTNBC). Leronlimab is an investigational humanized IgG4 mAb that blocks CCR5, a cellular receptor that is important in HIV infection, tumor metastases, and other diseases, including NASH. Leronlimab has successfully completed nine clinical trials in over 800 people, including meeting its primary endpoints in a pivotal Phase 3 trial (leronlimab in combination with standard anti-retroviral therapies in Highly Treatment Experienced (HTE) Multi-Drug Resistant (MDR) HIV Patients).

In the setting of HIV/AIDS, leronlimab is a viral-entry inhibitor; it masks CCR5, thus protecting healthy T cells from viral infection by blocking the predominant HIV (R5) subtype from entering those cells. Leronlimab has been the subject of nine clinical trials, each of which demonstrated that leronlimab can significantly reduce or control HIV viral load in humans. 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 an important role in tumor invasion and metastasis. Increased CCR5 expression is an indicator of disease status in several cancers. Published studies have shown that blocking CCR5 can reduce tumor metastases in laboratory and animal models of aggressive breast and prostate cancer. Leronlimab reduced human breast cancer metastasis by more than 98 percent in a murine xenograft model. CytoDyn is, therefore, conducting a Phase 2 human clinical trial in metastatic triple-negative breast cancer and was granted Fast Track designation in May 2019. Additional research is being conducted with leronlimab in the setting of cancer and NASH with plans to conduct additional clinical studies when appropriate.

The CCR5 receptor appears to play a central role in modulating immune cell trafficking to sites of inflammation and may be important in the development of acute graft-versus-host disease (GvHD) and other inflammatory conditions. Clinical studies by others further support the concept 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, a novel humanized monoclonal antibody targeting the CCR5 receptor. CCR5 appears to play a key role in the ability of HIV to enter and infect healthy T-cells.

The CCR5 receptor also appears to be implicated in tumor metastasis and immune-mediated illnesses, such asgraft-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. CytoDyn plans to seek FDA approval for leronlimab in combination therapy and plans to complete the filing of a Biologics License Application (BLA) in 2019 for that indication. CytoDyn is also conducting a Phase 3 investigative trial with leronlimab (PRO 140) 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 (PRO 140) 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 has received clearance to initiate a clinical trial with leronlimab in metastatic triple-negative breast cancer. More information is at www.cytodyn.com.

About Vyera

Vyera is a United States based biopharmaceutical company committed to developing and commercializing treatments that address serious and rare diseases with high unmet medical needs. Vyera supports programs that offer financial assistance to patients in need and gives discounts to organizations that provide care to underserved populations. Vyera's research and development efforts focus on novel treatment options for toxoplasmosis and other rare or serious health conditions. https://www.vyera.com/.

Forward-Looking Statements

This press release contains certain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and as that term is defined in the Private Securities Litigation Reform Act of 1995, that involve risks, uncertainties, and assumptions that are difficult to predict. CytoDyn and Vyera (collectively, the "Companies") intend that such forward-looking statements be subject to the safe harbors created thereby. 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 Companies' 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 sufficiency of the Companies' cash position, (ii) the Companies' ability to raise additional capital to fund its operations, (iii) the Companies' ability to meet its debt obligations, if any, (iv) the Companies' ability to enter into partnership or licensing arrangements with third parties, (v) the Companies' ability to identify patients to enroll in its clinical trials in a timely fashion, (vi) the Companies' ability to achieve

approval of a marketable product, (vii) the design, implementation and conduct of the Companies' clinical trials, (viii) the results of the Companies' 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 Companies' products, (xi) regulatory initiatives, compliance with governmental regulations and the regulatory approval process, (xii) general economic and business conditions, (xiii) changes in foreign, political, and social conditions, and (xiv) various other matters, many of which are beyond the Companies' control. CytoDyn 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, neither Company the Company undertakes any responsibility to update any forward-looking statements to take into account events or circumstances that occur after the date of this press release.

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