Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended May 31, 2023

or

☐ **TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number 000-49908

CYTODYN INC.
(Exact name of registrant as specified in its charter)

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

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.**

Securities registered pursuant to Section 12(g) of the Act:

Title of class
Common Stock, par value $0.001 per share

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by checkmark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by checkmark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer" "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		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. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and ask price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter: $295,738,201 as of November 30, 2022.

As of August 31, 2023, the registrant had 930,960,097 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Document	**Parts Into Which Incorporated**
Portions of the Proxy Statement for the 2023 Annual Meeting of Stockholders	**Part III**

CYTODYN INC.
FORM 10-K FOR THE YEAR ENDED MAY 31, 2023
Table of Contents

FORWARD-LOOKING STATEMENTS

This annual report 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. Our forward-looking statements are not guarantees of performance, and actual results could vary materially from those contained in or expressed by such statements. In evaluating all such statements, we urge you to specifically consider various risk factors identified in this annual report, including the matters set forth under the heading Risk Factors, any of which could cause actual results to differ materially from those indicated by our forward-looking statements.

Our forward-looking statements reflect our current views with respect to future events and are based on currently available financial, economic, scientific, and competitive data and information on current business plans. Forward-looking statements include, among others, statements about leronlimab, its ability to have positive health outcomes, the Company's ability to resolve the clinical holds imposed by the U.S. Food and Drug Administration (the "FDA") and information regarding future operations, future capital expenditures, and future net cash flows. You should not place undue reliance on our forward-looking statements, which are subject to risks and uncertainties relating to, among other things: the regulatory determinations of leronlimab's safety and effectiveness by the FDA and various drug regulatory agencies in other countries; the Company's ability to raise additional capital to fund its operations; the Company's ability to meet its debt and other payment obligations; the Company's ability to enter into or maintain partnership or licensing arrangements with third-parties; the Company's ability to recruit or retain key employees; the timely and sufficient development, through internal resources or third-party consultants, of analyses of the data generated from the Company's clinical trials required by the FDA or other regulatory agencies in connection with the Company's Biologic License Application ("BLA") resubmission or other applications for approval of the Company's drug product; the Company's ability to achieve approval of a marketable product; the design, implementation, and conduct of the Company's clinical trials; the results of the Company's clinical trials, including the possibility of unfavorable clinical trial results; the market for, and marketability of, any product that is approved; 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; regulatory initiatives, compliance with governmental regulations and the regulatory approval process; legal proceedings, including but not limited to investigations or inquiries affecting the Company or its products; general economic and business conditions; changes in foreign, political, and social conditions; stockholder actions or proposals with regard to the Company, its management, or its Board of Directors (the "Board"); and various other matters, many of which are beyond the Company's control. Should one or more of these risks or uncertainties develop, or should underlying assumptions prove to be incorrect, actual results may vary materially and adversely from those anticipated, believed, estimated, or otherwise indicated by our forward-looking statements.

We intend that all forward-looking statements made in this annual report on Form 10-K will be subject to the safe harbor protection of the federal securities laws pursuant to Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), to the extent applicable. Except as required by law, we do not undertake any responsibility to update these forward-looking statements to take into account events or circumstances that occur after the date of this annual report. Additionally, we do not undertake any responsibility to update you on the occurrence of any unanticipated events that may cause actual results to differ from those expressed or implied by these forward-looking statements.

PART I

Item 1. BUSINESS

Corporate History/Business Overview

CytoDyn Inc. was originally incorporated under the laws of Colorado on May 2, 2002, under the name RexRay Corporation and, effective August 27, 2015, reincorporated under the laws of Delaware. The Company is a clinical-stage biotechnology company focused on the clinical development of innovative treatments for multiple therapeutic indications based on its product candidate, leronlimab (also referred to as PRO 140), a novel humanized monoclonal antibody targeting the C-C chemokine receptor type 5 ("CCR5"). The pre-clinical and early clinical development of PRO 140 was led by Progenics Pharmaceuticals, Inc. ("Progenics") through 2011. The Company acquired the asset from Progenics in October 2012. In November 2018, the United States Adopted Names Council adopted "leronlimab" as the official nonproprietary name for PRO 140. The Company has conducted clinical trials of leronlimab as a viral entry inhibitor for human immunodeficiency virus ("HIV"), believed to competitively bind to the N-terminus and second extracellular loop of the CCR5 receptor. For immunology, the CCR5 receptor is believed to be implicated in immune-mediated illnesses such as non-alcoholic steatohepatitis ("NASH"). The CCR5 receptor may also be present on cells that undergo malignant transformation and may also be present in the tumor microenvironment. Studies of leronlimab have also been conducted in NASH and solid tumors in oncology, in addition to HIV, where CCR5 is believed to play an integral role.

Our principal business office is located at 1111 Main Street, Suite 660, Vancouver, Washington 98660. Our website can be found at www.cytodyn.com. We make available on our website, free of charge, the proxy statements and reports on Forms 8K, 10K, and 10Q that we file with the SEC, as soon as reasonably practicable after such materials are electronically filed with or furnished to the SEC. By making this and other references to the Company's website, we do not intend to incorporate any reference into this Form 10-K any information posted on our website. The website should not be considered part of this Form 10-K.

The consolidated financial statements included in this Form 10-K include the accounts of CytoDyn Inc. and its wholly owned subsidiary CytoDyn Operations Inc.

Business Overview

CytoDyn's core areas of clinical development are HIV, NASH, and solid tumors in oncology. The current areas of clinical focus in HIV are the lifting of the clinical hold, creation of a long-acting formulation of leronlimab and an HIV functional cure in using adenovirus vectors ("AAV"). In NASH, our focus will be on the general population of those affected by NASH, and the subpopulation of patients with NASH and HIV. Regarding oncology, our focus remains on combination therapy for solid tumors to explore the potential of leronlimab in the tumor microenvironment and the potential benefit for decreasing angiogenesis, potential macrophage repolarization, decreasing metastasis, and the potential to mitigate regulatory T-cells ("Tregs") infiltration of the tumor microenvironment. At this time, there are no approved therapies for NASH and current highly active antiretroviral therapy ("HAART") regimens often contribute to hepatoxicity. Patients with HIV and NASH represent an unmet medical need, and we believe leronlimab may play a vital role in this population to reduce HIV viral load, steatosis, and fibro-inflammation. Additionally, even after FDA approves therapies for NASH, because of the complexity of NASH affecting multiple systems in the body, we believe that an opportunity exists for a combination therapy.

Our current business strategy is to continue to pursue the clinical development of leronlimab, utilizing the resources available to us and through additional fundraising, which may include the following:

1. Seeking to lift the FDA partial clinical hold placed on our HIV program.
2. Advancing our NASH program to a Phase 2b or Phase 2b/3 trial for steatosis and liver fibrosis associated with NASH, and/or advancing a pre-clinical study to identify the potential for a combination therapy clinical trial.
3. Exploring a study for patients with HIV and NASH.
4. Continuing to identify the next steps in clinical development and exploring potential business opportunities to continue the investigation of leronlimab for solid tumors in oncology, based on data generated to date by the Company, including potential opportunities to continue our Phase 2 program for metastatic triple-negative

breast cancer with current standard of care, as well as exploring a Phase 2 colon cancer trial with current standard of care and other cancer and immunologic indications.

5. Continuing our work on developing a long-acting version of leronlimab and pursuing proof of concept studies for HIV treatment and HIV pre-exposure prophylaxis ("PrEP") using leronlimab and AAV.

We will need significant additional funding to execute the above business strategy and conduct additional pre-clinical studies or clinical trials as we seek FDA approval to commercialize leronlimab.

As further discussed in Part II, Item 8, Note 2, *Summary of Significant Accounting Policies - Inventories,* and Note 3, *Inventories, net,* in this Form 10-K, the Company previously capitalized procured or produced pre-launch inventories in preparation for product launches. As of May 31, 2023, the Company had reserved for or written-off the full $99.2 million of previously capitalized pre-launch inventories. Although these inventories have been written-off from an accounting perspective, they can be used in certain clinical contexts, and could possibly be sold commercially upon regulatory approval if the shelf-lives can be extended as a result of the performance of on-going and future stability tests.

Recent Corporate Developments

Cyrus Arman, who was our President beginning on July 9, 2022, was appointed as the Company's Senior Vice President, Business Operations, a part time, nonexecutive position, by the Board effective July 7, 2023, following a medical leave of absence that began on May 18, 2023. Antonio Migliarese, our Chief Financial Officer, has been appointed to also fill the position of interim President beginning May 18, 2023. The Board has commenced a search for a new President and/or Chief Executive Officer.

Background: Leronlimab as a CCR5 Antagonist

We are focused on developing leronlimab, a CCR5 receptor antagonist, to be used as a platform drug for various indications. The CCR5 receptor is a protein located on the surface of various cells including white blood cells and cancer cells. On white blood cells, it serves as a receptor for chemical attractants called chemokines. Chemokines are the key orchestrators of leukocyte trafficking by attracting immune cells to the sites of inflammation. At the site of an inflammatory reaction, chemokines are released. These chemokines are specific for CCR5 and cause the migration of T-cells to these sites promoting further inflammation. The CCR5 receptor is also the co-receptor needed for certain strains of HIV to infect healthy T-cells.

The mechanism of action ("MOA") of leronlimab has the potential to orchestrate the movement of T-cells to inflammatory sites, which could be instrumental in diminishing the inflammatory responses. Leronlimab is a unique humanized monoclonal antibody. Leronlimab binds to the second extracellular loop and N-terminus of the CCR5 receptor, and due to its selectivity and target-specific mechanism of action, it does not appear to activate the immune function of the CCR5 receptor through agonist activity. This apparent target specificity differentiates leronlimab from other CCR5 antagonists. Leronlimab is a competitive rather than allosteric inhibitor of the CCR5 receptor. Other potential advantages of leronlimab are believed to include longer half-life and less frequent dosing requirements compared to current standard of care daily regimens.

We believe leronlimab prevents CCR5 tropic strains of HIV, which are the majority of all cases, from using the CCR5 receptor as an entry gateway for healthy cells. Pre-clinical research has shown that leronlimab blocks calcium channel signaling of the CCR5 receptor when present on the cancer cell surface. Research also suggests calcium channel signaling of the CCR5 receptor is a crucial component to the spread of metastatic cancer. We view the CCR5 receptor as more than the door for HIV to enter T-cells; it may also be a crucial component in inflammatory responses. The CCR5 receptor has been identified as a potential target in HIV, graft-versus-host disease ("GvHD"), NASH, cancer metastasis, transplantation medicine, multiple sclerosis, traumatic brain injury, stroke recovery, and a variety of inflammatory conditions, including COVID-19. This could present the potential for multiple opportunities for leronlimab, such as NASH, cancers, and transplantation rejection, among other indications.

Leronlimab and HIV

We believe that leronlimab shows promise as a powerful antiviral agent with the potential advantage of lower toxicity and less frequent dosing requirements as compared to certain daily drug therapies currently in use for the treatment of HIV. Leronlimab belongs to a class of HIV therapies known as viral entry inhibitors that block HIV from

entering and infecting specific cells. Leronlimab blocks HIV from entering a cell by binding to a receptor called CCR5, a normal cell surface receptor protein to which CCR5 tropic strains of HIV, referred to as "R5" strains, attach as part of HIV's entry into a cell. Leronlimab binds to a precise site on CCR5 that R5 strains of HIV use to enter the cell and, in doing so, inhibits the ability of these strains of HIV to infect the cell. As a result, we believe leronlimab represents a distinct class of CCR5 inhibitors with advantageous virological and immunological properties and may provide a unique tool to treat HIV-infected patients. We plan to explore the potential for leronlimab to be used in PrEP if a longer acting version of subcutaneous leronlimab is successfully developed. This longer acting version could also potentially be used in combination with standard of care therapies to treat HIV patients.

We continue to believe leronlimab is uniquely positioned to address the HIV market, as an alternative, or in addition to current therapies, which are failing primarily due to patient non-compliance, which causes drug resistance. Several factors give rise to patient non-compliance issues, such as toxicity and side effects, coupled with the need for a strict daily dosing regimen. In 26 clinical studies previously conducted, leronlimab was generally well tolerated. In addition, there were no dose-limiting toxicities or patterns of drug-related toxicities observed during these trials. We believe the results of these trials establish that leronlimab's antiviral activity is potent, rapid, prolonged, dose-dependent, and statistically significant. Because leronlimab's MOA as a monoclonal antibody in HIV is a relatively new therapeutic approach, it provides a potentially advantageous method of suppressing the virus in treatment-experienced patients who have failed a prior HIV regimen and need new treatment options.

To date, leronlimab has been tested and administered to patients predominantly as a subcutaneous injection once per week. We believe that if leronlimab is approved by the FDA for use as an injectable for HIV, it may be an attractive and marketable therapeutic option for patients, particularly in the following scenarios:

- Patients experiencing difficulties with existing treatment regimens due to side effects or medical comorbidities;
- Patients with difficulty adhering to daily drug regimens;
- Patients who poorly tolerate existing therapies; and
- Patients with compromised organ function, such as hepatoxicity or renal insufficiency.

In 2016, we initiated a pivotal Phase 2b/3 trial for leronlimab as a combination therapy with existing HAART drug regimens for highly treatment-experienced HIV patients. The trial was completed in February 2018 and achieved its primary endpoint with a p-value of 0.0032. Most of the patients who completed this trial transitioned to an FDA-cleared rollover study, as requested by the treating physicians, to enable them to have continued access to leronlimab. This pivotal trial was the basis for the Company's BLA submission to the FDA which was subsequently withdrawn by the Company as further discussed below. We also conducted a rollover study for HIV, as combination therapy, designed for patients who had successfully completed the Phase 2b/3 combination therapy trial and for whom the treating physicians requested a continuation of leronlimab therapy to maintain suppressed viral load. Some of the patients reached four years of treatment in this extension arm. As part of the partial clinical hold imposed in March 2022, these patients were transitioned to current standard of care.

Partial clinical hold on HIV program

During 2019 and 2020, the Company's efforts centered on the preparation and submission of a BLA for leronlimab as a combination therapy for HAART patients. In July 2020, the Company received a Refusal to File letter from the FDA regarding its BLA submission. The FDA informed us that the BLA did not contain certain information and data needed to complete a substantive review and, therefore, the FDA would not file the BLA. In November 2021, the Company resubmitted the non-clinical and chemistry, manufacturing, and controls ("CMC") sections of the BLA. In March 2022, the FDA notified the Company that it had placed a partial clinical hold on the Company's HIV program in the United States. Under the partial clinical hold, no new clinical studies may be initiated under the investigational new drug ("IND") authorization for our HIV program until the clinical hold is resolved. In October 2022, the Company voluntarily withdrew its BLA submission due to management's conclusion that a significant risk existed that the BLA would not receive FDA approval due to the inadequate process and performance around the monitoring and oversight of the clinical data from its clinical trials by its former contract research organization ("CRO").

Recent efforts by the Company have been focused on actions that will allow us to resolve this partial clinical hold. During the third fiscal quarter ended February 28, 2023, the Company submitted the documents requested by the FDA in

its March 2022 clinical hold letter. Subsequently, the FDA responded through written communication to the Company, requesting additional information and clarification regarding our benefit-risk assessment for the HIV population, which had previously been submitted, and made a supplemental request that the Company submit an IND amendment containing the proposed general investigational plan for the coming year, appropriate protocols, and any additional information supporting the proposed investigation under the HIV program IND. In March 2023, the Company responded to and submitted to the FDA the additional information and clarifications requested for the items previously requested. The FDA then responded with an additional written request for information relating to the benefit-risk assessment, as well as requesting the submission of a new protocol for the HIV indication. At the end of March 2023, the Company and the FDA held an informal meeting in which the FDA clarified certain questions with respect to the clinical hold submission and further information requests made by the FDA. The Company is currently preparing a supplemental submission to address items discussed with the FDA during the informal meeting.

Also, the Company is in a legal dispute with its former CRO in which it alleges that the former CRO failed to perform services to an acceptable professional standard and certain services required by the parties' agreements, that the Company was billed for services the CRO did not perform and that, as a result of these failures, the Company has suffered avoidable delays in obtaining regulatory approval of leronlimab and has paid for services not performed. See Part II, Item 8, Note 10, *Commitments and Contingencies – Amarex Dispute* in this Form 10-K for further information.

HIV Pre-Clinical Development of Long-Acting CCR5 Antagonist

In December 2022, researchers from Oregon Health and Sciences University ("OHSU"), an academic research collaboration partner of the Company, presented at the HIV DART Conference and the HIV Persistence During Therapy Conference results from two recently completed pre-clinical studies performed on macaque monkeys for two different potential longer-acting therapeutics targeting the CCR5 receptor. The first longer-acting potential therapeutic is a modified monoclonal antibody designed to have a longer half-life, which could lead to the development of an HIV prophylactic for humans at high risk of contracting HIV. The second longer-acting potential therapeutic is a gene therapy that could lead to the development of a functional cure for humans living with HIV. While both longer-acting therapeutics are still in the early stages of development, early data from the macaque monkey studies suggest that dosing intervals could be increased from once weekly to once every three months. Data from both potential therapeutics were also presented during the Company's R&D Investor Update on December 7, 2022, which is available on the Company's website.

In March 2023, the Company entered into a joint development agreement with a third-party company to develop one or more longer-acting molecules. These development efforts could potentially lead to a modified therapeutic that will have greater acceptance by patients, which may also lead to extended intellectual property protection thus expanding the Company's patent portfolio.

Leronlimab and NASH

We believe that the CCR5 receptor is also a crucial component in inflammatory responses. Some disease processes that could potentially benefit from CCR5 blockade include transplantation rejection, neuroinflammation, chronic inflammation, cancer, and NASH. Due to leronlimab's MOA, we believe leronlimab may have the potential for reduced side effects over other CCR5 antagonists and may be able to prevent the progression of Non-Alcoholic Fatty Liver Disease ("NAFLD") into NASH. NAFLD is an inflammatory disease caused by the build-up of fat in hepatocytes (steatosis). In severe cases, NAFLD progresses into NASH. NASH is a chronic liver disease characterized by the presence of hepatic inflammation and fibrosis. Patients with advanced fibrosis due to NASH are at significantly higher risk of liver‑related mortality. There is currently no approved drug for NASH. It is estimated that 30% to 40% of adults in the United States have NAFLD, while 3% to 12% of adults in the United States have NASH. If left untreated, NASH may progress to hepatocellular carcinoma and is expected to become the leading cause of liver transplantation. Further, liver disease is one of the leading causes of non-AIDS-related death in HIV patients. The Company is identifying the next steps in clinical development to continue the investigation of leronlimab in the NASH indication and in HIV patients with NASH.

In NASH, liver homeostasis is impaired due to an accumulation of toxic lipids which can activate both Kupffer cells (KCs) and tissue-resident macrophages resulting in the production of fibrogenic cytokines and chemoattractant chemokines such as transforming growth factor-beta (TGF-β) and monocyte chemoattractant protein1 (MCP1). Not only do these cytokines/chemokines promote transdifferentiation of hepatic stellate cells (HSCs) into myofibroblasts (the

primary source for fibrillary collagens), but they also amplify the immune response by recruiting additional cells into the damaged area. Recruitment of extra-hepatic inflammatory cells to the site of hepatic injury is typically mediated by interactions between cytokines/chemokines and their receptors. It has also been shown that patients with NASH also have high levels of CCR5 and the associated ligand, CCL5, thus demonstrating a potential role of CCR5 and its ligands in liver fibrosis.

NASH Pre-Clinical Development

The potential for leronlimab in the treatment of NASH was demonstrated in a pre-clinical model of fatty liver disease. Immunodeficient, NOD-SCID Gamma (NSG) mice were fed a high fat, NASH-inducing diet, transplanted with human stem cells to repopulate the deficient immune system, and treated with leronlimab. Sixteen (16) male NOD.Cg-*Prkdcscid Il2rgtm1Wjl/SzJ*, commonly known as the NOD *scid* IL-2 receptor gamma knockout mice (NSG), were first humanized by intravenous inoculation with normal human umbilical cord blood cells (105). After 5 weeks on normal mouse chow, mice were successfully humanized, demonstrating >25% human CD45 cells in peripheral blood. Mice were switched to high fat (52%) high cholesterol (1.25%) diet (FPC diet: fructose, palmitate, cholesterol, trans-fat; Envigo-Teklad TD.160785). Leronlimab and control antibody (normal human IgG, Sigma) were administered i.p. at a dose of 2mg i.p. twice weekly, n=8 mice/group. The results showed that leronlimab inhibited fatty liver development, a key characteristic of early-stage NASH, such that treatment of humanized NSG mice with leronlimab caused a three-fold reduction in hepatic steatosis compared to control in an animal model of high fructose, high palmitate, high cholesterol diet.

NASH Phase 2a Exploratory Study

The Company has reported clinical data from patients with NASH from the CDI-NASH-01 trial which was designed as a multi-center Phase 2a study and was subsequently converted into an exploratory study to evaluate the dose, efficacy, and safety of leronlimab at 350 mg and 700 mg, versus placebo. The study also included an expansive biomarker program designed to inform future clinical trials and to more fully understand leronlimab's mechanism of action within the NASH setting. CDI-NASH-01 was conducted in two parts. Part 1 of the study was to assess the efficacy of leronlimab 700 mg (n=22) in improving NAFLD/NASH measures in adult patients diagnosed with NASH compared to placebo (n=28). Part 2 was subsequently added to assess leronlimab 350 mg in improving NAFLD/NASH measures in adult patients diagnosed with NASH (n=22). In Part 1 of the study, eligible subjects were randomized 1:1 to one of the two study arms to receive either leronlimab 700mg (Group A), or placebo (Group B), given once per week (±1day) at the study site for up to 13 weeks during the treatment period (with up to 60 participants). In Part 2 of the study, eligible subjects enrolled to receive leronlimab 350 mg open-label given once per week (±1day) at the study site for up to 13 weeks during the treatment period (with up to 28 participants). The primary efficacy objective was percent change from baseline in hepatic fat fraction, as assessed by magnetic resonance imaging-derived proton density fat fraction (MRI-PDFF) at week 14. The secondary efficacy objective was absolute change from baseline in fibro-inflammatory activity in the liver as assessed by MRI-corrected T1 imaging (MRI-cT1) at week 14. MRI-cT1 is obtained by multiparametric magnetic resonance imaging of the liver and is a quantitative metric for assessing a composite of liver inflammation and fibrosis, expressed in milliseconds (msec). MRI-PDFF is being studied as an imaging surrogate endpoint for the fat density in the liver. MRI-cT1 is being studied as an imaging surrogate endpoint for hepatic fibro-inflammation. This is a critical unmet need in the NASH space, as many agents have been unable to show reductions in fibro-inflammation despite reductions in hepatic steatosis.

All analyses performed are being treated as exploratory. Treatment with leronlimab was well tolerated in both Part 1 and Part 2 compared to placebo. In Part 1 of the study, leronlimab 700 mg did not reduce mean change in PDFF and cT1 from baseline to week 14 vs. placebo. In Part 2, leronlimab 350 mg reduced mean change in PDFF and cT1 from baseline to week 14 vs. the placebo group from Part 1, despite increased degree of baseline fibro-inflammation. In the combined group of patients with moderate (≥ 875 msec) and severe (≥ 950 msec) cT1 values at baseline, leronlimab 350 mg reduced cT1 from baseline to week 14 vs. placebo. Based on post hoc CCR5 haplotype analysis of a small subgroup (n=5), we are considering further investigation of the 700mg dose of leronlimab for specific haplotypes.

Leronlimab and Cancer

Research indicates that the CCR5 receptor is a potential "GPS" system of a cancer cell that promotes metastatic disease. Pre-clinical studies have shown that leronlimab blocks the calcium channel signaling of the CCR5 receptor and has the potential to disable this GPS system. CCR5 inhibition may disrupt signaling and ultimately the spread of CCR5+

Circulating Tumor Cells ("CTCs"). Most current therapies are directed to the primary tumor rather than the movement or spread of cancer in the bloodstream. It is metastatic disease and not the primary tumor that is the cause of death in most cancer patients.

Research has shown that most sampled breast cancer patients in certain studies had increased CCR5 expression in their tumors. Increased CCR5 expression is an indicator of disease status in several cancers. Research has shown multiple key properties of the CCR5's role in cancer. The first is that the CCR5 receptor on cancer cells potentially plays a role in the migration and invasion of cells into the bloodstream, which may lead to metastasis of breast, prostate, and colon cancer. The second is that blocking the CCR5 receptor on Tregs also turns on anti-tumor fighting properties restoring immune function. The third key finding is that blockage of the CCR5/CCL5 interaction had a synergistic effect with chemotherapy and controlled cancer progression. Chemotherapy traditionally increased expression of CCR5, so blocking CCR5 is expected to reduce the levels of invasion and metastasis. Fourth, animal studies revealed a significant decrease in angiogenesis following administration of leronlimab. Lastly, we are currently studying the effect of leronlimab on macrophage repolarization due to macrophage plasticity.

Metastatic Triple-Negative Breast Cancer Pre-Clinical Development

In late November 2018, we received FDA approval of our IND submission and subsequently initiated a Phase 1b/2 clinical trial for metastatic Triple-Negative Breast Cancer ("mTNBC") patients. We reported that our pre-clinical research with leronlimab reduced the incidence of human breast cancer metastasis in a mouse xenograft model for cancer through six weeks with leronlimab by more than 98%. The temporal equivalency of this six-week study in mice may be up to six years in humans. In May 2019, the FDA granted Fast Track designation for leronlimab for use in combination with carboplatin to treat patients with CCR5-positive mTNBC.

Metastatic Trial for Triple-Negative Breast Cancer Phase 1b/2 Trial

This trial evaluated the feasibility of leronlimab in combination with carboplatin in patients with CCR5+ mTNBC. This trial advanced from a Phase 1b/2 to Phase 2. The Phase 2 trial was a single arm study with 30 patients to test the hypothesis that the combination of carboplatin intravenously and maximum tolerated dose of leronlimab subcutaneously will increase progression free survival. The change in CTCs was evaluated every 21 days during treatment and will be used as an initial prognostic marker for efficacy. The first patient was treated in September 2019. Leronlimab, in combination with carboplatin was well-tolerated at all three dose levels of 350mg, 525mg, and 700mg. Leronlimab showed early signs of anti-tumor activity in patients with CCR5+ mTNBC.

Metastatic Triple-Negative Breast Cancer Compassionate Use Study

This was a single-arm, compassionate use study with 30 patients for leronlimab combined with a treatment of Physician's Choice ("TPC") in patients with CCR5+ mTNBC. Leronlimab was administered subcutaneously as a weekly dose of 350 mg until disease progression or intolerable toxicity. Based on our success in the Phase 1b/2 mTNBC trial with 350 mg dose, we were able to transition the compassionate use patients to 525 mg dose. TPC is defined as one of the following single-agent chemotherapy drugs administrated according to local practice: eribulin, gemcitabine, capecitabine, paclitaxel, nab-paclitaxel, vinorelbine, ixabepilone, or carboplatin. In this study, patients were evaluated for tumor response approximately every three (3) months or according to the institution's standard practice by CT, PET/CT or MRI with contrast (per treating investigator's discretion) using the same method as at baseline. This trial is no longer active.

Locally Advanced or Metastatic Solid Tumors for CCR5+ Phase 2 Basket Trial

This was a single arm Phase 2 study of leronlimab in patients with CCR5+ locally advanced or metastatic solid tumors. Leronlimab was administered subcutaneously as a weekly dose of 350 mg and 525 mg until disease progression or intolerable toxicity. Subjects participating in this study were also allowed to receive/continue standard-of-care chemotherapy or radiotherapy. In this study, patients were evaluated for tumor response approximately every three months or according to the institution's standard practice by CT, PET/CT or MRI with contrast using the same method as at baseline. This trial is no longer active.

Leronlimab and Other Immunological Applications

SARS-CoV 2 was identified as the cause of an outbreak of respiratory illness first detected in Wuhan, China. The virus is highly contagious and has developed several variants. COVID-19 typically transmits person to person through

respiratory droplets, commonly resulting from close personal contact. Coronaviruses are a large family of viruses, some causing illness in people and others that circulate among animals. For confirmed COVID-19 infections, symptoms have included fever, cough, and shortness of breath, amongst many others. The symptoms of COVID-19 may appear in as few as two days or as long as 14 days after exposure. Clinical manifestations in patients have ranged from non-symptomatic to severe and fatal.

Based upon analyses of leronlimab's potential effect on the immune system and the results from over 60 Emergency Investigation New Drug ("EIND") authorizations provided by the FDA, the Company conducted clinical trials in the United States for COVID-19 starting in fiscal 2020 ending in fiscal 2022. Additionally, the Company paused two clinical trials in Brazil which commenced during fiscal 2022. Further, the Company withdrew its COVID-19 IND with the FDA, and the FDA put the COVID-19 program on a full clinical hold in March 2022. If CytoDyn were to continue to pursue the COVID-19 indication, we believe that subgroup analyses from our previous trials may inform the design of future clinical trials investigating leronlimab for the treatment of COVID-19.

Patents, Proprietary Technology and Data Exclusivity

Protection of the Company's intellectual property rights is important to our business. We may file patent applications in the U.S., Canada, China, Japan, European countries that are party to the European Patent Convention, and other countries on a selective basis, to protect inventions we consider to be important to the development of our business.

Generally, patents issued in the U.S. are effective for 20 years from the earliest asserted filing date. A U.S. patent, to be selected by us upon receipt of FDA regulatory approval, may be subject to up to a five-year patent term extension in certain instances. While the duration of foreign patents varies in accordance with the provisions of applicable local law, most countries provide for a patent term of 20 years measured from the application filing date and some may also allow for patent term extension to compensate for regulatory approval delay.

We pursue opportunities for seeking new meaningful patent protection on an ongoing basis. Absent patent protection, others may attempt to make and use the leronlimab antibody for uses not covered by later patent filings, such as attempts to produce and sell the leronlimab antibody as a research reagent and/or as a component for use in diagnostics. However, the formulation composition patent protection remains viable, and third parties face additional regulatory hurdles together with CytoDyn's various method patents with respect to any contemplated attempts to commercialize leronlimab for therapeutic indications. We currently anticipate, absent patent term extension, that patent protection relating to the leronlimab antibody itself started to expire in 2023, the leronlimab concentrated protein formulation will start to expire in 2031, certain methods of using leronlimab for treatment of HIV1 will start to expire on or before 2035, certain methods of using leronlimab for cancer indications if granted will start to expire in 2040, certain methods of using leronlimab for treatment of COVID-19 will start to expire in 2040, and certain methods of using leronlimab for treatment of NASH if granted will start to expire in 2043.

Patents do not enable us to preclude competitors from commercializing drugs in direct competition with our products that are not covered by granted and enforceable patent claims. Consequently, patents may not provide us with any meaningful competitive advantage. Refer to "Risk Factors" for the related risks. We may also rely on data exclusivity, trade secrets, and proprietary know-how to develop and attempt to achieve a competitive position with our product candidates. We require our employees, consultants, and partners who have access to our proprietary information to sign confidentiality agreements to protect our intellectual property.

Separate from and in addition to the patent rights noted above, we expect that leronlimab will be subject to market and data exclusivity period, during which period no other applications referencing leronlimab will be approved by FDA. Accordingly, this period of regulatory exclusivity is expected to provide a term of protection against competing products shown to be biosimilar or interchangeable with leronlimab. Similar data exclusivity or data protection periods may be provided in other countries. We note that data exclusivity is not an extension of patent rights, and it does not prevent the introduction of generic versions of the innovative drug during the data exclusivity period, as long as the marketing approval of the generic version does not use or rely upon the innovator's test data.

Patents and data exclusivity are different concepts, protect different subject matter, arise from different efforts, and have different legal effects over different time periods. Information with respect to our current patent portfolio as of May 31, 2023 is as follows:

	Number of Patents			Number of Patent Applications	
	U.S.	International	Expiration Dates[1]	U.S.	International
Leronlimab (PRO 140) product candidate[2]	2	16	2024-2032	1	3
Methods of treatment by indication (e.g., HIV-1; COVID-19; GvHD) [2]	3	9	2035-2040	1	10
Methods of treatment – Cancer, NASH	—	—		9	29

(1) Patent term extensions and pending patent applications may extend periods of patent protection.
(2) Leronlimab (PRO 140) patents and applications relate to the antibody and formulations.

Research, development and commercialization of a biopharmaceutical product often requires choosing between alternative development and optimization routes at various stages in the development process. Preferred routes depend upon current availability of financial resources, may also be affected by subsequent discoveries, test results and other factors, and therefore cannot be identified with certainty. There are numerous third-party patents in fields in which we work, and we may need to obtain licenses under patents of others to pursue a preferred development route of one or more of our product candidates. The need to obtain a license would decrease the ultimate value and profitability of an affected product. If we cannot negotiate such a license, we might have to pursue a less desirable development route or terminate the program altogether.

Government Regulation

The research, development, testing, manufacture, quality control, packaging, labeling, storage, record-keeping, distribution, import, export, promotion, advertising, marketing, sale, and reimbursement of pharmaceutical products are extensively regulated by governmental authorities in the United States and other countries. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with compliance with applicable statutes and regulations and other requirements, both pre-approval and post-approval, require the expenditure of substantial time and financial resources. The regulatory requirements applicable to product development, approval and marketing are subject to change, and regulations and administrative guidance often are revised or reinterpreted by the agencies in ways that may have a significant impact on our business.

Licensure and Regulation of Biological Products in the United States

In the United States, the FDA regulates human drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and in the case of biological products, also under the Public Health Service Act, or the PHSA, and their implementing regulations. The failure to comply with the applicable U.S. requirements may result in FDA refusal to approve any pending applications or delays in development and may subject an applicant to administrative or judicial sanctions, such as issuance of warning letters, or the imposition of fines, civil penalties, product recalls, product seizures, total or partial suspension of production or distribution, and injunctions and/or civil or criminal prosecution brought by the FDA and the U.S. Department of Justice or other governmental entities.

The FDA must approve product candidates for therapeutic indications before they may be marketed in the United States. For biological products, such as our product candidate, leronlimab, the FDA must approve a BLA. An applicant seeking approval to market and distribute a new biologic in the United States generally must satisfactorily complete each of the following steps:

- completion of pre-clinical laboratory tests, animal studies, and formulation studies according to good laboratory practices, or GLP, regulations, or other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin and must be updated when certain changes are made;

- approval by an independent institutional review board, ("IRB"), or ethics committee representing each clinical trial site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, good clinical practices, or GCPs, and other clinical-trial related regulations to evaluate the safety and efficacy of the investigational product for each proposed indication;
- preparation and submission to the FDA of a BLA requesting marketing approval for one or more proposed indications, including payment of application user fees;
- review of the BLA by an FDA advisory committee, where applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the biologic is produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of any FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data submitted in support of the BLA; and
- FDA review and approval of the BLA, which may be subject to additional post-approval requirements, including the potential requirement to implement a REMS, and any post-approval studies required by the FDA.

Pre-clinical Studies

Before an applicant begins testing a product candidate with potential therapeutic value in humans, the product candidate enters the pre-clinical testing stage. Pre-clinical tests include laboratory evaluations of product chemistry, formulation, and stability, as well as other studies to evaluate, among other things, the toxicity of the product candidate. The conduct of the pre-clinical tests and formulation of the compounds for testing must comply with federal regulations and requirements, including GLP regulations and standards. The results of the pre-clinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND. Some long-term pre-clinical testing, such as animal tests of reproductive adverse events and carcinogenicity, and long-term toxicity studies, may continue after the IND is submitted.

The IND and IRB Processes

An IND is an exemption from the premarket approval requirements of the FDCA allowing an unapproved product candidate to be shipped in interstate commerce for use in an investigational clinical trial. An IND must be in effect prior to interstate shipment and administration of any product candidate that is not the subject of an approved NDA or BLA. When submitting an IND to FDA, applicants must submit a protocol for each planned clinical trial, and any subsequent protocol amendments must be submitted to the FDA as part of the IND. The FDA requires a 30-day waiting period after the filing of each IND before clinical trials may begin. This waiting period is designed to allow the FDA to review the IND to determine whether human research subjects will be exposed to unreasonable health risks. At any time during this 30-day period, the FDA may raise concerns or questions about the conduct of the trials as outlined in the IND and impose a clinical hold or partial clinical hold. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin.

At any time after the IND goes into effect, the FDA may also place a clinical hold or partial clinical hold on the IND or on any clinical trial that has commenced under the IND. A clinical hold is an order issued by the FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. A partial clinical hold is a delay or suspension of only part of the clinical work requested under the IND. For example, a partial clinical hold might state that a specific protocol or part of a protocol may not proceed, while other parts of a protocol or other protocols may do so. No more than 30 days after the imposition of a clinical hold or partial clinical hold, the FDA will provide the sponsor a written explanation of the basis for the hold. Following the issuance of a clinical hold or partial clinical hold, a clinical investigation may only resume once the FDA has notified the sponsor that the investigation may proceed. The FDA will base that determination on information provided by the sponsor correcting the deficiencies previously cited or otherwise satisfying the FDA that the investigation can proceed or recommence.

For each foreign clinical study, a sponsor may choose, but is not required, to conduct it under an IND. When a foreign clinical study is conducted under an IND, all IND requirements must be met unless waived by the FDA. When a

foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with certain regulatory requirements of the FDA in order to use the study as support for an IND or application for marketing approval. Specifically, the studies must be conducted in accordance with GCP, including undergoing review and receiving approval by an independent ethics committee, or IEC, and seeking and receiving informed consent from subjects. The GCP requirements in the final rule encompass both ethical and data integrity standards for clinical studies. The FDA's regulations are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical studies, as well as the quality and integrity of the resulting data.

In addition to the foregoing IND requirements, an IRB must review and approve the plan for any clinical trial before it commences at each institution participating in the clinical trial, and the IRB must conduct continuing review and reapprove the study at least annually. The IRB, which must operate in compliance with FDA regulations, must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients.

Additionally, some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board, or DSMB. This group provides authorization as to whether or not a trial may move forward at designated checkpoints based on review of available data from the study, to which only the DSMB maintains access. Suspension or termination of development during any phase of a clinical trial can occur if the DSMB determines that the participants or patients are being exposed to an unacceptable health risk. A sponsor may suspend or terminate development for other reasons, including evolving business objectives and/or a competitive climate.

Expanded Access

Expanded access, sometimes called "compassionate use," is the use of investigational new drug products outside of clinical trials to treat patients with serious or immediately life-threatening diseases or conditions when there are no comparable or satisfactory alternative treatment options. The rules and regulations related to expanded access are intended to improve access to investigational drugs for patients who may benefit from investigational therapies. FDA regulations allow access to investigational drugs under an IND by the company or the treating physician for treatment purposes on a case-by-case basis for: individual patients (single-patient IND applications for treatment in emergency settings and non-emergency settings); intermediate-size patient populations; and larger populations for use of the drug under a treatment protocol or Treatment IND Application. FDA's regulations also provide for emergency procedures if there is a situation that requires the patient to be treated before a written submission can be made.

