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): May 17, 2021 (May 11, 2021)

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

Delaware	**000-49908**	**83-1887078**
(State or other jurisdiction of incorporation)	**(Commission 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:

☐ 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.

Effective May 11, 2021, CytoDyn Inc. (the "Company") entered into an Exclusive Supply and Distribution Agreement with Macleods Pharmaceuticals Ltd., an Indian corporation, which is a vertically integrated, global pharmaceutical company ("Macleods"), pursuant to which the Company granted Macleods the exclusive right to distribute and sell up to 200,000 vials in calendar year 2021 of the Company's product Vyrologix™ (leronlimab), to treat COVID-19 patients in India under Compassionate Special Permits ("CSP") or Emergency Use Authorization ("EUA") from the India Central Drugs Standard Control Organization ("CDSCO").

Under the Agreement, the Company would sell Vyrologix to Macleods, and Macleods would hold the exclusive right to distribute Vyrologix for COVID-19 in India for a three-year period in accordance with the treatment protocols approved under the applicable CSP or EUA. Under the Agreement, Macleods is responsible for applying for and obtaining CSP or EUA for the treatment of patients with COVID-19, and the Company is responsible for providing all necessary data, information, samples, presentations and assistance to Macleods to allow it to obtain regulatory approval to import, market, promote and sell Vyrologix in India. The parties have additionally agreed to negotiate in good faith and use commercially reasonable efforts to enter into a Quality Agreement, which agreement will set forth the policies, procedures and standards by which the parties will coordinate and implement the operation and quality assurance activities and regulatory compliance objectives with respect to Vyrologix. Either Party may terminate the Agreement for a material breach not cured within thirty (30) days of written notice or for convenience upon sixty (60) days-notice.

The above description of the Agreement does not purport to be complete and is qualified in its entirety by the full text of the Agreement, which the Company intends to file as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended May 31, 2021.

Item 7.01 Regulation FD Disclosure

On May 13, 2021, the Company issued a press release announcing its entry into the Exclusive Supply and Distribution Agreement with Macleods as described above under Item 1.01. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K ("Current Report").

The information in Exhibit 99.1 shall not be deemed as "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of such Section, nor shall it be deemed incorporated by reference in any filing by the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, regardless of any general incorporation language in such filing, unless expressly incorporated by specific reference in such filing.

Forward-Looking Statements

This Current Report on Form 8-K contains certain forward-looking statements that involve risks, uncertainties and assumptions that are difficult to predict. 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 Vyrologix, its ability to have positive health outcomes, the ability to obtain regulatory approval for commercial sales, and the market for actual commercial sales once approval has been granted. 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 sufficiency of the Company's cash position, (ii) the Company's ability to raise additional capital to fund its operations, (iii) the Company's ability to meet its debt obligations, if any, (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) general economic and business conditions, (xiii) changes in foreign, political, and social conditions, and (xiv) 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 report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated May 13, 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.

Dated: May 17, 2021

By: /s/ Arian Colachis
Arian Colachis
Senior Vice President, General Counsel and Corporate Secretary

CytoDyn Signs Distribution Agreement with Macleods Pharmaceuticals Ltd. to Pursue EUA and Compassionate Use Access to Leronlimab in India

Macleods is one of the largest pharmaceutical companies in India with presence in over 140 countries

VANCOUVER, Washington, May 13, 2021 (GLOBE NEWSWIRE) — **CytoDyn Inc. (OTC.QB: CYDY)**, ("CytoDyn" or the "Company"), a late-stage biotechnology company developing leronlimab (Vyrologix or PRO 140), a CCR5 antagonist with the potential for multiple therapeutic indications, announced today it has executed an exclusive supply and distribution agreement with Macleods Pharmaceuticals Ltd. in India. This commercial agreement will enable Macleods to sell leronlimab in India following regulatory clearance.

Nader Pourhassan, Ph.D., President and Chief Executive Officer of CytoDyn, stated, "We are delighted Macleods Pharmaceuticals reached out to CytoDyn and equally excited to reach this agreement with their team so quickly. From the time they first contacted us about our drug, we were able to conclude this agreement within a few days. It is an honor to work with an organization so motivated to bring leronlimab to COVID-19 patients in India. Currently India has zero product approved for critically ill Covid-19 patients and we are delighted to be working toward being the first approved drug for this population."

Vijay Agarwal, a Business Development Director at Macleods, commented, "We are thrilled with our recently executed exclusive supply and distribution agreement with CytoDyn. We believe there is an immediate need for leronlimab in our country, to save COVID-19 infected patients who are on ventilators. We need to bring this product to market ASAP for them!"

About Macleods Pharmaceuticals Ltd.

Macleods, headquartered in Mumbai, India, is a vertically integrated, global pharmaceutical company. Established in 1986, Macleods features in top 10 pharmaceutical companies in India. Macleods specializes in the development and manufacturing of active pharmaceutical ingredients and finished dosage pharmaceutical formulations. More information is available at www.macleodspharma.com.

About Leronlimab (PRO 140)

Leronlimab has been studied in 11 clinical trials involving more than 1,200 people and met its primary endpoints in a pivotal Phase 3 trial (leronlimab combined with standard antiretroviral therapies in HIV-infected treatment-experienced patients).

Leronlimab is a viral-entry inhibitor in HIV/AIDS. It masks CCR5, thus protecting healthy T cells from viral infection by blocking the predominant HIV (R5) subtype from entering those cells. Nine clinical trials have demonstrated leronlimab could significantly reduce or control HIV viral load in humans. The leronlimab antibody appears to be a powerful antiviral agent with fewer side effects and less frequent dosing requirements than currently used daily drug therapies.

CytoDyn has successfully completed a Phase 3 pivotal trial using leronlimab combined with standard antiretroviral therapies in HIV-infected treatment-experienced patients. CytoDyn has been working diligently to resubmit its Biologics License Application ("BLA") for this HIV combination therapy since receiving a Refusal to File letter in July 2020 and subsequently meeting with the FDA telephonically to address their written guidance concerning the submission. CytoDyn expects to resubmit its BLA via a rolling submission starting in the third quarter of calendar 2021.

About CytoDyn

CytoDyn is a late-stage biotechnology company developing innovative treatments for multiple therapeutic indications using leronlimab, a novel humanized monoclonal antibody targeting the CCR5 receptor. CCR5 appears to play a critical role in the ability of HIV to enter and infect healthy T-cells. 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. 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 sufficiency of the Company's cash position, (ii) the Company's ability to raise additional capital to fund its operations, (iii) the Company's ability to meet its debt obligations, if any, (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) general economic and business conditions, (xiii) changes in foreign, political, and social conditions, and (xiv) 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 press release.

CONTACTS

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