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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549**

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**FORM 8-K**

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**Current Report  
Pursuant to Section 13 or 15(d)  
of The Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): November 3, 2023**

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**CytoDyn Inc.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction of incorporation or organization)

**000-49908**  
(Commission File Number)

**83-1887078**  
(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)

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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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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.

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**Item 7.01 Regulation FD Disclosure.**

On November 3, 2023, CytoDyn Inc. (the “Company”) published its Letter to Shareholders dated November 3, 2023 to the Company website and circulated the same via press release.

**Item 9.01 Financial Statements And Exhibits.**

(d) Exhibits.

99.1 [Letter to Shareholders dated November 3, 2023.\\*\\*](#)

Exhibit 104 The cover page from this Current Report on Form 8-K formatted in Inline XBRL.

\*\* Furnished, not filed.

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**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: November 3, 2023

By /s/ Antonio Migliarese  
Antonio Migliarese  
Chief Financial Officer and Interim President

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November 3, 2023

**November 2023 Letter to Shareholders**

Dear Shareholders,

We write to provide an update on CytoDyn Inc. (“CytoDyn” or “Company”), and to thank you for your continued support of the Company.

Throughout our history, CytoDyn has made great strides in developing leronlimab from a single indication molecule into a platform molecule with the potential for multiple therapeutic indications. Through CytoDyn’s investment in clinical trials, we have generated valuable data demonstrating how leronlimab might be used in HIV, oncology, metabolic dysfunction-associated steatohepatitis (“MASH” formerly “NASH”), and metabolic dysfunction-associated steatotic liver disease (“MASLD”). We have also successfully transferred our manufacturing technology allowing us to manufacture leronlimab at scale in preparation for clinical trials and potential FDA approval.

Fiscal year 2023 proved to be a very difficult year for CytoDyn. We had planned to be off clinical hold and back to conducting clinical trials by now. Unfortunately, to date, we have been delayed in our efforts to satisfy the FDA with our clinical hold submission(s). We have embarked on a more comprehensive effort to resolve the FDA’s lingering questions. These efforts include the Company’s hosting of a number of advisory board meetings with key opinion leaders (KOLs). Adding to our delay was the unanticipated medical leave taken by our then President, Dr. Arman creating additional delays in our subsequent resubmission.

However, these unforeseen circumstances provided the time needed to help us gain new insights and understanding of leronlimab in the current HIV treatment environment. Further, we were able to receive and incorporate the perspectives of some of the top HIV KOLs worldwide as to how they believe leronlimab can play a significant role in helping HIV patients, notwithstanding other therapeutic options currently available to patients. As part of this process, the Company engaged various new clinical, regulatory, and medical consultants and advisors with relevant experience and expertise that we believe will continue to benefit the Company for years to come.

The Company has taken necessary actions to position us for near-term and long-term success. During the last fiscal year, the Company implemented significant reductions to its workforce, cash burn rate, and operating expenses, in order to conserve our resources and devote them to critical corporate priorities. In addition to our work in HIV, we have worked with top experts to develop a MASH clinical trial protocol and identify potential MASH pre-clinical combination therapy trial concepts, which trials we believe could be attractive to a partner and position the Company for a greater chance of success within the MASH space. We also began development of a longer-acting therapeutic with a partner who has a very strong and reputable artificial intelligence (“AI”) platform, which we believe may provide significant increases in shareholder value in the years to come. We also believe that the Company is positioned for success in the Amarex litigation. We fully funded Sidley Austin LLP – the preeminent law firm representing the Company in this matter, filed a more-detailed statement of claim, and scheduled a final hearing date (August 12, 2024) in the arbitration.

We understand that CytoDyn’s recent challenges may have tested your confidence. We want to assure you that we remain dedicated to developing important therapeutics that can make a difference in

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patients' lives, and at the same time provide value for our shareholders. Again, we are grateful for your ongoing support and trust.

We will continue our efforts to prioritize and execute on goals that will enhance value for all shareholders. Our efforts are focused on successfully completing the resolution of the FDA's partial clinical hold – having recently made a submission that we hope will be successful – and strengthening our leadership team. Additionally, the Company will be evaluating the various potential indications for leronlimab to maximize the effective and efficient use of our resources. We have always believed leronlimab holds great promise, and we are determined to explore all avenues by which patients and medical practitioners can benefit from its use. We believe that with the improvements we have made and continue to pursue, our company is positioned for long-term success.