When considering an IND application for expanded access to an investigational product with the purpose of treating a patient or a group of patients, the sponsor and treating physicians or investigators will determine suitability when all of the following criteria apply: patient(s) have a serious or immediately life-threatening disease or condition, and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition; the potential patient benefit justifies the potential risks of the treatment and the potential risks are not unreasonable in the context or condition to be treated; and the expanded use of the investigational drug for the requested treatment will not interfere with the initiation, conduct, or completion of clinical investigations that could support marketing approval of the product or otherwise compromise the potential development of the product.

There is no obligation for a sponsor to make its drug products available for expanded access; however, as required by the 21st Century Cures Act, or Cures Act, passed in 2016, a sponsor must make its policy regarding how it evaluates and responds to expanded access requests public and readily available. Sponsors are required to make such policies publicly available upon the earlier of initiation of a Phase 2 or Phase 3 study; or 15 days after the investigational drug or biologic receives designation as a breakthrough therapy, fast track product, or regenerative medicine advanced therapy.

In addition, on May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a manufacturer to make its products available to eligible patients as a result of the Right to Try Act, but the manufacturer must develop an internal policy and respond to patient requests according to that policy.

Human Clinical Trials in Support of an NDA or BLA

Clinical trials involve the administration of the investigational product candidate to human subjects under the supervision of a qualified investigator in accordance with GCP requirements which include, among other things, the requirement that all research subjects provide their informed consent in writing before they participate in any clinical trial. Clinical trials are conducted under written clinical trial protocols detailing, among other things, the objectives of the study, inclusion and exclusion criteria, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated.

Human clinical trials are typically conducted in three sequential phases, but the phases may overlap or be combined. Additional studies may also be required after approval. As described in FDA's regulations at 21 CFR 312.21, the three phases are as follows:

Phase 1 includes the initial introduction of an investigational new drug into humans. Phase 1 studies are typically closely monitored and may be conducted in patients or normal volunteer subjects. These studies are designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. During Phase 1, sufficient information about the drug's pharmacokinetics and pharmacological effects should be obtained to permit the design of well-controlled, scientifically valid, Phase 2 studies. The total number of subjects and patients included in Phase 1 studies varies with the drug but is generally in the range of 20 to 80. Phase 1 studies also include studies of drug metabolism, structure-activity relationships, and mechanism of action in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes.

Phase 2 includes the controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug. Phase 2 studies are typically well controlled, closely monitored, and conducted in a relatively small number of patients, usually involving no more than several hundred subjects.

Phase 3 studies are expanded controlled and uncontrolled trials. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. Phase 3 studies usually include from several hundred to several thousand subjects.

In some cases, the FDA may approve an NDA or BLA for a product candidate but require the sponsor to conduct additional clinical trials to further assess the product candidate's safety and effectiveness after approval. Such post-approval trials are typically referred to as Phase 4 clinical trials. These trials are used to gain additional experience from the treatment of a larger number of patients in the intended treatment group and to further verify and describe clinical benefit in the case of products approved under FDA's accelerated approval regulations. Failure to exhibit due diligence with regard to conducting Phase 4 clinical trials could result in withdrawal of FDA approval for products.

Progress reports detailing the results of clinical trials must be submitted annually to the FDA. In addition, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other studies or animal or in vitro testing that suggest a significant risk in humans exposed to the product; and any clinically important increase in the occurrence of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Expedited reporting is required for unexpected fatal or life-threatening suspected adverse reactions. Phase 1, Phase 2, and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted.

Expedited Programs for Serious Conditions

The FDA is authorized to expedite the development and review of new therapeutic products to address unmet need in the treatment of a serious or life-threatening condition. A product development program may qualify for one or more of FDA's expedited programs for serious conditions: fast track designation, breakthrough therapy designation, accelerated approval, and priority review designation.

Any product candidate submitted to the FDA for marketing, including under a Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as breakthrough therapy designation, priority review, and accelerated approval.

- *Fast Track Designation.* The sponsor of a product candidate may request the FDA to designate the product for a specific indication as a Fast Track product concurrent with or after the filing of the IND. Candidate products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and nonclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. In addition to other benefits, such as the ability to have greater interactions with the FDA, the FDA may initiate review of sections of a Fast Track application before the application is complete, a process known as rolling review.
- *Breakthrough therapy designation.* To qualify for the breakthrough therapy designation, product candidates must be intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence must indicate that such product candidates may demonstrate substantial improvement on one or more clinically significant endpoints over existing therapies. Features of breakthrough therapy designation include intensive guidance on an efficient development program, intensive involvement of senior managers and experienced staff on a proactive, collaborative and cross-disciplinary review, and rolling review.
- *Priority review.* A product candidate is eligible for priority review if it treats a serious condition and, if approved, it would be a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention compared to marketed products. In addition, specific statutory provisions provide for priority review for various types of applications. FDA aims to complete its review of priority review applications within six months as opposed to 10 months for standard review.
- *Accelerated approval*. FDA may grant accelerated approval to a product that treats a serious condition, generally provides a meaningful advantage over available therapies, and has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on an intermediate clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity and prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug or biological product candidate receiving accelerated approval perform adequate and well controlled post-marketing clinical trials. In addition, the FDA currently requires, as a condition for accelerated approval, pre-submission of promotional materials.

None of these expedited programs change the standards for approval but they may help expedite the development or approval process of product candidates.

Emergency Use Authorizations

The FDA has the authority to permit the use of unapproved medical products following a determination of a public health emergency ("PHE") by the Secretary of Health and Human Services (the "Secretary") and a declaration by the Secretary that circumstances exist justifying the authorization of emergency use of particular types of medical products to respond to the PHE. Once the Secretary has made the requisite determination and declaration, the FDA may issue Emergency Use Authorizations, or EUAs, for specific unapproved medical products if the following statutory criteria have been met: (1) the pathogen that is the subject of the PHE can cause a serious or life-threatening condition; (2) based on the totality of the scientific evidence available, it is reasonable to believe that (i) the product may be effective in preventing or treating such condition, and (ii) the known and potential benefits of the product outweigh the known and potential risks; and (3) there is no adequate, approved, and available alternative to the product.

If an EUA is granted, it generally will remain in effect until the Secretary's declaration that circumstances exist justifying the authorization of emergency use of the type of products at issue or the product is approved under one of FDA's traditional approval pathways. The EUA also may be revoked or revised for other reasons, including a finding that the criteria for its issuance are no longer met or other circumstances make a revision or revocation appropriate to protect public health or safety.

Review and Approval of BLAs

Assuming successful completion of the required clinical testing, the results of the pre-clinical studies and clinical trials, along with information relating to the product's chemistry, manufacturing, and controls and proposed labeling, are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety, potency, and purity of the investigational product to the satisfaction of the FDA. The fee required for the submission of an NDA or BLA under the Prescription Drug User Fee Act, or PDUFA, is substantial (for example, for FY2023 this application fee is approximately $3.24 million), and the sponsor of an approved BLA is also subject to an annual program fee, currently more than $390,000 per program. These fees are typically adjusted annually, but exemptions and waivers may be available under certain circumstances.

The FDA conducts a preliminary review of all BLAs within 60 days of receipt and informs the sponsor by the 74th day after the FDA's receipt of the submission whether an application is sufficiently complete to permit substantive review. In the event that the FDA determines that a BLA does not satisfy this standard, it will issue a Refuse to File, or RTF, determination to the applicant. Typically, an RTF for a BLA will be based on administrative incompleteness, such as clear omission of information or sections of required information; scientific incompleteness, such as omission of critical data, information, or analyses needed to evaluate safety, purity, and potency or provide adequate directions for use; or inadequate content, presentation, or organization of information such that substantive and meaningful review is precluded. The FDA may request additional information rather than accept a BLA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing.

After the submission is accepted for filing, the FDA begins an in-depth substantive review of the application. Under the goals and policies agreed to by the FDA under PDUFA, the FDA aims to review and act on 90 percent of standard submissions within ten months of the filing date and 90 percent of priority review submissions within six months of the filing date. The review process may be extended by the FDA for three additional months to consider new information or, in the case of a clarification provided by the applicant, to address an outstanding deficiency identified by the FDA following the original submission. Despite these review goals, it is not uncommon for FDA review of a BLA to extend beyond the PDUFA goal date.

Before approving a BLA, the FDA will typically conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether the manufacturing processes and facilities comply with GMPs. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA also may inspect the sponsor and one or more clinical trial sites to assure compliance with GCP requirements and the integrity of the clinical data submitted to the FDA.

Additionally, the FDA may refer a BLA, including applications for novel product candidates which present difficult questions of safety or efficacy, to an advisory committee for review, evaluation, and recommendation as to whether the application should be approved and under what conditions. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts. The FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations when making final decisions on approval. The FDA also may require submission of a risk evaluation and mitigation strategy, or REMS, if it determines that a REMS is necessary to ensure that the benefits of the product outweigh its risks and to assure the safe use of the biological product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS and the FDA will not approve the BLA without a REMS.

The FDA reviews a BLA to determine, among other things, whether the product is safe, pure, and potent and whether the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity, and potency. The approval process is lengthy and often difficult, and the FDA may refuse to approve a BLA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data and information. After evaluating the application and all related information, including the advisory committee recommendations, if any, and inspection reports of manufacturing facilities and clinical trial sites, the FDA may issue either an approval letter or a Complete Response Letter, or CRL.

An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A CRL generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. The CRL may require additional clinical or other data, additional pivotal Phase 3 clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, pre-clinical studies, or manufacturing. If a CRL is issued, the applicant may either resubmit the BLA addressing all the deficiencies identified in the letter or withdraw the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the BLA, the FDA will issue an approval letter. The FDA has committed to reviewing and acting on 90 percent of such resubmissions in response to an issued CRL in either two or six months depending on the type of information included. Even with the submission of this additional information, however, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If a product receives marketing approval from the FDA, the approval is limited to the conditions of use (e.g., patient population, indication) described in the FDA-approved labeling. Further, depending on the specific risk(s) to be addressed, the FDA may require that contraindications, warnings, or precautions be included in the product labeling, require that post-approval trials, including Phase 4 clinical trials, be conducted to further assess a product's safety after approval, require testing and surveillance programs to monitor the product after commercialization or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing trials or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Reference Product Exclusivity for Biological Products

With approval of a BLA, a biological product is licensed for marketing by FDA, and the product may be entitled to certain types of market and data exclusivity barring FDA from approving competing products for certain periods of time. For example, in March 2010, the Patient Protection and Affordable Care Act was enacted in the United States and included the Biologics Price Competition and Innovation Act of 2009, or the BPCIA. The BPCIA amended the PHSA to create an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed biological reference product. To date, the FDA has approved several biosimilars, and in 2021, the FDA approved the first interchangeable biologic. The FDA has also issued several guidance documents outlining its approach to reviewing and approving biosimilars and interchangeable biologics.

Under the BPCIA, a manufacturer may submit an application for a product that is "biosimilar to" or "interchangeable with" a previously approved biological product or "reference product." For the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and the proposed biosimilar product in terms of safety, purity, and potency. For the FDA to approve an interchangeable biological product, the agency must find that the biological product is biosimilar to the reference product, can be expected to produce the same clinical results as the reference product, and "for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch." Upon licensure by the FDA, an interchangeable biosimilar may be substituted for the reference product without the intervention of the healthcare provider who prescribed the reference product, although the substitutability of drug and biological products are determined at the state level.

The biosimilar applicant generally must demonstrate that the product is biosimilar based on data from analytical studies showing that the biosimilar product is highly similar to the reference product, data from animal studies (including toxicity) and data from one or more clinical studies to demonstrate safety, purity, and potency in one or more appropriate conditions of use for which the reference product is approved. The FDA, however, may waive any of these data requirements upon a finding that the data are "unnecessary." In addition, the applicant must show that the biosimilar and reference products have the same mechanism of action for the approved conditions of use, route of administration, dosage and strength, and the production facility must meet standards designed to assure product safety, purity, and potency.

In the US, a reference biological product is granted 12 years of exclusivity from the time of first licensure of the product, and the first approved interchangeable biological product will be granted an exclusivity period of up to one year after it is first commercially marketed. The FDA will not accept an application for a biosimilar or interchangeable product until four years after the date of first licensure of the reference product.

The BPCIA is complex, and there have been various legislative proposals to change certain aspects of the BPCIA. As a result, the ultimate impact, implementation, and meaning of aspects of the BPCIA are subject to significant uncertainty.

Orphan Drug Designation and Exclusivity

Orphan drug designation in the United States is designed to encourage sponsors to develop products intended for treatment of rare diseases or conditions. In the United States, a rare disease or condition is statutorily defined as a condition that affects fewer than 200,000 individuals in the United States or that affects more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available the drug for the disease or condition will be recovered from sales of the product in the United States.

Orphan drug designation may qualify a company for certain tax credits and market exclusivity for seven years following the date of the product's marketing approval if granted by the FDA. An application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. A product that has received orphan drug designation must go through the review and approval process like any other product.

A sponsor may request orphan drug designation of a previously unapproved product or new orphan indication for an already marketed product. In addition, a sponsor of a product that is otherwise the same drug as an already approved orphan drug may seek and obtain orphan drug designation for the subsequent product for the same rare disease or condition if it can present a plausible hypothesis that its product may be clinically superior to the first drug. More than one sponsor may receive orphan drug designation for the same drug for the same rare disease or condition, but each sponsor seeking orphan drug designation must file a complete request for designation.

If a product with orphan drug designation receives the first FDA approval for the rare disease or condition for which it has such designation, the product generally will receive orphan drug exclusivity. Orphan drug exclusivity means that the FDA may not approve another sponsor's marketing application for the same drug for the same disease or condition for seven years, except in certain limited circumstances.

The period of exclusivity begins on the date that the marketing application is approved by the FDA. Orphan drug exclusivity will not bar approval of another product under certain circumstances, including if the company with orphan drug exclusivity is not able to meet market demand or the subsequent product that is otherwise considered the same drug for the same disease or condition is shown to be clinically superior to the approved product based on greater efficacy or safety, or providing a major contribution to patient care. Additionally, the statute requires that a sponsor must demonstrate clinical superiority in order to receive orphan drug exclusivity for a product that is considered the same drug as a previously approved product for the same rare disease or condition.

Patent Term Restoration and Extension

In the United States, a patent claiming a new biological product, its method of use or its method of manufacture may be eligible for a limited patent term extension under the Hatch Waxman Act, which permits a patent extension of up to five years for patent term lost during product development and FDA regulatory review. Assuming grant of the patent for which the extension is sought, the restoration period for a patent covering a product is typically one half the time between the effective date of the IND involving human beings and the submission date of the BLA, plus the time between the submission date of the BLA and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date in the United States. Only one patent applicable to an approved product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent for which extension is sought. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. The USPTO reviews and approves the application for any patent term extension in consultation with the FDA.

Post-approval Requirements

Following approval of a new product, the manufacturer and the approved product are subject to pervasive and continuing regulation by the FDA, governing, among other things, monitoring and recordkeeping activities, reporting of adverse experiences with the product and product problems to the FDA, product sampling and distribution, manufacturing, and promotion and advertising. Although physicians may prescribe legally available products for unapproved uses or patient populations (i.e., "off-label uses"), manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Specifically, if a company is found to have promoted off-label uses, it may become subject to adverse public relations and administrative and judicial enforcement by the FDA, the Department of Justice, or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the way a company promotes or distributes drug products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

Further, if there are any modifications to the product, including changes in indications, labeling, or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new BLA or a BLA supplement, which may require the applicant to develop additional data or conduct additional pre-clinical studies and clinical trials. The FDA may also place other conditions on approvals including the requirement for a REMS to assure the safe use of the product, which may require substantial commitment of resources post-approval to ensure compliance. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription, or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

In addition, FDA regulations require that biological products be manufactured in specific approved facilities and in accordance with cGMPs. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports, and returned or salvaged products. The manufacturing facilities for our product candidates must meet cGMP requirements and satisfy the FDA or comparable foreign regulatory authorities' satisfaction before any product is approved and our commercial products can be manufactured.

We rely, and expect to continue to rely, on third parties to produce clinical (and, in the future, commercial) supplies of our product candidate in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations, including requirements for quality control and quality assurance, the maintenance of records and documentation, and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved drugs or biologics are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Inspections by the FDA and other regulatory agencies may identify compliance issues at facilities that may disrupt production or distribution or require substantial resources to correct. In addition, the discovery of conditions that violate these rules, including failure to conform to cGMPs, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including voluntary recall and regulatory sanctions as described below.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information,

imposition of post-market clinical trials requirement to assess new safety risks or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- safety alerts, Dear Healthcare Provider letters, press releases, or other communications containing warnings or other safety information about a product;
- mandated modification of promotional materials and labeling and issuance of corrective information;
- fines, warning letters, untitled letters or other enforcement-related letters, or clinical holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs/BLAs or supplements to approved NDAs/BLAs, or suspension or revocation of product approvals;
- product seizure or detention or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties; and
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal health care programs; or mandated modification of promotional materials and labeling and the issuance of corrective information.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of samples at the federal level and sets minimum standards for the registration and regulation of drug distributors by the states. Additionally, the Drug Supply Chain Security Act, or DSCSA, imposes requirements related to identifying and tracing certain prescription products distributed in the United States, including most biological products.

Other U.S. Healthcare Laws and Regulations

In the United States, biopharmaceutical manufacturers and their products are subject to extensive regulation at the federal and state level, such as laws intended to prevent fraud and abuse in the healthcare industry. These laws, some of which apply only to approved products, include:

- federal false claims, false statements, and civil monetary penalties laws prohibiting, among other things, any person from knowingly presenting, or causing to be presented, a false claim for payment of government funds or knowingly making, or causing to be made, a false statement to get a false claim paid;
- federal healthcare program anti-kickback law, which prohibits, among other things, persons from offering, soliciting, receiving, or providing remuneration, directly or indirectly, to induce either the referral of an individual for, or the purchasing or ordering of, a good or service for which payment may be made under federal healthcare programs such as Medicare and Medicaid;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which, in addition to privacy protections applicable to healthcare providers and other entities, prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- FDCA, which among other things, strictly regulates marketing, prohibits manufacturers from marketing such products prior to approval or for off-label use, and regulates the distribution of samples;
- federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;
- federal transparency law, which requires pharmaceutical companies to report certain payments to healthcare providers;
- state laws and regulations analogous to the above; and

- laws and regulations prohibiting bribery and corruption such as the Foreign Corrupt Practices Act ("FCPA"), which, among other things, prohibits U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations or foreign government-owned or affiliated entities, candidates for foreign public office, and foreign political parties or officials thereof.

Violations of these laws are punishable by criminal and/or civil sanctions, including, in some instances, exclusion from participation in federal and state health care programs, such as Medicare and Medicaid. Ensuring compliance is time consuming and costly.

Similar healthcare laws and regulations exist in the European Union (the "EU") and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of personal information.

U.S. Privacy Law

In the U.S., there are numerous state and federal laws and regulations governing the security and privacy of personal information. Additionally, state and federal regulators have begun to pay more attention to companies' data processing activities.

At the state level, laws require companies to safeguard personal information and take action in the event of a data breach (e.g., notifying governmental authorities and data subjects). State attorneys general have been active in using their consumer protection authority to investigate companies' data security practices. A number of states have passed laws governing data privacy and many others have similar legislation under consideration. Although many of these laws contain exceptions for certain health data, these exceptions are not comprehensive. All of these laws give rights to residents in their states and require businesses to take certain actions with respect to those rights (similar to the General Data Protection Regulation in effect in the EU, but with notable differences).

At the federal level, the Federal Trade Commission has been active in using its Section 5 authority to bring enforcement actions against companies for deceptive or unreasonable data processing activities.

Registrational Clinical Trials Process

Described below is the traditional registrational drug development track.

Phase 1 includes the initial introduction of an investigational new drug or biologic into humans. These studies are closely monitored and may be conducted in patients but are usually conducted in a small number of healthy volunteer patients. These studies are designed to determine the metabolic and pharmacologic actions of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. During Phase 1, sufficient information about the investigational product's pharmacokinetics and pharmacological effects are obtained to permit the design of well-controlled, scientifically valid, Phase 2 studies. Phase 1 studies of PRO 140 were conducted and completed by or on behalf of Progenics by certain principal investigators prior to our acquisition of PRO 140.

Phase 2 includes the early controlled clinical studies conducted to obtain some preliminary data on the effectiveness of the drug for a particular indication or indications in patients with the disease or condition. This phase of testing also helps determine the common short-term side effects and risks associated with the drug. Phase 2 studies are typically well-controlled, closely monitored, and conducted in a relatively small number of patients, typically no more than several hundred people. In some cases, depending upon the need for a new drug, a particular drug candidate may be licensed for sale in interstate commerce after a "pivotal" Phase 2 trial. Phase 2 is often broken into Phase 2a, which can be used to refer to "pilot trials," or more limited trials evaluating exposure response in patients, and Phase 2b trials that are designed to evaluate dosing efficacy and ranges.

Phase 3 studies are expanded controlled clinical studies. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained in Phase 2 and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit/risk relationship of the drug. Phase 3 studies also provide an adequate basis for extrapolating the results to the general population and transmitting that information in the physician labeling. Phase 3 studies usually involve significantly larger groups of patients, and considerable additional

expense. We were required to pay significant fees to third parties upon the first patient dosing in a Phase 3 trial of leronlimab, and we may be required to make additional fee payments to third parties upon the completion of additional milestones. Refer to Note 10, *Commitments and Contingencies - PRO 140 Acquisition and Licensing Arrangements,* for further information.

Manufacturing

We do not own or operate manufacturing facilities to produce leronlimab or perform CMC related activities. As such, we must depend on third-party manufacturing organizations and suppliers for all of our CMC activities. We continue to explore alternative CMC partners and sources to obtain access to adequate resources to support our CMC efforts for leronlimab in a cost-efficient manner.

We engaged Samsung Biologics and AGC Biologics, two global contract manufacturing organizations ("CMOs"), to initiate the scale-up to commercial batch quantities of product and develop the necessary controls and specifications to manufacture product on a consistent and reproducible manner. We have also contracted with suitable CMOs to fill, finish, label, and package product into the final commercial package for commercial use. In order to commercialize product, this scaled-up material will need to be validated under best practices and demonstrated to meet approved specifications on an ongoing basis. GMP material will be produced as needed to support clinical trials for all therapeutic indications and until commercial product is approved by the FDA. We will rely on CMOs for all of our developmental and commercial needs. We currently have sufficient drug product to support the Company's anticipated development activities.

As discussed in more detail above, the FDA issued a Refusal to File letter regarding the Company's BLA submission for leronlimab and placed a partial clinical hold on the Company's HIV program in the United States. All manufacturing and CMC activities, which are not necessary to maintain the shelf-lives of the manufactured leronlimab, have been paused until the Company addresses deficiencies to allow the clinical hold to be removed.

Also refer to Part II, Item 8, Note 10, *Commitments and Contingencies - Commitments with Samsung BioLogics Co., Ltd. ("Samsung"),* of this Form 10-K for additional information.

Research and Development Costs

The Company's research and development expenses totaled approximately $2.6 million and $27.0 million for the fiscal years ended May 31, 2023, and 2022, respectively.

Properties

We lease the space at which our principal executive offices are located at a monthly cost of approximately $15.2 thousand. We do not own or lease any other properties.

Employees and Human Capital Resources

As of August 21, 2023, we had 12 employees, as well as several independent consultants assisting us with the Company's regulatory, quality, and medical matters. Our research and development team is geographically dispersed throughout the United States. CytoDyn is committed to pay equity regardless of gender or race/ethnicity. We invest in our workforce by offering competitive salaries and benefits. We may award stock options or other stock-based awards to selected employees under our equity incentive plan. We also offer various benefits to all eligible employees, including health care coverage and a 401(k) plan. None of our employees are subject to a collective bargaining agreement. We consider our relationship with our employees to be good. There can be no assurance, however, that we will be able to identify or hire and retain additional employees or consultants on acceptable terms in the future.

Item 1A. RISK FACTORS

Our business is subject to numerous risks and uncertainties, including those highlighted in this section, that represent challenges we face in our efforts to successfully implement our strategy. You should carefully consider the risks described below in addition to other information set forth in this Form 10-K, including Item 7, *Management's Discussion and Analysis of Financial Condition and Results of Operations* and the consolidated financial statements and related notes in Part II, Item 8. These risks, some of which have occurred and any of which may occur, alone or in combination with other events or circumstances in the future, may have a material adverse effect on our business, financial condition, cash flows, results of operations, or the trading price of our common stock. The risks described below are not the only risks we face. Additional risks and uncertainties not currently known to us, or that we currently deem to be immaterial, may occur or become material in the future. Therefore, historical financial and business performance, events and trends are often not a reliable indicator of future operating results, financial and business performance, events or trends.

Summary of Risk Factors

Risks Related to Our Financial Position and Need for Additional Capital

- Our cash reserves are extremely low, requiring that we raise substantial additional financing to satisfy our current payment obligations and to fund our operations.
- We are a clinical stage biotechnology company with a history of significant operating losses; we expect to continue to incur operating losses, and we may never achieve profitability.
- The amount of financing we require will depend on various factors, many of which are beyond our control. Our results of operations, financial condition, and stock price are likely to be adversely affected if we are unable to obtain additional funding on improved terms compared to previous financings.
- Our future cash requirements may differ significantly from our current estimates.
- Our auditors have issued a going concern opinion, and we will not be able to achieve our objectives and will have to cease operations if we cannot find adequate financing.
- We have written off the value of our pre-launch inventories of leronlimab and related raw materials, the costs of which were previously capitalized, and may be unable to use all or a portion of those inventories in the development of our product candidate.

Risks Related to Our Ability to Maintain Effective Operational and Internal Controls Environment

- The recruitment and retention of skilled directors, executives, employees and consultants may be difficult and expensive, may result in dilution to our stockholders, and any failure to attract and retain such individuals may adversely affect our drug development and commercialization activities.
- Our Chief Financial Officer has also been appointed as interim President while we search for a new President and/or Chief Executive Officer. The loss, temporary loss, or transition of members of our senior management team or any other key employees may adversely affect our business.
- If we are unable to effectively maintain a system of internal control over financial reporting, we may not be able to accurately or timely report our financial results and our stock price could be adversely affected.
- Our information technology systems could fail to perform adequately or experience data corruption, cyber-based attacks, or network security breaches.

Risks Related to Legal Proceedings

- Our business, operating results, and financial condition could be negatively affected as a result of litigation and other demands made by stockholders.
- Class-action litigation filed against us could harm our business, and insurance coverage may not be sufficient to cover all related costs and damages.

- We are subject to oversight by the SEC, FDA, and other regulatory agencies. Investigations and proceedings by those agencies may divert management's focus and have a material adverse effect on our reputation and financial condition.
- We face risks and uncertainties related to litigation and other claims.

Risks Related to Development and Commercialization of Our Drug Candidate

- We have been notified by Samsung of alleged breaches of our payment obligations to Samsung, which ultimately could result in termination of our agreements for manufacturing of our drug product and related services we expect Samsung to provide under the agreements.
- Certain agreements and related license agreements require us to make significant milestone, royalty, and other payments, which will require additional financing and, in the event we do commercialize leronlimab, will decrease the revenues we may ultimately receive on sales. To the extent that such milestone, royalty and other payments are not timely made, the counterparties to such agreements in certain cases have repurchase and termination rights thereunder with respect to leronlimab.
- If we are unable to obtain all required regulatory approvals for leronlimab, we will not be able to commercialize our primary product candidate, which would materially and adversely affect our business, financial condition, and stock price.
- We are substantially dependent on the success of leronlimab. If we, either alone or with collaborators, are unable to complete the clinical development of, obtain and maintain marketing approval for, or successfully commercialize leronlimab, including with respect to adequate coverage and reimbursement, or if we continue to experience significant delays in doing so, our business will be seriously harmed.
- Our competitors may develop drugs that are more effective, safer, and less expensive than ours.
- We may not be able to identify, negotiate, and maintain the strategic alliances necessary to develop and commercialize our products and technologies, and we will be dependent on our corporate partners if we do.
- Known third-party patent rights could delay or otherwise adversely affect our planned development and sale of leronlimab. We have identified but not exhaustively analyzed other patents that could relate to our proposed products.

Risks Related to Our Dependence on Third Parties

- We have a very limited number of internal research and development personnel, making us dependent on consulting relationships and strategic alliances with industry partners.
- We may continue to rely on third parties, such as CROs and third-party manufacturers, to conduct clinical trials for our product candidate, leronlimab, and to produce our pre-clinical and clinical product candidate supplies. Such third parties are subject to significant regulation. A failure by such third parties to properly and successfully perform their obligations to us, or failure of manufacturers on which we rely to meet regulatory requirements, may result in our inability to obtain regulatory approvals for or commercialize our product candidate.

Risks Related to Our Intellectual Property Rights

- Our success depends substantially upon our ability to obtain and maintain intellectual property protection relating to our product candidate and future product candidates.
- If we are sued for infringing on third-party intellectual property rights, it will be costly and time-consuming, and an unfavorable outcome would have a significant adverse effect on our business. We may also undertake infringement or other legal proceedings against third parties, causing us to spend substantial resources on litigation and exposing our own intellectual property portfolio to challenge.
- We may become involved in disputes with our present or future contract partners over intellectual property ownership or other matters, which could have a significant adverse effect on our business.

Risks Related to Ownership of Our Common Stock

- Our common stock is classified as "penny stock" and trading of our shares may be restricted by the SEC's penny stock regulations.
- The trading price of our common stock has been and could remain volatile, and the market price of our common stock may decrease.
- Since our inception, we have been insolvent and have required debt and equity financing to maintain operations. We expect our debt service obligations and our need for additional funding to finance operations will cause additional substantial dilution to our existing stockholders and could adversely affect the trading price of our common stock.
- Our certificate of incorporation permits our Board to create new series of preferred stock without further approval by our stockholders, which could adversely affect the rights of the holders of our common stock.
- Anti-takeover provisions of our certificate of incorporation, our bylaws, and Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult, and may prevent attempts by our stockholders to replace or remove the current members of our Board and management.
- We do not expect to pay cash dividends on our common shares for the foreseeable future.

Risks Related to Our Financial Position and Need for Additional Capital

Our cash reserves are extremely low, requiring that we raise substantial additional financing to satisfy our current payment obligations and to fund our operations, which continues to be difficult in light of the low trading price of our common stock.

As of May 31, 2023, we had an unrestricted cash balance of approximately $2.5 million and a reserved cash balance of approximately $6.5 million. We must continue to raise substantial additional funds in the near term to meet our payment obligations and fund our operations. Additional funding may not be available on acceptable terms or at all. In addition, as of August 31, 2023, we had only approximately 20.7 million shares of common stock unreserved for other purposes and available for issuance in new financing transactions. We will need to use some of the additional authorized shares (or funds raised through the sale of such shares) to satisfy a portion of our outstanding accounts payable and accrued liabilities, which totaled approximately $69.4 million on May 31, 2023. If we are not able to raise additional funds on a timely basis, we may be forced to delay, reduce the scope of, or eliminate one or more of our planned operating activities, including continuing to seek removal of the clinical hold placed on us by the FDA, analyzing clinical trial data for purposes of responding to FDA requirements, and preparing additional regulatory submissions, developing additional clinical trials for indications we plan to pursue, regulatory and compliance activities, and legal defense activities. Any delay or inability to pursue our planned activities likely will adversely affect our business, financial condition, and stock price. The continued low trading price of our common stock (with a closing price of $0.21 per share on August 31, 2023) presents a significant challenge to our ability to raise additional funds. If we deplete our cash reserves, we may have to discontinue our operations and liquidate our assets.

We are a clinical stage biotechnology company with a history of significant operating losses; we expect to continue to incur operating losses, and we may never achieve profitability.

We have not generated significant revenue from product sales, licensing, or other income opportunities to date. Since our inception, we have incurred operating losses in each year due to costs incurred for research and development activities and general and administrative expenses related to our operations. We expect to incur losses for the foreseeable future, with no or only minimal revenues as we continue to pursue development of, and seek regulatory approvals for, leronlimab. If leronlimab fails to gain regulatory approval, or if it or other drug or biologic candidates we may acquire or license in the future do not achieve approval or market acceptance, we will not be able to generate revenue or explore other opportunities to enhance stockholder value, such as through a sale. If we fail to generate revenue or if we are unable to fund our continuing operations, our stockholders could lose a portion or all of their investments.

The amount of financing we require will depend on various factors, many of which are beyond our control. Our results of operations, financial condition, and stock price are likely to be adversely affected if we are unable to obtain additional funding on improved terms compared to previous financings.

Our future funding requirements will depend on many factors, including, but not limited to:

- the costs of preparing required regulatory submissions, as well as any clinical trial programs and pre-clinical studies we may pursue and other development activities conducted by us directly,
- the costs involved with our CMC activities,
- the satisfaction of payment obligations we have already incurred,
- the costs and timing of obtaining regulatory approvals and making related milestone payments due to third parties with whom we have licensing or similar agreements,
- the costs of filing, prosecuting, maintaining, and enforcing patents and other intellectual property rights and defending against potential claims of infringement,
- the costs associated with hiring and retaining needed scientific and administrative employees, advisors, and consultants,
- the cost of legal and other professional advisors needed to support our development efforts, responsibilities as a public reporting company, regulatory compliance and investigations, and legal proceedings,
- the costs of compliance with laws, regulations, or judicial decisions applicable to us, and
- the costs of general and administrative infrastructure required to manage our business and protect corporate assets and stockholder interests.

If any of these factors cause our funding needs to be greater than expected, our ability to continue operations, financial condition, and stock price may be adversely affected.

Our future cash requirements may differ significantly from our current estimates.

Our cash requirements may differ significantly from our estimates from time to time, depending on a number of factors, including:

- our ability to attract strategic partners to pay for or share costs related to our product development efforts,
- whether our outstanding convertible notes are converted into equity,
- whether we receive additional cash upon the exercise of our outstanding warrants and stock options for common stock, and
- our ability to obtain funding under future licensing agreements or other collaborative relationships.

If we deplete our cash reserves and are unable to obtain additional funding, we may be forced to discontinue our operations and liquidate our assets.

Our auditors have issued a going concern opinion, and we will not be able to achieve our objectives and will have to cease operations if we cannot find adequate financing.

Our auditors issued an opinion, which includes a going concern explanatory paragraph, in connection with the audit of our annual consolidated financial statements for the fiscal year ended May 31, 2023. A going concern paragraph in an audit opinion means that there is substantial doubt that we can continue as an ongoing business for the 12 months from the date the consolidated financial statements are issued. If we are unable to continue as an ongoing business, we might have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements. In addition, the inclusion of an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern and our lack of cash resources may materially adversely affect our share price and our ability to raise new capital or to enter into critical contractual relations with third parties. There is no assurance that we will be able to adequately fund our operations in the future.

We have written off the value of our pre-launch inventories of leronlimab and related raw materials, the costs of which were previously capitalized, and may be unable to use all or a portion of those inventories in the development of our product candidate.

Pre-launch inventories consist of costs of raw materials and work-in-progress related to our product candidate leronlimab. As of May 31, 2023, our inventories had been written off in full for accounting purposes. Although the inventories continue to be physically maintained and currently may be eligible for use in certain clinical contexts, we may be unable to use all or a portion of these inventories in the development of our product candidate.

Risks Related to Our Ability to Maintain an Effective Operational and Internal Controls Environment

The recruitment and retention of skilled directors, executives, employees, and consultants may be difficult and expensive, may result in dilution to our stockholders, and any failure to attract and retain such individuals may adversely affect our drug development and commercialization activities.

Our business depends on the skills, performance, and dedication of our officers and key scientific and technical advisors, as well as our directors. All of our current scientific advisors are independent contractors and are either self-employed or employed by other organizations. As a result, they may have conflicts of interest or other commitments, such as consulting or advisory contracts with other organizations, that may affect their ability to provide services to us in a timely manner. We are currently conducting a search for a new president and/or chief executive officer, and may need to recruit additional directors, executive management, employees, and advisors, particularly scientific and technical personnel. In addition, there is currently intense competition for skilled directors, executives, and employees with relevant scientific and technical expertise, and this competition is likely to continue. We compete for these qualified personnel against companies with greater financial resources than ours. These recruitment and retention efforts likely will require additional financial resources. In order to successfully recruit and retain qualified employees, we will need to offer a combination of salary, cash incentives, and equity compensation. Future issuances of our equity securities for compensatory purposes will dilute existing stockholders' ownership interests and reduce the shares available for future funding transactions. If we are unable to attract and retain individuals with relevant scientific, technical, and managerial experience, we may be forced to limit or delay our product development activities or may experience difficulties in successfully conducting our business, which would adversely affect our operations and financial condition.

Our Chief Financial Officer has also been appointed as interim President while we search for a new President and/or Chief Executive Officer. The loss, temporary loss, or transition of members of our senior management team or any other key employees may adversely affect our business.

During the past 18 months, we have experienced significant turnover among our senior executives, and currently have only one executive officer. Cyrus Arman, who was our President beginning on July 9, 2022, was appointed as the Company's Senior Vice President, Business Operations, a part time, nonexecutive position, by the Board effective July 7, 2023, following a medical leave of absence. Antonio Migliarese, our Chief Financial Officer, has been appointed to also fill the position of interim President beginning May 18, 2023. The Board has commenced a search for a new President and/or Chief Executive Officer. If we are successful in recruiting one or more individuals to executive positions, the complexity inherent in integrating a new key member of the senior management team with existing senior management may limit the effectiveness of any such successor or otherwise adversely affect our business. Leadership transitions and any disruptions that result are inherently difficult to manage and may cause uncertainty or a disruption to our business or increase the likelihood of turnover of other key officers and employees. Further, we may incur significant expenses related to any executive transition costs. Finding suitable replacements for senior management and other key employees can be difficult, and there is no assurance we will be successful in attracting or retaining qualified personnel.

Our success depends significantly on the individual and collective contributions of our senior management team and key employees. The individual and collective efforts of these employees are important as we continue our efforts to develop leronlimab. The loss of the services of a member of our senior management team or the inability to hire and retain experienced management personnel likely would have a material adverse effect on our business and operations.

If we are unable to effectively maintain a system of internal control over financial reporting, we may not be able to accurately or timely report our financial results and our stock price could be adversely affected.

Section 404 of the Sarbanes-Oxley Act of 2002 and related regulations require us to evaluate the effectiveness of our internal control over financial reporting as of the end of each fiscal year, and to include a management report assessing the effectiveness of our internal control over financial reporting in our Form 10K for that fiscal year. Failure to maintain our controls or operation of these controls may harm our operations, decrease the reliability of our financial reporting, and cause us to fail to meet our financial reporting obligations, which could adversely affect our business and reduce our stock price.

Our information technology systems could fail to perform adequately or experience data corruption, cyber-based attacks, or network security breaches.

We rely on information technology networks and systems, including the internet, to process, transmit, and store electronic information. In particular, we depend on our information technology infrastructure to effectively manage our business data, finance, and other business processes and electronic communications between our personnel and corporate partners. If we do not allocate and effectively manage the resources necessary to build and sustain an appropriate technology infrastructure, security breaches or system failures of this infrastructure may result in system disruptions, shutdowns, or unauthorized disclosure of confidential information, including patient information in violation of HIPAA requirements. In addition, our employees, contractors, and other corporate partners increasingly are working from remote locations. As a result, we rely on information technology systems that are outside our direct control. These systems are potentially vulnerable to cyber-based attacks and security breaches. In addition, cyber criminals are increasing their attacks on individual employees, including scams designed to trick victims into transferring sensitive data or funds or stealing credentials that compromise information systems. If one of our employees falls victim to these attacks, or our information technology systems or those of our partners are compromised, our operations could be disrupted, or we may suffer financial loss, loss or misappropriation of intellectual property or other critical assets, reputational harm, and regulatory fines and intervention, and our business and financial condition may be adversely affected.

