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): September 29, 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 8.01. Other Events.

On September 29, 2021, CytoDyn Inc. issued a press release responding to the "plan" put forward by an activist group led by Paul Rosenbaum and Bruce Patterson.

A copy of the press release is included as Exhibit 99.1 to this Report and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

99.1	Press Release, dated September 29, 2021
104	Cover Page Interactive Data File (formatted as inline XBRL)

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 hereunto duly authorized.

Date: September 29, 2021

CYTODYN INC.

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

Exhibit 99.1

CytoDyn Comments on Rosenbaum/Patterson Activist Group "Plan"

Company is Successfully Executing on Multi-Faceted Strategy to Bring Leronlimab to Market

Activist Group Offers No New Compelling Strategic Direction and its "Plan" Includes Numerous Misrepresentations and Misleading Statements

Activist Group's Continued Attempts to Link CytoDyn to IncellDx Are Troubling, Given Connections Between IncellDx and Group's Nominees

Shareholders Do Not Need to Take Any Action at this Time

VANCOUVER, Washington – September 29, 2021 – CytoDyn Inc. (OTCQB: CYDY) ("CytoDyn" or the "Company"), a late-stage biotechnology company developing leronlimab, a CCR5 antagonist with the potential for multiple therapeutic indications, today responded to the "plan" put forward by an activist group led by Paul Rosenbaum and Bruce Patterson (the "Rosenbaum/Patterson Group" or the "Activist Group"):

CytoDyn is highly focused on the expeditious development of leronlimab to help patients with critical needs. Clinical development of any product is a multi-year endeavor. Within this context, the Company has acted as quickly as possible – bringing leronlimab from the Phase 2b stage to successfully completing a pivotal Phase 3 (p=0.0032) in seven years, which was significantly faster than leronlimab's progress with its prior owner. CytoDyn is exploring several different indications for leronlimab. These include COVID-19 critical and severe hospitalized patients as well as long-haulers, HIV and 22 different cancer types. The Company strongly believes in the drug's potential – especially given that it is variant agnostic when it comes to treating COVID-19.

The Activist Group's missive is not a "plan"; it appears to be a misguided and misleading attempt to discredit the significant efforts of CytoDyn to bring leronlimab's lifesaving potential to market to help patients and drive value for shareholders. The success of these efforts is clearly demonstrated by the increasingly long list of positive developments that CytoDyn has announced recently, including the clearance from Brazil's regulatory authority, ANVISA (Agência Nacional de Vigilância Sanitária), to begin an additional Phase 3 CD16 clinical trial of leronlimab with IV treatment, which the Company believes will have an enormous advantage over treatment via subcutaneous (SQ) injections. CytoDyn will continue to work tirelessly towards approvals for leronlimab and are laser focused on doing what is best for all shareholders.

Readers of the Activist Group's "plan" should consider the following:

The Activist Group Offers No New Compelling Strategic Direction with Respect to Cancer Therapy Approval

- CytoDyn is currently working with some of the top oncological opinion leaders in the world from well-respected academic institutions. These experts will assist CytoDyn in determining the appropriate targets and the most efficient path to Breakthrough Therapy designation and approval of leronlimab.[1]
- CytoDyn has already stated publicly that it believes leronlimab has a potential synergistic effect withPD-L1/PD-1 inhibitors, PARP inhibitors, antibody-drug conjugates, and chemotherapy. However, since the first cancer indication with mTNBC has shown what the Company believes to be very strong results, CytoDyn will focus obtaining Breakthrough Therapy designation as the fastest path to approval. Approval of leronlimab in combination with other therapies will take at least another two to three years – but if the Company receives approval for mTNBC, then label expansion would be much faster for any additional cancer indication.[2]

1 CytoDyn Form 10-K, May 31, 2020, https://www.sec.gov/Archives/edgar/data/1175680/000119312520220598/d923315d10k.htm

2 "Investment Community Webcast," September 8, 2021, https://78449.themediaframe.com/dataconf/productusers/cydy/mediaframe/46521/indexl.html

- CytoDyn recently signed a contract with a top oncology academic institution to evaluate the anti-tumor effect of leronlimab and checkpoint inhibitors.[3]
- The Company has already publicly discussed the potential value of leronlimab with combination therapy. Further, current management has first-hand experience with the potential of leronlimab in monotherapy for patients who respond to leronlimab single agent therapy and in combination therapy when other treatments have failed – or when a patient is intolerant of certain standard of care regimens and therefore their background therapy is their last recourse.[4]
- Regarding pharmaceutical partners, CytoDyn has been in contact with potential partners both domestically and internationally. The main catalyst for partnerships is data, which CytoDyn did not have previously. The Company now has that data and is evaluating options including partnerships with academic institutions and major pharmaceutical companies.[5]