We deeply value your investment in CytoDyn and are committed to acting in your best interests. We look forward to continuing to communicate as additional developments occur. We realize the updates above may not answer all the questions you have. We therefore include a November 2023 "Frequently Asked Questions" supplement with this letter. This FAQ supplement is something we intend to update from time to time and it will be posted on the Company's website in the near future.

Finally, in advance of our upcoming Annual Meeting on November 9, 2023, we want to remind you to submit your votes, if you have not already done so. If you were a shareholder as of September 11, 2023, you are considered a shareholder of record. Notably, the Company has asked for the shareholders' approval to amend the Company's Certificate of Incorporation to increase the total number of authorized shares of common stock. This increased share allowance is critical to the ongoing viability of the Company, and we therefore encourage everyone to vote if you have not already done so. If you have any questions or require any assistance in voting your shares, please call the Company's proxy solicitor, Alliance Advisors LLC, at (833) 814-9456.

Sincerely,

Tanya Durkee Urbach  
Board Chair

#### **Note Regarding Forward-Looking Statements**

This letter and the accompanying Frequently Asked Questions supplement contain forward-looking statements relating to, among other things, future operating and financial performance, product development, market position 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.

#### **CONTACT**

Investor Relations  
CytoDyn Inc.  
ir@cytodyn.com

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## FREQUENTLY ASKED QUESTIONS

*November 2023 Update*

### **What operational and financial adjustments did the Company make in fiscal year 2023?**

During FY23, the Company made significant reductions to its workforce, cash burn rate, and operating expenses, to preserve its resources and use them where they are most needed. This transformation consisted of reducing our force of full-time employees by approximately 70%, adding five part-time employees, and leveraging experienced consultants and advisors on a part-time basis. This, along with other expense reduction measures, led to significant improvements in the Company's cash burn, G&A expense, and R&D expense run rates. Compared to the prior fiscal year, in FY23 we saw decreases in the Company's cash used in operating activities of 68%, decreases in G&A expense of 61%, and decreases in R&D expense of 90%.

By restructuring our workforce and electing to retain specialized consultants where possible, we believe we have significantly enhanced our regulatory, clinical, and medical capabilities, and further assembled a team that places the Company in the best position to be successful. We are optimistic that the latest clinical hold submission to the FDA will result in the lifting of the clinical hold. If successful, our current team stands ready to implement the best strategies to maximize shareholder value in the near- and long-term.

### **What is the status of the clinical hold?**

The Company recently provided additional information to the FDA that we believe answers the FDA's remaining questions. We hope this submission will lead to the removal of the clinical hold. The Company is on standby to address any other issues that may be noted by the FDA, and is optimistic that the time, effort and significant cost investment over the past year will result in the removal of the hold.

### **What is the short-term development plan for leronlimab following the resolution of the clinical hold?**

The Company has continually evaluated the various indications for leronlimab, and worked to strategically determine how to best focus and advance each indication – whether in-house and/or through strategic partnerships. This work did not cease during the clinical hold process.

Following the resolution of the clinical hold, we will continue to focus on a multiple therapeutic development approach to leronlimab. We have already been working toward eventual decisions as to the most opportunistic, least capital-intensive manner to develop and create value through various means for leronlimab, identifying strategies that are time- and cost-effective and create the opportunity for non-dilutive financing opportunities such as license agreements, co-development, partnerships, etc. For example, KOLs consulting with the Company identified a clinical trial in the HIV space they feel strongly about that will help patients and can be conducted in a time- and cost-effective manner. Further, we will continue to evaluate pre-clinical combination therapy trials in MASH and oncology. Positive developments in the foregoing initiatives could also result in more substantive interest from third parties by way of licensing and collaboration agreements, joint development initiatives, and other partnership opportunities.

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**What is the current status of the longer-acting therapeutic project?**

Early in 2023, the Company entered into a partnership directed toward developing a long-acting therapeutic to bolster our existing IP portfolio and patent protection with the goals of attracting partnership opportunities, preserving and increasing the value of our patent portfolio, and creating additional shareholder value.