Risks Related to Legal Proceedings

Our business, operating results, and financial condition could be negatively affected as a result of litigation and other demands made by stockholders.

We are and have been involved in legal proceedings and other claims brought by stockholders, including class actions alleging securities law violations, derivative actions alleging waste of corporate assets, unjust enrichment, other breaches of fiduciary duties by former directors and current and former executive officers, and demands by activist investors. Similar actions may occur in the future. While the Company welcomes opinions of all stockholders, responding to demands, litigation, proxy contests, or other initiatives by stockholders or activist investors may divert the attention of our Board, management team, and employees from their regular duties in the pursuit of business opportunities to enhance stockholder value. Such actions may also cause our existing or potential employees, strategic partners, and stockholders to have questions or doubts about the future direction of the Company and may provide our competitors with an opportunity to exploit these concerns. Such circumstances could cause significant fluctuations in our stock price based on temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business. Refer to Part II, Item 8, Note 10, *Commitments and Contingencies – Legal Proceedings* in this Form 10-K for additional information.

Class-action litigation filed against us could harm our business, and insurance coverage may not be sufficient to cover all related costs and damages.

The market price of our common stock has historically experienced and may continue to experience significant volatility. In the past, we had been subject to putative class action lawsuits in which plaintiffs cited, among other things, volatility of our common stock. Litigation, whether or not successful, may result in diversion of our management's attention and resources, and may require us to incur substantial costs, some of which may not be covered in full by insurance, which could harm our business and financial condition. During the course of litigation, there may be negative public announcements of the results of hearings, motions, or other interim proceedings or developments, which could

have a further negative effect on the market price of our common stock. Refer to Part II, Item 8, Note 10, *Commitments and Contingencies – Legal Proceedings* in this Form 10-K for further information.

We are subject to oversight by the SEC, FDA, and other regulatory agencies. Investigations and proceedings by those agencies may divert management's focus and have a material adverse effect on our reputation and financial condition.

We are subject to the regulation and oversight by the Securities and Exchange Commission ("SEC") and state regulatory agencies, in addition to the FDA and other federal regulatory agencies. As a result, we may face legal or administrative proceedings by these agencies. We have received subpoenas from the SEC and the U.S Department of Justice (the "DOJ") requesting documents and information concerning, among other matters, leronlimab, our public statements regarding the use of leronlimab as a potential treatment for COVID19, HIV, and triple-negative breast cancer, related communications with the FDA, investors, and others, litigation involving former employees, our retention of investor relations consultants, and trading in our securities. On December 20, 2022, the DOJ announced the unsealing of a criminal indictment charging both our former CEO, Nader Z. Pourhassan, and Kazem Kazempour, CEO of Amarex Clinical Research LLC ("Amarex"), our former CRO. That same day, the SEC announced charges against both Mr. Pourhassan and Mr. Kazempour for alleged violations of federal securities laws. The Company is cooperating fully with the DOJ and SEC investigations. We are unable to predict the effect of any governmental investigations on our business, financial condition, or reputation. In addition, publicity surrounding any investigation, even if ultimately resolved in our favor, could have a material adverse effect on our business. Refer to Part II, Item 8, Note 10, *Commitments and Contingencies – Legal Proceedings* in this Form 10-K for further information.

We face risks and uncertainties related to litigation and other claims.

We are parties to a variety of litigation and other claims, in addition to the regulatory investigations and related proceedings described above. For example, two putative class action lawsuits have been filed against us and certain former officers and directors, asserting violations of federal securities laws under Section 10(b) and Section 20(a) of the Exchange Act, and alleging that the Company and certain former officers and directors made purportedly false or misleading statements and that some of the individual defendants violated Section 20A of the Exchange Act by selling shares of the Company's common stock, purportedly while in possession of material nonpublic information. Separately, three purported stockholder derivative actions have been filed against certain former officers and directors; the Company was named as a nominal defendant. Refer to Part II, Item 8, Note 10, *Commitments and Contingencies – Legal Proceedings* in this Form 10-K for further information.

In addition, from time to time, we may also be involved in legal proceedings and investigations arising in the ordinary course of business, including those relating to employment matters, relationships with partners, intellectual property disputes, and other business matters. Any such claims or investigations may be time-consuming, costly, divert management resources, or otherwise have a material adverse effect on our business, financial condition, or results of operations. Any claims or litigation, even if fully indemnified or insured, could damage our reputation and make it more difficult to compete effectively or obtain adequate insurance in the future.

Risks Related to Development and Commercialization of Our Drug Candidate

We have been notified by Samsung of alleged breaches of our payment obligations to Samsung, which ultimately could result in termination of our agreements for manufacturing of our drug product and related services we expect Samsung to provide under the agreements.

Beginning in fiscal 2022, we have received communications from Samsung regarding alleged breaches of our agreements with Samsung relating to past due balances. The Company has been pursuing negotiations with Samsung regarding potential approaches to resolve the issues short of litigation, including proposals by each party for an alternative schedule of payments, and proposals by the Company to satisfy a portion of the Company's payment obligations in the form of equity securities of the Company and to postpone or cancel provisions in the agreements calling for the manufacturing of additional drug product. There can be no assurance that we will be able to address the issues raised by Samsung or avoid being found in breach of our agreements with Samsung. Failure to resolve the issues may ultimately result in termination of our agreements with Samsung, which could jeopardize our ability to properly store our inventories of drug product and manufacture additional drug product when needed. Refer to Part II, Item 8, Note 10, *Commitments and Contingencies – Commitments with Samsung BioLogics Co., Ltd. ("Samsung")* in this Form 10-K for further information.

Certain agreements and related license agreements require us to make significant milestone, royalty, and other payments, which will require additional financing and, in the event we do commercialize leronlimab, decrease the revenues we may ultimately receive on sales. To the extent that such milestone, royalty, and other payments are not timely made, the counterparties to such agreements in certain cases have repurchase and termination rights thereunder with respect to leronlimab.

Under agreements we have with Progenics and Lonza Sales AG ("Lonza"), as well as a Development and License Agreement (the "PDL License") between Protein Design Labs (now AbbVie Inc. ("AbbVie")) and Progenics, we are required to pay significant milestone payments, license fees for "system know-how" technology, and royalties related to leronlimab upon the occurrence of specified events. In order to make these milestone and license payments, we will need to raise additional funds. In addition, our royalty obligations will reduce the economic benefits to us of future sales, if any. To the extent that such milestone payments and royalties are not timely made, under their respective agreements, Progenics has certain repurchase rights relating to the assets sold to us, and AbbVie has certain termination rights relating to our license of leronlimab under the PDL License. Refer to Part II, Item 8, Note 10, *Commitments and Contingencies – PRO 140 Acquisition and Licensing Arrangements* in this Form 10-K for further information.

If we are unable to obtain all required regulatory approvals for leronlimab, we will not be able to commercialize our primary product candidate, which would materially and adversely affect our business, financial condition, and stock price.

Clinical testing is expensive, difficult to design and implement, may take many years to complete, and its outcome is uncertain. The research, testing, manufacturing, labeling, packaging, storage, approval, sale, marketing, advertising and promotion, pricing, export, import, and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, with regulations differing from country to country. We are not permitted to market a drug candidate as prescription pharmaceutical products in the United States until we receive approval from the FDA, or in foreign markets until we receive the requisite approval from comparable regulatory authorities in foreign countries. In the United States, the FDA generally requires the completion of clinical trials of each drug to establish its safety and efficacy, and extensive pharmaceutical development to ensure its quality before approval. Regulatory authorities in other jurisdictions impose similar requirements. Of the large number of drugs in development, only a small percentage are approved for commercialization. Receipt of necessary regulatory approval for the use of leronlimab for one or more indications is subject to a number of risks which include, among others:

- the FDA or comparable foreign regulatory authorities or institutional review boards ("IRBs") may disagree with the future design or implementation of our clinical trials,
- we may not be able to provide acceptable evidence of the safety and efficacy of our drug candidate,
- the results of our clinical trials may not be satisfactory or may not meet the level of statistical or clinical significance required by the FDA or foreign regulatory authorities for marketing approval,

- patients in our clinical trials may suffer adverse effects for reasons that may or may not be related to our drug candidate,
- the data collected from clinical trials may not be sufficient to support the submission of an application for marketing approval in the United States or elsewhere,
- the FDA or foreign regulatory authorities may not approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies, and
- the approval policies or regulations of the FDA or foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

We cannot guarantee that regulators will agree with our assessment of the results of our past or future clinical trials or that such trials will be considered by regulators to have shown safety or efficacy of our product candidate. In particular, there is no guarantee that the FDA will lift the partial clinical hold placed on our HIV program. The FDA has substantial discretion in the approval process and may refuse to accept any application or may require additional clinical trials or pre-clinical or other studies. Additionally, we have limited experience in filing the applications necessary to gain regulatory approvals and expect to continue to rely on consultants and our CROs to assist us in this process. Securing FDA approval requires the submission of pre-clinical, clinical, and/or pharmacokinetic data, information about product manufacturing processes and inspection of facilities, and supporting information for each therapeutic indication to establish a product candidate's safety and efficacy for each indication. Our drug candidate may prove to have undesirable or unintended side effects, toxicities, or other characteristics that may preclude us from obtaining regulatory approval or prevent or limit commercial use with respect to one or all intended indications. Failure to obtain regulatory approval for leronlimab will prevent us from commercializing it as a prescription product, and our ability to generate revenue will be seriously impaired.

We are substantially dependent on the success of leronlimab. If we, either alone or with collaborators, are unable to complete the clinical development of, obtain and maintain marketing approval for, or successfully commercialize leronlimab, including with respect to adequate coverage and reimbursement, or if we continue to experience significant delays in doing so, our business will be seriously harmed.

We currently have no products approved for sale and are investing a significant portion of our resources in the development of leronlimab for marketing approval in the United States and potentially other countries. Our prospects are substantially dependent on our ability to develop, obtain marketing approval for, and successfully commercialize leronlimab in the United States in one or more disease indications. The success of our Company will depend on a number of factors, including the following:

- a safety, tolerability, and efficacy profile for leronlimab that is satisfactory to the FDA and potential foreign regulatory authorities,
- timely receipt of marketing approvals for leronlimab from applicable regulatory authorities, including the FDA,
- the performance of third-party contractors that we engage to manage our clinical studies and the resulting data,
- obtaining and maintaining patent, trade secret protection, and regulatory exclusivity, both in the United States and internationally, including our ability to maintain our license agreement with AbbVie, as successor to Progenics,
- protection of our rights in our intellectual property portfolio, including our ability to maintain our license agreement with AbbVie,
- a continued acceptable safety profile for leronlimab following marketing approval, if any,
- commercial acceptance of leronlimab by patients, the medical community, and third-party payors, and
- our ability to position leronlimab to compete with other therapies.

Many of these factors are beyond our control. If we are unable to develop, receive marketing approval for, and successfully provide for commercialization of leronlimab on our own or through third parties, or if we continue to experience delays as a result of any of these factors or otherwise, our business will be substantially harmed.

Our competitors may develop drugs that are more effective, safer and less expensive than ours.

The biopharmaceutical industry is intensely competitive, and our future success depends on our ability to demonstrate and maintain a competitive advantage with respect to the design, development, and commercialization of product candidates. For example, new or improved therapies in the oncology and immunology arenas are the subject of frequent announcements. If approved for marketing by the FDA, depending on the approved clinical indication, leronlimab may be competing with existing and future treatments. Our competitors may:

- develop drug candidates and market drugs that increase the levels of safety or efficacy that our product candidate will need to show in order to obtain regulatory approval,
- develop drug candidates and market drugs that are less expensive or more effective than ours,
- commercialize competing drugs before we or our partners can launch any products we are working to develop,
- hold or obtain proprietary rights that could prevent us from commercializing our products, and
- introduce therapies or market drugs that render our product candidate obsolete.

We expect to compete against large pharmaceutical and biotechnology companies and smaller companies that are collaborating with larger pharmaceutical companies, new companies, academic institutions, government agencies, and other public and private research organizations. These competitors, in nearly all cases, operate research and development programs that have substantially greater financial resources than we do. Our competitors also have significantly greater experience in:

- developing drug and other product candidates,
- undertaking pre-clinical testing and clinical trials,
- building relationships with key customers and opinion-leading physicians,
- obtaining and maintaining FDA and other regulatory approvals,
- formulating and manufacturing drugs,
- launching, marketing, and selling drugs, and
- providing management oversight for all of the above-listed operational functions.

If we fail to achieve superiority over other existing or newly developed treatments, we may be unable to obtain regulatory approval. If our competitors market drugs that are less expensive, safer, or more effective than our product candidate, or which gain or maintain greater market acceptance, we may not be able to compete effectively.

We may not be able to identify, negotiate, and maintain the strategic alliances necessary to develop and commercialize our products and technologies, and we will be dependent on our corporate partners if we do.

We may seek to enter into a strategic alliance with a pharmaceutical company for further development and approval of our product candidate in one or more indications. Strategic alliances could potentially provide us with additional funds, expertise, access, and other resources in exchange for exclusive or non-exclusive licenses or other rights to the technologies and products that we are currently developing or may explore in the future. We cannot give any assurance we will be able to enter into strategic relationships with a pharmaceutical company or other strategic partner in the near future or at all or maintain our current relationships. In addition, we cannot assure that any agreements we may reach will achieve our goals or be on terms that prove to be economically beneficial to us. We anticipate that if we were to enter into strategic or contractual relationships, we may become dependent on the successful performance of our partners or counterparties. If they fail to perform as expected, such failure could adversely affect our financial condition, lead to increases in our capital needs, or hinder or delay our development efforts.

Known third-party patent rights could delay or otherwise adversely affect our planned development and sale of leronlimab. We have identified but not exhaustively analyzed other patents that could relate to our proposed products.

We are aware of patent rights held by a third party that may cover certain compositions within our leronlimab candidate. The patent holder has the right to prevent others from making, using, or selling a drug that incorporates the

patented compositions, while the patent remains in force. While we believe that the third party's patent rights will not affect our planned development, regulatory clearance, and eventual commercial production, marketing, and sale of leronlimab, there can be no assurance that this will be the case. We believe the relevant patent expires before we expect to commercially introduce leronlimab. In addition, the Hatch-Waxman exemption to U.S. patent law permits all uses of compounds in clinical trials and for other purposes reasonably related to obtaining the FDA clearance of drugs that will be sold only after patent expiration; we believe our use of leronlimab in those FDA-related activities would not infringe the patent holder's rights. However, were the patent holder to assert its rights against us before expiration of the patent for activities unrelated to the FDA clearance, the development and ultimate sale of a leronlimab product could be significantly delayed, and we could incur expenses for defending a patent infringement suit and for damages that may relate to periods prior to the patent's expiration. In connection with our acquisition of rights to leronlimab, our patent counsel conducted a freedom-to-operate search that identified other patents that could relate to our proposed leronlimab candidate. Based upon research and analysis to date, we believe leronlimab likely does not infringe those patent rights. If any of the holders of the identified patents were to assert patent rights against us, the development and sale of leronlimab could be delayed, we could be required to spend time and money defending patent litigation, and we could incur liability for infringement or be enjoined from producing our products if the patent holders prevailed in an infringement suit.

Risks Related to Our Dependence on Third Parties

We have a very limited number of internal research and development personnel, making us dependent on consulting relationships and strategic alliances with industry partners.

We have few employees dedicated to quality control and CMC activities. We rely and intend to continue to rely on third parties to supplement many of these critical functions. If we commence additional clinical trials, we will contract with third-party, full-service CROs to manage our trials. As a result, we are likely to be dependent on consultants and strategic partners in our development activities, and it may be administratively challenging for us to monitor and coordinate these relationships. If we do not appropriately manage our relationships with third parties, we may not be able to successfully manage development, testing, and preparation of regulatory filings for our product or commercialize any approved product, which would have a material and adverse effect on our business, financial condition and stock price.

We may continue to rely on third parties, such as CROs and third-party manufacturers, to conduct clinical trials for our product candidate, leronlimab, and to produce our pre-clinical and clinical product candidate supplies. Such third parties are subject to significant regulation. A failure by such third parties to properly and successfully perform their obligations to us, or failure of manufacturers on which we rely to meet regulatory requirements, may result in our inability to obtain regulatory approvals for or commercialize our product candidate.

We are dependent on third parties for important aspects of our product development strategy. We do not have the required financial and human resources to carry out independently the pre-clinical and clinical development of our current product candidate. We also do not have the capability or resources to manufacture, store, market or sell our current product candidate. As a result, we contract with and rely on third parties to perform such important functions. We compete with larger companies for the resources of these third parties. Although we plan to continue to rely on these third parties to conduct any future clinical trials and manufacturing, we are responsible for ensuring that each of our clinical trials is conducted in accordance with its general investigational plan and protocol and adheres to the FDA's regulations regarding Good Laboratory Practice and that the manufacturing of our product complies with the FDA's current good manufacturing practices ("cGMP") enforced through its facilities inspection program. Moreover, we are required to comply with regulations and standards, including good clinical practices, for designing, conducting, monitoring, recording, analyzing, and reporting the results of clinical trials to assure that the data and results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. The third parties on whom we rely generally may terminate their engagements with us at any time. If these third parties do not successfully carry out their duties under their agreements with us, if the quality or accuracy of the data they obtain, process, and analyze is compromised for any reason, or if they otherwise fail to comply with clinical trial protocols or meet expected deadlines, future clinical trials that we may undertake may experience delays or may fail to meet regulatory requirements. If our clinical trials do not meet regulatory requirements or if these third parties need to be replaced, our pre-clinical development activities or clinical trials may be extended, delayed, suspended, or terminated. If any of these events occur, or if problems develop in our relationships with third parties, or if such parties fail to perform as expected, we may experience delays or lack of progress, significant cost increases, changes in our strategies, and even failure of our

product initiatives, potentially resulting in our inability to obtain regulatory approval of our product candidate and harming our reputation. Refer to Part II, Item 8, Note 10, *Commitments and Contingencies – Commitments with Samsung BioLogics Co., Ltd.* and – *Amarex Dispute* in this Form 10-K for further information.

Risks Related to Our Intellectual Property Rights

Our success depends substantially upon our ability to obtain and maintain intellectual property protection relating to our product candidate and future product candidates.

Due to evolving legal standards relating to the patentability, validity, and enforceability of patents covering pharmaceutical inventions and the claim scope of patents, our ability to enforce our existing patents and to obtain and enforce patents that may issue from any pending or future patent applications is uncertain and involves complex legal, scientific, and factual questions. To date, no consistent policy has emerged regarding the breadth of claims allowed in biotechnology and pharmaceutical patents. We have pending patents for certain indications for our core product candidate and continue to seek patent coverage for various potential therapeutic applications for leronlimab. However, we cannot be sure that any patents will issue from any pending or future patent applications owned by or licensed to us. Even if patents do issue, we cannot be sure that the claims of these patents will be held valid or enforceable by a court of law, will provide us with any significant protection against competing products, or will afford us a commercial advantage over competitive products. If one or more products resulting from our product candidate is approved for sale by the FDA and we do not have adequate intellectual property protection for those products, competitors could duplicate them for approval and sale in the United States without repeating the extensive testing required of us or our partners to obtain FDA approval, once our data exclusivity period has expired.

If we are sued for infringing on third-party intellectual property rights, it will be costly and time-consuming, and an unfavorable outcome would have a significant adverse effect on our business. We may also undertake infringement or other legal proceedings against third parties, causing us to spend substantial resources on litigation and exposing our own intellectual property portfolio to challenge.

Our ability to commercialize our product candidate depends on our ability to use, manufacture, and sell that product without infringing on the patents or other proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the monoclonal antibody therapeutic area in which we are developing our product candidate and seeking new potential product candidates. There may be existing patents, unknown to us, on which our activities with our product candidate could infringe.

If a third party claims our actions or products or technologies infringe on its patents or other proprietary rights, we could face a number of issues that could seriously harm our competitive position, including, but not limited to:

- infringement and other intellectual property claims that, even if meritless, can be costly and time-consuming, delay the regulatory approval process, and divert management's attention from our core business operations,
- substantial damages for infringement if a court determines that our products or technologies infringe a third party's patent or other proprietary rights,
- a court prohibiting us from selling or licensing our products or technologies unless the holder licenses the patent or other proprietary rights to us, which it is not required to do, and
- even if a license is available from a holder, we may have to pay substantial royalties or grant cross-licenses to our patents or other proprietary rights.

If any of these events occur, it could significantly harm our operations and financial condition and negatively affect our stock price. Additionally, although no third party asserted a claim of infringement against us, others may hold proprietary rights that could prevent our product candidate from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to our product candidate or our processes could subject us to potential liability for damages and require us to obtain a license to continue to manufacture or market leronlimab or any other product candidates. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Further, we cannot be sure that we could redesign leronlimab or any other product candidates or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain

necessary licenses, could prevent us from developing and commercializing leronlimab or another product candidate, which could harm our business, financial condition, and operating results.

We may come to believe that third parties are infringing on our patents or other proprietary rights. To prevent infringement or unauthorized use, we may need to file infringement and/or misappropriation suits, which are very expensive and time-consuming and would distract management's attention. Also, in an infringement or misappropriation proceeding, a court may decide that one or more of our patents is invalid, unenforceable, or both, in which case third parties may be able to use our technology without paying license fees or royalties. Even if the validity of our patents is upheld, a court may refuse to stop the other party from using the technology at issue on the ground that the other party's activities are not covered by our patents.

We may become involved in disputes with our present or future contract partners over intellectual property ownership or other matters, which could have a significant adverse effect on our business.

Inventions discovered in the course of performance of contracts with third parties may become jointly owned by our strategic partners and us, in some cases, and the exclusive property of one of us, in other cases. Under some circumstances, it may be difficult to determine who owns a particular invention or whether it is jointly owned, and disputes could arise regarding ownership or use of those inventions. Other disputes may also arise relating to the performance or alleged breach of our agreements with third parties. Any disputes could be costly and time-consuming, and an unfavorable outcome could have a significant adverse effect on our business.

Risks Related to Ownership of Our Common Stock

Our common stock is classified as "penny stock" and trading of our shares may be restricted by the SEC's penny stock regulations.

Rules 15g-1 through 15g-9 promulgated under the Exchange Act impose sales practice and disclosure requirements on certain brokers-dealers who engage in transactions involving a "penny stock." The SEC has adopted regulations which generally define "penny stock" to be any equity security that has a market price of less than $5.00 per share or an exercise price of less than $5.00 per share, subject to certain exceptions. Our common stock is covered by the penny stock rules, which impose additional sales practice requirements on broker-dealers who sell to persons other than established customers and "accredited investors." The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document in a form prepared by the SEC that provides information about penny stocks and the nature and level of risks in the penny stock market. The broker-dealer also must provide the prospective investor with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and its salesperson in the transaction, and monthly account statements showing the market value of each penny stock held in the investor's account. In addition, the penny stock rules require that, prior to a transaction in a penny stock that is not otherwise exempt, the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written agreement to the transaction. These disclosure requirements may have the effect of reducing the level of trading activity in the secondary market for stock that is subject to these penny stock rules. Consequently, these penny stock rules may affect the ability of broker-dealers to trade our securities. We believe that the penny stock rules may discourage investor interest in and limit the marketability of our common stock.

The trading price of our common stock has been and could remain volatile, and the market price of our common stock may decrease.

The market price of our common stock has historically experienced and may continue to experience significant volatility. From June 1, 2022 through May 31, 2023, the market price of our common stock has fluctuated from a high of $1.26 per share to a low of $0.15 per share. The volatile nature of our common share price may cause investment losses for our stockholders. In addition, the market price of stock in small capitalization biotech companies is often driven by investor sentiment, expectation, and perception, all of which may be independent of fundamental, objective, and intrinsic valuation metrics or traditional financial performance metrics, thereby exacerbating volatility. In addition, our common stock is quoted on the OTCQB of the OTC Markets marketplace, which may increase price quotation volatility and could limit liquidity, all of which may adversely affect the market price of our shares.

Since our inception, we have been insolvent and have required debt and equity financing to maintain operations. We expect our debt service obligations and our need for additional funding to finance operations will cause additional substantial dilution to our existing stockholders and could adversely affect the trading price of our common stock.

Since our inception, we have not achieved cash flows from revenues sufficient to cover basic operating costs. As a result, we have relied heavily on debt and equity financing. Equity financing, including securities convertible into equity, in particular has had a dilutive effect on our common stock, which has hampered our ability to attract reasonable financing terms.

The terms of our convertible note financings require us to make periodic debt repayments to reduce the outstanding balance of our debt. As a result, we likely will be required to use a significant portion of our available cash to repay our debt and satisfy other payment obligations, which will reduce the amount of capital available to finance our operations and other business activities. We expect to continue to seek to exchange all or part of our outstanding debt for shares of common stock. If the Company enters into any future exchange offers, they will likely be negotiated at a discount to the market price of our common stock and will cause additional dilution to our existing stockholders. If the convertible noteholders sell the common stock they receive in exchange for outstanding debt, this could result in a decline in our stock price. In addition, the exercise of our outstanding warrants and stock options, which are exercisable for or convertible into shares of our common stock, and the exercise of which we have encouraged through public or private warrant exchange offers from time to time, would dilute our existing common stockholders.

Issuances of additional equity or convertible debt securities will continue to reduce the percentage ownership of our then-existing stockholders. We may also be required to grant potential investors new securities rights, preferences, or privileges senior to those possessed by our then-existing stockholders in order to induce them to invest in our company. The issuance of these senior securities may adversely affect the holders of our common stock as a result of preferential dividend and liquidation rights over the common stock and dilution of the voting power of the common stock.

As the result of these and other factors, the issuance of additional equity or convertible debt securities may have an adverse impact on the market price of our common stock. For the foreseeable future, we will be required to continue to rely on debt and equity financing to maintain our operations.

Our certificate of incorporation permits our Board to create new series of preferred stock without further approval by our stockholders, which could adversely affect the rights of the holders of our common stock.

Our Board has the authority to fix and determine the relative rights and preferences of preferred stock. Currently, our Board has the authority to designate and issue approximately 4.9 million additional shares of our preferred stock without further stockholder approval. As a result, our Board could authorize the issuance of another series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock, and the right to redemption of the shares, together with a premium, prior to the redemption of our common stock. In addition, our Board could authorize the issuance of a series of preferred stock that has greater voting power than our common stock or that is convertible into our common stock, which could decrease the relative voting power of our common stock or result in dilution to our existing stockholders.

Anti-takeover provisions of our certificate of incorporation, our bylaws, and Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult, and may prevent attempts by our stockholders to replace or remove the current members of our Board and management.

Certain provisions of our amended and restated certificate of incorporation and bylaws could discourage, delay or prevent a merger, acquisition, or other change of control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for shares of common stock. Furthermore, these provisions could frustrate attempts by our stockholders to replace or remove members of our Board. These provisions also could limit the price that investors might be willing to pay in the future for our common stock, thereby depressing the market price of our common stock. Stockholders who wish to participate in these transactions may not have the opportunity to do so. Among other things, these provisions:

- allow us to designate and issue shares of preferred stock, without stockholder approval, that could adversely affect the rights, preferences, and privileges of the holders of our common stock and could make it more difficult or less economically beneficial to acquire or seek to acquire us,

- provide that special meetings of stockholders may be called only by the Board acting pursuant to a resolution approved by the affirmative majority of the entire Board, and
- do not include a provision for cumulative voting in the election of directors. Under cumulative voting, a minority stockholder holding a sufficient number of shares may be able to ensure the election of one or more directors. The absence of cumulative voting may have the effect of limiting the ability of minority stockholders to effect changes in the composition of our Board.

In addition, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (the "DGCL"), which may, unless certain criteria are met, prohibit large stockholders, in particular those owning 15% or more of our voting stock, from merging or combining with us for a prescribed period of time.

We do not expect to pay cash dividends on our common shares for the foreseeable future.

We have never declared or paid a cash dividend on our common shares and we do not anticipate declaring or paying dividends on our common shares for the foreseeable future. We expect to use future financing proceeds and earnings, if any, to fund operating expenses. Consequently, common stockholders' only opportunity to achieve a return on their investment is if the price of our stock appreciates and they sell their shares at a profit. We cannot assure common stockholders of a positive return on their investment when they sell their shares or that stockholders will not lose the entire amount of their investment.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

Our principal office location is 1111 Main Street, Suite 660, Vancouver, Washington 98660. The space is subject to a lease effective through April 30, 2026.

Item 3. LEGAL PROCEEDINGS

For a description of material legal proceedings, refer to Part II, Item 8, Note 10, *Commitments and Contingencies* in this Form 10-K.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Part II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is quoted on the OTCQB of the OTC Markets marketplace under the trading symbol CYDY. Over-the-counter market quotations reflect inter-dealer prices, without retail mark-up, mark-down, or commission, and may not necessarily represent actual transactions. Historically, trading in our stock has been limited and the trades that occurred cannot be characterized as those in the established public trading market. As a result, the trading prices of our common stock may not reflect the price that would result if our stock was more actively traded.

Holders

The number of record holders of our common stock on August 31, 2023 was approximately 1,000.

Dividends

Holders of our common stock are entitled to receive dividends if declared by our Board. While we have no contractual restrictions or restrictions in our governing documents on our ability to pay dividends, other than the preferential rights provided to the holders of our outstanding preferred stock, we have never paid cash dividends to

holders of common stock and do not anticipate paying any in the foreseeable future as we retain earnings, if any, for use in our operations.

Also, under Section 170 of the Delaware General Corporation Law (the "DGCL"), we are permitted to pay dividends only out of capital surplus or, if none, out of net profits for the fiscal year in which the dividend is declared or net profits from the preceding fiscal year. As of May 31, 2023, the Company had an accumulated deficit of approximately $841.7 million and had net loss in each fiscal year since inception and therefore is prohibited from paying any dividends whether in cash, other property, or in shares of capital stock.

Refer to Part II, Item 8, Note 6, *Convertible Instruments and Accrued Interest* in this Form 10-K for additional information.

Unregistered Sales of Equity Securities

Private Placements of Common Stock and Warrants through Placement Agent

In August 2023, the Company continued a private placement (the "Mid-2023 Offering") to accredited investors of units through a placement agent. Each unit consisted of one share of common stock and one warrant to purchase one share of common stock. The purchase price per unit will be equal to 90% of the lower of (i) the intraday volume weighted average price ("VWAP") of the common stock as of the first closing on July 31, 2023, and (ii) the intraday VWAP on the date of the final closing in the Mid-2023 Offering, which has not yet occurred. From August 11, 2023 through August 31, 2023, the Company received binding subscription agreements to purchase an estimated total of approximately 9.0 million units at a total purchase price of approximately $1.8 million, based on a price of $0.20 per unit.

The warrants to be issued to investors in the Mid-2023 Offering will be fully exercisable and will have a five-year term and an exercise price of $0.50 per share. The warrants will be exercisable in full when issued. Other than as described above, the terms of the warrants will be substantially similar to the form of warrant filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on September 7, 2021, and listed as Exhibit 4.15 in the Exhibit Index of this Form 10-K.

The Company has agreed to pay a cash fee to the placement agent in the Mid-2023 Offering equal to 12% of the gross proceeds received from qualified investors. The Company has also agreed to issue to the placement agent or its designees warrants with a 10-year term to purchase 15% of the total number of shares of common stock sold to qualified investors in the Mid-2023 Offering.

The Company has agreed to use commercially reasonable efforts to prepare and file with the SEC, and cause the SEC to declare effective, a registration statement under the Securities Act covering the resale of the shares and shares covered by warrants to purchase shares of common stock issued in the private placements described above.

The Company relied on the exemption provided by Rule 506 of Regulation D and Section 4(a)(2) of the Securities Act in the sale and issuance of shares and warrants in the private placements described above.

Issuances of Shares in Convertible Note Exchange Transactions

In August 2023, the Company and the holder of its secured convertible promissory note issued April 2, 2021, in partial satisfaction of the holder's redemption rights, entered into exchange agreements pursuant to which the original note was partitioned and a new note was issued, resulting in an aggregate principal reduction of $0.5 million. The new notes were exchanged concurrently with issuance for a total of approximately 3.3 million newly issued shares of common stock. The Company relied on the exemption provided by Section 3(a)(9) of the Securities Act of 1933, as amended (the "Securities Act"), in connection with the exchange transactions.

Item 6. [Reserved]

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the other sections of this Form 10-K, including our consolidated financial statements and related notes set forth in Part II, Item 8. This discussion and analysis contains forward-looking statements, including information about possible or assumed results of our operations, our performance, financial condition, plans, and objectives, that involve risks, uncertainties, and assumptions. The actual results may differ materially from those anticipated and set forth in such forward-looking statements. See *Forward-Looking Statements* preceding Part I and Item 1A, *Risk Factors* in this Form 10-K.

Overview

The Company is a clinical stage biotechnology company focused on the clinical development and potential commercialization of its product candidate, leronlimab, which is being studied for NASH, NASH-HIV, solid tumors in oncology, and other HIV indications. Our current business strategy is to seek the removal of the partial clinical hold imposed by the FDA in March 2022. In October 2022, the Company voluntarily withdrew its BLA submission for leronlimab as a combination therapy for highly treatment experienced HIV patients, due to management's conclusion that a significant risk existed that the BLA would not receive FDA approval due to the inadequate process and performance around the monitoring and oversight of the clinical data from its clinical trials by its former CRO.

As further discussed in Part II, Item 8, Note 2, *Summary of Significant Accounting Policies - Inventories,* and Note 3, *Inventories, net,* the Company previously capitalized procured or produced pre-launch inventories in preparation for product launches. The Company has written off $99.2 million in previously capitalized pre-launch inventories. Although these inventories have been written off from an accounting perspective, they may still have clinical use.

The Company's strategy and efforts are currently primarily directed toward obtaining the removal of the partial clinical hold on its HIV program, preparation for and development of a Phase 2b/3 NASH clinical trial protocol, research and development of longer-acting molecules including for the treatment and/or prevention of HIV, maintenance and testing of clinical drug product, and resolving legal and regulatory matters. See Part I, Item 1, Business in this Form 10-K for additional information regarding these initiatives.

Fiscal 2023 Overview

Actions taken by the Company during the fiscal year 2023 included:

- Hiring of a biotech veteran, Cyrus Arman, Ph.D., as the Company's new President in July 2022, along with other leadership transitions; Dr. Arman became the Company's Senior Vice President, Business Operations on July 9, 2023, following a brief medical leave of absence;
- Strengthening the Company's Board of Directors through the addition of two highly qualified and experienced members;
- Withdrawing the BLA previously submitted to the FDA for the HIV multi-drug resistant population;
- Revamping our clinical strategy to focus on NASH, oncology, and development of a modified, longer-acting molecule, potentially for use in the HIV population among other potential applications;
- Submitting our clinical response(s) to the FDA and continuing our dialogue with FDA to clarify what they are now additionally seeking to lift the clinical hold;
- Entering into a partnership with a third-party generative artificial intelligence drug discovery and development company to develop a long-acting modified therapeutic;
- Closing multiple financing transactions to provide funding for the Company's business operations and initiatives.

Additional information regarding corporate and clinical developments is included in Part I, Item 1, *Business* in this Form 10-K.

Results of operations for the fiscal years ended May 31, 2023 and 2022

Fluctuations in Operating Results

The Company's operating results may fluctuate significantly depending on the outcomes, number and timing of pre-clinical and clinical studies, patient enrollment and/or completion rates in the studies, and their related effect on research and development expenses, regulatory and compliance activities, activities related to seeking removal of the partial clinical hold and FDA approval of our drug product, general and administrative expenses, professional fees, and legal and regulatory proceedings and related consequences. We require a significant amount of capital to continue to operate; therefore, we regularly conduct financing offerings to raise capital, which may result in various forms of non-cash interest expense or other expenses. Additionally, we periodically seek to negotiate settlement of debt payment obligations in exchange for equity securities of the Company and enter into warrant exchanges or modifications that may result in non-cash charges. Our ability to continue to fund operations will depend on our ability to raise additional funds. Refer to *Risk Factors*, *Liquidity and Capital Resources*, and *Going Concern* sections included in this report.

The results of operations were as follows for the periods presented:

(in thousands, except for per share data)	Fiscal years ended May 31,		Change	
	2023	2022	$	%
Revenue	$ —	$ 266	$ (266)	(100)%
Cost of goods sold	—	53	(53)	(100)
Gross profit	—	213	(213)	(100)
Operating expenses:				
General and administrative	17,136	44,303	(27,167)	(61)
Research and development	2,632	27,043	(24,411)	(90)
Amortization and depreciation	175	781	(606)	(78)
Inventory charge	20,633	73,490	(52,857)	(72)
Total operating expenses	40,576	145,617	(105,041)	(72)
Operating loss	(40,576)	(145,404)	104,828	(72)
Interest and other expenses:				
Interest on convertible notes	(4,624)	(5,417)	793	(15)
Amortization of discount on convertible notes	(2,126)	(2,958)	832	(28)
Amortization of debt issuance costs	(9,747)	(87)	(9,660)	11,103
Loss on induced conversion	(5,312)	(37,381)	32,069	(86)
Finance charges	(8,689)	(9,029)	340	(4)
Inducement interest expense	—	(6,691)	6,691	(100)
Legal settlement	—	(3,853)	3,853	(100)
Loss on derivatives	(8,750)	—	(8,750)	100
Total interest and other expenses	(39,248)	(65,416)	26,168	(40)
Loss before income taxes	(79,824)	(210,820)	130,996	(62)
Income tax benefit	—	—	—	—
Net loss	$ (79,824)	$ (210,820)	$ 130,996	(62)%
Basic and diluted:				
Weighted average common shares outstanding	836,528	676,900	159,628.00	24
Loss per share	$ (0.10)	$ (0.31)	$ 0.21	(67)%

Product revenue, Cost of goods sold ("COGS") and Gross margin

We had no revenue in the fiscal year ended May 31, 2023 as compared to approximately $266 thousand in the fiscal year ended May 31, 2022. Revenue was related to the fulfillment of orders under a Compassionate Special Permit ("CSP") in the Philippines for the treatment of COVID-19 patients. Sales were made under the April 2021 exclusive supply and distribution agreement granting Chiral the right to distribute and sell up to 200,000 vials of leronlimab through April 15, 2022. At the time of the sales, FDA approval had not been received for leronlimab and the product sold was previously expensed as research and development expense due to its being manufactured prior to the commencement of the manufacturing of commercial grade pre-launch inventories. Therefore, COGS consists only of the costs of packaging and shipping of the vials, including related customs and duties.

