May 16, 2024

May 2024 Letter to Shareholders

VANCOUVER, Washington, May 16, 2024 (GLOBE NEWSWIRE) --

Dear Shareholders,

I write today to provide an update on CytoDyn Inc. (“CytoDyn” or “Company”), as we approach the end of our 2024 fiscal year (May 31, 2024), and to sincerely thank you for your unwavering support.

Fiscal year 2024 was a significant year for CytoDyn, and one that I believe will be remembered as the beginning of a turnaround. The Company achieved the lifting of the FDA’s clinical hold in late February 2024 and is now working to return to the clinic. Over the past several months, the Company has made significant internal progress on key initiatives which we believe will lead to marked external developments in the form of the commencement of clinical trials, the rollout of a number of pre-clinical research initiatives, and the continued publication of leronlimab data.

Shortly after my appointment as the Company’s CEO in November 2023, I hosted an investment update at which I committed to prioritizing the following: (i) getting off clinical hold, which required the submission of a revised trial protocol to the FDA; (ii) publishing clinical data that had not yet been released; and (iii) exploring how to extend leronlimab’s platform wherever it made sense. As I reflect on my first six months as CEO, I am pleased with the progress, but our work is not yet done.

Over the next six months, we expect to commence at least one, and potentially two clinical trials. The prospective clinical trials, in order of priority, are: (i) a Phase II study of leronlimab in patients with relapsed/refractory microsatellite stable colorectal cancer; and (ii) a Phase II study exploring leronlimab’s effects on inflammation. The Company’s priority will be the oncology trial which, if successful, will put us on track towards a commercial approval of leronlimab in that indication. The inflammation study is aimed at clarifying certain provocative observations related to leronlimab, and to help define the dose and underlying mechanism of anti-inflammatory action. It is imperative that the Company generate unassailable results in the clinic and I believe the above trials can accomplish this. Starting the oncology study and related fundraising is the top priority of the Company at this time, but our current hope is that we can initiate both studies before the end of this calendar year.

Research and development partnership opportunities are important to the Company as we search for cost-effective ways to further build out our product development portfolio. We have identified several such opportunities that we believe are intriguing, and anticipate finalizing agreements with these partners in the very near future. Such potential partnerships include an investigator-initiated pilot study of leronlimab in patients with Alzheimer’s Disease, and a project that will evaluate the use of leronlimab in patients living with HIV who are undergoing stem cell transplantation in a proof of cure study. Following lifting of the clinical hold, we have observed a significant increase in third parties that are interested in partnering with the Company. We will continue to review opportunities as they arise, given

the potential for significant value return at little or no cost to the Company.

Finally, as promised, CytoDyn has submitted several leronlimab manuscripts for peer review and is in the process of completing final drafts of several others. The clinical endpoint data from the Long COVID trial (CD 15) was recently published in the Journal of Infection. All publications will be available on the Company's website soon after publication.

I believe the Company is building for success and has made significant strides toward initiating a number of key pre-clinical and clinical leronlimab trials. I am also pleased to share that things are progressing well as to the development of a longer-acting therapeutic with our partner who utilizes its proprietary artificial intelligence platform.

As shareholders, you are the lifeblood of the Company and we remain committed to acting in your best interests. Your questions and feedback are always appreciated. Included herewith is a copy of the May 2024 "Frequently Asked Questions" supplement. This FAQ supplement is something that is also posted on the Company's website and updated from time to time. You are always welcome to submit questions to the Company's IR email account: ir@cytodyn.com.

I understand that the Company's historical challenges may have tested your confidence, and I am grateful for your ongoing support and trust. My dedication to the Company is founded in my belief that leronlimab has the potential to be a life-changing therapeutic. As always, our commitment is to bring better healthcare to patients in need, and to maximize shareholder value.

Sincerely,

Dr. Jay Lalezari
CEO

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 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 our Annual Report on Form 10-K for the fiscal year ended May 31, 2023, including the section captioned "Forward-Looking Statements" and in Item 1A, as supplemented by Part I, Item 2 and Part II, Item 1A in our Quarterly Report on Form 10-Q for the quarter ended February 29, 2024. CytoDyn Inc. does not undertake to update any forward-looking statement as a result of new information or future events or developments.

CONTACT
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FREQUENTLY ASKED QUESTIONS

May 2024 Update

What clinical trials is the Company currently working on?

In order of priority, the clinical trials currently under development are:

(i) a Phase II study of leronlimab in patients with relapsed/refractory microsatellite stable colorectal cancer; and

(ii) a Phase II study exploring leronlimab and its effects on inflammation.

The oncology trial, if successful, will put the Company on track towards a commercial approval in that indication. The inflammation study is aimed at clarifying a number of past clinical observations as it relates to leronlimab.

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

In order to develop a long-acting therapeutic, we have partnered with an experienced drug development company that 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 a robust development path for this modified, longer-acting therapeutic for the Company. This joint development initiative remains in progress at this time and the Company will provide further updates when appropriate.

Is leronlimab, an unapproved drug, currently available to the public outside of a clinical trial?

As an unapproved drug, leronlimab is not available to the general public. However, certain patients who are facing serious illnesses, and who have exhausted all available treatment options, may be able to receive early access to investigational drugs that haven't yet been approved by government regulatory agencies. The FDA allows for two options for treating patients with an unapproved drug, biologic or test article outside of a clinical trial. One option is "Expanded Access." The other option is "Right to Try." For additional information about potentially obtaining leronlimab, through your medical provider, under an Expanded Access allowance, please feel free to email: dai@cytodyn.com.

For the most up-to-date information regarding The Right to Try Act, and/or potential access for patients who have been diagnosed with life-threatening diseases or conditions, have tried all approved treatment options, and are unable to participate in a clinical trial to access certain investigational treatment options, please visit FDA.gov and review its overview regarding "Right to Try" allowances. https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/right-try

WARNING: Leronlimab has not received regulatory approval from the FDA. The potential risks and benefits are not known. Doctors and patients should consider all possible benefits and risks before applying for expanded access (or right to try) to leronlimab.

What is the current status of the Amarex litigation effort?

In July 2023, the Company took steps toward 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. 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 was recently rescheduled, and is now ordered to commence on November 11, 2024. The parties are in the discovery phase of the litigation, and will also be participating in structured settlement discussions over the next several months.

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

Each year, the Company's Board of Directors selects at least three independent members of the Board to serve on its compensation committee (the "Compensation Committee"). Among other duties, the Compensation Committee oversees compensation plans for directors, as well as 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 annual cash retainer fees and option grants for directors, as well as 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. Compensation paid to directors and executive officers is disclosed in the Company's annual proxy statements as required by SEC rules. The Compensation Committee's decisions are based on consultation, at least annually, with an independent executive compensation advisory firm retained by the Compensation Committee. At the direction of the Compensation Committee, the independent compensation consultant analyzes peer companies and other benchmarking and comparison data, and then provides advice as to the competitiveness of the Company's executive compensation program and mix of compensation elements. The above process helps to ensure that the Company's practices are in-line with industry standards, and competitive with companies of similar size and financial condition. This process also helps the Company 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 Company's required SEC filings, including the Company's Definitive Proxy Statement filed on September 25, 2023.

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 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 our Annual Report on Form 10-K for the fiscal year ended May 31, 2023, including the section captioned “Forward-Looking Statements” and in Item 1A, as supplemented by Part I, Item 2 and Part II, Item 1A in our Quarterly Report on Form 10-Q for the quarter ended February 29, 2024. CytoDyn Inc. does not undertake to update any forward-looking statement as a result of new information or future events or developments.



Source: CytoDyn Inc.