The partner company is an experienced drug development company and uses generative artificial intelligence (AI), among other technologies, in its development activities. If successful, such a modified therapeutic would require less frequent injections for patients on drug, furthering the convenience and overall marketability of the product. Working with a company with established AI-capabilities allows for an expedited and robust development path for this modified, longer-acting therapeutic for the Company.

**What is the current status of the CEO search?**

As previously announced, the Board has been searching for a new Chief Executive Officer, with a focus on identifying a candidate possessing the requisite experience and expertise to enhance the Company's overall business strategies and efforts to achieve regulatory approval and commercialization of leronlimab. Currently, the search has been narrowed to several highly qualified candidates, and we anticipate having a new CEO in place by the end of the year.

**How does the Company make decisions as it relates to executive compensation?**

Each year, the Company's Board of Directors reviews and appoints at least three independent members of the Board to serve on a compensation committee (the "Compensation Committee"). Among other duties, the Compensation Committee oversees incentive, equity-based and other compensatory plans for executive officers of the Company.

On an annual basis, the Compensation Committee evaluates the Company's overall compensation philosophy and determines base salaries and other forms of compensation to be paid to executive officers, including cash incentive compensation and grants of stock options and other stock-based awards, which are all disclosed in the Company's annual proxy statements. The Compensation Committee's decisions are based on (annual) recommendations received from an independent executive compensation advisory firm retained by the Compensation Committee. The independent compensation consultant analyzes peer companies and other benchmarking and comparison data, and then makes recommendations as to the competitiveness of the Company's executive compensation program, and a proposed mix of compensation elements. The above process ensures that the Company and Compensation Committee's practices are in-line with industry standards, and companies of similar size and financial condition. This process also helps ensure that the Company is able to attract and retain talented key employees.

At the 2019 Annual Meeting of the Company, our stockholders approved the Board's recommendation that an advisory vote on executive compensation be conducted annually. Accordingly, each fiscal year, the shareholders are asked to place an advisory vote as to the compensation of our executive officers.

Additional information as it relates to responsibilities and processes of the Compensation Committee is set forth in its charter and director and executive officer compensation policy, which are posted on our website under Governance Documents. Additional, more-detailed information in relation to the compensation paid to executive officers can be found in the

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Company's required SEC filings, including the Company's Definitive Proxy Statement filed on September 25, 2023.

**What is the current status of the Amarex litigation effort?**

In July 2023, the Company took the next step towards holding Amarex, its former clinical research organization (CRO), accountable for its numerous failures in relation to clinical trial management and regulatory services it was supposed to have provided to CytoDyn. The Company is seeking damages in excess of \$100 million from Amarex in this action. We have fully funded the Company's counsel, Sidley Austin LLP, for this litigation effort in advance, which allows them to take all steps necessary to maximize the Company's recovery from Amarex. The final arbitration hearing is set to commence August 12, 2024. We would then expect the arbitrator to issue their final order sometime in the weeks following the conclusion of the final hearing, perhaps in late September 2024. We are confident in our case and have one of the preeminent litigation firms in the world representing the Company in this proceeding. We will continue to vigorously pursue this matter.

**What is the status of the new communication strategy?**

The Company is in the process of making a marked shift in its communications with stakeholders. These renewed engagement efforts will be clear, concise, measured, and compliant with pertinent regulatory requirements. We will continue to update shareholders as required with material information and developments via our SEC filings, but we also anticipate communicating more frequently with investors via direct communications. We will also communicate more frequently with the market at large, and we actively review and respond to investor inquiries.

You already may have noticed a change in our responsiveness with investors via the Company's IR email account ([ir@cytodyn.com](mailto:ir@cytodyn.com)) over the past several months. Additionally, we actively review all investor communications for recurring themes which helps better inform the Company on what is most important to current and potential investors. We are also in the process of setting up a FAQ section on the Company's website where we intend to post and respond to the most important questions. This FAQ page will be updated on a regular basis.

**Note Regarding Forward-Looking Statements**

This Frequently Asked Questions supplement contains forward-looking statements relating to, among other things, future operating and financial performance, product development, market position 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.

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