General and administrative expenses

G&A expenses consisted of the following:

(in thousands)	Fiscal years ended May 31, 2023	2022	Change $	Change %
Salaries, benefits, and other compensation	$ 4,114	$ 6,336	$ (2,222)	(35)%
Stock-based compensation	4,222	6,263	(2,041)	(33)
Legal fees	2,805	21,993	(19,188)	(87)
Directors and officers liability insurance	2,399	4,512	(2,113)	(47)
Other	3,596	5,199	(1,603)	(31)
Total general and administrative	$ 17,136	$ 44,303	$ (27,167)	(61)%

The decreases in G&A expenses for the fiscal year ended May 31, 2023, compared to the prior fiscal year, were due to reductions in all categories. The decreases in legal fees were due to lower legal fees related to the SEC and DOJ investigations, Pestell employment dispute (which was resolved in May 2022), and Amarex dispute, the absence of legal fees related to the prior year proxy contest and related lawsuits, and the payment of certain legal fees by the Company's insurance carriers. The decreases in salaries, benefits, and other compensation and stock-based compensation were the result of decreased headcount, cash compensation, and option forfeitures during the year. The decrease in directors and officers liability insurance was due to less insurance premiums due to a lower market capitalization. The decreases in other expenses were the result of a reduction in expenses related to the prior year proxy contest and recruiting and contract services, partially offset by an increase in auditor fees.

Research and development expenses

R&D expenses consisted of the following:

(in thousands)	Fiscal years ended May 31, 2023	2022	Change $	Change %
Clinical	$ (92)	$ 20,347	$ (20,439)	(100)%
Non-clinical	136	986	(850)	(86)
CMC	1,687	4,995	(3,308)	(66)
License and patent fees	901	715	186	26
Total research and development	$ 2,632	$ 27,043	$ (24,411)	(90)%

The decreases in R&D expenses in the fiscal year ended May 31, 2023, compared to the prior fiscal year, were primarily the result of clinical trials related to COVID-19, NASH, HIV extension, and oncology studies being completed, paused, or closed that had been active in the prior year, as well as decreased activity related to the BLA resubmission, partially offset by increased costs related to activities focused on addressing the HIV program partial clinical hold. The credit balance in clinical expenses for the fiscal year ended May 31, 2023, is due to vendor credit memos issued related to the paused Brazilian COVID-19 trials. The decrease in non-clinical expenses from the same periods in the prior year was the result of decreased activity from non-clinical studies related to the BLA submission. The decrease in CMC-related expenses from the prior year was the result of decreased activity related to CMC manufacturing.

The future trend of our R&D expenses is dependent on the timing of the FDA's potential lifting of the clinical hold and any future clinical trials, our decision-making and timing of the selection of which indications on which to focus our future efforts toward the clinical development and study of leronlimab, which may include the treatment of NASH, NASH-HIV, oncology, and other HIV-related indications, and the timing and outcomes of such efforts.

Inventory charge

The decrease in the inventory charge for the fiscal year ended May 31, 2023, compared to the prior fiscal year was attributable to the majority of inventory being written-off in the prior year. The remaining inventory was written-off in the fiscal year ended May 31, 2023 due to pre-launch inventories no longer qualifying for inventory capitalization due to the withdrawal of the BLA submission. See Note 3, *Inventories, net*, for additional information.

Interest and other expense

Interest and other expenses consisted of the following:

	Fiscal years ended May 31,		Change	
	2023	2022	$	%
(in thousands)				
Interest on convertible notes payable	$ 4,624	$ 5,417	$ (793)	(15) %
Amortization of discount on convertible notes	2,126	2,958	(832)	(28)
Amortization of debt issuance costs	9,747	87	9,660	11,103
Loss on induced conversion	5,312	37,381	(32,069)	(86)
Finance charges	8,689	9,029	(340)	(4)
Inducement interest expense	—	6,691	(6,691)	(100)
Legal settlement	—	3,853	(3,853)	(100)
Loss on derivatives	8,750	—	8,750	100
Total interest and other expenses	$ 39,248	$ 65,416	$ (26,168)	(40)%

The decreases in interest and other expenses for the fiscal year ended May 31, 2023, compared to the same period in the prior year were primarily due to a decrease in non-cash loss on induced conversion, inducement interest expense, and legal settlement, partially offset by an increase in amortization of debt issuance costs and loss on derivatives. The decreased non-cash loss on induced conversions resulted from the Company settling less outstanding convertible debt with common stock during the fiscal year ended May 31, 2023 compared to the prior year. The decrease in inducement interest expense is the result of it now being recorded in stockholders' equity as a result of the adoption of ASU No. 2021-04 (see Part II, Item 8, Note 2, *Summary of Significant Accounting Policies – Recently Adopted Accounting Pronouncements*). The decrease in legal settlement expense is due to no legal settlements being finalized in the fiscal year ended May 31, 2023, resulting in zero expense. The increase of debt issuance cost was primarily attributable to recognition of the issuance costs of the private placement of common stock and warrants through a placement agent in the current fiscal year as an expense. See Note 7, *Equity and Warrants –Private placement of common stock and warrants through placement agent* for more information. The increase in loss on derivatives was primarily attributable to the change in the fair value of liability-classified warrants issued in connection with a Surety Backstop Agreement relating to the Amarex litigation proceeding and placement agent warrants issued in connection with an offering for which the related warrants subsequently became equity classified upon stockholder approval of an increase in authorized shares on August 31, 2022.

Liquidity and Capital Resources

As of May 31, 2023, we had a total of approximately $2.5 million in cash, $6.5 million in restricted cash, and approximately $119.8 million in short-term liabilities consisting primarily of approximately $45.0 million representing the principal of and accrued interest on convertible notes payable, net of unamortized debt discount, and approximately $69.4 million in accounts payable and accrued liabilities and compensation. We will continue to incur operating losses and the Company will require a significant amount of additional capital in the future as we continue to seek approval to commercialize leronlimab. Despite the Company's negative working capital position, vendor relations remain relatively accommodative given liquidity constraints. We cannot be certain, however, that future funding will be available to us when needed on terms that are acceptable to us, or at all. We sell securities and incur debt when the terms of such agreements are deemed favorable to both parties under then current circumstances and as necessary to fund our current and projected cash needs.

Cash

The Company's cash and restricted cash position of approximately $2.5 million and $6.5 million, respectively, at May 31, 2023, decreased by approximately $1.7 million and increased by $6.5 million, respectively, compared to the cash balance of approximately $4.2 million and no restricted cash at May 31, 2022. During the fiscal year ended May 31, 2023, we funded our operations by obtaining a total of approximately $29.9 million of net cash proceeds primarily funded through the sales of common stock and warrants.

Summary of cash flows and changes between the periods presented is as follows:

(in thousands)	Fiscal years ended May 31, 2023	2022	Change $
Net cash (used in) provided by:			
Net cash used in operating activities	$ (25,110)	$ (77,723)	$ 52,613
Net cash provided by/ used in investing activities	$ —	$ —	$ —
Net cash provided by financing activities	$ 29,927	$ 48,011	$ (18,084)

Cash used in operating activities

Net cash used in operating activities totaled approximately $25.1 million during the fiscal year ended May 31, 2023, representing an improvement of approximately $52.6 million compared to the prior year. The decrease in the net amount of cash used was primarily attributable to decreased G&A and R&D expenses, and working capital fluctuations, all of which are highly variable, and which led to a significant decrease in our net loss. Refer to *General and administrative expenses* and *Research and development expenses* above for further discussion.

Cash provided by financing activities

Net cash provided by financing activities totaled approximately $29.9 million, a decrease of approximately $18.1 million compared to the prior year. The decrease in net cash provided was primarily the result of raising less funds from private placements of common stock and warrants, and a decrease in cash received from warrant transactions and exercises.

Pre-launch inventories

The Company previously capitalized pre-launch inventories that were subsequently charged-off in October 2022 for GAAP accounting purposes due to no longer qualifying for pre-launch inventory capitalization resulting from the withdrawal of the BLA submission. Work-in-progress and finished drug product inventories continue to be physically maintained, can be used for clinical trials, and can be sold commercially upon regulatory approval if the shelf-lives can be extended as a result of the performance of on-going stability tests. Raw materials continue to be maintained so that they can be used in the future if needed.

During the first quarter of fiscal year 2023, the Company reviewed purchase commitments made by its manufacturing partner, Samsung, under the master agreement between the Company and Samsung, and its vendors for specialized raw materials for which the Company made a prepayment in the amount of $2.7 million in the third quarter of fiscal year 2022, which were recorded as prepaid expenses in the consolidated financial statements as of May 31, 2022. As discussed in Note 10, *Commitments and Contingencies – Commitments with Samsung BioLogics Co., Ltd. ("Samsung")*, the Company and Samsung remain in ongoing discussions about, among other things, deferring the unfulfilled commitments. These additional specialized raw materials are estimated to have shelf-lives ranging from 2023 to 2026. The entire amount of approximately $2.7 million was charged-off as of August 31, 2022.

In October 2022, the Company voluntarily withdrew its BLA submission after concluding that a significant risk existed that the BLA would not receive FDA approval due to the inadequate process and performance by the Company's former CRO around the monitoring and oversight of the clinical data from its trials. Following this decision, none of the Company's inventories qualified for capitalization as pre-launch inventories. For the three months ended November 30, 2022, the Company charged-off the remaining raw material resin and work-in-progress bulk product inventories of approximately $16.3 million and $1.7 million, respectively.

The table below summarizes previously capitalized pre-launch inventories that were subsequently charged-off for GAAP accounting purposes due to no longer qualifying for pre-launch inventory capitalization due to the withdrawal of the BLA submission and estimated expiration based on remaining shelf life.

		Raw Materials				Work-in-progress		
(in thousands, Expiration period ending May 31,)	**Remaining shelf-life (mos)**	**Specialized**	**Resins**	**Other**	**Total Raw Materials**	**Bulk drug product**	**Finished drug product**	**Total inventories**
2024	0 to 12	$ 5,332	$ 16,264	$ 1,589	$ 23,185	$ -	$ -	$ 23,185
2025	13 to 24	2,099	-	-	2,099	1,661	29,142	32,902
2026	25 to 36	728	-	-	728	-	32,343	33,071
2027	37 to 48	1,420	-	-	1,420	-	-	1,420
Thereafter	49 or more	-	-	-	-	-	-	-
Inventories, gross		9,579	16,264	1,589	27,432	1,661	61,485	90,578
Inventory charge		(9,579)	(16,264)	(1,589)	(27,432)	(1,661)	(61,485)	(90,578)
Inventories, net		$ -	$ -	$ -	$ -	$ -	$ -	$ -

Convertible debt

April 2, 2021 Convertible Note

On April 2, 2021, we issued a convertible note with a principal amount of $28.5 million resulting in net cash proceeds of $25.0 million, after $3.4 million of debt discount and $0.1 million of offering costs. The note accrues interest daily at a rate of 10% per annum, contains a stated conversion price of $10.00 per share, and matures in April 2025. The April 2, 2021 Note required monthly debt reduction payments of $7.5 million for the six months beginning in May 2021, which could also be satisfied by payments on other notes held by the noteholder or its affiliates. Beginning six months after the issuance date, the noteholder may request monthly redemptions of up to $3.5 million. As of May 31, 2023, the outstanding balance of the April 2, 2021 Note, including accrued interest, was approximately $9.9 million.

April 23, 2021 Convertible Note

On April 23, 2021, we issued a convertible note with a principal amount of $28.5 million resulting in net cash proceeds of $25.0 million, after $3.4 million of debt discount and $0.1 million of offering costs. The note accrues interest daily at a rate of 10% per annum, contains a stated conversion price of $10.00 per share, and matures in April 2025. Beginning six months after the issuance date, the noteholder may request monthly redemptions of up to $7.0 million. As of May 31, 2023, the outstanding balance of the April 23, 2021 Note, including accrued interest, was approximately $36.2 million.

Notes Issued through Placement Agent

During April and May 2023, we issued notes with an aggregate principal amount of $1.0 million, resulting in net cash proceeds of approximately $0.9 million after approximately $0.1 million of offering costs. The notes accrued interest daily at a rate of 6% per annum, contained a default provision allowing the investors to convert unpaid principal and interest into shares of the Company's common stock at a 25% discount at the date of conversion, and mature in December 2024. As of May 31, 2023, the outstanding balance of the notes was approximately $1.0 million. The entire principal balance of and accrued interest on the notes were converted into shares of common stock in August 2023, in addition to the notes that were issued in the first quarter of fiscal year 2024.

Refer to Part II, Item 8, Note 6, *Convertible Instruments and Accrued Interest* and Note 13, *Subsequent Events* in this report for additional information.

Common stock

We have 1,350.0 million authorized shares of common stock. The table below summarizes intended uses of common stock.

(in millions)	As of May 31, 2023
Issuable upon:	
Warrants exercise	259.9
Convertible preferred stock and undeclared dividends conversion	34.1
Outstanding stock options exercise or vesting of outstanding RSUs and PSUs	21.1
Reserved for issuance pursuant to future stock-based awards under equity incentive plan	19.7
Reserved and issuable upon conversion of outstanding convertible notes	12.0
Reserved for issuance of warrants to investors	1.0
Reserved for issuance of warrants to placement agents	0.3
Total shares reserved for future uses	348.1
Common stock outstanding	918.6

As a result, as of May 31, 2023, we had approximately 83.3 million unreserved authorized shares of common stock available for issuance. Our ability to continue to fund our operations depends on our ability to raise capital. The funding necessary for our operations may not be available on acceptable terms, or at all. If we deplete our cash reserves, we may have to discontinue our operations and liquidate our assets. In extreme cases, we could be forced to file for bankruptcy protection, discontinue operations or liquidate assets.

Off-Balance Sheet Arrangements

As of May 31, 2023, we did not have any off-balance sheet arrangements that have, or are reasonably likely to have, a material effect on our current or future financial condition, results of operations, liquidity, capital expenditures, or capital resources.

Contractual Obligations

Refer to Note 6, *Convertible Instruments and Accrued Interest,* Note 10, *Commitments and Contingencies* and Note 13, *Subsequent Events* included in Part II, Item 8 of this Form 10-K.

Legal Proceedings

The Company is a party to various legal proceedings described in Part II, Item 8, Note 10, *Commitments and Contingencies - Legal Proceedings* of this Form 10-K The Company recognizes accruals for such proceedings to the extent a loss is determined to be both probable and reasonably estimable. The best estimate of a loss within a possible range is accrued; however, if no estimate in the range is more probable than another, then the minimum amount in the range is accrued. If it is determined that a material loss is not probable but reasonably possible and the loss or range of loss can be estimated, the possible loss is disclosed.

It is not possible to determine the outcome of these proceedings, including the defense and other litigation-related costs and expenses that may be incurred by the Company, as the outcomes of legal proceedings are inherently uncertain, and the outcomes could differ significantly from recognized accruals. Therefore, it is possible that the ultimate outcome of any proceeding, if in excess of a recognized accrual, or if no accrual has been made, could be material to the Company's consolidated financial statements. Refer to Note 10, *Commitments and Contingencies – Legal Proceedings* for further discussion of legal proceedings.

Regulatory Matters

Voluntary Withdrawal of HIV BLA Submission

In July 2020, the Company received a Refusal to File letter from the FDA regarding its BLA submission for leronlimab as a combination therapy with HAART for highly treatment-experienced HIV patients. In October 2022, the Company voluntarily withdrew its BLA submission due to management's conclusion that a severe risk of the BLA not receiving approval by the FDA existed due to the Company's former CRO's inadequate process and performance around

the monitoring and oversight of the clinical data. For additional information, see Part II, Item 8, Note 10, *Commitments and Contingencies – Legal Proceedings* in this report.

FDA warning letter re COVID-19 misbranding of investigational drug

In January 2022, the Company received a Warning Letter from the FDA alleging that its former CEO had made references in a video interview to COVID-19 and leronlimab in a promotional context to the effect that leronlimab, an investigational new drug, is safe and effective for the purpose for which it is being investigated or otherwise promoted the drug. The FDA warned the Company that leronlimab has not been approved or authorized by the FDA, its safety and effectiveness have not yet been established, and the related clinical trial data was mischaracterized in the video. The FDA further alleged that the video misbranded leronlimab under section 502(f)(1) of the Federal Food, Drug and Cosmetic Act, and in violation of section 301(a) of the same, as the claims in the video made representations in a promotional context regarding the safety and efficacy of an investigational new drug that has not been approved or authorized by the FDA. CytoDyn has completed all the corrective steps requested by the FDA. On September 26, 2022, CytoDyn sent a letter to the FDA informing the FDA that it had completed all corrective steps. On April 27, 2023, the FDA notified the Company that it had concluded its review of the Company's corrective actions and concluded that violations have been appropriately addressed by the Company.

FDA HIV partial clinical hold and COVID-19 full clinical hold letters

In March 2022, the FDA placed a partial clinical hold on the Company's HIV program and a full clinical hold on its COVID-19 program in the United States. The Company was not enrolling any new patients in the trials placed on hold in the United States. Under the full clinical hold on the COVID-19 program, no new clinical studies may be initiated for the COVID-19 indication until the clinical hold is resolved. The Company has made a business decision not to pursue the use of leronlimab in COVID-19 patients, has no plans for further trials under the COVID-19 indication and has withdrawn the IND for COVID-19. Should the opportunity arise, the Company may explore potential non-dilutive clinical development options. CytoDyn is working diligently with the FDA to resolve the partial clinical hold for HIV as soon as possible, as no new clinical studies can be initiated or resumed for the HIV indication until the partial clinical hold is resolved.

During the third quarter ended February 28, 2023, the Company submitted the documents requested by the FDA in its March 2022 clinical hold letter. Subsequently, the FDA responded through written communication to the Company, requesting additional information and clarification regarding an item that was previously submitted, the benefit-risk assessment for the HIV population, and made a supplemental request that the Company submit an IND amendment containing the proposed general investigational plan for the coming year, appropriate protocols, and any additional information supporting the proposed investigation under the HIV program IND.

In March 2023, the Company responded to and submitted to the FDA the additional information and clarifications requested for the items previously requested. The FDA responded with further written communication requesting information relating to the benefit-risk assessment, as well as requesting the submission of a new protocol for the HIV indication. At the end of March 2023, the Company and the FDA held an informal meeting in which the FDA addressed certain clarifying questions with respect to the clinical hold submission and further information requests made by the FDA. As of the date of this filing, the Company has submitted the following to the FDA in connection with resolving the clinical hold: an aggregate analysis of cardiovascular events across all leronlimab clinical programs, a Safety Surveillance Plan, an aggregate safety data analysis, an updated Investigator's Brochure, annual reports, a benefit-risk assessment, and a general investigational plan. The Company is currently working on a supplemental submission to address items discussed with the FDA during the informal meeting.

Going Concern

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. As presented in the accompanying consolidated financial statements, the Company had losses for all periods presented. The Company incurred a net loss of $79.8 million for the fiscal year ended May 31, 2023, and had an accumulated deficit of $841.7 million as of May 31, 2023. These factors, among several others, raise substantial doubt about our ability to continue as a going concern. The consolidated financial statements do not include any adjustments relating to the recoverability and

classification of assets and liabilities that might be necessary should the Company be unable to continue as a going concern.

The Company has had limited to no activities that produced revenue in the periods presented and has operated at a loss since inception. The Company's continuation as a going concern is dependent upon its ability to obtain a significant amount of additional operating capital to continue to fund operations and pay its liabilities and commitments, its research into multiple indications for and development of its product candidate, to obtain FDA approval of its product candidate for use in treating one or more indications, to outsource manufacturing of its product, and ultimately to attain profitability. We intend to seek additional funding through equity or debt offerings, licensing agreements, supply and distribution agreements, and strategic alliances to implement our business plan. There are no assurances, however, that we will be successful in these endeavors. If we are not able to raise capital on a timely basis on favorable terms, if at all, we may need to significantly change or scale back operations, including seeking removal of the FDA's clinical hold, pursuing other development and commercialization initiatives, and obtaining adequate funding to cover the costs of the legal proceedings in which we are involved, all of which individually or in combination could materially impede our ability to achieve profitability. The Company's failure to raise additional capital could also affect our relationships with key vendors, including Samsung, disrupting our ability to timely execute our business plan. In extreme cases, the Company could be forced to file for bankruptcy protection, discontinue operations, or liquidate assets.

Since inception, the Company has financed its activities principally from the public and private sale of equity securities, as well as with proceeds from issuance of convertible notes and related party notes payable. The Company intends to finance its future operating activities and its working capital needs largely from the sale of equity and debt securities. As of August 31, 2023, the Company had only approximately 20.7 million shares of common stock, authorized for issuance under its certificate of incorporation, as amended, and available for future uses. The sale of equity and convertible debt securities to raise additional capital is likely to result in dilution to stockholders and those securities may have rights senior to the common stock. If the Company raises funds through the issuance of additional preferred stock, convertible debt securities, or other debt or equity financing, the related transaction documents could contain covenants restricting its operations.

In April 2021, the Company entered into long-term convertible notes that are secured by all of our assets (excluding our intellectual property), and include certain restrictive provisions, including limitations on incurring additional indebtedness and future dilutive issuances of securities, any of which could impair our ability to raise additional capital on acceptable terms. Future third-party funding arrangements may also require the Company to relinquish valuable rights. Additional capital, if available, may not be available on reasonable or non-dilutive terms.

Refer to Part I, Item 1A, *Risk Factors* of this Form 10-K for additional information.

New Accounting Pronouncements

Refer to Part II, Item 8, Note 2, *Summary of Significant Accounting Policies – Recent Accounting Pronouncements* in this Form 10-K.

Critical Accounting Policies and Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, and expense and related disclosures. On an ongoing basis, management bases and evaluates estimates on historical experience and on various other market specific and other relevant assumptions believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ significantly from those estimates. We believe the following critical policies reflect the more significant judgments and estimates used in preparation of the consolidated financial statements.

Pre-launch Inventories

For inventories capitalized prior to FDA marketing approval in preparation of product launch, anticipated future sales, shelf-lives, and expected approval date are considered when evaluating realizability of pre-launch inventories. The

shelf-life of a product is determined as part of the regulatory approval process; however, in assessing whether to capitalize pre-launch inventory the Company considers the stability data of all inventories. As inventories approach their shelf-life expiration, the Company may perform additional stability testing to determine if the inventory is still viable, which can result in an extension of its shelf-life. Further, in addition to performing additional stability testing, certain raw materials inventory may be sold in its then current condition prior to reaching expiration. We also consider potential delays associated with regulatory approval in determining whether pre-approval inventory remains salable. In determining whether pre-approval inventory remains salable, the Company considers a number of factors ranging from potential delays associated with regulatory approval, whether the introduction of a competing product could negatively impact the demand for our product and affect the realizability of our inventories, whether physicians would be willing to prescribe leronlimab to their patients, or if the target patient population would be willing to try leronlimab as a new therapy. See Note 2, *Summary of Significant Accounting Policies*, for additional information.

Stock-based compensation

We use the Black-Scholes option pricing model to estimate the fair value of equity awards on the date of grant utilizing certain assumptions that require judgments and estimates. These assumptions include estimates for stock price volatility, expected term, and risk-free interest rates in determining the fair value of the equity awards. The risk-free interest rate assumption is based on observed interest rates appropriate for the expected term of the equity award. The expected volatility is based on the historical volatility of the Company's common stock at monthly intervals. The computation of the expected option term is based on the "simplified method," as the options issued by the Company are considered "plain vanilla" options. We estimate forfeitures at the time of grant and revise them, if necessary, in subsequent periods, if actual forfeitures differ from those estimates. We estimated future unvested forfeitures at 0% for all periods presented. Quarterly expense is reduced during the period when grants are forfeited, such that the full expense is recorded at the time of grant and only reduced when the grant is forfeited.

We at times issue restricted common stock and/or restricted stock units to executives or third parties as compensation for services rendered. Such awards are valued at fair market value on the effective date of the Company's obligation. From time to time, we also issue stock options and warrants to consultants as compensation for services. Costs for these transactions are measured at the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more readily measurable.

Contingent liabilities

We have significant license and contingent milestone and royalty liabilities. We estimate the likelihood of paying these contingent liabilities periodically based on the progress of our clinical trials, regulatory approval status, and status of commercialization. We are also party to various legal proceedings. We recognize accruals for such proceedings to the extent a loss is determined to be both probable and reasonably estimable. The best estimate of a loss within a possible range is accrued; however, if no estimate in the range is more probable than another, then the minimum amount in the range is accrued. If it is determined that a material loss is not probable but reasonably possible it is disclosed, and if the loss or range of loss can be estimated, the possible loss is also disclosed. It is not possible to determine the ultimate outcome of these proceedings, including the defense and other litigation-related costs and expenses that may be incurred by the Company, as the outcomes of legal proceedings are inherently uncertain, and the outcomes could differ significantly from recognized accruals. Therefore, it is possible that the ultimate outcome of any proceeding, if in excess of a recognized accrual, or if an accrual had not been made, could be material to the Company's consolidated financial statements. We periodically reassess these matters when additional information becomes available and adjust our estimates and assumptions when facts and circumstances indicate the need for any changes. Refer to Part II, Item 8, Note 10, *Commitments and Contingencies* of this report for additional information.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

We are exposed to market risks in the ordinary course of business. Our primary exposure to market risk is sensitivity to changes in interest rates. We hold our cash in interest-bearing money market accounts; due to the short-term maturities of such financial instruments, a 100 basis point change in interest rates would not have a material effect on the fair market value of our cash. As of May 31, 2023, we had $2.5 million in cash and $6.5 million in restricted cash.

Common Stock Price Volatility

The Compensation Committee of the Board of Directors has historically granted stock incentive awards to management and employees in the form of stock options. Stock-based compensation expense is recognized for stock options over the requisite service period using the fair value of these grants as estimated at the awards grant date using the Black-Scholes pricing model and the market value of our publicly traded common stock on the date of grant. In addition to the market value of our common stock, one of the inputs into this model that significantly impacts the fair value of the options is the expected volatility of our common stock over the estimated life of the option. We estimate expected volatility by using the most recent historical experience. Since November 2019, our common stock has experienced periods of high trading volatility. Grants of stock options and warrants during the fiscal year ended May 31, 2023, continued to reflect expected volatility as part of the estimated fair value of stock options. Additionally, we negotiate the settlement of debt payment obligations in exchange for equity securities of the Company, which can create a non-cash charge upon extinguishment of debt as the price of our common stock fluctuates. If we continue to enter into these settlements, the increased levels of volatility in our common stock trading price will result in increased dilution and extinguishment gains or losses.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

CYTODYN INC.

CONTENTS

Report of Independent Registered Public Accounting Firm (PCAOB ID No. 324)

To the Board of Directors and Stockholders

CytoDyn Inc.

Vancouver, Washington

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of CytoDyn, Inc. (the "Company") as of May 31, 2023 and 2022, the related consolidated statements of operations, changes in stockholders' deficit and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of May 31, 2023 and 2022, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt as to the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 2, *Summary of Significant Accounting Policies – Going Concern* to the consolidated financial statements, the Company incurred a net loss of approximately $70,146,000 for the year ended May 31, 2023 and has an accumulated deficit of approximately $832,012,000 through May 31, 2023, which raises substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting for the fiscal year ended May 31, 2023. As part of our audit, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion except as noted below.

We have audited the Company's internal controls over financial reporting as of May 31, 2022, based on criteria established in the *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO criteria"), as referenced in our report dated August 15, 2022.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial *statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing se*parate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Unfulfilled Commitments with Samsung BioLogics Co., Ltd. ("Samsung")

Critical Audit Matter Description

As explained in Note 10, *Commitments and Contingencies* to the consolidated financial statements, the Company has been subject to allegations by Samsung asserting material breaches of the Master Services and Project Specific Agreements. The Company continues to be in ongoing discussions with Samsung and Samsung paused manufacturing all unfulfilled commitments not needed by the Company starting in January of 2022. Accordingly, the Company has not recorded any accruals associated with the unfulfilled commitments as of May 31, 2023. In the event negotiations are unsuccessful, the Company may have to accrue a liability related to the unfulfilled commitments. The outcome of ongoing discussions between Samsung and the Company involves significant uncertainty, which requires extensive judgements about the likelihood of outcomes and potential financial effects. These judgments could have a material impact on the financial statements.

How the Critical Audit Matter was Addressed in the Audit

Our audit procedures related to address this critical audit matter included:

- External confirmation of accounts payable balance due to Samsung.
- Review of Samsung's invoices for the year ended May 31, 2023, to ensure no invoices related to new manufacturing of inventory during the year ended May 31, 2023. The absence of new manufacturing substantiates the company's claim that Samsung is in negotiations with the Company to modify the contract and is not adhering to original contract terms and manufacturing dates therein.
- Discussions with management and internal and external legal counsel.
- Evaluate management's assessments of the likelihood of outcomes, and analysis of potential financial impact.
- Review the Company's application of ASC 450 *Contingencies* and ASC 330 I*nventory* to known factual situations as of May 31, 2023 and evaluate its conclusion that an accrual is not required.
- Evaluate relevant and material developments or changes that occurred after the balance sheet date but before the issuance of the financial statements.

/s/ Macias Gini & O'Connell LLP

We have served as the Company's auditor since 2022.

San Jose, California

September 13, 2023

CytoDyn Inc.
Consolidated Balance Sheets
(In thousands, except par value)

	May 31, 2023	May 31, 2022
Assets		
Current assets:		
Cash	$ 2,541	$ 4,231
Restricted cash	6,507	—
Prepaid expenses	1,167	5,198
Prepaid service fees	590	1,086
Total current assets	10,805	10,515
Inventories, net	—	17,929
Other non-current assets	487	741
Total assets	$ 11,292	$ 29,185
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 62,725	$ 67,974
Accrued liabilities and compensation	6,669	8,995
Accrued interest on convertible notes	10,598	5,974
Accrued dividends on convertible preferred stock	5,308	3,977
Convertible notes payable, net	34,417	36,241
Derivative liability	79	—
Total current liabilities	119,796	123,161
Notes payable, net	714	—
Operating leases	283	422
Total liabilities	120,793	123,583
Commitments and Contingencies (Note 10)		
Stockholders' deficit:		
Preferred stock, $0.001 par value; 5,000 shares authorized:		
Series B convertible preferred stock, $0.001 par value; 400 authorized; 19 issued and outstanding at May 31, 2023 and May 31, 2022	—	—
Series C convertible preferred stock, $0.001 par value; 8 authorized; 6 and 7 issued and outstanding at May 31, 2023 and May 31, 2022, respectively	—	—
Series D convertible preferred stock, $0.001 par value; 12 authorized; 9 issued and outstanding at May 31, 2023 and May 31, 2022	—	—
Common stock, $0.001 par value; 1,350,000 shares authorized; 919,053 and 720,028 issued, and 918,610 and 719,585 outstanding at May 31, 2023 and May 31, 2022, respectively	919	720
Treasury stock, $0.001 par value; 443 shares at May 31, 2023 and May 31, 2022	—	—
Additional paid-in capital	731,270	671,013
Accumulated deficit	(841,690)	(766,131)
Total stockholders' deficit	(109,501)	(94,398)
Total liabilities and stockholders' deficit	$ 11,292	$ 29,185

See accompanying notes to consolidated financial statements.

CytoDyn Inc.
Consolidated Statements of Operations
(In thousands, except per share amounts)

	Fiscal years ended May 31,	
	2023	2022
Revenue	$ —	$ 266
Cost of goods sold	—	53
Gross profit	—	213
Operating expenses:		
General and administrative	17,136	44,303
Research and development	2,632	27,043
Amortization and depreciation	175	781
Inventory charge	20,633	73,490
Total operating expenses	40,576	145,617
Operating loss	(40,576)	(145,404)
Interest and other expenses:		
Interest on convertible notes	(4,624)	(5,417)
Amortization of discount on convertible notes	(2,126)	(2,958)
Amortization of debt issuance costs	(9,747)	(87)
Loss on induced conversion	(5,312)	(37,381)
Finance charges	(8,689)	(9,029)
Inducement interest expense	—	(6,691)
Legal settlement	—	(3,853)
Loss on derivatives	(8,750)	—
Total interest and other expenses	(39,248)	(65,416)
Loss before income taxes	(79,824)	(210,820)
Income tax benefit	—	—
Net loss	$ (79,824)	$ (210,820)
Basic and diluted:		
Weighted average common shares outstanding	836,528	676,900
Loss per share	$ (0.10)	$ (0.31)

See accompanying notes to consolidated financial statements.

CytoDyn Inc.
Consolidated Statements of Stockholders' Deficit
(In thousands)

	Preferred stock		Common stock		Treasury stock		Additional paid-in capital	Accumulated deficit	Total stockholders' deficit
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance May 31, 2021	96	$ —	626,123	$ 626	443	$ —	$ 532,031	$ (553,675)	$ (21,018)
Issuance of stock for convertible note repayment	—	—	37,110	37	—	—	68,344	—	68,381
Issuance of legal settlement warrants	—	—	—	—	—	—	2,863	—	2,863
Stock option exercises	—	—	510	1	—	—	389	—	390
Stock issued for compensation and tendered for income tax	—	—	2,582	2	—	—	666	—	668
Stock issued for private offerings	—	—	38,035	38	—	—	46,473	—	46,511
Offering costs related to stock issuance	—	—	—	—	—	—	(5,316)	—	(5,316)
Conversion of Series B and C preferred stock to common stock	(61)	—	3,200	3	—	—	(3)	—	—
Private warrant exchanges	—	—	7,920	8	—	—	5,382	—	5,390
Warrant exercises	—	—	1,642	2	—	—	1,034	—	1,036
Inducement interest expense related to private warrant exchanges	—	—	2,293	2	—	—	6,689	—	6,691
Preferred stock dividends accrued and paid in common stock upon conversion	—	—	613	1	—	—	305	(1,636)	(1,330)
Stock-based compensation	—	—	—	—	—	—	5,571	—	5,571
Finance charges related to warrant issuance for surety bond backstop agreement	—	—	—	—	—	—	6,585	—	6,585
Net loss for May 31, 2022	—	—	—	—	—	—	—	(210,820)	(210,820)
Balance May 31, 2022	35	—	720,028	720	443	—	671,013	(766,131)	(94,398)
Issuance of stock for convertible note repayment	—	—	17,260	17	—	—	3,983	—	4,000
Loss on induced conversion	—	—	—	—	—	—	5,312	—	5,312
Warrants issued in note offering	—	—	—	—	—	—	114	—	114
Stock issued for compensation	—	—	2,751	3	—	—	982	—	985
Stock issued for private offerings	—	—	157,390	157	—	—	37,067	—	37,224
Offering costs related to stock issuance	—	—	—	—	—	—	(1,760)	—	(1,760)
Conversion of Series C preferred stock to common stock	(1)	—	1,136	1	—	—	(1)	—	—
Private warrant exchanges, net of offering costs	—	—	13,094	13	—	—	2,794	—	2,807
Warrant exercises	—	—	1,898	2	—	—	437	—	439
Make-whole shares related to private warrant exchange	—	—	23	—	—	—	—	—	—
Deemed dividend paid in common stock due to down round provision, recorded in additional paid-in capital	—	—	5,154	6	—	—	(6)	—	—
Preferred stock dividends accrued and paid in common stock upon conversion	—	—	319	—	—	—	(1,331)	—	(1,331)
Reclassification of warrants from liability to equity classified	—	—	—	—	—	—	8,756	—	8,756
Stock-based compensation	—	—	—	—	—	—	3,290	—	3,290
Finance charges related to warrant issuance for surety bond backstop agreement	—	—	—	—	—	—	4,885	—	4,885
Reclassification of prior period preferred stock dividends	—	—	—	—	—	—	(4,265)	4,265	—
Net loss for May 31, 2023	—	—	—	—	—	—	—	(79,824)	(79,824)
Balance May 31, 2023	34	$ —	919,053	$ 919	443	$ —	$ 731,270	$ (841,690)	$ (109,501)

See accompanying notes to consolidated financial statements.

CytoDyn Inc.
Consolidated Statements of Cash Flows
(In thousands)

	Fiscal years ended May 31,	
	2023	2022
Cash flows from operating activities:		
Net loss	$ (79,824)	$ (210,820)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization and depreciation	175	781
Amortization of debt issuance costs	9,747	87
Amortization of discount on convertible notes	2,126	2,958
Warrants issued for legal settlement	—	3,663
Finance charges related to surety bond backstop agreement	4,885	6,585
Loss on derivatives	8,750	—
Loss on induced conversion	5,312	37,381
Inducement interest expense and non-cash finance charges	—	6,691
Change in fair value of derivative liabilities	6	—
Inventory charge	20,633	73,490
Stock-based compensation	4,275	6,239
Changes in operating assets and liabilities:		
Decrease (increase) in inventories	—	2,060
(Increase) decrease in prepaid expenses and other assets	1,902	(4,125)
Decrease in accounts payable and accrued expenses	(3,097)	(2,713)
Net cash used in operating activities	(25,110)	(77,723)
Cash flows from investing activities:		
Net cash provided by/ used in investing activities	—	—
Cash flows from financing activities:		
Proceeds from warrant transactions, net of offering costs	2,807	5,390
Proceeds from sale of common stock and warrants, net of issuance costs	25,786	41,195
Proceeds from warrant exercises	439	1,036
Proceeds from convertible note and warrant issuances, net of issuance costs	895	—
Proceeds from stock option exercises	—	390
Net cash provided by financing activities	29,927	48,011
Net change in cash and restricted cash	4,817	(29,712)
Cash at beginning of fiscal year	4,231	33,943
Cash and restricted cash at end of fiscal year	$ 9,048	$ 4,231
Cash and restricted cash consisted of the following:		
Cash	$ 2,541	$ 4,231
Restricted cash	6,507	—
Total cash and restricted cash	$ 9,048	$ 4,231
Supplemental disclosure:		
Cash paid for interest	$ 19	$ 63
Non-cash investing and financing transactions:		
Derivative liability associated with warrants	$ 8,750	$ —
Issuance of common stock for principal and interest of convertible notes	$ 4,000	$ 31,000
Accrued dividends on Series C and D convertible preferred stock	$ 1,490	$ 1,636
Cashless exercise of warrants	$ —	$ 1
Dividend paid in common stock on Series B and C convertible preferred stock conversions	$ 159	$ 305
Warrants issued to placement agent, recorded in additional paid-in capital	$ 7,640	$ 3,597
Warrants issued for surety bond backstop agreement	$ 4,885	$ 6,585
Deemed dividend due to equity modifications, recorded in additional paid-in capital	$ 5,417	$ —

See accompanying notes to consolidated financial statements.

CYTODYN INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
AS OF MAY 31, 2023

Note 1. Organization

CytoDyn Inc. (together with its wholly owned subsidiaries, the "Company") was originally incorporated under the laws of Colorado on May 2, 2002, under the name RexRay Corporation and, effective August 27, 2015, reincorporated under the laws of Delaware. The Company is a clinical-stage biotechnology company focused on the clinical development of innovative treatments for multiple therapeutic indications based on its product candidate, leronlimab, a novel humanized monoclonal antibody targeting the CCR5 receptor.

The Company has been investigating leronlimab as a viral entry inhibitor for treatment of HIV, believed to competitively bind to the N-terminus and second extracellular loop of the CCR5 receptor. For immunology, the CCR5 receptor is believed to be implicated in immune-mediated illnesses such as NASH. Leronlimab is being studied in NASH, NASH-HIV, solid tumors in oncology, and other HIV indications where CCR5 is believed to play an integral role.

Note 2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of CytoDyn Inc. and its wholly owned subsidiaries, CytoDyn Operations Inc. intercompany transactions and balances are eliminated in consolidation.