The Activist Group's Continued Attempts to Link CytoDyn to IncellDx Are Troubling

Patient safety and data accuracy will always remain CytoDyn's main concern. Based on its first-hand experience in working with IncellDx, CytoDyn sees any relationship between IncellDx and the Company as a liability for shareholders rather than an asset. That is why the Activist Group's suggestion to define cancer targets using the IncellDx H-Scoring system is misguided – particularly since the Group proposes that CytoDyn license this system from IncellDx. Consider the following:

- It is clearly a direct conflict of interest for Dr. Bruce Patterson to continuously seek to force a relationship between IncellDx and CytoDyn while trying to gain a seat on the Board of Directors of CytoDyn.
- Together with his wife, Dr. Patterson owns approximately 34% of IncellDx and Jeff Beaty, another member of the Activist Group, owns about 2.3% of IncellDx. They previously failed to disclose the frequent requests for CytoDyn to purchase IncellDx for as much as $350 million. They clearly have a financial interest in licensing the IncellDx H-scoring system. While the Activist Group's proposed slate of directors recently tried to distance themselves from any relationship between IncellDx and CytoDyn, we believe it is evident this is not truly the case.
- To add insult to injury, the Activist Group not only choose Dr. Patterson to be on its slate, it also supports the use of Dr. Patterson's unproven test, which would allow Dr. Patterson to profit from CytoDyn.

The Activist Group's Plan Includes Numerous Mistakes

These mistakes include the following:

- The Activist Group's implication that CytoDyn would use Amarex as its clinical research organization (CRO) for its current oncology studies is incorrect. CytoDyn has already announced publicly that it will not be using Amarex for current oncology studies going forward and the Company is identifying and interviewing Oncology-focused CRO's with the input of the executive team, KOL's, and Scientific Advisory Board.[6]

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3 "Investment Community Webcast," September 8, 2021, https://78449.themediaframe.com/dataconf/productusers/cydy/mediaframe/46521/indexl.html

4 CytoDyn Form 8-K, September 22, 2021, https://www.sec.gov/ix?doc=/Archives/edgar/data/1175680/000119312521279389/d218561d8k.htm

5 "Investment Community Webcast," September 8, 2021, https://78449.themediaframe.com/dataconf/productusers/cydy/mediaframe/46521/indexl.html

6 "Investment Community Webcast," September 8, 2021, https://78449.themediaframe.com/dataconf/productusers/cydy/mediaframe/46521/indexl.html

- CytoDyn's current oncology program is not dependent on the success of the potential approval of the long hauler's indication, as the Activist Group implies. Dr. Nader Pourhassan has a proven track record of raising capital of over $420 million to support the various indications of leronlimab. By contrast, the Activist Group's proposed slate of directors does not have a proven track record of raising capital, putting the Company potentially at financial risk. We believe the Activist Group's financing proposal is a clear indication of their lack of experience.
- The Activist Group's depiction of the timing for CytoDyn's cancer trial is incorrect. The Company's executive team is in final stage of completion of the protocol for submission of its basket trial for 22 cancers with the advice of top oncologists with clinical experience (not pathologists, such as Dr. Bruce Patterson).[7] Current FDA guidelines estimate an approval process for a drug to be 12 years, yet CytoDyn has come close to potential approval for multiple indications in just seven years.

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Shareholders should not be fooled by the Activist Group's misleading "plan". The bottom line is that this Group has motives and incentives that differ greatly from those of all other shareholders – while misleading shareholders about their intentions, conflicts of interest, legal transgressions and professional competencies.

Litigation/Proxy Process Update

Shareholders do not need to take any action at this time. CytoDyn urges shareholders to ignore any calls, emails or mailings from the Activist Group. As a reminder, CytoDyn believes that the Activist Group's notice of director nominations was invalid because it failed to comply with the Company's by-laws. The Activist Group has sued the Company in the Delaware Court of Chancery, seeking declaratory judgment that their nomination notice was valid. This case remains pending, and the Court has scheduled a hearing for October 6, 2021. Unless the Court disagrees with CytoDyn, the Activist Group's director nominations will be disregarded, and no proxies or votes in favor of its nominees will be recognized or tabulated at the 2021 Annual Meeting.

