
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 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): June 12, 2019

CytoDyn Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

000-49908
(Commission
File Number)

83-1887078
(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

Not Applicable
(Former name or former address, if changed since last report.)

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
Common Stock, par value \$0.001 per share	CYDY	OTC QB of OTC Markets Group, Inc.

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 3.02 Unregistered Sales of Equity Securities.

The disclosure in Item 8.01 of this Form 8-K is incorporated by reference into this Item 3.02.

In addition, from December 27, 2018 to June 3, 2019, CytoDyn Inc., a Delaware corporation, (the “Company”), received redemption notices from the holder of the Company’s convertible note issued on June 26, 2018 requesting the redemption of an aggregate of \$1,605,000 of the outstanding balance thereof. In satisfaction of the redemption notices, the Company issued 4,217,767 shares of Common Stock to the note holder in accordance with the terms of the convertible note. Following the redemption, the outstanding balance of the convertible note, including accrued but unpaid interest, was approximately \$4,635,000. The Company relied upon the exemption from registration provided by Section 3(a)(9) of the Securities Act of 1933, as amended, and upon similar exemptions under applicable state laws, in connection with these redemptions.

Item 7.01. Regulation FD Disclosure

On June 14, 2019, the Company, issued a press release announcing the results of its warrant tender offers. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K.

Item 8.01 Other Events*Warrant Tender Offer*

The Company previously reported its tender offer (the “Warrant Tender Offer”) for certain outstanding series of eligible warrants, offering the holders of such warrants the opportunity to amend and exercise their warrants at a reduced exercise price equal to the lower of (i) their respective existing exercise price (the “Original Exercise Price”) or (ii) \$0.40 per share of common stock. As an inducement to holders to participate in the Warrant Tender Offer, the Company offered to issue to participating holders shares of common stock equal to an additional 50% of the number of shares issuable upon exercise of the eligible warrants (collectively, the “Additional Shares”). The Warrant Tender Offer was made upon the terms and subject to the conditions set forth in the Offer to Amend and Exercise Warrants to Purchase Common Stock of CytoDyn Inc., previously mailed to the holders of eligible warrants on May 14, 2019, and which was included in the Company’s Schedule TO-I initially filed with the Securities and Exchange Commission (the “SEC”) on May 14, 2019.

At 5:00 P.M. (Eastern time) on June 12, 2019, the offering period and withdrawal rights for the Warrant Tender Offer expired. Upon completion of the Warrant Tender Offer, 368 Original Warrants to purchase up to 22,943,159 shares of common stock had been validly tendered and not withdrawn in the Warrant Tender Offer, for gross cash proceeds to the Company of approximately \$9.13 million. Accordingly, an aggregate of 11,471,551 Additional Shares will be issued to participating holders of eligible warrants. Solicitation fees of approximately \$820,000 were paid to the solicitation agent in the Warrant Tender Offer.

5,137,289 of the shares of common stock sold to investors in the Warrant Tender Offer were sold pursuant to the Company’s Registration Statements on Form S-3 (File No. 333-223195) declared effective on March 7, 2018, and the prospectuses and prospectus supplements filed thereunder. 34,414,710 shares of common stock, including all of the Additional Shares, were sold to accredited investors in reliance upon the exemption provided by Rule 506 of Regulation D and Section 4(a)(2) of the Securities Act of 1933, as amended.

Dr. Scott A. Kelly validly tendered Original Warrants beneficially owned by him, covering an aggregate of 50,000 shares of Common Stock, and received 25,000 Additional Shares. Additionally, two entities affiliated with Carl Dockery validly tendered Original Warrants beneficially owned by him, covering an aggregate of 1,425,000 shares of Common Stock, and received 712,500 Additional Shares. Dr. Kelly and Mr. Dockery are members of the Company's board of directors and participated on terms identical to those applicable to other holders of Original Warrants.

Accordingly, the Company is instructing its transfer agent to issue an aggregate of 34,414,710 shares of common stock to participants in the Warrant Tender Offer.

Item 9.01 Financial Statements and Exhibits.

(d)	Exhibit No.	Description
	99.1	<u>Press Release, dated June 14, 2019.</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.

June 14, 2019

By: /s/ Michael D. Mulholland

Name: Michael D. Mulholland

Title: Chief Financial Officer



CytoDyn Raises over \$12 Million in New Capital from Private and Public Warrant Offers in the Last Five Weeks with Minimum Dilution

VANCOUVER, Washington (June 14, 2019)– **CytoDyn Inc. (OTC.QB: CYDY)**, (“CytoDyn” or the “Company”), a late-stage biotechnology company developing leronlimab (PRO 140), a CCR5 antagonist with the potential for multiple therapeutic indications announced today that it raised approximately \$9.1 million from its recently completed public warrant tender offer. Combined with \$3 million raised from a private warrant exercise offer in May, new capital injected on a gross basis in the last five weeks now totals over \$12 million with only about 15 million shares of dilution.

“When evaluating the advancement of leronlimab, we continue to be very excited on several fronts, including:

- The completion of our first BLA submission in the third quarter of this year, as a combination therapy for HIV
- The recent submission to the FDA of a protocol for a pivotal trial for a monotherapy indication as a label expansion after potential first approval
- The evaluation of multiple potential indications for leronlimab in cancer, GvHD and NASH

These evolving prospects present many potential pathways to leverage the capabilities of leronlimab. The level of investor participation in the recent capital raises brings credence to our mission. The warrant tender offers present an efficient means to continue to engage our current shareholder base while minimizing the potentially dilutive impact of other sources of capital. This and other funding platforms (licensing/partnering opportunities) will continue to be explored by CytoDyn for the remainder of 2019,” added Dr. Nader Pourhassan, CytoDyn’s President and Chief Executive Officer.

“In addition to these developments, CytoDyn is about to enter the world of cancer therapeutics with the long-awaited first patient injection for TNBC approaching. We continue our product-readiness planning with Samsung BioLogics and look forward to preparing for our future with the objectives of benefiting patients and rewarding our shareholders,” concluded Dr. Nader Pourhassan.

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. 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 700 people, including meeting its primary endpoints in a pivotal Phase 3 trial (leronlimab in combination with standard anti-retroviral therapies in HIV-infected treatment-experienced 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 >98% 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 in immune-mediated illnesses, such as graft-vs-host disease (GvHD) and NASH. CytoDyn has successfully completed a Phase 3 pivotal trial with leronlimab in combination with standard anti-retroviral therapies in HIV-infected treatment-experienced patients. 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.

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. 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

Investors:

Nader Pourhassan, Ph.D.
President & CEO
NPourhassan@CytoDyn.com

Marek Ciszewski, J.D.
Edison, Inc.
MCiszewski@EdisonGroup.com