Reclassifications

Certain prior year amounts shown in the accompanying consolidated financial statements have been reclassified to conform to the current period presentation. Such reclassifications did not have a material effect, if any, on the Company's previously reported financial position, results of operations, stockholders' (deficit) equity, or net cash provided by operating activities.

During the fiscal year ended May 31, 2023, the Company reclassified amounts recorded as accumulated dividends for Series C and D preferred stockholders from accumulated deficit to additional paid-in capital. These reclassifications were made to reflect the proper presentation for accrued dividends when an entity has accumulated deficit.

Going Concern

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates realization of assets and satisfaction of liabilities in the ordinary course of business. As shown in the accompanying consolidated financial statements, the Company had losses for all periods presented. The Company incurred a net loss of $79.8 million and $210.8 million for the fiscal years ended May 31, 2023, and 2022, respectively, and has an accumulated deficit of $841.7 million as of May 31, 2023. These factors, among others, raise substantial doubt about the Company's ability to continue as a going concern.

The Company's continuance as a going concern is dependent upon its ability to obtain additional operating capital, complete the development of its product candidate, leronlimab, obtain approval to commercialize leronlimab from regulatory agencies, continue to outsource manufacturing of leronlimab, and ultimately achieve revenues and attain profitability. The Company plans to continue to engage in research and development activities related to leronlimab for multiple indications and expects to incur significant research and development expenses in the future, primarily related to its regulatory compliance, including seeking the lifting of the FDA's clinical hold with regard to the Company's HIV program, performing additional clinical trials in various indications, and seeking regulatory approval for its product candidate for commercialization. These research and development activities are subject to significant risks and uncertainties. The Company intends to finance its future development activities and its working capital needs primarily from the sale of equity and debt securities, combined with additional funding from other sources. However, there can be no assurance that the Company will be successful in these endeavors.

Use of Estimates

The preparation of the consolidated financial statements in accordance with accounting principles generally accepted in the United States ("U.S. GAAP" or "GAAP") requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, and the disclosure of contingent assets and liabilities at the date of consolidated financial statements, and the reported amounts of revenue and expenses during the reporting period. Estimates are assessed each period and updated to reflect current information, such as the status of our analysis of the results of our clinical trials and/or discussions with the FDA, which could have an impact on the Company's significant accounting estimates and assumptions. The Company's estimates are based on historical experience and on various markets and other relevant, appropriate assumptions. Significant estimates include, but are not limited to, those relating to capitalization of pre-launch inventories, charges for excess and obsolete inventories, research and development expenses, commitments and contingencies, stock-based compensation, and the assumptions used to value warrants and warrant modifications. Actual results could differ from these estimates.

Cash

Cash is maintained at federally insured financial institutions and, at times, balances may exceed federally insured limits. The Company has never experienced any losses related to cash balances. Balances in excess of federally insured limits were approximately $2.3 million of the cash balance and approximately $5.5 million of the restricted cash balance at May 31, 2023. Balances in excess of federally insured limits were approximately $4.0 million at May 31, 2022.

As of May 31, 2023, the Company had recorded approximately $6.5 million of restricted cash. The restricted cash balance is related to cash held as collateral in connection with a Surety Bond, as defined in Note 7, *Equity Awards and Warrants*, that was posted as required in the litigation with Amarex and will remain as restricted cash until the litigation is resolved. For further information, See Note 7, *Equity Awards and Warrants – Private Placement of Warrants under Surety Bond Backstop Agreement*.

Identified Intangible Assets

The Company follows the provisions of ASC 350, *Intangibles-Goodwill and Other*, which establishes accounting standards for the impairment of long-lived assets such as intangible assets subject to amortization. The Company reviews long-lived assets to be held and used for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. If the sum of the undiscounted expected future cash flows over the remaining useful life of a long-lived asset group is less than its carrying value, the asset is considered impaired. Impairment losses are measured as the amount by which the carrying amount of the asset group exceeds the fair value of the asset.

Inventories

Previously Expensed Inventories

The Company recorded revenue in the fiscal year ended May 31, 2022, related to sales of vials for emergency purposes only, solely to treat critically ill COVID-19 patients in the Philippines under a Compassionate Special Permit. Cost of goods sold was minimal because the vials sold were expensed in prior periods as research and development expense because they were manufactured prior to the Company's capitalization of pre-launch inventories as described below. All capitalized inventory amounts represent pre-launch inventories and do not include any inventories previously expensed as research and development expense.

Capitalized Pre-launch Inventories

Pre-launch inventories comprised raw materials required to commercially produce leronlimab and substantially completed commercially produced leronlimab in anticipation of commercial sales of the product upon potential regulatory approval as a combination therapy for HIV patients in the United States, and potential emergency use authorizations for COVID-19. The Company's pre-launch inventories consisted of (1) raw materials purchased for commercial production, (2) work-in-progress materials which consist of bulk drug substance, which is the manufactured drug stored in bulk storage, and (3) drug product, which is the manufactured drug in unlabeled vials. The consumption of raw materials during production is classified as work-in-progress until saleable. Once it is determined to be in saleable condition, following regulatory approval, inventory is classified as finished goods.

The Company capitalizes inventories procured or produced in preparation for product launches. Typically, capitalization of such inventory begins when the results of clinical trials have reached a status sufficient to support regulatory approval, uncertainties regarding ultimate regulatory approval have been significantly reduced, and the Company has determined it is probable that these capitalized costs will provide future economic benefit in excess of capitalized costs. The material factors considered by the Company in evaluating these uncertainties include the receipt and analysis of positive Phase 3 clinical trial results for the underlying product candidate, results from meetings with the relevant regulatory authorities prior to the filing of regulatory applications, and status of the Company's regulatory applications. The Company closely monitors the status of the product within the regulatory review and approval process, including all relevant communications with regulatory authorities. If the Company becomes aware of any specific material risks or contingencies other than the normal regulatory review and approval process or if there are any specific issues identified relating to safety, efficacy, manufacturing, marketing, or labeling, it may make a determination that the related inventory may no longer qualify for capitalization.

The Company determines whether raw materials purchased for commercial production are usable for production based on the manufacturer's assigned expiration date. In evaluating whether raw materials included in the pre-launch inventories will be usable for production, the Company takes into account the shelf-life of raw materials at the time they are expected to be used in manufacturing. Any raw materials past expiration date at the time of the next manufacturing run are removed from inventory.

As one stage of the manufacturing process, the Company produces work-in-progress materials which consist of bulk drug substance, which is the manufactured drug stored in bulk storage. The initial shelf-life of bulk drug substance is established based on periodically performed stability studies and is set at four years from the date of manufacturing. Bulk drug substance is subject to deep freeze stability studies performed on a periodic basis in accordance with the established stability protocols. If drug substance meets suitability criteria beyond the initial shelf-life, its shelf-life is extended by another four years. Regardless of the number of stability studies performed, if drug substance continues to meet prespecified suitability parameters it may be used in manufacturing; if drug substance fails to meet suitability criteria beyond its at that time assigned shelf-life, it may no longer be used and is considered to be expired.

The Company utilizes resins, a reusable raw material, in its bulk drug manufacturing process. Shelf-life of a resin used in commercial manufacturing of biologics is determined by the number of cycles for which it has been validated to be used in a manufacturing process before it is considered unusable. Unpacked and unused resins have a manufacturer's expiration date by which resins are expected to start being used in the manufacturing process without loss of their properties. Prior to a new manufacturing campaign, and between manufacturing campaigns, the resins are removed from storage, are treated and tested for suitability. Once resins are used in the manufacturing process, their shelf-life is measured by a validated predetermined number of manufacturing cycles they are usable for, conditional on appropriate storage solution under controlled environment between production campaigns, as well as by performing pre-production usability testing. Before a manufacturing campaign, each resin is tested for suitability. Regardless of the number of cycles, if a resin fails to meet prespecified suitability parameters it may not be used in manufacturing; likewise, even if the resin meets suitability criteria beyond the lifetime cycles, it may no longer be used. The cost of the resins used in a manufacturing campaign is allocated to the cost of the drug product in vials.

The Company values its inventory at the lower of cost or net realizable value using the average cost method. Inventory is evaluated for recoverability by considering the likelihood that revenue will be obtained from the future sale of the related inventory considering the status of the product within the regulatory approval process. The Company evaluates its inventory levels on a quarterly basis and writes down inventory that became obsolete, has a cost in excess of its expected net realizable value, or is in quantities in excess of expected requirements. In assessing the lower of cost or net realizable value for pre-launch inventory, the Company relies on independent analyses provided by third parties knowledgeable about the range of likely commercial prices comparable to current comparable commercial product. Quarterly, the Company also evaluates whether certain raw materials held in its inventory are expected to reach the end of their estimated shelf-lives based on passage of time, the number of manufacturing cycles they are used in and results of pre-production testing prior to the expected production date, or when resins used in the manufacturing process fail suitability tests. If any of such events occur, the Company may make a determination to record a charge if it is expected that such inventories will become obsolete prior to the expected production date.

Anticipated future sales, shelf lives, and expected approval date are considered when evaluating realizability of capitalized inventory. The shelf-life of a product is determined as part of the regulatory approval process; however, in

assessing whether to capitalize pre-launch inventories, the Company considers the product stability data for all of the pre-approval inventory procured or produced to date to determine whether there is adequate shelf-life. When the remaining shelf-life of drug product inventory is less than 12 months, it is likely that it will not be accepted by potential customers. However, as inventories approach their shelf-life expiration, the Company may perform additional stability testing to determine if the inventory is still viable, which can result in an extension of its shelf-life and re-evaluation of the need for and the amount of the previously recorded reserves. Further, in addition to performing additional stability testing, certain raw materials inventory may be sold in its then current condition prior to reaching expiration. If the Company determines that it is not likely that shelf-life may be extended or the inventory cannot be sold prior to expiration, the Company may record a charge to bring inventory to its net realizable value. See Note 3, *Inventories, net*, for more information.

Revenue Recognition

The Company accounts for and recognizes revenue in accordance with ASC 606, *Revenue from Contracts with Customers*. To date, the Company's revenue has been generated solely through the sale of leronlimab. The Company accounts for a contract when it has approval and commitment from both parties, the rights of the parties are identified, payment terms are identified, the contract has commercial substance and collectability of consideration is probable.

For the Company's sole contract to date, the customer submitted purchase orders to purchase a specified quantity of leronlimab vials; therefore, the delivery of the ordered quantity per the purchase order was accounted for as one performance obligation. The Company does not offer discounts or rebates.

The transaction price was determined based on the agreed upon rates per vial indicated in the purchase order or master supply agreement applied to the quantity of leronlimab vials that the customer requested in the purchase order. As the Company's contract included only one performance obligation, the delivery of the product to the customer, all of the transaction price was allocated to the one performance obligation. Therefore, upon delivery of the product quantity equal to the quantity requested in the purchase order, there were deemed to be no remaining performance obligations. The Company's shipping and handling activities are considered a fulfillment cost. The Company elected to exclude all sales and value added taxes from the measurement of the transaction price. The Company did not adjust the transaction price for financing since the time period between the transfer of goods and payment was less than one year.

The Company recognizes revenue at a point in time when control of the products is transferred to the customer. Management applies judgment in evaluating when a customer obtains control of the promised goods, which generally occurs when the product is delivered to the customer. The Company's customer contract includes a standard assurance warranty to guarantee that its products comply with agreed specifications. The Company grants a conditional right of return of product in the customer's inventory upon an adverse regulatory ruling. The Company continually evaluates the probability of such occurrence. If necessary, the Company will defer revenue recognized based on its estimate of the amount of products that may be subject to the right of return.

Disaggregation of Revenue – The Company's revenues have been derived solely from the sale of leronlimab vials. The Company believes the revenues are presented at the appropriate level of detail in the accompanying consolidated statements of operations.

Contract Assets and Liabilities – The Company's performance obligations for its contract with a customer are satisfied at a point in time through the delivery of leronlimab vials to its customer. The Company did not have revenues in the fiscal year ended May 31, 2023, and had $0.3 million in revenues in the fiscal year ended May 31, 2022. The Company did not have any contract assets or liabilities as of May 31, 2023 or 2022. For all periods presented, the Company did not recognize revenues from amounts that were previously included in a contract liability balance. In addition, for all periods presented, there was no revenue recognized in a reporting period from performance obligations satisfied in previous periods.

Performance Obligations – The Company does not disclose the value of unsatisfied performance obligations for (i) contracts with an original expected length of one year or less and (ii) contracts for which the variable consideration is allocated entirely to a wholly unsatisfied performance obligation. Under the Company's contract, each unit of product delivered to the customer represents a separate performance obligation; therefore, future deliveries of the product are wholly unsatisfied, and disclosure of the transaction price allocated to remaining performance obligations is not required.

Research and Development

Research and development costs are expensed as incurred. Clinical trial costs incurred through third parties are expensed commensurate with the contracted work performed. Contingent milestone payments that are due to third parties under research and development collaboration arrangements or other contractual agreements are expensed when the milestone conditions are probable and the amount of payment is reasonably estimable. See Note 10, *Commitments and Contingencies* for additional discussion.

Fair Value of Financial Instruments

The Company's financial instruments consist primarily of cash, accounts payable and accrued liabilities, and debt. As of May 31, 2023, the carrying value of the Company's assets and liabilities approximate their fair value due to the short-term maturity of the instruments. Debt is reported at amortized cost in the consolidated balance sheets which approximate fair value. The remaining financial instruments are reported in the consolidated balance sheets at amounts that approximate current fair values. The fair value hierarchy specifies three levels of inputs that may be used to measure fair value as follows:

- Level 1. Quoted prices in active markets for identical assets or liabilities.
- Level 2. Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices in markets with insufficient volume or infrequent transactions (less active markets), or model-derived valuations in which all significant inputs are observable or can be derived principally from or corroborated with observable market data for substantially the full term of the assets or liabilities. Level 2 inputs also include non-binding market consensus prices that can be corroborated with observable market data, as well as quoted prices that were adjusted for security-specific restrictions.
- Level 3. Unobservable inputs to the valuation methodology which are significant to the measurement of the fair value of assets or liabilities. These Level 3 inputs also include non-binding market consensus prices or non-binding broker quotes that cannot be corroborated with observable market data.

In accordance with the prescribed accounting guidance, the Company measured the fair value of the liability classified warrants using the fair value hierarchy during the fiscal year ended May 31, 2023. The Company did not have any assets or liabilities measured at fair value using the fair value hierarchy as of May 31, 2022.

Leases

Operating lease right-of-use ("ROU") assets are included in other non-current assets and the current portion of operating lease liabilities are included in accrued liabilities and compensation on the consolidated balance sheets. The long-term operating lease liabilities are presented separately as operating leases on the consolidated balance sheets. Lease ROU assets, and liabilities, are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. As the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of future payments. The operating lease ROU asset also includes any lease payments made and excludes lease incentives and initial direct costs incurred. The Company's lease terms do not include options to extend or terminate the lease as it is not reasonably certain that it would exercise these options. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term.

Stock-Based Compensation

U.S. GAAP requires companies to measure the cost of services received in exchange for the award of equity instruments based on their fair value at the date of grant. The related expense is recognized over the period during which services are expected to be performed in exchange for the award (requisite service period), when designated milestones have been achieved or when pre-defined performance conditions are met.

The Company values its stock-based awards using the Black-Scholes option pricing model utilizing assumptions that include stock price volatility, expected term of the award, and risk-free interest rates. The Company estimates forfeitures at the time of grant and makes revisions in subsequent periods, if necessary, if actual forfeitures differ from those estimates. The Company estimated future unvested forfeitures at zero for all periods presented.

Debt

The Company historically issued promissory notes at a discount and incurred direct debt issuance costs. Debt discount and issuance costs are netted against the debt and amortized over the life of the promissory note in accordance with ASC 470-35, *Debt Subsequent Measurement*.

Offering Costs

The Company periodically incurs direct incremental costs associated with the sale of equity securities; refer to Note 7*, Equity Awards and Warrants* for additional information. The costs are recorded as a component of equity upon receipt of the proceeds.

Income Taxes

Deferred taxes are recorded using the asset and liability method, whereby deferred tax assets are recognized for deductible temporary differences and operating loss and tax credit carry forwards; deferred tax liabilities are recognized for taxable temporary differences. Temporary differences are the differences between the reported amounts of assets and liabilities and their tax basis. Future tax benefits for net operating loss carryforwards are recognized to the extent that realization of these benefits is considered more likely than not. Deferred tax assets are reduced by a valuation allowance when it is more likely than not that some portion or all the deferred tax assets will not be realized.

The Company follows the provisions of ASC 740-10, *Uncertainty in Income Taxes*. A reconciliation of the beginning and ending amount of unrecognized tax benefits has not been provided since there are no unrecognized benefits for all periods presented. The Company has not recognized interest expense or penalties from the implementation of ASC 740-10. If there were an unrecognized tax benefit, the Company would recognize interest accrued related to unrecognized tax benefit in interest expense and penalties in operating expenses.

In accordance with Section 15 of the Internal Revenue Code, the Company utilized a federal statutory rate of 21% for our fiscal 2023 and 2022 tax years. The net tax expense for the fiscal years ended May 31, 2023 and May 31, 2022 was zero. As of May 31, 2023 and 2022, the Company has a full valuation allowance as management does not consider it more than likely than not that the benefits from the deferred tax assets will be realized.

Recent Accounting Pronouncements

In August 2020, the FASB issued ASU No. 2020-06, *Debt with Conversion and Other Options (Subtopic 470-20)* and *Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40)*, which simplifies the accounting for convertible instruments. The guidance removes certain accounting models that separate the embedded conversion features from the host contract for convertible instruments. Either a modified retrospective method of transition or a fully retrospective method of transition is permissible for the adoption of this standard. ASU No. 2020-06 is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. The Company adopted ASU No. 2020-06 as of June 1, 2022, using the modified retrospective method. The adoption of ASU No. 2020-06 had no impact on the Company's balance sheets, statements of operations, cash flows or financial statement disclosures.

In May 2021, the FASB issued ASU No. 2021-04, *Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation - Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options*. ASU 2021-04 addresses the accounting for certain modifications or exchanges of freestanding equity-classified written call options (e.g., warrants). Entities should treat a modification of the terms or conditions, or an exchange of a freestanding equity-classified written call option that remains equity-classified after modification or exchange, as an exchange of the original instrument for a new instrument. Guidance should be applied prospectively after the date of initial application. ASU 2021-04 is effective for fiscal years beginning after December 15, 2021, and interim periods within those fiscal years, with early adoption permitted.

The Company adopted the new guidance prospectively as of June 1, 2022, and used the framework to record modifications to equity classified instruments during the fiscal year ended May 31, 2023. The modifications consisted of the following approximate amounts: induced warrant exercises recorded as $2.2 million of issuance cost, modification to the warrants issued in connection with the Surety Bond Backstop Agreement recorded as a $0.4 million finance charge, and triggers of down-round provisions and modifications recorded as deemed dividends with an aggregate $5.4 million

charge to additional paid-in capital. The deemed dividends were included in the loss per share calculation, see Note 8, *Loss per Common Share*. Refer to Note 7, *Equity Awards and Warrants* for further information on each transaction.

Note 3. Inventories, net

Inventories, net of write-offs, were as follows:

(in thousands)	May 31, 2023	May 31, 2022
Raw materials	$ —	$ 16,264
Work-in-progress	—	1,665
Total inventories, net	$ —	$ 17,929

During the fourth quarter of fiscal 2022, the Company concluded that certain inventories no longer qualified for capitalization as pre-launch inventories due to expiration of shelf-life prior to expected commercial sales and the ability to obtain additional commercial product stability data until after shelf-life expiration. This was due to delays experienced from the originally anticipated BLA approval date from the FDA. The inventories written-off for GAAP accounting purposes continue to be physically maintained, can be used for clinical trials, and can be commercially sold if the shelf-lives can be extended as a result of the performance of on-going continued stability testing of drug product. In the event the shelf-lives of these written-off inventories are extended, and the inventories are sold commercially, the Company will not recognize any costs of goods sold on the previously expensed inventories. The Company also concluded that, due to delays of future production, certain raw materials would expire prior to production and as such no longer qualified for capitalization. Specifically, the Company evaluated its raw materials, which consist of specialized raw materials, resins, and other, against the anticipated production date and determined that while the next production date is indeterminable as of May 31, 2022, specialized raw materials have remaining shelf-life ranging from 2023 to 2026. Therefore, a write-off of $10.2 million for the entire remaining value of specialized and other raw materials was recorded as of May 31, 2022. The Company also concluded that approximately $29.1 million, comprised of five batches of drug product, out of total of nine manufactured, is likely to expire prior to the anticipated date the product may be approved for commercialization. Additionally, the Company anticipates that approximately $34.2 million of the drug product comprised of the remaining four manufactured batches, with shelf-lives lasting into 2026, may expire prior to receiving approval for commercialization. The Company wrote-off the entire remaining balance of the drug product, in the amount of $63.3 million, for a total of $73.5 million in inventory write-offs in the fiscal year ended May 31, 2022.

During the first quarter of fiscal year 2023, the Company reviewed purchase commitments made by its manufacturing partner, Samsung BioLogics Co., Ltd. (“Samsung”), under the master agreement between the Company and Samsung, and its vendors for specialized raw materials for which the Company made a prepayment in the amount of approximately $2.7 million in the third quarter of fiscal year 2022, which was recorded as prepaid expenses in the consolidated financial statements as of May 31, 2022. As discussed in Note 10, *Commitments and Contingencies – Commitments with Samsung BioLogics Co., Ltd. (“Samsung”)*, the Company and its manufacturing partner remain in ongoing discussions about, among other things, deferring the unfulfilled commitments. The entire amount of approximately $2.7 million was charged-off during the quarter ended August 31, 2022.

In October 2022, the Company voluntarily withdrew its rolling BLA submission after concluding that a significant risk existed that the BLA would not receive FDA approval due to the inadequate process and performance by its former CRO around the monitoring and oversight of the clinical data from its trials. Following this decision, the Company’s remaining inventories no longer qualified for capitalization as pre-launch inventories. During the three months ended November 30, 2022, the Company charged-off the remaining raw material resin and work-in-progress bulk product inventories of approximately $16.3 million and $1.7 million, respectively.

Note 4. Intangible Assets, net

Intangible assets were as follows:

(in thousands)	May 31, 2023	May 31, 2022
Leronlimab (PRO 140) patent	$ 3,500	$ 3,500
Website development costs	20	20
Gross carrying value	3,520	3,520
Accumulated amortization, net of impairment	(3,520)	(3,388)
Total intangible assets, net	$ —	$ 132

Amortization expense related to the intangible assets for the fiscal years ended May 31, 2023 and 2022 was approximately $0.1 million and $0.7 million, respectively.

In November 2018, the Company completed the acquisition of substantially all the assets of ProstaGene, LLC ("ProstaGene") which included patents related to clinical research, a proprietary CCR5 algorithm technology for early cancer diagnosis, and a noncompetition agreement with ProstaGene's founder and Chief Executive Officer, Richard G. Pestell. The Company accounted for the ProstaGene acquisition as an asset acquisition under ASC 805-10-55, *Business Combinations*. In March 2021, the Company concluded an arbitration hearing concerning a claim by ProstaGene for approximately 3.1 million shares of common stock that the Company had withheld for damages incurred by the Company in connection with the purchase of the proprietary algorithm as part of the ProstaGene acquisition. Based on the information revealed during the arbitration, the Company concluded that the algorithm's value is fully impaired; the Company recorded an intangible asset impairment charge of approximately $10.0 million during the quarter ended February 28, 2021, resulting from the write-off of the allocated purchase price of $12.2 million and $2.2 million of associated accumulated amortization. In May 2022, in connection with an employment dispute with Dr. Pestell, the Company reached a settlement agreement with Dr. Pestell in which the Company agreed, among other things, to transfer all rights to intangible assets that were acquired as part of the ProstaGene transaction in 2018. The Company recorded a $0.8 million non-cash charge, representing the remaining carrying amount of the ProstaGene patent, as part of legal settlement expense in its consolidated statements of operations in connection with this transfer of assets for the fiscal year ended May 31, 2022.

As of May 31, 2023, the Company fully amortized all intangible assets in the form of patents attributable to the leronlimab acquisition.

Note 5. Accounts Payable and Accrued Liabilities

As of May 31, 2023 and 2022, the accounts payable balance was approximately $62.7 million and $68.0 million, respectively. The Company had two vendors that together accounted for approximately 72% and 73% of the total balance of accounts payable as of each respective date.

The components of accrued liabilities were as follows:

(in thousands)	May 31, 2023	May 31, 2022
Compensation and related expense	$ 335	$ 1,522
Legal fees and settlement	168	2,006
Clinical expense	187	3,727
Accrued inventory charges and expenses	4,978	1,392
License fees	862	150
Lease payable	139	134
Other liabilities	—	64
Total accrued liabilities	$ 6,669	$ 8,995

As of May 31, 2023 and 2022, the accrued legal fees and settlement balance was primarily related to legal fees.

Note 6. Convertible Instruments and Accrued Interest

Convertible Preferred Stock

	May 31, 2023			May 31, 2022		
(in thousands except conversion rate)	**Series B**	**Series C**	**Series D**	**Series B**	**Series C**	**Series D**
Shares of preferred stock outstanding	19	6	9	19	7	9
Common stock conversion rate	10:1	2,000:1	1,250:1	10:1	2,000:1	1,250:1
Total shares of common stock if converted	190	12,670	10,565	190	13,806	10,565
Undeclared dividends	$ 15	$ -	$ -	$ 10	$ -	$ -
Accrued dividends	$ -	$ 2,500	$ 2,808	$ -	$ 2,014	$ 1,963
Total shares of common stock if dividends converted	30	5,000	5,616	20	4,028	3,926

Under the Company's Amended and Restated Certificate of Incorporation, as amended (the "Certificate of Incorporation"), dividends on its outstanding shares of Series B Convertible Preferred Stock (the "Series B Preferred Stock") may be paid in cash or shares of the Company's common stock at the option of the Company. Dividends on outstanding shares of Series C Convertible Preferred Stock (the "Series C Preferred Stock") and Series D Convertible Preferred Stock (the "Series D Preferred Stock") are payable in cash or shares of common stock at the election of the holder. The preferred stockholders have the right to dividends only when and if declared by the Company's Board of Directors. Shares of common stock presented in the table above represent the number of shares that would have been issued had the dividend been paid in shares of the Company's common stock as of the end of each presented period; undeclared dividends of Series C Preferred Stock and Series D Preferred Stock are accrued as of May 31, 2023. Under Section 170 of the Delaware General Corporation Law, the Company is permitted to pay dividends only out of capital surplus or, if none, out of net profits for the fiscal year in which the dividend is declared or net profits from the preceding fiscal year. As of May 31, 2023, the Company had an accumulated deficit of approximately $841.7 million and had net loss in each fiscal year since inception and, therefore, is prohibited from paying any dividends, whether in cash, other property, or in shares of capital stock. Refer to the discussion below for additional information.

Series B Convertible Preferred Stock

Each share of the Series B Preferred Stock is convertible into ten shares of the Company's common stock. Dividends are payable to the Series B Preferred stockholders when and as declared by the Board at the rate of $0.25 per share per annum. Such dividends are cumulative and accrue whether or not declared and whether or not there are any profits, surplus, or other funds or assets of the Company legally available therefor. At the option of the Company, dividends on the Series B Preferred Stock may be paid in cash or restricted shares of the Company's common stock, valued at $0.50 per share. The preferred shareholders can only convert their shares to shares of common stock if the Company has sufficient authorized shares of common stock at the time of conversion. The Series B Preferred Stock has liquidation preferences over the common shares at $5.00 per share, plus any accrued and unpaid dividends. Except as provided by law, the Series B holders have no voting rights. The Company does not accrue dividends on Series B preferred stock until such dividends are declared.

Series C Convertible Preferred Stock

The Series C Certificate of Designation provides, among other things, that holders of Series C Preferred Stock shall be entitled to receive, when and as declared by the Board and out of any assets at the time legally available therefor, cumulative dividends at the rate of ten percent (10%) per share per annum of the stated value of the Series C Preferred Stock, which is $1,000 per share (the "Series C Stated Value"). Any dividends paid by the Company will be paid to the holders of Series C Preferred Stock prior and in preference to any payment or distribution to holders of common stock. Dividends on the Series C Preferred Stock are cumulative, and will accrue and be compounded annually, whether or not declared and whether or not there are any profits, surplus, or other funds or assets of the Company legally available therefor. There are no sinking fund provisions applicable to the Series C Preferred Stock. The Series C Preferred Stock does not have redemption rights. Dividends, if declared by the Board, are payable to holders in arrears on December 31 of each year. Subject to the provisions of applicable Delaware law, the holder may elect to be paid in cash or in restricted shares of common stock, with the number of shares to be based on the conversion price then in effect. In the event of liquidation, dissolution, or winding up of the Company, the holders of Series C Preferred Stock will be entitled to receive, on a pari passu basis with the holders of the Series D Preferred Stock and in preference to any payment or distribution to any holders of the Series B Preferred Stock or common stock, an amount per share equal to the Series C

Stated Value plus the amount of any accrued and unpaid dividends. If, at any time while the Series C Preferred Stock is outstanding, the Company effects a reorganization, merger or consolidation of the Company, sale of substantially all of its assets, or other specified transaction (each, as defined in the Series C Certificate of Designation, a "Fundamental Transaction"), a holder of the Series C Preferred Stock will have the right to receive any shares of the acquiring corporation or other consideration it would have been entitled to receive if it had been a holder of the number of shares of common stock then issuable upon conversion in full of the Series C Preferred Stock immediately prior to the Fundamental Transaction. Each share of Series C Preferred Stock is convertible at any time at the holder's option into that number of fully paid and nonassessable shares of common stock determined by dividing the Series C Stated Value by the conversion price of $0.50 (subject to adjustment as set forth in the Series C Certificate of Designation). No fractional shares will be issued upon the conversion of the Series C Preferred Stock. Except as otherwise provided in the Series C Certificate of Designation or as otherwise required by law, the Series C Preferred Stock has no voting rights.

Series D Convertible Preferred Stock

The Series D Certificate of Designation provides, among other things, that holders of Series D Preferred Stock shall be entitled to receive, when and as declared by the Company's Board of Directors and out of any assets at the time legally available therefor, cumulative dividends at the rate of ten percent (10%) per share per annum of the stated value of the Series D Preferred Stock, which is $1,000 per share (the "Series D Stated Value"). Any dividends paid by the Company will first be paid to the holders of Series D Preferred Stock prior and in preference to any payment or distribution to holders of common stock. Dividends on the Series D Preferred Stock are cumulative, and will accrue and be compounded annually, whether or not declared and whether or not there are any profits, surplus, or other funds or assets of the Company legally available therefor. There are no sinking fund provisions applicable to the Series D Preferred Stock. The Series D Preferred Stock does not have redemption rights. Dividends, if declared by the Board, are payable to holders in arrears on December 31 of each year. Subject to the provisions of applicable Delaware law, the holder may elect to be paid in cash or in restricted shares of common stock at the rate of $0.50 per share. In the event of liquidation, dissolution, or winding up of the Company, the holders of Series D Preferred Stock will be entitled to receive, on a pari passu basis with the holders of the Series C Preferred Stock, and in preference to any payment or distribution to any holders of the Series B Preferred Stock, $0.001 par value per share, or common stock, an amount per share equal to the Series D Stated Value plus the amount of any accrued and unpaid dividends. If, at any time while the Series D Preferred Stock is outstanding, the Company effects any reorganization, merger or consolidation of the Company, sale of substantially all of its assets, or other specified transaction (each, as defined in the Series D Certificate of Designation, a "Fundamental Transaction"), a holder of the Series D Preferred Stock will have the right to receive any shares of the acquiring corporation or other consideration it would have been entitled to receive if it had been a holder of the number of shares of common stock then issuable upon conversion in full of the Series D Preferred Stock immediately prior to the Fundamental Transaction. Each share of Series D Preferred Stock is convertible at any time at the holder's option into that number of fully paid and nonassessable shares of common stock determined by dividing the Series D Stated Value by the conversion price of $0.80 (subject to adjustment as set forth in the Series D Certificate of Designation). No fractional shares will be issued upon the conversion of the Series D Preferred Stock. Except as otherwise provided in the Series D Certificate of Designation or as otherwise required by law, the Series D Preferred Stock has no voting rights.

Convertible Notes and Accrued Interest

The outstanding balance of convertible notes, including accrued interest, were as follows:

	May 31, 2023				May 31, 2022		
(in thousands)	April 2, 2021 Note	April 23, 2021 Note	Placement Agent Notes	Total	April 2, 2021 Note	April 23, 2021 Note	Total
Convertible notes payable outstanding principal	$ 6,081	$ 29,369	$ 1,000	$ 36,450	$ 9,819	$ 28,500	$ 38,319
Less: Unamortized debt discount and issuance costs	(211)	(822)	(286)	(1,319)	(512)	(1,566)	(2,078)
Convertible notes payable, net	5,870	28,547	714	35,131	9,307	26,934	36,241
Accrued interest on convertible notes	3,804	6,789	5	10,598	2,599	3,375	5,974
Outstanding convertible notes payable, net and accrued interest	$ 9,674	$ 35,336	$ 719	$ 45,729	$ 11,906	$ 30,309	$ 42,215

Changes in the outstanding balance of convertible notes, including accrued interest, were as follows:

(in thousands)	April 2, 2021 Note	April 23, 2021 Note	Placement Agent Notes	Total
Outstanding balance at May 31, 2022	$ 11,906	$ 30,309	$ -	$ 42,215
Consideration received			696	696
Amortization of issuance discount and costs	564	1,613	18	2,195
Interest expense	1,205	3,414	5	4,624
Fair market value of shares exchanged for repayment	(5,312)	-	-	(5,312)
Difference between market value of common shares and reduction of principal	1,311	-	-	1,311
Outstanding balance at May 31, 2023	$ 9,674	$ 35,336	$ 719	$ 45,729

Convertible Note – April 2, 2021 Note

On April 2, 2021, the Company entered into a securities purchase agreement pursuant to which the Company issued a secured convertible promissory note with a two-year term in the initial principal amount of $28.5 million (the "April 2, 2021 Note"). The maturity date has been extended an additional two years to April 2025. See *April 2, 2021 and April 23, 2021 Note Extensions* below. The Company received consideration of $25.0 million, reflecting an original issue discount of $3.4 million and issuance costs of $0.1 million.

Interest accrues at an annual rate of 10% on the outstanding balance, with the rate increasing to the lesser of 22% per annum or the maximum rate permitted by applicable law upon occurrence of an event of default. In addition, upon any event of default, the investor may accelerate the outstanding balance payable under the April 2, 2021 Note; upon such acceleration, the outstanding balance will increase automatically by 15%, 10%, or 5%, depending on the nature of the event of default. The events of default are listed in Section 4 of the April 2, 2021 Note filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed on April 8, 2021, and listed as Exhibit 4.17 in Item 15 to this report. The April 2, 2021 Note is secured by all the assets of the Company, excluding the Company's intellectual property.

Pursuant to the terms of the securities purchase agreement and the April 2, 2021 Note, the Company must obtain the investor's consent before assuming additional debt with aggregate net proceeds to the Company of less than $50.0 million. In the event of any such approval, the outstanding principal balance of the April 2, 2021 Note will increase automatically by 5% upon the issuance of such additional debt.

The investor may convert all or any part of the outstanding balance of the April 2, 2021 Note into shares of common stock at an initial conversion price of $10.00 per share upon five trading days' notice, subject to certain adjustments and volume and ownership limitations. In addition to standard anti-dilution adjustments, the conversion price of the April 2, 2021 Note is subject to full-ratchet anti-dilution protection, pursuant to which the conversion price will be automatically reduced to equal the effective price per share in any new offering by the Company of equity securities that have registration rights, are registered, or become registered under the Securities Act of 1933, as amended (the "Securities Act"). The April 2, 2021 Note provides for liquidated damages upon failure to deliver common stock within specified timeframes and requires the Company to maintain a share reservation of 6.0 million shares of common stock. The investor may redeem any portion of the note, at any time beginning six months after the issue date upon three trading days' notice, subject to a maximum monthly redemption amount of $3.5 million. The April 2, 2021 Note requires the Company to satisfy its redemption obligations in cash within three trading days of the Company's receipt of such notice. The Company may prepay the outstanding balance of the note, in part or in full, plus a 15% premium, at any time upon 15 trading days' notice.

In addition, beginning in May 2021 and for each of the following five months, the Company was obligated through November 2021, at the discretion of the noteholder, to reduce the outstanding balance of the April 2, 2021 Note by $7.5 million per month. Payments under the April 23, 2021 Note, described below, could be applied toward the payment of each monthly debt reduction amount. These payments are not subject to the 15% prepayment premium, which would otherwise be triggered if the Company were to make payments against such notes exceeding the allowed maximum monthly redemption amount.

The conversion feature of the April 2, 2021 Note was analyzed under ASC 815, *Derivatives and Hedging*, to determine if it achieved equity classification or required bifurcation as a derivative instrument. The embedded conversion feature was considered indexed to the Company's own stock and met the conditions for equity classification. Accordingly, the embedded conversion feature did not require bifurcation from the host instrument. The Company determined there was no beneficial conversion feature since the effective conversion rate was greater than the market value of the Company's common stock upon issuance. Certain default put provisions were considered not to be clearly and closely related to the host instrument, but the Company concluded that the value of these default put provisions was de minimis. The Company evaluates the value of the default put provisions each reporting period to determine if the value becomes material to the financial statements.

During the fiscal year ended May 31, 2023, in satisfaction of redemptions, the Company and the April 2, 2021 Noteholder entered into eight exchange agreements, pursuant to which the April 2, 2021 Note was partitioned into new notes (the "Partitioned Notes") with an aggregate principal amount of $4.0 million, which was exchanged concurrently with the issuance of an aggregate amount of approximately 17.3 million shares of common stock. The outstanding balance of the April 2, 2021 Note was reduced by the Partitioned Notes to a principal amount of $6.1 million. The Company accounted for the Partitioned Notes and exchange settlement as an induced conversion, and, accordingly, in the fiscal years ended May 31, 2023 and 2022, the Company recorded a non-cash loss on convertible debt induced conversion of $5.3 million and $18.9 million, respectively.

Convertible Note – April 23, 2021 Note

On April 23, 2021, the Company entered into securities purchase agreements pursuant to which the Company issued a secured convertible promissory note with a two-year term to an institutional accredited investor affiliated with the holder of the April 2, 2021 Note in the initial principal amount of $28.5 million (the "April 23, 2021 Note"). The maturity date has been extended another two years to April 2025. See *April 2, 2021 and April 23, 2021 Note Extensions* below. The Company received consideration of $25.0 million, reflecting an original issue discount of $3.4 million and issuance costs of $0.1 million. The April 23, 2021 Note is secured by all the assets of the Company, excluding the Company's intellectual property.

Interest accrues at an annual rate of 10% on the outstanding balance of the April 23, 2021 Note, with the rate increasing to the lesser of 22% per annum or the maximum rate permitted by applicable law upon the occurrence of an event of default. In addition, upon any event of default, the investor may accelerate the outstanding balance payable under the April 23, 2021 Note; upon such acceleration, the outstanding balance will increase automatically by 15%, 10%, or 5%, depending on the nature of the event of default. The events of default are listed in Section 4 of the April 23, 2021 Note filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed on April 29, 2021, and listed as Exhibit 4.18 in Item 15 to this report.