The Company has filed its preliminary proxy materials with the SEC. Shareholders will be receiving the Company's definitive proxy materials once they have been reviewed by the SEC. To the extent shareholders have voted on the Activist Group's proxy card, they can vote on the Company's proxy card once it becomes available to revoke their vote on the Activist Group's card. Only the latest-dated proxy card counts.

CytoDyn will continue to update shareholders on further developments as appropriate.

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 plays a critical role in the ability of HIV to enter and infect healthy T-cells and appears to be implicated in tumor metastasis and immune-mediated illnesses, such as NASH.

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7 CytoDyn Press Release, September 22, 2021, https://www.sec.gov/Archives/edgar/data/1175680/000119312521279389/d218561dex991.htm; "Investment Community Webcast ," September 8, 2021, https://78449.themediaframe.com/dataconf/productusers/cydy/mediaframe/46521/indexl.html

CytoDyn successfully completed a Phase 3 pivotal trial using leronlimab combined with standard antiretroviral therapies inHIV-infected patients who were heavily treatment-experienced individuals with limited treatment options. CytoDyn is working diligently to resubmit its BLA for this HIV combination therapy since receiving a Refusal to File in July 2020 and subsequently meeting with the FDA telephonically to address their written guidance concerning the filing. On July 1, 2021, CytoDyn announced that it had submitted a dose justification report to the FDA, an integral step in the resubmission process for its BLA. CytoDyn also completed a Phase 2b/3 investigative trial with leronlimab used as a once-weekly monotherapy for HIV-infected patients. CytoDyn plans to initiate a registration-directed study of leronlimab monotherapy indication. If successful, it could support a label expansion approval. Clinical results to date from two trials have shown that leronlimab can maintain a suppressed viral load in a sub-population of R5 HIV patients who chose to switch from their daily pills regimen to once-a-week subcutaneous dose of leronlimab. Several patients on leronlimab's Phase 2b extension arm have remained virally suppressed for almost 7 years and many patients in our Phase 2b/3 investigative trial are passing two and some four years of monotherapy with suppressed viral load.

CytoDyn is also conducting a Phase 2 clinical trial with leronlimab in mTNBC, a Phase 2 basket trial in solid tumor cancers (22 different cancer indications), Phase 2 investigative trial for post-acute sequelae of SARS COV-2, also known as COVID-19 long haulers, and a Phase 2 clinical trial for NASH. CytoDyn has already completed a Phase 2 and Phase 3 trial for mild-to-moderate and severe-to-critical COVID-19 patients, respectively, for which CytoDyn did not meet its primary or secondary endpoints, except for the secondary endpoint in the critically ill subpopulation. 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 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 press release.

Important Information

CytoDyn intends to file with the SEC a definitive proxy statement and associated proxy card in connection with the solicitation of proxies for the Company's 2021 Annual Meeting. Details concerning the nominees of the Company's Board of Directors for election at the 2021 Annual Meeting will be included in the proxy statement. BEFORE MAKING ANY VOTING DECISION, INVESTORS AND STOCKHOLDERS OF THE COMPANY ARE URGED TO READ ALL RELEVANT DOCUMENTS FILED WITH OR FURNISHED TO THE SEC, INCLUDING THE COMPANY'S DEFINITIVE PROXY STATEMENT AND ANY SUPPLEMENTS THERETO, BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION. Investors and stockholders will be able to obtain a copy of the definitive proxy statement and other documents filed by the Company free of charge from the SEC's website, www.sec.gov. The Company's stockholders will also be able to obtain, without charge, a copy of the definitive proxy statement and other relevant filed documents by directing a request by mail to CytoDyn Inc. at 1111 Main Street, Suite 660, Vancouver, Washington 98660.

Participants in the Solicitation

The Company, its directors and certain of its executive officers will be deemed participants in the solicitation of proxies from stockholders in respect of the 2021 Annual Meeting. Information regarding the names of the Company's directors and executive officers and their respective interests in the Company by security holdings or otherwise is set forth in the Company's Annual Report on Form 10-K for the fiscal year ended May 31, 2021, filed with the SEC on July 30, 2021, and the Company's definitive proxy statement for the 2020 annual meeting, filed with the SEC on September 1, 2020. To the extent holdings of such participants in the Company's securities have changed since the amounts described in the proxy statement for the 2020 annual meeting, such changes have been reflected on Initial Statements of Beneficial Ownership on Form 3 or Statements of Change in Ownership on Form 4 filed with the SEC. These documents can be obtained free of charge from the sources indicated above. Additional information regarding the interests of these participants in any proxy solicitation and a description of their direct and indirect interests, by security holdings or otherwise, will also be included in any proxy statement and other relevant materials to be filed with the SEC, if and when they become available.

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