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 14, 2023

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 December 14, 2023, CytoDyn Inc. (the "Company") held a webcast for investors via the internet to provide an update regarding recent developments at the Company since the appointment of Jacob P. Lalezari, M.D., as the Company's interim CEO. Information covered in the update included discussion about recent communications with the U.S. Food and Drug Administration (the "FDA") and the status of the clinical hold imposed by the FDA and protocol submission. The webcast was recorded and will be available on the Company's website at www.cytodyn.com through January 14, 2024. The website should not be considered part of this Form 8-K. The Company will post an update to one of the questions included under Frequently Asked Questions on its website to add information provided during the webcast, as follows:

What is the status of the clinical hold?

The Company received a letter from the FDA at the beginning of December 2023 notifying the Company that: (i) the "partial hold" implemented by the FDA in March 2022 had been lifted; and (ii) a new "full hold" had been applied as it relates to the newly proposed clinical trial protocol submitted in November 2023 alongside the Company's complete response to the partial clinical hold.

As a whole, the Company views this as a significant step in the right direction, as the partial clinical hold that had been in place since March 2022 has been resolved. That being said, the Company now needs to resolve the FDA's comments associated with its newly proposed clinical trial protocol which resulted in the procedural "full hold" that is currently in place. The Company believes the "full hold" will be removed after we adequately respond to the FDA's comments and incorporate the FDA's specific guidance as it relates to the proposed protocol.

The Company believes the proposed HIV study will allow the Company to further establish leronlimab's mechanism of action in a cost-effective manner, and is currently working to incorporate the FDA's feedback and submit an amended protocol as soon as practicable. The Company expects to submit a revised protocol to the FDA in January 2024.

Note Regarding Forward-Looking Statements

The information included in this report contains forward-looking statements relating to, among other things, our communications with the U.S. Food and Drug Administration, decisions by the FDA, future clinical trials, and business strategy. The reader is cautioned not to rely on these statements, which are based on current expectations of future events. For important information about these statements and/or our Company, including the risks, uncertainties and other factors that could cause actual results to vary materially from the assumptions, expectations and projections expressed in any forward-looking statements, the reader should review the Annual Report on Form 10-K for the fiscal year ended May 31, 2023, including in the sections captioned "Forward Looking Statements" and "Item 1A. Risk Factors", as later supplemented by our Form 10-Q for the quarter ended August 31, 2023, in the section captioned "Item 1A. Risk Factors". CytoDyn Inc. does not undertake to update any forward-looking statement as a result of new information or future events or developments.

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: December 14, 2023

By /s/ Antonio Migliarese
Antonio Migliarese
Chief Financial Officer