The investor may convert all or any part of the outstanding balance into shares of common stock at an initial conversion price of $10.00 per share upon five trading days' notice, subject to certain adjustments and volume and ownership limitations specified in the April 23, 2021 Note. In addition to standard anti-dilution adjustments, the conversion price of the April 23, 2021 Note is subject to full-ratchet anti-dilution protection, pursuant to which the conversion price will be automatically reduced to equal the effective price per share in any new offering by the Company of equity securities that have registration rights, are registered, or become registered under the Securities Act. The April 23, 2021 Note provides for liquidated damages upon failure to deliver common stock within specified timeframes and requires the Company to maintain a share reservation of 6.0 million shares of common stock.

The investor may redeem any portion of the April 23, 2021 Note, at any time beginning six months after the issue date, upon three trading days' notice, subject to a maximum monthly redemption amount of $7.0 million. The April 23, 2021 Note requires the Company to satisfy its redemption obligations in cash within three trading days of the Company's receipt of such notice. The Company may prepay the outstanding balance of the April 23, 2021 Note, in part or in full, plus a 15% premium, at any time upon 15 trading days' notice.

Pursuant to the terms of the securities purchase agreement and the April 23, 2021 Note, the Company must obtain the investor's consent before assuming additional debt with aggregate net proceeds to the Company of less than $75.0 million. In the event of any such approval, the outstanding principal balance of the April 23, 2021 Note will increase automatically by 5% upon the issuance of such additional debt.

The conversion feature in the April 23, 2021 Note was analyzed under ASC 815, *Derivatives and Hedging*, to determine if it achieved equity classification or required bifurcation as a derivative instrument. The embedded conversion feature was considered indexed to the Company's own stock and met the conditions for equity classification. Accordingly, the embedded conversion feature does not require bifurcation from the host instrument. The Company determined there was no beneficial conversion feature since the effective conversion rate was greater than the market value of the Company's common stock upon issuance. Certain default put provisions were not considered to be clearly and closely related to the host instrument, but the Company concluded that the value of these default put provisions was de minimis. The Company evaluates the value of the default put provisions each reporting period to determine if the value becomes material to the financial statements.

The holders of the April 2 and April 23 Notes have waived provisions in the notes that would have resulted in the imposition of a default interest rate, a downward adjustment in the conversion price, or any other default, breach, or imposition of a penalty. The related transactions consisted of the issuance of warrants to purchase 45 million shares of common stock with registration rights to the Indemnitors pursuant to the Backstop Agreement, and the grant of a security interest in the Company's intellectual property to Indemnitors that were parties to the Backstop Agreement. The noteholders also waived similar registration rights in connection with the issuance of an additional note, and shares of common stock and warrants issued through a placement agent.

April 2, 2021 Note and April 23, 2021 Note Extensions

On April 10, 2023 the Company and the April 2, 2021 and April 23, 2021 noteholders entered into an amendment for each note that extended the maturity date an additional two years for each note. In exchange, the Company agreed to pay the noteholders an extension fee equal to two and one-half percent (2.5%) of the outstanding balance of each note as of April 10, 2023. As a result, the balances of the April 2, 2021 Note and April 23, 2021 increased by $0.3 million and $0.9 million, respectively.

The Company accounted for the note extensions as an increase to the discount on the convertible notes payable and will amortize the note extension fee over the term of the notes.

Placement Agent Notes

On April 28, 2023 and May 5, 2023, the Company entered into a securities purchase agreement pursuant to which the Company issued promissory notes bearing interest at a rate of 6% and with an 18-month term to accredited investors in the aggregate principal amount of $1.0 million through a placement agent ("Placement Agent Notes"). The Placement Agent Notes were secured by the net cash recovery, if any, by the Company in its dispute with Amarex and provided the investors with a right to convert the unpaid principal and accrued but unpaid interest into shares of common stock upon the occurrence of an event of default. The full balance matures in the fiscal year ending May 31, 2025. The Company also issued warrants to purchase 1.0 million shares of common stock with a three-year term and an exercise price of $0.50 as part of the sale. The net proceeds of $0.9 million reflect issuance costs of approximately $0.1 million. The Company also issued warrants to purchase 0.3 million shares of common stock to the placement agent with a ten-year term and an exercise price that will be based on the intraday volume weighted average price of the Company's common stock on the date of the final closing of the offering, which the Company accounted for as additional issuances costs. See Note 13, *Subsequent Events.* The Company allocated the proceeds between the liability-classified Placement Agent Notes and the equity-classified warrants based on their relative fair values.

Note 7. Equity Awards and Warrants

Approval of increase in authorized common stock

On August 31, 2022, at a special stockholders' meeting, the Company's stockholders approved a proposal to increase the total number of authorized shares of common stock from 1.0 billion shares to 1.35 billion shares.

Liability classified warrants

From June 24, 2022 through August 31, 2022, the Company had insufficient authorized common stock to reserve for the shares underlying the Surety Backstop warrants and warrants issued to a placement agent in connection with the June 2022 offering (refer to *Private Placement of Warrants under Surety Bond Backstop Agreement* and *Private*

Placement of Common Stock and Warrants through Placement Agent sections below). After approval by the Company's stockholders of an increase to the Company's authorized common stock, on August 31, 2022, sufficient shares were authorized to cover the shares underlying the warrants. Given that the Company did not have a sufficient number of authorized shares for the instruments at the time they were issued, the Company accounted for such warrants issued from June 24, 2022 through August 2022 as liability classified warrants consistent with ASC 815, *Derivatives and Hedging.*

On December 1, 2022, the Company entered into the second amendment of the Surety Bond Backstop Agreement which included the issuance of a warrant covering up to 7.5 million shares of common stock with an exercise price of $0.10 per share, with the ultimate number of shares to be covered by the second warrant to be calculated based on a formula relating to how quickly the Company relieved the balance of cash collateral pledged by the Indemnitors (refer to *Private Placement of Warrants under Surety Bond Backstop Agreement* section below). On February 28, 2023, the warrant was determined to cover 7.5 million shares of common stock. As the settlement amount of shares of common stock underlying the warrant was variable, the Company accounted for such warrant as a liability classified warrant consistent with ASC 815, *Derivatives and Hedging*, until the number of shares underlying the warrant was determined, at which point the warrant became equity classified.

During April and May 2023, the Company sold Placement Agent Notes through a placement agent. See Note 6, *Convertible Instruments and Accrued Interest – Placement Agent Notes*. The Company agreed to issue warrants to the placement agent as part of the issuance costs with an exercise price that was not determined until the final closing date. As the exercise price determination was contingent on a future financing closing, the Company accounted for the warrants as a liability classified warrant as of May 31, 2023. The value of the warrants at May 31, 2023 is recorded as a derivative liability on the balance sheet, and the change of the fair value of the warrants is recorded as a loss on derivatives.

In accordance with the prescribed accounting guidance, the Company measured fair value of liability classified warrants using fair value hierarchy included in Note 2, *Summary of Significant Accounting Policies – Fair Value of Financial Instruments*.

As of May 31, 2023, in accordance with ASC 815, *Derivatives and Hedging,* the Company reclassified warrants to equity when the warrants no longer qualified as liabilities. The Company recorded a loss on derivatives of approximately $8.8 million in the fiscal year ended May 31, 2023, due to change in fair market value of the liability classified warrants. The table below presents a reconciliation of the beginning and ending balances for liabilities measured at fair value as of May 31, 2022, and during the fiscal year ended May 31, 2023:

(in thousands)	**Liability Classified Warrants**
Balance at May 31, 2022	$ —
Classified as liability	16,664
Reclassified as equity	(25,335)
Loss on derivative due to change in fair market value	8,750
Balance at May 31, 2023	$ 79

The Company used a Black-Scholes valuation model to estimate the value of the liability classified warrants using assumptions presented in the table below. The Black-Scholes valuation model was used because management believes it reflects all the assumptions that market participants would likely consider in negotiating the transfer of the warrant. The Company's derivative liability is classified within Level 3.

Black-Scholes inputs for warrants that have been reclassified as equity as of May 31, 2023:

	Initial Fair Market Value at Issuance				Fair Market Value at Equity Classification			
	Backstop Warrant #1	Backstop Warrant #2	Placement Agent Warrants	Backstop Warrant #3	Backstop Warrant #1	Backstop Warrant #2	Placement Agent Warrants	Backstop Warrant #3
Fair value of underlying stock	$ 0.44	$ 0.42	$ 0.44	$ 0.35	$ 0.52	$ 0.52	$ 0.52	$ 0.32
Risk-free rate	3.17%	3.06%	3.13%	3.68%	3.34%	3.31%	3.16%	4.18%
Expected term (in years)	4.65	5.00	10.00	5.00	4.46	4.88	9.82	4.76
Stock price volatility	110.20%	109.49%	95.99%	124.36%	117.29%	113.59%	95.87%	126.67%
Expected dividend yield	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%

Black-Scholes inputs for warrants that remain liability classified as of May 31, 2023:

	Initial Fair Market Value at Issuance		Fair Market Value at May 31, 2023
	Placement Agent Warrants Closing #1	Placement Agent Warrants Closing #2	Placement Agent Warrants
Fair value of underlying stock	$ 0.29	$ 0.27	$ 0.26
Risk-free rate	3.44%	3.44%	3.64%
Expected term (in years)	10.00	10.00	10.00
Stock price volatility	98.22%	97.90%	97.90%
Expected dividend yield	0.00%	0.00%	0.00%

Equity Incentive Plan

As of May 31, 2023, the Company had one active equity incentive plan, the *CytoDyn Inc. Amended and Restated 2012 Equity Incentive Plan* (the "2012 Plan" or "Incentive Plan"). The 2012 Plan contains an "evergreen provision" whereby the total number of shares available to be issued automatically increases annually on the first day of each fiscal year in an amount equal to 1.0% of the total outstanding shares on the last day of the prior fiscal year, unless the Board determines otherwise before the fiscal year end. As of May 31, 2023, the Board determined to waive the "evergreen provision". As of May 31, 2023, the 2012 Plan covered a total of 56.3 million shares of common stock.

Stock options

Stock option activity is presented in the table below:

(in thousands, except per share data and years)	Number of shares	Weighted average exercise price	Weighted average remaining contractual life in years	Aggregate intrinsic value
Options outstanding at May 31, 2021	17,839	$ 1.58	7.93	$ 15,390
Granted	11,985	$ 1.38		
Exercised	(510)	$ 0.79		301
Forfeited, expired, and cancelled	(11,857)	$ 1.51		
Options outstanding at May 31, 2022	17,457	$ 1.53	7.79	$ —
Granted	12,417	$ 0.41		
Exercised	—	$ —		
Forfeited, expired, and cancelled	(10,051)	$ 1.16		
Options outstanding at May 31, 2023	19,823	$ 0.99	7.87	$ —
Options outstanding and exercisable at May 31, 2023	11,932	$ 1.21	7.02	$ —

The fair value of the equity awards granted is estimated using the Black-Scholes option-pricing model based on the closing stock prices at the grant date and the assumptions specific to the underlying award. Expected volatility assumptions are based on the historical volatility of the Company's common stock. The expected term assumption is based on the contractual and vesting term of the equity award. The risk-free interest rate is based on the U.S. Treasury yield curve with a maturity equal to the expected life assumed at the grant date. The following table summarizes the assumptions used in the determination of fair value:

	Fiscal years ended May 31,			
	2023		2022	
Expected Volatility	99.2 - 112.7	%	94.3 - 122.0	%
Weighted-Average Volatility	107.06	%	104.89	%
Expected Dividends	0	%	0	%
Expected Term (In years)	5.0 - 6.1		1.5 - 6.0	
Risk-Free Rate	3.83	%	1.67	%

In the fiscal years ended May 31, 2023, and 2022, stock-based compensation expense related to equity instruments totaled $4.3 million and $6.2 million, respectively; stock-based compensation expense is presented in general and administrative expense in the Company's consolidated statements of operations. The grant date fair value of options vested during the same periods was approximately $4.9 million and $3.9 million, respectively. As of May 31, 2023, there was approximately $3.0 million of unrecognized compensation expense related to share-based payments for unvested options, which is expected to be recognized over a weighted-average period of approximately 1.10 years.

During the fiscal year ended May 31, 2023, the Company granted stock options covering a total of approximately 1.8 million shares of common stock to non-executive employees, with exercise prices ranging between $0.35 and $0.67 per share. These stock option awards vest over four years, with a ten-year term and grant date fair values ranging between $0.29 and $0.54 per share. As of May 31, 2023 and May 31, 2022 there were approximately 12.0 million and 9.9 million vested stock options and approximately 7.8 million and 7.5 million unvested stock options outstanding, respectively.

RSUs and PSUs

The 2012 Plan provides for equity instruments, such as RSUs and PSUs, which grant the right to receive a specified number of shares over a specified period of time. RSUs and PSUs are service-based awards that vest according to the terms of the grant. PSUs have performance-based payout conditions.

The following table summarizes the Company's RSU and PSU activity:

(shares in thousands)	Number of RSUs and PSUs (1)	Weighted-average grant date fair value	Weighted average remaining contractual life in years
Unvested RSUs and PSUs at May 31, 2021	5,470	$ 2.96	1.01
RSUs and PSUs granted	—		
RSUs and PSUs forfeited	(4,356)	2.94	
RSUs and PSUs vested	(814)	3.01	
Unvested RSUs and PSUs at May 31, 2022	300	3.12	0.58
RSUs and PSUs granted	1,293	0.58	
RSUs and PSUs forfeited	(150)	3.12	
RSUs and PSUs vested	(150)	3.12	
Unvested RSUs and PSUs at May 31, 2023	1,293	$ 0.58	0.81

(1) The number of PSUs disclosed in this table are at the target level of 100%.

In July 2022, the Company awarded approximately 0.6 million RSUs and an equal number of PSUs to Cyrus Arman, then the Company's President. The vesting of the PSUs was contingent on the achievement of specified performance-based conditions, with a potential payout percentage ranging from 0% to 100%.

During the fiscal year ended May 31, 2023, the Company issued approximately 0.2 million shares of common stock to executives in connection with the time-based vesting of RSUs granted in June 2022.

Based on the estimated level of achievement of the performance targets associated with the PSUs as of May 31, 2023, unrecognized compensation expense related to the unvested portion of the Company's RSUs and PSUs totaled $0.4 million, which is expected to be recognized over a weighted-average period of 0.81 years. See Note 13, Subsequent Events.

Issuance of shares to former and current executives and consultants

During the fiscal year ended May 31, 2022, the employment of our CEO and General Counsel was terminated. Under the terms of their respective employment agreements, the Company was obligated to pay severance equal to 18 months of salary to our former CEO and 12 months of salary to our former General Counsel. As permitted by the employment agreements, in March 2022, the Board authorized the severance payments to our former CEO and the remaining severance payments to our former General Counsel to be made through the issuance of shares of common stock. The shares were issued outside of the 2012 Plan.

During the fiscal year ended May 31, 2023, the Company issued to our former General Counsel a total of 79,391 shares of common stock to satisfy in full its obligation under the terms of the employment agreement. During the same period, consistent with the terms of our former CEO's employment agreement, the Company also issued 380,704 shares of common stock as severance. The numbers of shares issued were based on the closing price of the common stock on the applicable date. As of December 2022, the Company ceased payment of severance to the Company's former CEO.

In order to preserve cash resources, in April 2022, the Board approved the issuance under the 2012 Plan, through November 2022, to then executive officers of shares of common stock with a value equal to 25 percent of salary in lieu of cash, net of payroll deductions and withholding taxes. During the fiscal years ended May 31, 2023 and 2022, a total of 522,382 and 317,441 shares of common stock were issued pursuant to this cash preservation program, respectively. The numbers of shares issued were based on the closing price of the common stock on each payroll date.

In March 2022, the Board approved the issuance under the 2012 Plan of shares of common stock to consultants as payment for services provided. During the fiscal years ended May 31, 2023 and 2022, a total of 1,617,760 and 128,001 shares of common stock, respectively, were issued pursuant to the respective award agreements with the consultants.

Issuance of warrants under Surety Bond Backstop Agreement

On February 14, 2022, the Company entered into a Surety Bond Backstop Agreement (as amended, the "Backstop Agreement") with an accredited investor, Dr. David Welch, in his individual capacity and as trustee of a revocable trust, as well as certain other related parties (collectively, the "Indemnitors"). Pursuant to the original terms of the Backstop Agreement, the Indemnitors agreed to assist the Company in obtaining a surety bond (the "Surety Bond") for posting in connection with the Company's ongoing litigation with Amarex by, among other things, agreeing to indemnify the issuer of the Surety Bond (the "Surety") with respect to the Company's obligations under the Surety Bond through August 13, 2022. As consideration for the Indemnitors' agreement to indemnify the Surety, the Company agreed (i) to issue to 4-Good Ventures LLC, an affiliate of the Indemnitors ("4-Good"), a warrant for the purchase of 15.0 million shares of common stock as a backstop fee (the "Initial Warrant"), (ii) to issue to 4-Good a warrant for the purchase of an additional 15.0 million shares, to be exercisable only if the Indemnitors were required to make any payment to the Surety (the "Make-Whole Warrant" and, together with the Initial Warrant, the "4-Good Warrants"), and (iii) if the Indemnitors were required to make a payment to the Surety, (A) within 90 days of such payment, to reimburse the Indemnitors for any amount paid to the Surety and (B) to pay to the Indemnitors an indemnification fee in an amount equal to 1.5 times the amount paid by the Indemnitors to the Surety. The payment obligations of the Company to the Indemnitors bore interest at 10% per annum and were secured by substantially all of the patents held by the Company. The Company recognized a finance charge of approximately $6.6 million related to the warrant issuance for the fiscal year ended May 31, 2022.

Pursuant to amendments to the Backstop Agreement executed in July and December of 2022, among other matters: (i) each of the 4-Good Warrants has a five-year term from the date of issuance and a reduced exercise price of $0.10 per share; (ii) the Make-Whole Warrant became fully exercisable in July 2022; (iii) the Indemnitors were issued, in December 2022, a fully exercisable warrant to purchase 7.5 million shares of common stock at an exercise price of $0.10 per share; (iv) the Indemnitors were issued a second warrant in December 2022 covering up to 7.5 million shares of common stock with an exercise price of $0.10 per share, with the ultimate number of shares to be covered by the second warrant to be calculated on or before February 14, 2023, based on a formula relating to how quickly the Company relieved the balance of cash collateral pledged by the Indemnitors; and (v) the obligation of the Indemnitors to indemnify the Surety was extended to January 31, 2023; provided that the Company would relieve the Indemnitors of a minimum of $1.5 million of cash collateral pledged by the Indemnitors in support of the Surety Bond by January 5, 2023, with the balance of the cash collateral to be relieved by January 31, 2023. The Indemnitor extended the amount and date to be relieved of the cash collateral to $5.1 million by February 28, 2023, and $1.4 million by March 10, 2023. As of February 28, 2023, the second warrant was determined to cover the full 7.5 million shares of common stock. See *Liability Classified Warrants* above for the accounting treatment of the July 2022 amendment to the Backstop Agreement and the final warrant for 7.5 million shares. The Company recorded a finance charge of approximately $4.9 million related to the warrant issuances for the fiscal year ended May 31, 2023. The Company recorded $6.5 million of restricted cash in connection with cash collateral for the Surety Bond as of May 31, 2023.

Except as described above, the terms of the additional warrants issued in December 2022 are similar to the warrants issued under the original Backstop Agreement, filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed on February 17, 2022. The shares covered by the warrants are entitled to registration rights.

Following the issuance of the additional warrants, Dr. Welch was deemed to beneficially own in excess of five percent of the Company's outstanding shares of common stock.

Private placement of common stock and warrants through placement agent

In April 2022, the Company initiated a private placement of common stock and warrants, completed in June 2022, to accredited investors through a placement agent. Between April and June 2022, the Company sold a total of approximately 85.4 million shares of common stock for a total of approximately $18.9 million of proceeds, net of issuance costs. Of these, approximately $7.7 million of proceeds, net of issuance costs, relating to approximately 34.6 million shares were remitted to the Company by May 31, 2022. Each unit sold included a fixed combination of one share of common stock and three-quarters of one warrant to purchase one share of common stock for a purchase price of $0.255 per unit. The Company issued approximately 64.0 million of immediately exercisable warrants to investors, with each such warrant having a five-year term and an exercise price of 120% of the final unit price, or $0.306 per share. The Company paid the placement agent a total cash fee of approximately $2.8 million, equal to 13% of the gross proceeds of

the offering, as well as a one-time fee for expenses of $50,000, and issued a total of approximately 19.4 million warrants with an exercise price of $0.255 per share and a ten-year term, representing 13% of the total number of shares, including shares subject to warrants sold in the offering, to the placement agent and its designees. The issuance of the warrants to the placement agent was subject to the approval by the Company's stockholders of an increase in authorized shares of common stock, which was approved on August 31, 2022.

In January 2023, the Company commenced a private placement of units consisting of common stock and warrants, completed March 3, 2023, to accredited investors through a placement agent. Each unit sold included a fixed combination of one share of common stock and one warrant to purchase one share of common stock. Each unit had a purchase price of $0.23, which was equal to 90% of the closing price of the common stock on January 12, 2023. During January, February, and March 2023, the Company sold a total of approximately 71.1 million units for a total of approximately $14.4 million of proceeds, net of issuance costs. The Company classified the securities issued in the private placement through placement agent as equity. As part of the offering, the Company issued approximately 71.1 million warrants to investors, with each such warrant having a five-year term and an exercise price of $0.50 per share. The warrants were immediately exercisable. In connection with the above, the Company paid the placement agent a total cash fee of approximately $2.0 million, equal to 12% of the gross proceeds of the offering, as well as a one-time fee for expenses of $25.0 thousand, and issued a total of approximately 10.7 million warrants with an exercise price of $0.23 per share and a ten-year term, representing 15% of the total number of common stock sold in the offering, to the placement agent and its designees.

In April 2023, The Company sold a total of approximately 0.5 million units for a total of approximately $0.1 million proceeds, net of offering costs, as part of a follow-on offering with the same terms as the units sold in January through March. As part of the offering, the Company issued approximately 0.5 million warrants to investors, with each such warrant having a five-year term and an exercise price of $0.50 per share. The warrants were immediately exercisable. In connection with the above, the Company paid the placement agent a total cash fee of approximately $13.8 thousand, equal to 12% of the gross proceeds of the offering, and issued a total of approximately 75.0 thousand warrants with an exercise price of $0.23 per share and a ten-year term, representing 15% of the total number of common stock sold in the offering, to the placement agent and its designees.

Based on contractual payment terms, certain of the private placement transactions above are considered convertible debt instruments prior to final settlement, and the issuance costs associated with such issuances are capitalized and subsequently amortized through the statement of operations as interest expense. During the fiscal year ended May 31, 2023, the Company recognized $9.7 million in interest expense associated with issuance costs for these private placements.

Private placement of shares of common stock and warrants

On February 13, 2023, Cyrus Arman, who was then President of the Company, entered into a private transaction with the Company in which he purchased 0.4 million units consisting of one share of common stock and one warrant to purchase one share of common stock at an exercise price of $0.50. The terms and conditions of the investment totaling $0.1 million made by Mr. Arman were identical to those offered to other investors in the concurrent offering being conducted through a placement agent as described above. The Company classified the securities issued in the private placement as equity. See Note 11, *Related Party Transactions*, for additional information.

Down round provision issuance and modification to previous private offerings and private warrant exchanges

During the fiscal year ended May 31, 2023, common stock and warrants previously issued between February and April 2022 to accredited investors directly by the Company in a private placement became subject to a down round provision under the original purchase agreements requiring the Company to reduce the purchase price of common stock from the original price of $0.40 to $0.255 per share, to increase the percentage of the warrant coverage from 50% to 75% based on the revised amount of total shares issued, and to reduce the exercise price of the warrants from the original price of $0.40 to $0.306, the terms in the financing conducted by the Company during 2022 through the placement agent as described above. As a result, an approximate additional 4.6 million shares of common stock and 5.5 million warrants were issued. The incremental fair value of the warrants was measured using the Black-Scholes pricing model, resulting in an approximately $4.2 million charge to additional paid-in capital which was accounted for as a deemed dividend, and

was included in the loss per share calculation for the year ended May 31, 2023 (refer to Note 8, *Loss per Common Share*).

During the fiscal year ended May 31, 2023, common stock previously issued in November 2022 to accredited investors directly by the Company in a private warrant exchange became subject to a down round provision under the original induced exercise agreements as a result of the transaction described below under *Private Warrant Exchanges through Placement Agent,* The required adjustments resulted in the issuance of approximately 0.5 million additional shares of common stock. The incremental fair value of the shares was measured using the share price on the date the down round provision was triggered, resulting in an approximately $0.1 million charge to additional paid-in capital which was accounted for as a deemed dividend, and was included in the loss per share calculation for the year ended May 31, 2023 (refer to Note 8, *Loss per Common Share*).

Warrants

Warrant activity is presented in the table below:

(in thousands, except for share data and years)	Number of shares	Weighted average exercise price	Weighted average remaining contractual life in years	Aggregate intrinsic value
Warrants outstanding at May 31, 2021	42,934	$ 0.68	2.89	$ 52,671
Granted	38,220	$ 0.52		
Exercised	(5,167)	$ 0.70		5,514
Forfeited, expired, and cancelled	(2,740)	$ 0.73		
Warrants outstanding at May 31, 2022	73,248	$ 0.59	3.18	$ 352
Granted	201,771	$ 0.33		
Exercised	(6,207)	$ 0.63		758
Forfeited, expired, and cancelled	(8,902)	$ 0.75		
Warrants outstanding at May 31, 2023	259,910	$ 0.37	4.57	$ 7,276
Warrants outstanding and exercisable at May 31, 2023	259,910	$ 0.37	4.57	$ 7,276

Private warrant exchanges

During the fiscal year ended May 31, 2023, the Company entered into various separate privately negotiated warrant exchange agreements directly with certain accredited investors, pursuant to which the investors exercised warrants with an original exercise price of $1.00 per share in exchange for the issuance of approximately 9.7 million shares of common stock upon exercise of the warrants, including approximately 8.4 million shares issued as an inducement for the exercises. Gross and net aggregate proceeds from the private warrant exchanges were approximately $2.1 million. In connection with these transactions, the Company recognized approximately $2.1 million as issuance costs and $0.5 million as a deemed dividend, which was included in the loss per share calculation for the year ended May 31, 2023 (refer to Note 8, *Loss per Common Share*).

Private warrant exchanges through placement agent

During the fiscal year ended May 31, 2023, the Company entered into various separate privately negotiated warrant exchange agreements with certain accredited investors through a placement agent, pursuant to which the investors exercised warrants with an original exercise price of $0.50 – $0.75 per share in exchange for the issuance of approximately 3.4 million shares of common stock upon exercise of the warrants, including approximately 0.6 million shares issued as an inducement for the exercises. Gross and net aggregate proceeds from the private warrant exchanges were approximately $0.7 million. In connection with these transactions, the Company recognized approximately $0.1 million as issuance costs.

Warrant expiration extension

During the fiscal year ended May 31, 2023, the Company extended the expiration dates of approximately 3.8 million warrants to January 31, 2023. The previous expiration dates for the warrants ranged from September 2022 to December 2022. The modification to these equity instruments resulted in an approximate $0.6 million deemed dividend recorded in equity and was included in the loss per share calculation for the year ended May 31, 2023 (refer to Note 8, *Loss per Common Share*).

Warrant exercises

During the fiscal year ended May 31, 2023, the Company issued approximately 1.8 million shares of common stock in connection with the exercise of an equal number of warrants. The stated exercise prices ranged from $0.10 to $0.75 per share, which resulted in aggregate gross proceeds of approximately $0.4 million. Additionally, during the fiscal year ended May 31, 2023, the Company issued approximately 0.1 million shares of common stock in connection with the cashless exercise of approximately 0.3 million warrants with stated exercise prices ranging from $0.26 to $0.50 per share.

Note 8. Loss per Common Share

Basic loss per share is computed by dividing the net loss adjusted for preferred stock dividends by the weighted average number of common shares outstanding during the period. Diluted loss per share would include the weighted average common shares outstanding and potentially dilutive common stock equivalents. Because of the net losses for all periods presented, the basic and diluted weighted average shares outstanding are the same, since including the additional shares would have an anti-dilutive effect on the loss per share.

The reconciliation of the numerators and denominators of the basic and diluted net loss per share computations are as follows:

	Fiscal years ended May 31,	
(in thousands, except per share amounts)	**2023**	**2022**
Net loss	$ (79,824)	$ (210,820)
Less: Deemed dividends	(5,417)	—
Less: Accrued preferred stock dividends	(1,495)	(1,628)
Net loss applicable to common stockholders	$ (86,736)	$ (212,448)
Basic and diluted:		
Weighted average common shares outstanding	836,528	676,900
Loss per share	$ (0.10)	$ (0.31)

Refer to Note 13, *Subsequent Events* for additional information regarding the shares issued subsequent to May 31, 2023.

The table below shows the numbers of shares of common stock issuable upon the exercise, vesting, or conversion of outstanding options, warrants, unvested restricted stock including those subject to performance conditions, convertible preferred stock (including undeclared dividends), and convertible notes that were not included in the computation of basic and diluted weighted average number of shares of common stock outstanding for the periods presented:

	Fiscal years ended May 31,	
(in thousands)	**2023**	**2022**
Stock options, warrants, and unvested restricted stock units	281,023	106,002
Convertible notes	12,000	12,000
Convertible preferred stock	34,071	32,535

Note 9. Income Taxes

Deferred taxes are recorded for all existing temporary differences in the Company's assets and liabilities for income tax and financial reporting purposes. As noted below, there was no net deferred tax benefit or expense for the periods ended May 31, 2023 and 2022. Reconciliation of the federal statutory income tax rate of 21% to the effective income tax rate is as follows:

	Fiscal years ended May 31,	
	2023	2022
Income tax provision at statutory rate:	21.0 %	21.0 %
Derivative loss	(2.3)	—
Non-deductible debt issuance costs	(2.6)	—
Non-deductible interest on convertible notes	(1.2)	(0.5)
Inducement interest expense	—	(0.7)
Other	0.8	1.1
Credit carry-forward released	—	(0.2)
Non-deductible loss on induced conversion	(1.4)	(3.7)
Non-deductible debt discount amortization	(0.6)	(0.3)
IRC section 162(m) limitation	—	(0.1)
Non-deductible expense on induced conversion of debt	—	(0.3)
Valuation allowance	(13.7)	(16.3)
Effective income tax rate	0.0 %	0.0 %

Net deferred tax assets and liabilities, non-current, are composed of the following:

	As of May 31,	
(in thousands)	2023	2022
Net operating loss	$ 96,338	$ 106,965
Credits	2,063	2,063
ASC 718 expense on non-qualified stock options	6,400	6,057
Charitable contribution carry forward	—	14
Accrued vacation and payroll	21	68
Right-of-use asset	(84)	(112)
Lease liability	89	117
Inventory charges	6,173	2,138
Inventory write-off	13,739	—
Issued warrants	2,317	—
Section 174 R&D costs	858	—
Accrued legal settlements	13	—
Accrued legal fees	3	—
Accrued expenses	36	89
Amortization	609	238
Fixed assets	4	1
Valuation allowance	(128,579)	(117,638)
Deferred tax asset, non-current	$ —	$ —
Non-current asset	128,579	117,638
Valuation allowance	(128,579)	(117,638)
Deferred tax asset (liability) non-current	$ —	$ —

The income tax benefit for the period presented is offset by a valuation allowance established against deferred tax assets arising from operating losses and other temporary differences, the realization of which is not considered more likely than not. In future periods, tax benefits and related tax deferred assets will be recognized when management considers realization of such amounts to be more likely than not. As of May 31, 2023 and 2022, the Company had

available net operating loss carry forwards of approximately $458.8 million and $509.4 million, respectively, which began expiring in 2023. The Company's income tax returns remain subject to examination by all tax jurisdictions for tax years ended May 31, 2020 through 2022.

Note 10. Commitments and Contingencies

Commitments with Samsung BioLogics Co., Ltd. ("Samsung")

In April 2019, the Company entered into an agreement with Samsung, pursuant to which Samsung will perform technology transfer, process validation, manufacturing, pre-approval inspection, and supply services for the commercial supply of leronlimab bulk drug substance effective through calendar year 2027. In 2020, the Company entered into an additional agreement, pursuant to which Samsung will perform technology transfer, process validation, vial filling, and storage services for clinical, pre-approval inspection, and commercial supply of leronlimab drug product. Samsung is obligated to procure necessary raw materials for the Company and manufacture a specified minimum number of batches, and the Company is required to provide a rolling three-year forecast of future estimated manufacturing requirements to Samsung that are binding.

On January 6, 2022, Samsung provided written notice to the Company alleging that the Company had materially breached the parties' Master Services and Project Specific Agreements for failure to pay $13.5 million due on December 31, 2021. An additional $22.8 million became due under the agreements on January 31, 2022. Under the agreements, Samsung may be entitled to terminate its services if the parties cannot agree on the past-due balance. Management continues to be in ongoing discussions with Samsung regarding potential approaches to resolve these issues, including proposals by both parties of a revised schedule of payments over an extended period, proposals by the Company of satisfaction of a portion of the Company's payment obligations in equity securities, through future financing, and/or potential licensing opportunities of the Company, proposals to postpone the manufacturing of unfulfilled commitments until a future regulatory approval, and proposals offsetting the unfulfilled commitments with other future potential R&D drug development needs related to the longer-acting therapeutic the Company is currently studying. Samsung paused manufacturing all unfulfilled commitments not needed by the Company starting in January of 2022. Accordingly, the Company has not recorded any accruals associated with the unfulfilled commitments as of May 31, 2023. In the event negotiations are unsuccessful, the Company may have to accrue a liability related to the unfulfilled commitments. As of May 31, 2023, the Company had past due balances of approximately $33.7 million due to Samsung, which were included in accounts payable.

As of May 31, 2023, the future commitments pursuant to these agreements are estimated as follows (in thousands):

Fiscal Year	Amount
2024	$ 156,388
2025	$ 76,400
2026 and thereafter	—
Total	$ 232,788

Distribution and Licensing

In December 2019, the Company entered into a Commercialization and License Agreement, and Supply Agreement (together the "License Agreements") with Vyera Pharmaceuticals, LLC ("Vyera") under which the Company granted Vyera an exclusive royalty-bearing license to commercialize pharmaceutical preparations containing leronlimab for treatment of HIV in the United States. The License Agreements gave Vyera the right to assign its rights and obligations under the License Agreements to an affiliate of Vyera. In October 2020, Vyera assigned the License Agreements to SevenScore Pharmaceuticals, which in turn, in December 2021, assigned them to Regnum Corp. Vyera, SevenScore and Regnum are each controlled by their parent Phoenixus AG.

The License Agreements, as assigned, provide that, pursuant to the terms and subject to the conditions set forth therein, Regnum will, at its cost, use commercially reasonable efforts to commercialize leronlimab for treatment of HIV in the United States. The Company retained the right to license leronlimab for uses in the United States for purposes other than the treatment of HIV and for any purposes outside the United States. The License Agreements obligate Regnum to pay the Company up to $85.3 million upon the achievement of certain sales and regulatory milestones.

Certain milestones are subject to reduction if not achieved within an agreed-upon timeframe. Regnum may also pay the Company additional potential milestone payments upon the regulatory approval of leronlimab for certain subsequent indications in the field. Whether a particular subsequent indication qualifies for an additional milestone payment will be determined in good faith by the parties at the time such an event occurs. In addition, during the Royalty Term, as defined in the License Agreements, but, in any event, a period of not less than 10 years following the first commercial sale under the License Agreements, Regnum is obligated to pay the Company a royalty equal to 50% of Regnum's net sales from product sales. The royalty is subject to reduction during the Royalty Term after patent expiry and expiry of regulatory exclusivity. Following expiration of the Royalty Term, Regnum has non-exclusive rights to commercialize the product. Regnum has the right to terminate the License Agreements (i) upon written notice to the Company on or after December 19, 2021 and prior to the Company's receipt of approval from the FDA of the BLA for the manufacture and sale of leronlimab for HIV, (ii) if Regnum fails to achieve certain aggregate Net Sales (as defined in the License Agreements) of leronlimab during the period beginning on the date of first commercial sale and ending on the date that is two years from the date of the first commercial sale, and (iii) with 180 days' prior written notice, at Regnum's convenience following the second anniversary of the first commercial sale of leronlimab.

PRO 140 Acquisition and Licensing Arrangements

We originally acquired leronlimab, as well as certain other related assets, including the existing inventory of PRO 140 bulk drug substance, intellectual property, and FDA regulatory filings, pursuant to an Asset Purchase Agreement, dated as of July 25, 2012, and effective October 16, 2012 (the "Progenics Purchase Agreement"), between CytoDyn and Progenics. Pursuant to the Progenics Purchase Agreement, we are required to pay Progenics a milestone payment and royalties as follows: (i) $5,000,000 at the time of the first U.S. new drug application approval by the FDA or other non-U.S. approval for the sale of leronlimab; and (ii) royalty payments of up to 5% on net sales during the period beginning on the date of the first commercial sale of leronlimab until the later of (a) the expiration of the last to expire patent included in the acquired assets, and (b) 10 years, in each case determined on a country-by-country basis. To the extent that such remaining milestone payment and royalties are not timely made, under the terms of the Progenics Purchase Agreement, Progenics has certain repurchase rights relating to the assets sold to us thereunder.

Payments to Progenics are in addition to payments due under a Development and License Agreement, dated April 30, 1999 (the "PDL License"), between Protein Design Labs (now AbbVie Inc.) and Progenics, which was assigned to us in the Progenics Purchase Agreement, pursuant to which we have an exclusive worldwide license to develop, make, have made, import, use, sell, offer to sell, or have sold products that incorporate the humanized form of the leronlimab antibody developed under the agreement. Pursuant to the PDL License, we are required to pay AbbVie Inc. milestone payments and royalties as follows: (i) $500,000 upon filing a Biologic License Application with the FDA or non-U.S. equivalent regulatory body; (ii) $500,000 upon FDA approval or approval by another non-U.S. equivalent regulatory body; and (iii) royalties of up to 3.5% of net sales for the longer of 10 years and the date of expiration of the last to expire licensed patent. Additionally, the PDL License provides for an annual maintenance fee of $150,000 until royalties paid exceed that amount. To the extent that such remaining milestone payments and royalties are not timely made, under the terms of the PDL License, AbbVie Inc. has certain termination rights relating to our license of leronlimab thereunder.

Effective July 29, 2015, we entered into a License Agreement (the "Lonza Agreement") with Lonza Sales AG ("Lonza") covering Lonza's "system know-how" technology with respect to our use of proprietary cell lines to manufacture new leronlimab material. The Lonza Agreement provides for an annual license fee and future royalty payments, both of which varies based on whether Lonza, or we or our strategic partner manufactures leronlimab. We currently use two independent parties as contract manufacturers for leronlimab, but are currently in the process of reviewing this arrangement. Should the arrangement continue as-is, an annual license fee of £0.6 million (approximately $0.7 million given current exchange rate) would continue to apply, as well as a royalty, up to 2% of the net selling price upon commercialization of leronlimab, excluding value added taxes and similar amounts.

Operating Leases

We lease our principal office location in Vancouver, Washington (the "Vancouver Lease"). The Vancouver Lease expires on April 30, 2026. Consistent with the guidance in ASC 842, Leases, we have recorded this lease in our consolidated balance sheet as an operating lease. For the purpose of determining the right of use asset and associated lease liability, we determined that the renewal of the Vancouver lease was not reasonably probable. The lease does not

include any restrictions or covenants requiring special treatment under ASC 842, Leases. Operating lease costs for the fiscal years ended May 31, 2023 and 2022 were approximately $0.2 million and $0.2 million, respectively. Operating lease right-of-use assets are included in other non-current assets and the current portion of operating lease liabilities are included in accrued liabilities and compensation on the consolidated balance sheets. The long-term operating lease liabilities are presented separately as operating leases on the consolidated balance sheets. The following table summarizes the operating lease balances.

(in thousands)	May 31, 2023	May 31, 2022
Assets		
Right-of-use asset	$ 400	$ 536
Liabilities		
Current operating lease liability	$ 139	$ 134
Non-current operating lease liability	283	422
Total operating lease liability	$ 422	$ 556

The minimum (base rental) lease payments reconciled to the carrying value of the operating lease liabilities as of May 31, 2023 are expected to be as follows (in thousands):

Fiscal Year	Amount
2024	$ 182
2025	185
2026	169
Total operating lease payments	536
Less: imputed interest	(114)
Present value of operating lease liabilities	$ 422

Supplemental information related to the operating leases was as follows:

	May 31, 2023
Weighted average remaining lease term	2.9 years
Weighted average discount rate	10.0 %

Legal Proceedings

The Company is a party to various legal proceedings. The Company recognizes accruals for such proceedings to the extent a loss is determined to be both probable and reasonably estimable. The best estimate of a loss within a possible range is accrued; however, if no estimate in the range is more probable than another, then the minimum amount in the range is accrued. If it is determined that a material loss is not probable but reasonably possible and the loss or range of loss can be estimated, the possible loss is disclosed. It is not possible to determine the outcome of proceedings that have not been concluded, including the defense and other litigation-related costs and expenses that may be incurred by the Company, as the outcomes of legal proceedings are inherently uncertain, and the outcomes could differ significantly from recognized accruals. Therefore, it is possible that the ultimate outcome of any proceeding, if in excess of a recognized accrual, or if an accrual had not been made, could be material to the Company's consolidated financial statements.

Securities Class Action Lawsuits

On March 17, 2021, a stockholder filed a putative class-action lawsuit (the "March 17, 2021 lawsuit") in the U.S. District Court for the Western District of Washington against the Company and certain former officers. The complaint generally alleges the defendants made false and misleading statements regarding the viability of leronlimab as a potential treatment for COVID-19. On April 9, 2021, a second stockholder filed a similar putative class action lawsuit in the same court, which the plaintiff voluntarily dismissed without prejudice on July 23, 2021. On August 9, 2021, the court appointed lead plaintiffs for the March 17, 2021 lawsuit. On December 21, 2021, lead plaintiffs filed an amended

complaint, which is brought on behalf of an alleged class of those who purchased the Company's common stock between March 27, 2020 and May 17, 2021. The amended complaint generally alleges that the defendants violated Sections 10(b) and/or 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder by making purportedly false or misleading statements concerning, among other things, the safety and efficacy of leronlimab as a potential treatment for COVID-19, the Company's CD10 and CD12 clinical trials, and its HIV BLA. The amended complaint also alleges that the individual defendants violated Section 20A of the Exchange Act by selling shares of the Company's common stock purportedly while in possession of material nonpublic information. The amended complaint seeks, among other relief, a ruling that the case may proceed as a class action and unspecified damages and attorneys' fees and costs. On February 25, 2022, the defendants filed a motion to dismiss the amended complaint. On June 24, 2022, lead plaintiffs filed a second amended complaint. The second amended complaint is brought on behalf of an alleged class of those who purchased the Company's common stock between March 27, 2020 and March 30, 2022, makes similar allegations, names the same defendants, and asserts the same claims as the prior complaint, adds a claim for alleged violation of Section 10(b) of the Exchange Act and Rule 10b-5(a) and (c) promulgated thereunder, and seeks the same relief as the prior complaint. All defendants have filed motions to dismiss the second amended complaint in whole or in part. The Company and the individual defendants deny all allegations of wrongdoing in the complaint and intend to vigorously defend the matter. Since this case is in an early stage where the number of plaintiffs is not known, and the claims do not specify an amount of damages, the Company is unable to predict the ultimate outcome of the lawsuit and cannot reasonably estimate the potential loss or range of loss the Company may incur.

2021 Shareholder Derivative Lawsuits

On June 4, 2021, a stockholder filed a purported derivative lawsuit against certain of the Company's former officers and directors, and the Company as a nominal defendant, in the U.S. District Court for the Western District of Washington. Two additional shareholder derivative lawsuits were filed against the same defendants in the same court on June 25, 2021 and August 18, 2021, respectively. The court has consolidated these three lawsuits for all purposes ("Consolidated Derivative Suit"). On January 20, 2022, the plaintiffs filed a consolidated complaint. The consolidated complaint generally alleges that the director defendants breached their fiduciary duties by allowing the Company to make false and misleading statements regarding, among other things, the safety and efficacy of leronlimab as a potential treatment for COVID-19, the Company's CD10 and CD12 clinical trials, and its HIV BLA, and by failing to maintain an adequate system of oversight and controls. The consolidated complaint also asserts claims against one or more individual defendants for waste of corporate assets, unjust enrichment, contribution for alleged violations of the federal securities laws, and for breach of fiduciary duty arising from alleged insider trading. The consolidated complaint seeks declaratory and equitable relief, an unspecified amount of damages, and attorneys' fees and costs. The Company and the individual defendants deny all allegations of wrongdoing in the complaints and intend to vigorously defend the litigation. In light of the fact that the Consolidated Derivative Suit is in an early stage and the claims do not specify an amount of damages, the Company cannot predict the ultimate outcome of the Consolidated Derivative Suit and cannot reasonably estimate the potential loss or range of loss the Company may incur.

Securities and Exchange Commission and Department of Justice Investigations

The Company has received subpoenas from the United States Securities and Exchange Commission ("SEC") and the United States Department of Justice ("DOJ") requesting documents and information concerning, among other matters, leronlimab, the Company's public statements regarding the use of leronlimab as a potential treatment for COVID-19, HIV, and triple-negative breast cancer, related communications with the FDA, investors, and others, litigation involving former employees, the Company's retention of investor relations consultants, and trading in the Company's securities. Certain former Company executives and directors have received subpoenas concerning similar issues and have been interviewed by the DOJ and SEC, including the Company's former CEO, Nader Z. Pourhassan.

On January 24, 2022, Mr. Pourhassan was terminated and removed from the Board of Directors and has had no role at the Company since. On December 20, 2022, the DOJ announced the unsealing of a criminal indictment charging both Mr. Pourhassan, and Kazem Kazempour, CEO of Amarex, a subsidiary of NSF International, Inc., and which had formerly served as the Company's CRO. Mr. Pourhassan was charged with one count of conspiracy, four counts of securities fraud, three counts of wire fraud, and three counts of insider trading. Mr. Kazempour was charged with one count of conspiracy, three counts of securities fraud, two counts of wire fraud, and one count of making a false statement. That same day, the SEC announced charges against both Mr. Pourhassan and Mr. Kazempour for alleged violations of federal securities laws.

The Company is committed to cooperating fully with the DOJ and SEC investigations, which are ongoing, and which the Company's counsel frequently engages with them on. Further, the Company has made voluminous productions of information and made witnesses available for voluntary interviews. The Company will continue to comply with the requests of the SEC and DOJ. The Company cannot predict the ultimate outcome of the DOJ and SEC investigations or the case against Mr. Pourhassan, nor can it predict whether any other governmental authorities will initiate separate investigations or litigation. The investigations and any related legal and administrative proceedings could include a wide variety of outcomes, including the institution of administrative, civil injunctive, or criminal proceedings involving the Company and/or former executives and/or former directors in addition to Mr. Pourhassan, the imposition of fines and other penalties, remedies and/or sanctions, modifications to business practices and compliance programs, and/or referral to other governmental agencies for other appropriate actions. It is not possible to accurately predict at this time when matters relating to the investigations will be completed, the final outcome of the investigations, what additional actions, if any, may be taken by the DOJ or SEC or by other governmental agencies, or the effect that such actions may have on our business, prospects, operating results and financial condition, which could be material.

The DOJ and SEC investigations, including any matters identified in the investigations and indictments, could also result in (1) third-party claims against the Company, which may include the assertion of claims for monetary damages, including but not limited to interest, fees, and expenses, (2) damage to the Company's business or reputation, (3) loss of, or adverse effect on, cash flow, assets, results of operations, business, prospects, profits, or business value, including the possibility of certain of the Company's existing contracts being cancelled, (4) adverse consequences on the Company's ability to obtain or continue financing for current or future projects, and/or (5) claims by directors, officers, employees, affiliates, advisors, attorneys, agents, debt holders or other interest holders, or constituents of the Company or its subsidiaries, any of which could have a material adverse effect on the Company's business, prospects, operating results, and financial condition. Further, to the extent that these investigations and any resulting third-party claims yield adverse results over time, such results could jeopardize the Company's operations, exhaust its cash reserves, and could cause stockholders to lose their entire investment.

Amarex Dispute

On October 4, 2021, the Company filed a complaint for declaratory and injunctive relief and a motion for a preliminary injunction against NSF International, Inc. and its subsidiary Amarex, the Company's former CRO. Over the past eight years, Amarex provided clinical trial management services to the Company and managed numerous clinical studies of the Company's drug product candidate, leronlimab. On December 16, 2021, the U.S. District Court for the District of Maryland issued a preliminary injunction requiring Amarex to provide the Company with access to all of its materials in the possession of Amarex. The court also granted CytoDyn the right to conduct an audit of Amarex's work for CytoDyn. That case has been administratively closed. The Company simultaneously filed a demand for arbitration with the American Arbitration Association. In response, Amarex filed a counterclaim alleging that CytoDyn has failed to pay certain invoices due under the contract between the parties.

On July 10, 2023, the Company filed a Statement of Particulars and requested a final hearing date be set in the proceeding against Amarex. The Statement of Particulars alleges that Amarex failed to perform services to an acceptable professional standard and failed to perform certain services required by the parties' agreements. Further, the Statement of Particulars alleges that Amarex billed the Company for services it did not perform. The Company contends that, due to Amarex's failures, it has suffered avoidable delays in obtaining regulatory approval of leronlimab and has paid for services not performed, among other damages. As the formal arbitration process is still at an early stage, the Company cannot predict the ultimate outcome of the lawsuit and cannot reasonably estimate the potential loss or range of loss that the Company may incur.

Following a formal scheduling request by the Company, the final arbitration hearing was recently ordered to commence on August 19, 2024, and the parties will now proceed into the discovery phase of the litigation.

Note 11. Related Party Transactions

The Board's Audit Committee and the Board of Directors review and approve all related party transactions. The terms and amounts described below are not necessarily indicative of the terms and amounts that could have been incurred had comparable transactions been entered into with independent parties.

On February 13, 2023, Cyrus Arman, then the Company's President, entered into a private placement with the Company in which he purchased approximately 0.4 million units consisting of one share of common stock and one warrant to purchase one share of common stock at an exercise price of $0.50. The terms and conditions of the investment totaling $0.1 million made by Mr. Arman were identical to those offered to other investors in a concurrent offering being conducted through a placement agent.

In 2021, the Company engaged the Center for Advanced Research & Education, LLC ("CARE"), owned by Dr. Christopher Recknor's spouse, Julie Recknor, Ph.D., (and owned by Dr. Christopher Recknor, then the Company's Chief Operating Officer, until March 11, 2021). CARE was one of several clinical locations for the Company's NASH COVID-19 long-hauler clinical trials, and mild-to-moderate and severe-to-critical COVID-19 clinical trials. Dr. Julie Recknor serves as the Site Director of CARE and manages its day-to-day operations. The Company entered into a Clinical Trial Agreement ("CTA") with CARE for each of the foregoing clinical trials. Each CTA was negotiated in the ordinary course of business by Amarex, then Company's clinical research organization, prior to Dr. Christopher Recknor's appointment as COO, and the operational and financial terms of the CTAs with CARE are comparable to the terms available to unrelated clinical locations. Dr. Christopher Recknor was not involved in the Company's decision to choose CARE as a clinical location for its ongoing trials, and he is not involved in patient treatment at the CARE site. In July 2021, the Company entered into an amendment to the previously approved CTA with CARE, wherein such amendment provided for the additional recording of patient information thus giving rise to the additional contract value of less than $0.1 million. The Company made payments of approximately $0.2 million and $1.7 million to CARE during the fiscal years ended May 31, 2023 and May 31, 2022.

In September 2021, Jordan G. Naydenov, a then member of the Board, entered into a private warrant exchange in which he exercised warrants to purchase approximately 0.6 million shares of common stock, as well as approximately 0.6 million additional shares that were offered as an inducement to exercise his warrants, for a total of approximately 1.3 million shares of common stock. The terms and conditions of the investment totaling $0.7 million made by Mr. Naydenov were identical to those offered to other investors.

Note 12. Employee Benefit Plan

The Company has an employee savings plan (the "401(k) Plan"), organized under Section 401(k) of the Internal Revenue Code (the "Code"), covering all employees. The Company makes a qualified non-elective contribution of 3%, which vests immediately. In addition, participants in the 401(k) Plan may contribute a percentage of their compensation, but not greater than the maximum allowed under the Code. During each of the years ended May 31, 2023 and 2022, the Company incurred an expense of approximately $0.1 million for qualified non-elective contributions.

Note 13. Subsequent Events

Issuance and Amendment of Placement Agent Notes

In June 2023, the Company entered into a securities purchase agreements pursuant to which the Company issued Placement Agent Notes with an 18-month term to accredited investors in the aggregate principal amount of approximately $1.3 million through a placement agent. The Company also issued warrants to purchase approximately 1.3 million shares of common stock with a three-year term and an exercise price of $0.50 as part of the debt issuance. The Company also issued warrants to purchase approximately 0.4 million shares of common stock to the placement agent with a ten-year term. The exercise price for the warrants issued to the placement agent was determined to be $0.26 per share, based on the intraday volume weighted average price of the Company's stock on June 23, 2023. The net proceeds of approximately $1.2 million reflect issuance costs of approximately $0.1 million.

Amendment to Placement Agent Notes

During June 2023, an amendment was entered into with the investors of the Placement Agent Notes, which stated that the principal amount and interest on the secured promissory notes would be converted to equity on the first close of the subsequent private placement of common stock and warrants through a placement agent. The units purchased have the same terms of the offering except for the exercise price of the warrants which would be set at $0.306 per share as opposed to $0.50 per share.

Private placement of common stock and warrants through placement agent

In July 2023, the Company commenced a private placement of units consisting of common stock and warrants to accredited investors through a placement agent. Each unit sold included a fixed combination of one share of common stock and one warrant to purchase one share of common stock. Each unit has a purchase price of $0.20, which was equal to 90% of the closing price of the common stock on July 31, 2023. During July and August 2023, the Company sold a total of approximately 14.7 million units for a total of approximately $2.6 million of proceeds, net of issuance costs and converted approximately $2.3 million principal and interest of the Placement Agent Notes to approximately 11.5 million units. The Company classified the securities issued in the private placement through placement agent as equity. As part of the offering, the Company will issue approximately 14.7 million warrants to investors, with each such warrant having a five-year term and an exercise price of $0.50 per share. The Company will also issue 11.5 million warrants to holders of the Placement Agent Notes having a five-year term and an exercise price of $0.306 per share. The warrants were immediately exercisable. In connection with the above, the Company paid the placement agent a total cash fee of approximately $0.4 million, equal to 12% of the gross proceeds of the offering, as well as a one-time fee for expenses of $5.0 thousand, and will issue a total of approximately 2.2 million warrants with an exercise price of $0.20 per share and a ten-year term, representing 15% of the total number of common stock sold in the offering, to the placement agent and its designees.

Induced Note conversions

During July and August 2023, in satisfaction of redemptions, the Company and the April 2, 2021 Noteholder entered into exchange agreements, pursuant to which a portion of the April 2, 2021 Note was partitioned into new notes with an aggregate principal amount of $1.5 million, which were exchanged concurrently with the issuance of approximately 8.7 million shares of common stock.

Form 12b-25

On August 30, 2023, the Company filed Form 12b-25 due to the Company's inability to file timely, without unreasonable effort and expense, its Annual Report on Form 10-K for the fiscal year ended May 31, 2023, because additional time was required before issuing the Company's financial statements for the fiscal year ended May 31, 2023, to evaluate the implications of an Order released by the Public Company Accounting Oversight Board (the "PCAOB") on August 29, 2023, shortly before the Company's filing deadline. The Company was subsequently able to determine that there was no substantive effect on the Company's financial statements, including its fiscal year end 2023 financials.

Item 9. Changes In and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934 (the "Exchange Act") is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our Principal Executive Officer, who is also our Principal Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Our management, with the participation of our Principal Executive Officer, who is also our Principal Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of May 31, 2023. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our Principal Executive Officer, who is also our Principal Financial Officer, has concluded, based upon the evaluation described above, that as of May 31, 2023, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act as the process designed by, or under the supervision of, our Principal Executive Officer, who is also our Principal Financial Officer, and effected by the Company's board of directors, management, and other personnel, to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of our financial statements for external purposes in accordance with generally accepted accounting principles ("GAAP"), and includes those policies and procedures that:

(i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the acquisition and disposition of assets;

(ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that our receipts and expenditures of the Company's assets are being made only in accordance with authorizations of management and the board of directors or a committee thereof as required; and

(iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of assets that could have a material effect on the financial statements.

Under the supervision and with the participation of our management, including our Principal Executive Officer, who is also our Principal Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework provided in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of May 31, 2023.

Remediation of Prior Year Material Weaknesses

A "material weakness" is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. The remediation steps described below were designed to address the material weaknesses previously identified by management and strengthen our internal control over financial reporting. As a result of these actions, management believes that the material weaknesses previously identified and described below have been fully remediated as of May 31, 2023.

Remediation of Material Weakness Related to Information Technology General Controls

As of May 31, 2022, management identified a material weakness in the design and operating effectiveness of information technology general controls ("ITGCs"), specifically user access, change management, and computer operations. Additionally, management did not fully document controls to respond to the Complementary User Entity Controls assumed in the design and implementation of third-party service organizations' controls.

During fiscal year 2023, management designed and implemented new controls to address the control deficiencies that led to this material weakness. Specifically, management undertook the following remediation activities:

- **Comprehensive Risk Assessment:** Conducted a thorough risk assessment of the IT environment, specifically focusing on systems that support the Company's financial reporting processes.
- **Redesign of IT General Controls:** Based on the risk assessment, the Company completely redesigned its ITGCs, with specific attention to user access controls, program change management controls, and operational controls.
- **Documentation of Controls:** Created detailed and comprehensive documentation for all ITGCs, clearly defining the purpose, design, implementation steps, and testing procedures for each control.
- **Response to Complementary User Entity Controls:** Established specific controls to respond to the Complementary User Entity Controls assumed in the design and implementation of third-party service organizations' controls.

- **Regular Monitoring and Testing:** Implemented a continuous monitoring program to regularly test the effectiveness of the ITGCs and make necessary adjustments based on the test results.
- **Engagement of IT Control Specialists:** Hired or engaged third-party IT control specialists to assist in the design, implementation, and testing of the ITGCs.

Remediation of Material Weakness Related to Complex Accounting Treatment

As of November 30, 2021, management identified a material weakness resulting from the failure to identify errors related to the evaluation of complex accounting issues and alternative accounting treatments with respect to certain equity transactions, together with an insufficient number of financial reporting and accounting personnel with the knowledge, experience, or training appropriate to address the Company's financial reporting requirements.

To address the material weakness related to the failure to identify errors in the evaluation of complex accounting issues for which alternative accounting treatments existed, the Company undertook the following remediation actions:

- **Engagement of External Experts:** As necessary, engaged external accounting consultants or advisors to provide expert advice on complex accounting issues and assist with the evaluation of alternative accounting treatments, adding an additional layer of expertise.
- **Addition of Skilled Personnel and Ongoing Training:** Hired personnel with appropriate skills and experience to strengthen internal control over financial reporting, specifically in the areas of internal controls, technical accounting, and financial reporting, as well as providing extensive and ongoing training for existing financial reporting and accounting personnel focused on the Company's specific financial reporting requirements and the proper evaluation and documentation of complex accounting issues.
- **Enhanced Review Procedures:** Implemented stringent review procedures for all equity transactions to ensure that alternative accounting treatments are rigorously considered and properly evaluated, with comprehensive documentation of the rationale for the chosen treatment.

Changes in Internal Control Over Financial Reporting

Other than as described above, during the quarter ended May 31, 2023, there were no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Exchange Act, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Attestation Report of the Registered Public Accounting Firm

This annual report does not include an attestation report by our registered public accounting firm of management's report regarding internal control over financial reporting pursuant to SEC rules that permit us to provide only management's report in this annual report.

Item 9B. Other Information

None.

Part III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by Item 10 will be contained in, and is incorporated herein by reference to, our definitive proxy statement for our 2023 Annual Meeting of Stockholders under the captions *Proposal 1: Election of Directors, Information about our Executive Officers,* and *Delinquent Section 16(a) Reports*, to be filed with the SEC within 120 days of the end of the Company's fiscal year May 31, 2023 (the "2023 Proxy Statement").

We have adopted a code of ethics and business conduct that applies to all of our directors, officers, and employees, including our principal executive officer (currently our Interim President), principal financial officer, and principal accounting officer (our Chief Financial Officer), and senior financial officers, or persons performing similar functions. We make our code of ethics and business conduct available free of charge on our website at www.cytodyn.com.

The Board of Directors has determined that Ryan C. Dunlap, who is chair of the Board's Audit Committee, is an "audit committee financial expert" as defined in Regulation S-K Item 407(d)(5)(ii) adopted by the SEC.

Item 11. Executive Compensation.

The information required by Item 11 relating to executive compensation will be contained in, and is incorporated herein by reference to, our 2023 Proxy Statement under the captions *Executive Compensation* (excluding *Pay versus Performance*) and *Director Compensation*.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by Item 12 relating to security ownership of certain beneficial owners and management and related stockholders' matters will be contained in, and is incorporated herein by reference to, our 2023 Proxy Statement under the captions *Stock Ownership by Principal Stockholders, Directors and Executive Officers* and *Equity Compensation Plan Information*.

Item 13. Certain Relationships and Related Transactions and Director Independence.

The information required by Item 13 relating to certain relationships and related transactions and director independence will be contained in, and is incorporated herein by reference, to our 2023 Proxy Statement under the captions *Related Person Transactions* and *Director Independence*.

Item 14. Principal Accountant Fees and Services.

The information required by Item 14 relating to principal accountant fees and services will be contained in, and is incorporated herein by reference to, our 2023 Proxy Statement under the caption *Matters Relating to the Company's Independent Registered Public Accounting Firm*.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) The following documents are filed as part of this Annual Report on Form 10-K:

(1) Consolidated Financial Statements

The consolidated financial statements for the fiscal years ended May 31, 2023 and 2022 are included under Part II, Item 8 of this report.

(2) Financial Statement Schedules:

All schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

(3) Exhibits

Exhibit No	Description	Filed Herewith	Incorporated by Reference Form	Exhibit No.	Filing Date
2.1	Asset Purchase Agreement, dated as of July 25, 2012, between CytoDyn Inc. and Progenics Pharmaceuticals, Inc		8-K	10.1	7/30/2012
3.1	Amended and Restated Certificate of Incorporation, as amended through August 31, 2022		10-Q	3.1	10/11/2022
3.2	Amended and Restated Bylaws of CytoDyn Inc.		8-K12G3	3.2	11/19/2018
4.1	Description of the Registrant's Capital Stock	X			
4.2	Form of Common Stock Certificate		8-K12G3	4.1	9/1/2015
4.3	Form of Warrant Agreement (Private Offerings)		8-K	4.1	9/4/2018
4.4	Form of Warrant Agreement (Registered Offerings)		8-K	4.1	4/5/2019
4.5	Form of Warrant Agreement (Series C Convertible Preferred Stock Offering)		8-K	4.1	4/20/2019
4.6	Form of Warrant Agreement (Series C Convertible Preferred Stock Offering)		8-K	4.1	10/22/2019
4.7	Form of Warrant Agreement (Series D Convertible Preferred Stock Offering)		8-K	4.1	2/3/2020
4.8	Form of Warrant to Purchase Common Stock (December 2018 Convertible Note Offering)		8-K	4.2	1/3/2019
4.9	Form of Warrant to Purchase Common Stock		8-K	4.1	1/31/2019
4.10	Form of Common Stock Purchase Warrant		8-K	4.1	8/29/2019
4.11	Form of Common Stock Purchase Warrant		8-K	4.1	12/27/2019
4.12	Warrant to Purchase Common Stock by and between CytoDyn Inc. and Iliad Research and Trading, L.P.		8-K	4.2	1/31/2019
4.13	Secured Convertible Promissory Note between CytoDyn Inc. and Streeterville Capital, LLC, dated April 2, 2021		8-K	4.1	4/8/2021

4.14	Secured Convertible Promissory Note between CytoDyn Inc. and Uptown Capital, LLC, dated April 23, 2021		8-K	4.1	4/29/2021
4.15	Form of Warrant		8-K	4.1	9/7/2021
4.16	Initial Warrant Issued under Surety Bond Backstop Agreement		8-K	4.1	2/17/2022
4.17	Make-Whole Warrant Issued under Surety Bond Backstop Agreement		8-K	4.2	2/17/2022
4.18	Warrant Issued to Richard G. Pestell		10-K	4.22	8/15/2022
4.19	Initial Warrant Issued under Surety Bond Backstop Extension	X			
4.20	Subsequent Warrant Issued under Surety Bond Backstop Extension	X			
10.1	Development and License Agreement between Protein Design Labs, Inc. (to which AbbVie Biotherapeutics Inc. is successor in interest) and Progenics Pharmaceuticals, Inc. (to which CytoDyn Inc. is successor in interest) effective as of April 30, 1999, as amended by letter agreement dated November 24, 2003		10-K	10.21	8/29/2013
10.2	License Agreement between CytoDyn Inc. and Lonza Sales AG dated July 29, 2015		8-K/A	10.1	8/19/2015
10.3#	Commercialization and License Agreement between CytoDyn Inc. and Vyera Pharmaceuticals, LLC, dated December 17, 2019		10-Q	10.5	1/9/2020
10.4#	Product Specific Agreement between CytoDyn Inc. and Samsung BioLogics Co., Ltd, dated April 1, 2019		10-K	10.12	8/14/2019
10.5#	Supply Agreement between CytoDyn Inc. and Vyera Pharmaceuticals, LLC, dated December 17, 2019		10-Q	10.6	1/9/2020
10.6	Development and Manufacturing Services Agreement, dated as of November 9, 2016, by and between CytoDyn Inc. and CMC ICOS Biologics, Inc.		10-Q	10.4	4/13/2017
10.7	Work Statement No. 01, dated as of November 9, 2016, by and between CytoDyn Inc. and CMC ICOS Biologics, Inc.		10-Q	10.5	4/13/2017

10.8#	Master Services Agreement between CytoDyn Inc. and Samsung BioLogics Co., Ltd, dated April 1, 2019		10-K	10.11	8/14/2019
10.9	Form of Indemnification Agreement		10-Q	10.2	10/9/2018
10.10	Security Agreement between CytoDyn Inc. and Streeterville Capital, LLC, dated April 2, 2021		8-K	10.2	4/8/2021
10.11	Security Agreement between CytoDyn Inc. and Uptown Capital, LLC, dated April 23, 2021		8-K	10.2	4/29/2021
10.12*	CytoDyn Inc. Amended and Restated 2012 Equity Incentive Plan (the "2012 Plan")		10-Q	10.4	1/9/2023
10.13*	Form of Stock Option Award Agreement for Executive Employees under the 2012 Plan		10-K	10.43	8/14/2020
10.14*	Form of Stock Option Award Agreement for Non-Employee Directors under the 2012 Plan		10-K	10.9	8/29/2013
10.15*	Employment Agreement between CytoDyn Inc. and Antonio Migliarese, effective May 18, 2021		10-Q	10.3	10/12/2021
21	Subsidiaries of the Registrant	X			
23	Consent of Macias Gini & O'Connell LLP	X			
31.1	Certification of Principal Executive Officer under Rule 13a-14(a)	X			
31.2	Certification of Chief Financial Officer under Rule 13a-14(a)	X			
32	Certification of Principal Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350	X			
101.INS	Inline XBRL Instance Document	X			
101.SCH	Inline XBRL Taxonomy Extension Schema Document	X			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	X			
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	X			

101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	X

Certain confidential portions of this Exhibit were omitted by means of marking such portions with asterisks because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

* Management contract, compensatory plan or arrangement

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

Date: September 13, 2023

CYTODYN INC.
(Registrant)

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated on September 13, 2023.

Principal Executive Officer:

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

Principal Financial and Accounting Officer:

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

Directors

/s/ Tanya Durkee Urbach
Tanya Durkee Urbach, Chair

/s/ Lishomwa C. Ndhlovu
Lishomwa C. Ndhlovu, M.D., Ph.D.

/s/ Karen J. Brunke
Karen J. Brunke, Ph.D.

/s/ Ryan M. Dunlap
Ryan M. Dunlap

/s/ Stephen M. Simes
Stephen M. Simes

Exhibit 4.1

DESCRIPTION OF THE REGISTRANT'S CAPITAL STOCK

General

CytoDyn, Inc. (the "Company" or "we") is authorized to issue up to 1,355,000,000 shares of capital stock, including 1,350,000,000 shares of common stock, par value $0.001 per share, and 5,000,000 shares of preferred stock, par value $0.001 per share. As of August 31, 2023, we had 930,960,097 shares of common stock, 19,000 shares of Series B Convertible Preferred Stock ("Series B Preferred Stock"), 6,335 shares of Series C Convertible Preferred Stock ("Series C Preferred Stock") and 8,452 shares of Series D Convertible Preferred Stock ("Series D Preferred Stock") issued and outstanding.

The additional shares of our authorized stock available for issuance may be issued at times and under circumstances so as to have a dilutive effect on earnings per share and on the equity ownership of the holders of our common stock. The ability of our Board of Directors (the "Board") to issue additional shares of stock could enhance the Board's ability to negotiate on behalf of the stockholders in a takeover situation but could also be used by the Board to make a change-in-control more difficult, thereby denying stockholders the potential to sell their shares at a premium and entrenching current management. The following description is a summary of the material provisions of our capital stock, and is qualified by reference to our amended and restated certificate of incorporation, as amended (the "Certificate of Incorporation"), and amended and restated by-laws, which are incorporated by reference in our Annual Report on Form 10-K for the fiscal year ended May 31, 2023 as Exhibits 3.1 and 3.2, respectively. The summary below is qualified by provisions of applicable law.

Common Stock

Each outstanding share of common stock entitles the holder to one vote, either in person or by proxy, on all matters submitted to a vote of stockholders, including the election of directors. There is no cumulative voting in the election of directors. All actions required or permitted to be taken by stockholders at an annual or special meeting of the stockholders must be effected at a duly called meeting, with a quorum present of a majority in voting power of the shares entitled to vote thereon. Special meetings of the stockholders may only be called by our Board acting pursuant to a resolution approved by the affirmative majority of the entire Board. Subject to the rights, if any, of any series of preferred stock to elect directors and to remove any director whom the holders of any such stock have the right to elect, any director (including persons elected by directors to fill vacancies in the Board) may be removed from office, with or without cause, only by the affirmative vote of the holders of at least a majority in voting power of the shares then entitled to vote at an election of directors. Other than with respect to actions permitted to be voted on by holders of preferred stock voting separately as a class or series, stockholders may not take action by written consent.

Subject to preferences which may be applicable to any outstanding shares of preferred stock from time to time, holders of our common stock have equal ratable rights to such dividends as may be declared from time to time by our Board out of funds legally available therefor. In the event of any liquidation, dissolution or winding-up of our affairs, holders of common stock will be entitled to share ratably in our remaining assets after provision for payment of amounts owed to creditors and preferences applicable to any outstanding shares of preferred stock. All outstanding shares of common stock are fully paid and nonassessable. Holders of common stock do not have preemptive rights.

The rights, preferences and privileges of holders of common stock are subject to the rights of the holders of any outstanding shares of preferred stock. As more fully described in our Certificate of Incorporation, holders of our

common stock are not entitled to vote on certain amendments to the Certificate of Incorporation related solely to our preferred stock.

Our common stock is presently quoted on the OTCQB of the OTC Markets marketplace under the trading symbol CYDY. Our transfer agent and registrar is Computershare Shareholder Services.

Preferred Stock

Our Board is authorized to issue up to 5 million shares of preferred stock, par value $0.001 per share, in one or more series, approximately 4.6 million of which shares are undesignated. Our Board has the authority, within the limitations and restrictions prescribed by law and without stockholder approval, to provide by resolution for the issuance of shares of preferred stock, and to fix the rights, preferences, privileges and restrictions thereof, including dividend rights, conversion rights, voting rights, terms of redemption, liquidation preference and the number of shares constituting any series of the designation of such series, by delivering an appropriate certificate of amendment to our Certificate of Incorporation to the Delaware Secretary of State pursuant to the Delaware General Corporation Law (the "DGCL"). The issuance of preferred stock could have the effect of decreasing the market price of the common stock, impeding or delaying a possible takeover and adversely affecting the voting and other rights of the holders of our common stock.

The designation of terms of a specific series of preferred stock will include:

- the title and stated value;
- the number of shares in the series and the liquidation preference per share;
- the dividend rate(s), period(s) and/or payment date(s), or method(s) of calculation for dividends, if any;
- whether dividends will be cumulative or non-cumulative and, if cumulative, the date from which dividends will accumulate;
- the provisions for a sinking fund, if any;
- the provisions for redemption, if applicable;
- whether the preferred stock will be convertible into our common stock, and, if applicable, the conversion price (or how it will be calculated) and conversion period;
- whether the preferred stock will be exchangeable into debt securities, and, if applicable, the exchange price (or how it will be calculated) and exchange period;
- voting rights, if any, of the preferred stock;
- the relative ranking and preferences of the preferred stock as to dividend rights and rights upon liquidation, dissolution or winding up of the affairs of the Company; and
- any material limitations on issuance of any class or series of preferred stock ranking senior to or on a parity with the series of preferred stock as to dividend rights and rights upon liquidation, dissolution or winding up of the Company.

Series B Convertible Preferred Stock

Each share of the Series B Preferred Stock is convertible into ten (10) shares of the Company's common stock. Dividends are payable to the Series B Preferred stockholders when and as declared by the Board at the rate of $0.25 per share per annum. Such dividends are cumulative and accrue whether or not declared and whether or not there are any profits, surplus or other funds or assets of the Company legally available therefor. At the option of the Company, dividends on the Series B Preferred Stock may be paid in cash or restricted shares of common stock, valued at $0.50 per share. The holders of the Series B Preferred Stock can convert their shares to shares of common stock only if the Company has sufficient shares of common stock authorized and available for issuance at the time of conversion. The Series B Preferred Stock has liquidation preferences over the common shares at $5.00 per share,

plus any accrued and unpaid dividends. Except as otherwise provided by law, the Series B holders have no voting rights.

Series C Convertible Preferred Stock

The Series C Certificate of Designation provides, among other things, that holders of Series C Preferred Stock shall be entitled to receive, when and as declared by the Board and out of any assets at the time legally available therefor, cumulative dividends at the rate of ten percent (10%) per share per annum of the stated value of the Series C Preferred Stock, which is $1,000 per share (the "Series C Stated Value"). Any dividends paid by the Company will be paid to the holders of Series C Preferred Stock, prior and in preference to any payment or distribution to holders of common stock. Dividends on the Series C Preferred Stock are cumulative, and will accrue and be compounded annually, whether or not declared and whether or not there are any profits, surplus or other funds or assets of the Company legally available therefor. There are no sinking fund provisions applicable to the Series C Preferred Stock. The Series C Preferred Stock does not have redemption rights. Dividends, if declared by the Board, are payable to holders in arrears on December 31 of each year. Subject to the provisions of applicable Delaware law, the holder may elect to be paid in cash or in restricted shares of common stock at the rate of $0.50 per share.

In the event of any liquidation, dissolution or winding up of the Company, the holders of Series C Preferred Stock will be entitled to receive, on a pari passu basis with the holders of the Series D Preferred Stock and in preference to any payment or distribution to any holders of the Series B Preferred Stock or common stock, an amount per share equal to the Series C Stated Value plus the amount of any accrued and unpaid dividends. If, at any time while the Series C Preferred Stock is outstanding, the Company effects a reorganization, merger or consolidation of the Company, sale of substantially all of its assets, or other specified transaction (each, as defined in the Series C Certificate of Designation, a "Fundamental Transaction"), a holder of the Series C Preferred Stock will have the right to receive any shares of the acquiring corporation or other consideration it would have been entitled to receive if it had been a holder of the number of shares of common stock then issuable upon conversion in full of the Series C Preferred Stock immediately prior to the Fundamental Transaction. Each share of Series C Preferred Stock is convertible at any time at the holder's option into that number of fully paid and nonassessable shares of common stock determined by dividing the Series C Stated Value by the conversion price of $0.50 (subject to adjustment as set forth in the Series C Certificate of Designation). The holders of the Series C Preferred Stock can convert their shares to shares of common stock only if the Company has sufficient shares of common stock authorized and available for issuance at the time of conversion. No fractional shares will be issued upon the conversion of the Series C Preferred Stock. Except as otherwise provided in the Series C Certificate of Designation or as otherwise required by law, the Series C Preferred Stock has no voting rights.

Series D Convertible Preferred Stock

The Series D Certificate of Designation provides, among other things, that holders of Series D Preferred Stock shall be entitled to receive, when and as declared by the Board and out of any assets at the time legally available therefor, cumulative dividends at the rate of ten percent (10%) per share per annum of the stated value of the Series D Preferred Stock, which is $1,000 per share (the "Series D Stated Value"). Any dividends paid by the Company will be paid to the holders of Series D Preferred Stock, prior and in preference to any payment or distribution to holders of common stock. Dividends on the Series D Preferred Stock are cumulative, and will accrue and be compounded annually, whether or not declared and whether or not there are any profits, surplus or other funds or assets of the Company legally available therefor. There are no sinking fund provisions applicable to the Series D Preferred Stock. The Series D Preferred Stock does not have redemption rights. Dividends, if declared by the Board, are payable to holders in arrears on December 31 of each year. Subject to the provisions of applicable Delaware law, the holder may elect to be paid in cash or in restricted shares of common stock at the rate of $0.50 per share.

In the event of any liquidation, dissolution or winding up of the Company, the holders of Series D Preferred Stock will be entitled to receive, on a pari passu basis with the holders of the Series C Preferred Stock, and in preference to any payment or distribution to any holders of the Series B Preferred Stock or common stock, an amount per share equal to the Series D Stated Value plus the amount of any accrued and unpaid dividends. If, at any time while the Series D Preferred Stock is outstanding, the Company effects a reorganization, merger or consolidation of the

Company, sale of substantially all of its assets, or other specified transaction (each, as defined in the Series D Certificate of Designation, a "Fundamental Transaction"), a holder of the Series D Preferred Stock will have the right to receive any shares of the acquiring corporation or other consideration it would have been entitled to receive if it had been a holder of the number of shares of common stock then issuable upon conversion in full of the Series D Preferred Stock immediately prior to the Fundamental Transaction. Each share of Series D Preferred Stock is convertible at any time at the holder's option into that number of fully paid and nonassessable shares of common stock determined by dividing the Series D Stated Value by the conversion price of $0.80 (subject to adjustment as set forth in the Series D Certificate of Designation). The holders of the Series D Preferred Stock can convert their shares to shares of common stock only if the Company has sufficient shares of common stock authorized and available for issuance at the time of conversion. No fractional shares will be issued upon the conversion of the Series D Preferred Stock. Except as otherwise provided in the Series D Certificate of Designation or as otherwise required by law, the Series D Preferred Stock has no voting rights.

Anti-takeover Effects of Delaware Law and our Certificate of Incorporation, as amended

As described above, our Board is authorized to designate and issue shares of preferred stock in series and define all rights, preferences and privileges applicable to such series. This authority may be used to make it more difficult or less economically beneficial to acquire or seek to acquire us.

Special meetings of the stockholders may only be called by our Board acting pursuant to a resolution approved by the affirmative majority of the entire Board.

EXHIBIT 4.19

Warrant Number _____

THE WARRANT REPRESENTED BY THIS CERTIFICATE AND THE SECURITIES ISSUABLE UPON EXERCISE HEREOF HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT") OR THE SECURITIES LAWS OF ANY STATE OR OTHER JURISDICTION. THIS WARRANT AND THE SECURITIES ISSUABLE UPON EXERCISE HEREOF MAY NOT BE OFFERED, SOLD, PLEDGED, ASSIGNED OR OTHERWISE TRANSFERRED UNLESS
(1) SUCH TRANSACTION IS MADE PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT FILED UNDER THE SECURITIES ACT AND THE APPLICABLE SECURITIES LAWS OF ANY STATE OR OTHER JURISDICTION OR
(2) THE COMPANY IS PROVDED WITH AN OPINION OF COUNSEL, SATISFACTORY TO THE COMPANY, STATING THAT SUCH TRANSACTION IS IN COMPLIANCE WITH EXEMPTIONS FROM REGISTRATION UNDER THE SECURITIES ACT AND SUCH OTHER APPLICABLE LAWS. NO TRANSFER OF ANY INTEREST IN THIS WARRANT OR THE SECURITIES ISSUABLE UPON EXERCISE HEREOF MAY BE EFFECTED WITHOUT FIRST SURRENDERING THIS WARRANT OR SUCH SECURITIES, AS THE CASE MAY BE, TO THE COMPANY OR ITS TRANSFER AGENT, IF ANY.

Warrant to Purchase Shares of
Common Stock As Herein
Described

December __, 2022

WARRANT TO PURCHASE COMMON STOCK OF CYTODYN

INC.

This is to certify that, for value received, 4-Good Ventures LLC, or a proper assignee (the "Holder"), is entitled to purchase up to 7,500,000 shares ("Warrant Shares") of common stock, $0.001 par value per share (the "Common Stock"), of CytoDyn Inc., a Delaware corporation (the "Company"), subject to the provisions of this Warrant. This Warrant shall be exercisable at $0.10 (the "Exercise Price"). This Warrant also is subject to the following terms and conditions:

1. Exercise and Payment; Exchange.

(a) This Warrant may be exercised in whole or in part at any time from and after the date hereof (the "Commencement Date") through 5:00 p.m., Pacific time, on the date that is five years following the Commencement Date (the "Expiration Date"), at which time this Warrant shall expire and become void, but if such date is a day on which federal or state chartered banking institutions located in the State of New York are authorized to close, then on the next succeeding day which shall not be such a day. Exercise shall be by presentation and surrender to the Company, or at the office of any transfer agent designated by the Company (the "Transfer Agent"), of (i) this Warrant, (ii) the attached exercise form properly executed, and (iii) a certified

or official bank check for the Exercise Price for the number of Warrant Shares specified in the exercise form. If this Warrant is exercised in part only, the Company or the Transfer Agent shall, upon surrender of the Warrant, execute and deliver a new Warrant evidencing the rights of the Holder to purchase the remaining number of Warrant Shares purchasable hereunder. Upon receipt by the Company of this Warrant, the properly executed exercise form, and payment as aforesaid, the Holder shall be deemed to be the holder of record of the Common Stock issuable upon such exercise, notwithstanding that the stock transfer books of the Company shall then be closed or that certificates representing such Warrant Shares shall not then be actually delivered to the Holder. Under no circumstance shall the Company be required to make any cash payments or net cash settlement to the Holder in lieu of delivery of the Warrant Shares.

(b) Conditions to Exercise or Exchange. The restrictions in Section 7 shall apply, to the extent applicable by their terms, to any exercise or exchange of this Warrant permitted by this Section 1.

2. Reservation of Shares. The Company shall, at all times until the expiration of this Warrant, reserve for issuance and delivery upon exercise of this Warrant the number of Warrant Shares that shall be required for issuance and delivery upon exercise of this Warrant.

3. Fractional Interests. The Company shall not issue any fractional shares or scrip representing fractional shares upon the exercise or exchange of this Warrant. Any and all calculations under this Section 3 shall be made to the nearest cent and/or rounded down to the nearest whole share, as the case may be. With respect to any fraction of a share resulting from the exercise or exchange hereof, the Company shall pay to the Holder an amount in cash equal to such fraction multiplied by the current fair market value per share of Common Stock, determined as follows:

(a) If the Common Stock is listed on a national securities exchange or admitted to unlisted trading privileges on such an exchange, the current fair market value shall be the last reported sale price of the Common Stock on such exchange on the last business day prior to the date of exercise of this Warrant or if no such sale is made on such day, the mean of the closing bid and asked prices for such day on such exchange;

(b) If the Common Stock is not so listed or admitted to unlisted trading privileges on a national securities exchange, the current fair market value shall be the mean of the last bid and asked prices reported on the last business day prior to the date of the exercise of this Warrant by the OTC Markets Group, Inc.; or

(c) If the Common Stock is not so listed or admitted to unlisted trading privileges on a national securities exchange and bid and asked prices are not so reported, the current fair market value shall be an amount, not less than book value, determined in such reasonable manner as may be prescribed by the Company in good faith.

4. No Rights as Shareholder. This Warrant shall not entitle the Holder to any rights as a shareholder of the Company, either at law or in equity. The rights of the Holder are limited to those expressed in this Warrant and are not enforceable against the Company except to the extent set forth herein.

5. Adjustments in Number and Exercise Price of Warrant Shares.

5.1 The number of shares of Common Stock for which this Warrant may be exercised and the Exercise Price therefor shall be subject to adjustment as follows, and all calculations under this Section 5 shall be made to the nearest cent and/or rounded down to the nearest whole share, as the case may be:

(a) If the Company is recapitalized through the subdivision or combination of its outstanding shares of Common Stock into a larger or smaller number of shares, the number of Warrant Shares shall be increased or reduced, as of the record date for such recapitalization, in the same proportion as the increase or decrease in the outstanding shares of Common Stock, and the Exercise Price shall be adjusted so that the aggregate amount payable for the purchase of all of the Warrant Shares issuable hereunder immediately after the record date for such recapitalization shall equal the aggregate amount so payable immediately before such record date.

(b) If the Company declares a dividend on Common Stock payable in Common Stock or securities convertible into Common Stock, the number of shares of Common Stock for which this Warrant may be exercised shall be increased as of the record date for determining which holders of Common Stock shall be entitled to receive such dividend, in proportion to the increase in the number of outstanding shares (and shares of Common Stock issuable upon conversion of all such securities convertible into Common Stock) of Common Stock as a result of such dividend, and the Exercise Price shall be adjusted so that the aggregate amount payable for the purchase of all the Warrant Shares issuable hereunder immediately after the record date for such dividend shall equal the aggregate amount so payable immediately before such record date.

(c) If the Company distributes to holders of its Common Stock, other than as part of its dissolution or liquidation or the winding up of its affairs, any evidence of indebtedness or any of its assets (other than cash, Common Stock or securities convertible into Common Stock), the Company shall give written notice to the Holder of any such distribution at least fifteen (15) days prior to the proposed record date in order to permit the Holder to exercise this Warrant on or before the record date. There shall be no adjustment in the number of shares of Common Stock for which this Warrant may be exercised, or in the Exercise Price, by virtue of any such distribution.

(d) If the Company offers rights or warrants to the holders of Common Stock which entitle them to subscribe to or purchase additional Common Stock or securities convertible into Common Stock, the Company shall give written notice of any such proposed offering to the Holder at least fifteen (15) days prior to the proposed record date in order to permit the Holder to exercise this Warrant on or before such record date. There shall be no adjustment in the number of shares of Common Stock for which this Warrant may be exercised, or in the Exercise Price, by virtue of any such distribution.

(e) If the event, as a result of which an adjustment is made under paragraph (a) or (b) above, does not occur, then any adjustments in the Exercise Price or number

of shares issuable that were made in accordance with such paragraph (a) or (b) shall be adjusted to the Exercise Price and number of shares as were in effect immediately prior to the record date for such event.

5.2 In the event of any reorganization or reclassification of the outstanding shares of Common Stock (other than a change in par value or from no par value to par value, or from par value to no par value, or as a result of a subdivision or combination) or in the event of any consolidation or merger of the Company with another entity after which the Company is not the surviving entity, at any time prior to the expiration of this Warrant, upon subsequent exercise of this Warrant the Holder shall have the right to receive the same kind and number of shares of common stock and other securities, cash or other property as would have been distributed to the Holder upon such reorganization, reclassification, consolidation or merger had the Holder exercised this Warrant immediately prior to such reorganization, reclassification, consolidation or merger, appropriately adjusted for any subsequent event described in this Section 5. The Holder shall pay upon such exercise the Exercise Price that otherwise would have been payable pursuant to the terms of this Warrant. If any such reorganization, reclassification, consolidation or merger results in a cash distribution in excess of the then applicable Exercise Price, the Holder may, at the Holder's option, exercise this Warrant without making payment of the Exercise Price, and in such case the Company shall, upon distribution to the Holder, consider the Exercise Price to have been paid in full, and in making settlement to the Holder, shall deduct an amount equal to the Exercise Price from the amount payable to the Holder. In the event of any such reorganization, merger or consolidation, the corporation formed by such consolidation or merger or the corporation which shall have acquired the assets of the Company shall execute and deliver a supplement hereto to the foregoing effect, which supplement shall also provide for adjustments which shall be as nearly equivalent as may be practicable to the adjustments provided in this Warrant.

5.3 If the Company shall, at any time before the expiration of this Warrant, dissolve, liquidate or wind up its affairs, the Holder shall have the right to receive upon exercise of this Warrant, in lieu of the shares of Common Stock of the Company that the Holder otherwise would have been entitled to receive, the same kind and amount of assets as would have been issued, distributed or paid to the Holder upon any such dissolution, liquidation or winding up with respect to such Common Stock receivable upon exercise of this Warrant on the date for determining those entitled to receive any such distribution. If any such dissolution, liquidation or winding up results in any cash distribution in excess of the Exercise Price provided by this Warrant, the Holder may, at the Holder's option, exercise this Warrant without making payment of the Exercise Price and, in such case, the Company shall, upon distribution to the Holder, consider the Exercise Price to have been paid in full and, in making settlement to the Holder, shall deduct an amount equal to the Exercise Price from the amount payable to the Holder.

6. Notices to Holder. So long as this Warrant shall be outstanding (a) if the Company shall pay any dividends or make any distribution upon the Common Stock otherwise than in cash or (b) if the Company shall offer generally to the holders of Common Stock the right to subscribe to or purchase any shares of any class of Common Stock or securities convertible into Common Stock or any similar rights or (c) if there shall be any capital reorganization of the Company in which the Company is not the surviving entity, recapitalization of the capital stock of the Company, consolidation or merger of the Company with or into another corporation, sale, lease

or other transfer of all or substantially all of the property and assets of the Company, or voluntary or involuntary dissolution, liquidation or winding up of the Company, then in such event, the Company shall cause to be mailed to the Holder, at least thirty (30) days prior to the relevant date described below (or such shorter period as is reasonably possible if thirty (30) days is not reasonably possible), a notice containing a description of the proposed action and stating the date or expected date on which a record of the Company's shareholders is to be taken for the purpose of any such dividend, distribution of rights, or such reclassification, reorganization, consolidation, merger, conveyance, lease or transfer, dissolution, liquidation or winding up is to take place and the date or expected date, if any is to be fixed, as of which the holders of Common Stock of record shall be entitled to exchange their shares of Common Stock for securities or other property deliverable upon such event.

7. Transfer, Exercise, Exchange, Assignment or Loss of Warrant, Warrant Shares or Other Securities.

7.1 This Warrant may be transferred, exercised, exchanged or assigned ("transferred"), in whole or in part, subject to the following restrictions. This Warrant and the Warrant Shares or any other securities ("Other Securities") received upon exercise of this Warrant shall be subject to restrictions on transferability until registered under the Securities Act of 1933, as amended (the "Securities Act"), unless an exemption from registration is available. Until this Warrant and the Warrant Shares or Other Securities are so registered, this Warrant and any certificate for Warrant Shares or Other Securities issued or issuable upon exercise of this Warrant shall contain a legend on the face thereof, in form and substance satisfactory to counsel for the Company, stating that this Warrant the Warrant Shares or Other Securities may not be sold, transferred or otherwise disposed of unless, in the opinion of counsel satisfactory to the Company, which may be counsel to the Company, that this Warrant, the Warrant Shares or Other Securities may be transferred without such registration. This Warrant and the Warrant Shares or Other Securities may also be subject to restrictions on transferability under applicable state securities or blue sky laws. Until this Warrant and the Warrant Shares or Other Securities are registered under the Securities Act, the Holder shall reimburse the Company for its expenses, including attorneys' fees, incurred in connection with any transfer or assignment, in whole or in part, of this Warrant or any Warrant Shares or Other Securities.

7.2 Until this Warrant, the Warrant Shares or Other Securities are registered under the Securities Act, the Company may require, as a condition of transfer of this Warrant, the Warrant Shares, or Other Securities, that the transferee (who may be the Holder in the case of an exercise or exchange) represent that such transferee is an "accredited investor" within the meaning of Rule 501 of Regulation D under the Securities Act and that the securities being transferred are being acquired for investment purposes and for the transferee's own account and not with a view to or for sale in connection with any distribution of the security.

7.3 Any transfer permitted hereunder shall be made by surrender of this Warrant to the Company or to the Transfer Agent at its offices with a duly executed request to transfer the Warrant, which shall provide adequate information to effect such transfer and shall be accompanied by funds sufficient to pay any transfer taxes applicable. Upon satisfaction of all transfer conditions, the Company or Transfer Agent shall, without charge, execute and deliver a

new Warrant in the name of the transferee named in such transfer request, and this Warrant promptly shall be cancelled.

7.4 Upon receipt by the Company of evidence satisfactory to it of loss, theft, destruction or mutilation of this Warrant and, in the case of loss, theft or destruction, of reasonably satisfactory indemnification, or, in the case of mutilation, upon surrender of this Warrant, the Company will execute and deliver, or instruct the Transfer Agent to execute and deliver, a new Warrant of like tenor and date, and any such lost, stolen or destroyed Warrant thereupon shall become void.

8. Representations and Warranties of the Holder. The Holder hereby represents and warrants to the Company with respect to the issuance of the Warrant as follows:

8.1 Experience. The Holder has substantial experience in evaluating and investing in securities in companies similar to the Company so that such Holder is capable of evaluating the merits and risks of such Holder's investment in the Company and has the capacity to protect such Holder's own interests.

8.2 Investment. The Holder is acquiring this Warrant (and the Warrant Shares issuable upon exercise of this Warrant) for investment for such Holder's own account, not as a nominee or agent, and not with the view to, or for resale in connection with, any distribution thereof. The Holder understands that this Warrant (and the Warrant Shares issuable upon exercise of the Warrant) have not been, and will not be, registered under the Securities Act by reason of a specific exemption from the registration provisions of the Securities Act which depends upon, among other things, the bona fide nature of the investment intent and the accuracy of such Holder's representations as expressed herein.

8.3 Held Indefinitely. The Holder acknowledges that this Warrant (and the Warrant Shares issuable upon exercise of this Warrant) must be held indefinitely unless subsequently registered under the Securities Act or an exemption from such registration is available.

8.4 Accredited Holder. The Holder is an "accredited investor" within the meaning of Rule 501 of Regulation D under the Securities Act.

8.5 Legends. The Holder understands and acknowledges that the certificate(s) evidencing the securities issued by the Company will be imprinted with a restrictive legend as referenced in Section 7.1 above.

8.6 Access to Data. The Holder has had an opportunity to discuss the Company's business, management, and financial affairs with the Company's management and the opportunity to review the Company's facilities and business plans. The Holder has also had an opportunity to ask questions of officers of the Company, which questions were answered to its satisfaction.

8.7 Authorization. This Warrant and the agreements contemplated hereby, when executed and delivered by the Holder, will constitute a valid and legally binding obligation of the Holder, enforceable in accordance with their respective terms.

8.8 Brokers or Finders. The Company has not incurred, and will not incur, directly or indirectly, as a result of any action taken by such Holder, any liability for brokerage or finders' fees or agents' commissions or any similar charges in connection with this Warrant or any transaction contemplated hereby.

9. Notices. All notices, requests, demands or other communications hereunder shall be in writing and shall be deemed to have been duly given, if delivered in person or mailed, certified, return-receipt requested, postage prepaid to the address previously provided to the other party, or sent by fax or email (to the extent stated below). Either party hereto may from time to time, by written notice to the other party, designate a different address. If any notice or other document is sent by certified or registered mail, return receipt requested, postage prepaid, properly addressed as aforementioned, the same shall be deemed delivered seventy-two (72) hours after mailing thereof. If any notice is sent by fax or email, it will be deemed to have been delivered on the date the fax or email thereof is actually received, provided the original thereof is sent by certified mail, in the manner set forth above, within twenty-four (24) hours after the fax or email is sent.

10. Amendment. Any provision of this Warrant may be amended or the observance thereof may be waived (either generally or in a particular instance and either retroactively or prospectively), only with the mutual written consent of the Company and the Holder.

11. Governing Law. This Warrant shall be governed by and construed in accordance with the laws of the State of New York.

[Signature page follows.]

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

CYTODYN INC.

By: _____ Name:
Antonio Migliarese
Title: Chief Financial Officer

FORM OF EXERCISE

To be executed upon exercise of Warrant (please print)

The undersigned hereby irrevocably elects to exercise the right, represented by this Warrant Number A-1888 certificate, to _____ shares of common stock, $0.001 par value per share ("Common Stock") of CytoDyn Inc. (the "Company") and herewith tenders payment for such shares of Common Stock to the order of the Company the amount of $0.50 per share in accordance with the terms hereof. The undersigned requests that a certificate for such shares of Common Stock be registered in the name of _____ whose address is _____. If said number of shares of Common Stock is less than all of the shares of Common Stock purchasable hereunder, the undersigned requests that a new Warrant Certificate representing the remaining balance of the shares of Common Stock be registered in the name of _____, whose address is _____, and that such Warrant Certificate be delivered to _____, whose address is _____.

Representations of the undersigned.

a) The undersigned acknowledges that the undersigned has received, read and understood the Warrant and agrees to abide by and be bound by its terms and conditions.

b) (i) The undersigned has such knowledge and experience in business and financial matters that the undersigned is capable of evaluating the Company and the proposed activities thereof, and the risks and merits of this prospective investment.

[ ] YES [ ] NO

(ii) If "No", the undersigned is represented by a "purchaser representative," as that term is defined in the Securities Act of 1933, as amended (the "Securities Act") and Regulation D thereunder.

[ ] YES [ ] NO

c) (i) The undersigned is an "accredited investor," as that term is defined in the Securities Act and Rule 501 of Regulation D thereunder.

[ ] YES [ ] NO

(ii) If "Yes," the undersigned comes within the following category of that definition (check one and complete the blanks as applicable):

[ ] 1. The undersigned is a natural person whose present net worth (or whose joint net worth with his or her spouse), excluding the value of the undersigned's primary residence, exceeds $1,000,000. For purposes of calculating the undersigned's present net worth, the undersigned has included the following as liabilities: (i) any indebtedness that is secured by the undersigned's primary residence in excess of the estimated fair market value of the undersigned's

primary residence at the time of the sale of the shares, and (ii) any incremental debt secured by the undersigned's primary residence that was incurred in the 60 days before the sale of the shares, other than as a result of the acquisition of the undersigned's primary residence.

[ ] 2. The undersigned is a natural person who had individual income in excess of $200,000 in each of the last two years or joint income with the undersigned's spouse in excess of $300,000 during such two years, and the undersigned reasonably expects to have the same income level in the current year.

[ ] 3. The undersigned holds in good standing a Series 7, 65 or 82 license. [ ] 4.

The undersigned is an officer or director of the Company.

[ ] 5. The undersigned is a corporation or partnership not formed for the specific purpose of acquiring the securities offered, with total assets in excess of $5,000,000.

[ ] 6. The undersigned is a trust with total assets in excess of $5,000,000 whose purchase is directed by a person with such knowledge and experience in financial and business matters that such person is capable of evaluating the merits and risks of the prospective investment.

[ ] 7. The undersigned is an entity, all of whose equity owners are accredited investors under paragraphs 1, 2, 3, 4, 5 or 6, above.

d) The undersigned understands that the shares purchased hereunder have not been registered under the Securities Act, in reliance upon the exemption from the registration requirements under the Securities Act pursuant to Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D thereunder; and, therefore, that the undersigned must bear the economic risk of the investment for an indefinite period of time since the securities cannot be sold, transferred or assigned to any person or entity without compliance with the provisions of the Securities Act.

Submitted by: Accepted by CytoDyn Inc.:

By:_____ By:_____ Date:_____

Date:_____ SS/Tax ID:_____

Tax ID: _____ Telephone:_____

Email: _____

(Signature must conform in all respects to name of holder as specified on the face of the Warrant Certificate.)

EXHIBIT 4.20

Warrant Number ____

THE WARRANT REPRESENTED BY THIS CERTIFICATE AND THE SECURITIES ISSUABLE UPON EXERCISE HEREOF HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT") OR THE SECURITIES LAWS OF ANY STATE OR OTHER JURISDICTION. THIS WARRANT AND THE SECURITIES ISSUABLE UPON EXERCISE HEREOF MAY NOT BE OFFERED, SOLD, PLEDGED, ASSIGNED OR OTHERWISE TRANSFERRED UNLESS
(1) SUCH TRANSACTION IS MADE PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT FILED UNDER THE SECURITIES ACT AND THE APPLICABLE SECURITIES LAWS OF ANY STATE OR OTHER JURISDICTION OR
(2) THE COMPANY IS PROVDED WITH AN OPINION OF COUNSEL, SATISFACTORY TO THE COMPANY, STATING THAT SUCH TRANSACTION IS IN COMPLIANCE WITH EXEMPTIONS FROM REGISTRATION UNDER THE SECURITIES ACT AND SUCH OTHER APPLICABLE LAWS. NO TRANSFER OF ANY INTEREST IN THIS WARRANT OR THE SECURITIES ISSUABLE UPON EXERCISE HEREOF MAY BE EFFECTED WITHOUT FIRST SURRENDERING THIS WARRANT OR SUCH SECURITIES, AS THE CASE MAY BE, TO THE COMPANY OR ITS TRANSFER AGENT, IF ANY.

Warrant to Purchase Shares of
Common Stock As Herein
Described

February __, 2023

WARRANT TO PURCHASE COMMON STOCK OF CYTODYN

INC.

This is to certify that, for value received, 4-Good Ventures LLC, or a proper assignee (the "Holder"), is entitled to purchase up to 7,500,000 shares ("Warrant Shares") of common stock, $0.001 par value per share (the "Common Stock"), of CytoDyn Inc., a Delaware corporation (the "Company"), subject to the provisions of this Warrant. This Warrant shall be exercisable at $0.10 (the "Exercise Price"). This Warrant also is subject to the following terms and conditions:

1. Exercise and Payment; Exchange.

(a) This Warrant may be exercised in whole or in part at any time from and after the date hereof (the "Commencement Date") through 5:00 p.m., Pacific time, on the date that is five years following the Commencement Date (the "Expiration Date"), at which time this Warrant shall expire and become void, but if such date is a day on which federal or state chartered banking institutions located in the State of New York are authorized to close, then on the next succeeding day which shall not be such a day. Exercise shall be by presentation and surrender to the Company, or at the office of any transfer agent designated by the Company (the "Transfer Agent"), of (i) this Warrant, (ii) the attached exercise form properly executed, and (iii) a certified

or official bank check for the Exercise Price for the number of Warrant Shares specified in the exercise form. If this Warrant is exercised in part only, the Company or the Transfer Agent shall, upon surrender of the Warrant, execute and deliver a new Warrant evidencing the rights of the Holder to purchase the remaining number of Warrant Shares purchasable hereunder. Upon receipt by the Company of this Warrant, the properly executed exercise form, and payment as aforesaid, the Holder shall be deemed to be the holder of record of the Common Stock issuable upon such exercise, notwithstanding that the stock transfer books of the Company shall then be closed or that certificates representing such Warrant Shares shall not then be actually delivered to the Holder. Under no circumstance shall the Company be required to make any cash payments or net cash settlement to the Holder in lieu of delivery of the Warrant Shares.

(b) Conditions to Exercise or Exchange. The restrictions in Section 7 shall apply, to the extent applicable by their terms, to any exercise or exchange of this Warrant permitted by this Section 1.

2. Reservation of Shares. The Company shall, at all times until the expiration of this Warrant, reserve for issuance and delivery upon exercise of this Warrant the number of Warrant Shares that shall be required for issuance and delivery upon exercise of this Warrant.

3. Fractional Interests. The Company shall not issue any fractional shares or scrip representing fractional shares upon the exercise or exchange of this Warrant. Any and all calculations under this Section 3 shall be made to the nearest cent and/or rounded down to the nearest whole share, as the case may be. With respect to any fraction of a share resulting from the exercise or exchange hereof, the Company shall pay to the Holder an amount in cash equal to such fraction multiplied by the current fair market value per share of Common Stock, determined as follows:

(a) If the Common Stock is listed on a national securities exchange or admitted to unlisted trading privileges on such an exchange, the current fair market value shall be the last reported sale price of the Common Stock on such exchange on the last business day prior to the date of exercise of this Warrant or if no such sale is made on such day, the mean of the closing bid and asked prices for such day on such exchange;

(b) If the Common Stock is not so listed or admitted to unlisted trading privileges on a national securities exchange, the current fair market value shall be the mean of the last bid and asked prices reported on the last business day prior to the date of the exercise of this Warrant by the OTC Markets Group, Inc.; or

(c) If the Common Stock is not so listed or admitted to unlisted trading privileges on a national securities exchange and bid and asked prices are not so reported, the current fair market value shall be an amount, not less than book value, determined in such reasonable manner as may be prescribed by the Company in good faith.

4. No Rights as Shareholder. This Warrant shall not entitle the Holder to any rights as a shareholder of the Company, either at law or in equity. The rights of the Holder are limited to those expressed in this Warrant and are not enforceable against the Company except to the extent set forth herein.

5. Adjustments in Number and Exercise Price of Warrant Shares.

5.1 The number of shares of Common Stock for which this Warrant may be exercised and the Exercise Price therefor shall be subject to adjustment as follows, and all calculations under this Section 5 shall be made to the nearest cent and/or rounded down to the nearest whole share, as the case may be:

(a) If the Company is recapitalized through the subdivision or combination of its outstanding shares of Common Stock into a larger or smaller number of shares, the number of Warrant Shares shall be increased or reduced, as of the record date for such recapitalization, in the same proportion as the increase or decrease in the outstanding shares of Common Stock, and the Exercise Price shall be adjusted so that the aggregate amount payable for the purchase of all of the Warrant Shares issuable hereunder immediately after the record date for such recapitalization shall equal the aggregate amount so payable immediately before such record date.

(b) If the Company declares a dividend on Common Stock payable in Common Stock or securities convertible into Common Stock, the number of shares of Common Stock for which this Warrant may be exercised shall be increased as of the record date for determining which holders of Common Stock shall be entitled to receive such dividend, in proportion to the increase in the number of outstanding shares (and shares of Common Stock issuable upon conversion of all such securities convertible into Common Stock) of Common Stock as a result of such dividend, and the Exercise Price shall be adjusted so that the aggregate amount payable for the purchase of all the Warrant Shares issuable hereunder immediately after the record date for such dividend shall equal the aggregate amount so payable immediately before such record date.

(c) If the Company distributes to holders of its Common Stock, other than as part of its dissolution or liquidation or the winding up of its affairs, any evidence of indebtedness or any of its assets (other than cash, Common Stock or securities convertible into Common Stock), the Company shall give written notice to the Holder of any such distribution at least fifteen (15) days prior to the proposed record date in order to permit the Holder to exercise this Warrant on or before the record date. There shall be no adjustment in the number of shares of Common Stock for which this Warrant may be exercised, or in the Exercise Price, by virtue of any such distribution.

(d) If the Company offers rights or warrants to the holders of Common Stock which entitle them to subscribe to or purchase additional Common Stock or securities convertible into Common Stock, the Company shall give written notice of any such proposed offering to the Holder at least fifteen (15) days prior to the proposed record date in order to permit the Holder to exercise this Warrant on or before such record date. There shall be no adjustment in the number of shares of Common Stock for which this Warrant may be exercised, or in the Exercise Price, by virtue of any such distribution.

(e) If the event, as a result of which an adjustment is made under paragraph (a) or (b) above, does not occur, then any adjustments in the Exercise Price or number

of shares issuable that were made in accordance with such paragraph (a) or (b) shall be adjusted to the Exercise Price and number of shares as were in effect immediately prior to the record date for such event.

5.2 In the event of any reorganization or reclassification of the outstanding shares of Common Stock (other than a change in par value or from no par value to par value, or from par value to no par value, or as a result of a subdivision or combination) or in the event of any consolidation or merger of the Company with another entity after which the Company is not the surviving entity, at any time prior to the expiration of this Warrant, upon subsequent exercise of this Warrant the Holder shall have the right to receive the same kind and number of shares of common stock and other securities, cash or other property as would have been distributed to the Holder upon such reorganization, reclassification, consolidation or merger had the Holder exercised this Warrant immediately prior to such reorganization, reclassification, consolidation or merger, appropriately adjusted for any subsequent event described in this Section 5. The Holder shall pay upon such exercise the Exercise Price that otherwise would have been payable pursuant to the terms of this Warrant. If any such reorganization, reclassification, consolidation or merger results in a cash distribution in excess of the then applicable Exercise Price, the Holder may, at the Holder's option, exercise this Warrant without making payment of the Exercise Price, and in such case the Company shall, upon distribution to the Holder, consider the Exercise Price to have been paid in full, and in making settlement to the Holder, shall deduct an amount equal to the Exercise Price from the amount payable to the Holder. In the event of any such reorganization, merger or consolidation, the corporation formed by such consolidation or merger or the corporation which shall have acquired the assets of the Company shall execute and deliver a supplement hereto to the foregoing effect, which supplement shall also provide for adjustments which shall be as nearly equivalent as may be practicable to the adjustments provided in this Warrant.

5.3 If the Company shall, at any time before the expiration of this Warrant, dissolve, liquidate or wind up its affairs, the Holder shall have the right to receive upon exercise of this Warrant, in lieu of the shares of Common Stock of the Company that the Holder otherwise would have been entitled to receive, the same kind and amount of assets as would have been issued, distributed or paid to the Holder upon any such dissolution, liquidation or winding up with respect to such Common Stock receivable upon exercise of this Warrant on the date for determining those entitled to receive any such distribution. If any such dissolution, liquidation or winding up results in any cash distribution in excess of the Exercise Price provided by this Warrant, the Holder may, at the Holder's option, exercise this Warrant without making payment of the Exercise Price and, in such case, the Company shall, upon distribution to the Holder, consider the Exercise Price to have been paid in full and, in making settlement to the Holder, shall deduct an amount equal to the Exercise Price from the amount payable to the Holder.

6. Notices to Holder. So long as this Warrant shall be outstanding (a) if the Company shall pay any dividends or make any distribution upon the Common Stock otherwise than in cash or (b) if the Company shall offer generally to the holders of Common Stock the right to subscribe to or purchase any shares of any class of Common Stock or securities convertible into Common Stock or any similar rights or (c) if there shall be any capital reorganization of the Company in which the Company is not the surviving entity, recapitalization of the capital stock of the Company, consolidation or merger of the Company with or into another corporation, sale, lease

or other transfer of all or substantially all of the property and assets of the Company, or voluntary or involuntary dissolution, liquidation or winding up of the Company, then in such event, the Company shall cause to be mailed to the Holder, at least thirty (30) days prior to the relevant date described below (or such shorter period as is reasonably possible if thirty (30) days is not reasonably possible), a notice containing a description of the proposed action and stating the date or expected date on which a record of the Company's shareholders is to be taken for the purpose of any such dividend, distribution of rights, or such reclassification, reorganization, consolidation, merger, conveyance, lease or transfer, dissolution, liquidation or winding up is to take place and the date or expected date, if any is to be fixed, as of which the holders of Common Stock of record shall be entitled to exchange their shares of Common Stock for securities or other property deliverable upon such event.

7. Transfer, Exercise, Exchange, Assignment or Loss of Warrant, Warrant Shares or Other Securities.

7.1 This Warrant may be transferred, exercised, exchanged or assigned ("transferred"), in whole or in part, subject to the following restrictions. This Warrant and the Warrant Shares or any other securities ("Other Securities") received upon exercise of this Warrant shall be subject to restrictions on transferability until registered under the Securities Act of 1933, as amended (the "Securities Act"), unless an exemption from registration is available. Until this Warrant and the Warrant Shares or Other Securities are so registered, this Warrant and any certificate for Warrant Shares or Other Securities issued or issuable upon exercise of this Warrant shall contain a legend on the face thereof, in form and substance satisfactory to counsel for the Company, stating that this Warrant the Warrant Shares or Other Securities may not be sold, transferred or otherwise disposed of unless, in the opinion of counsel satisfactory to the Company, which may be counsel to the Company, that this Warrant, the Warrant Shares or Other Securities may be transferred without such registration. This Warrant and the Warrant Shares or Other Securities may also be subject to restrictions on transferability under applicable state securities or blue sky laws. Until this Warrant and the Warrant Shares or Other Securities are registered under the Securities Act, the Holder shall reimburse the Company for its expenses, including attorneys' fees, incurred in connection with any transfer or assignment, in whole or in part, of this Warrant or any Warrant Shares or Other Securities.

7.2 Until this Warrant, the Warrant Shares or Other Securities are registered under the Securities Act, the Company may require, as a condition of transfer of this Warrant, the Warrant Shares, or Other Securities, that the transferee (who may be the Holder in the case of an exercise or exchange) represent that such transferee is an "accredited investor" within the meaning of Rule 501 of Regulation D under the Securities Act and that the securities being transferred are being acquired for investment purposes and for the transferee's own account and not with a view to or for sale in connection with any distribution of the security.

7.3 Any transfer permitted hereunder shall be made by surrender of this Warrant to the Company or to the Transfer Agent at its offices with a duly executed request to transfer the Warrant, which shall provide adequate information to effect such transfer and shall be accompanied by funds sufficient to pay any transfer taxes applicable. Upon satisfaction of all transfer conditions, the Company or Transfer Agent shall, without charge, execute and deliver a

new Warrant in the name of the transferee named in such transfer request, and this Warrant promptly shall be cancelled.

7.4 Upon receipt by the Company of evidence satisfactory to it of loss, theft, destruction or mutilation of this Warrant and, in the case of loss, theft or destruction, of reasonably satisfactory indemnification, or, in the case of mutilation, upon surrender of this Warrant, the Company will execute and deliver, or instruct the Transfer Agent to execute and deliver, a new Warrant of like tenor and date, and any such lost, stolen or destroyed Warrant thereupon shall become void.

8. Representations and Warranties of the Holder. The Holder hereby represents and warrants to the Company with respect to the issuance of the Warrant as follows:

8.1 Experience. The Holder has substantial experience in evaluating and investing in securities in companies similar to the Company so that such Holder is capable of evaluating the merits and risks of such Holder's investment in the Company and has the capacity to protect such Holder's own interests.

8.2 Investment. The Holder is acquiring this Warrant (and the Warrant Shares issuable upon exercise of this Warrant) for investment for such Holder's own account, not as a nominee or agent, and not with the view to, or for resale in connection with, any distribution thereof. The Holder understands that this Warrant (and the Warrant Shares issuable upon exercise of the Warrant) have not been, and will not be, registered under the Securities Act by reason of a specific exemption from the registration provisions of the Securities Act which depends upon, among other things, the bona fide nature of the investment intent and the accuracy of such Holder's representations as expressed herein.

8.3 Held Indefinitely. The Holder acknowledges that this Warrant (and the Warrant Shares issuable upon exercise of this Warrant) must be held indefinitely unless subsequently registered under the Securities Act or an exemption from such registration is available.

8.4 Accredited Holder. The Holder is an "accredited investor" within the meaning of Rule 501 of Regulation D under the Securities Act.

8.5 Legends. The Holder understands and acknowledges that the certificate(s) evidencing the securities issued by the Company will be imprinted with a restrictive legend as referenced in Section 7.1 above.

8.6 Access to Data. The Holder has had an opportunity to discuss the Company's business, management, and financial affairs with the Company's management and the opportunity to review the Company's facilities and business plans. The Holder has also had an opportunity to ask questions of officers of the Company, which questions were answered to its satisfaction.

8.7 Authorization. This Warrant and the agreements contemplated hereby, when executed and delivered by the Holder, will constitute a valid and legally binding obligation of the Holder, enforceable in accordance with their respective terms.

8.8 Brokers or Finders. The Company has not incurred, and will not incur, directly or indirectly, as a result of any action taken by such Holder, any liability for brokerage or finders' fees or agents' commissions or any similar charges in connection with this Warrant or any transaction contemplated hereby.

9. Notices. All notices, requests, demands or other communications hereunder shall be in writing and shall be deemed to have been duly given, if delivered in person or mailed, certified, return-receipt requested, postage prepaid to the address previously provided to the other party, or sent by fax or email (to the extent stated below). Either party hereto may from time to time, by written notice to the other party, designate a different address. If any notice or other document is sent by certified or registered mail, return receipt requested, postage prepaid, properly addressed as aforementioned, the same shall be deemed delivered seventy-two (72) hours after mailing thereof. If any notice is sent by fax or email, it will be deemed to have been delivered on the date the fax or email thereof is actually received, provided the original thereof is sent by certified mail, in the manner set forth above, within twenty-four (24) hours after the fax or email is sent.

10. Amendment. Any provision of this Warrant may be amended or the observance thereof may be waived (either generally or in a particular instance and either retroactively or prospectively), only with the mutual written consent of the Company and the Holder.

11. Governing Law. This Warrant shall be governed by and construed in accordance with the laws of the State of New York.

[Signature page follows.]

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

CYTODYN INC.

By: _____ Name:
Antonio Migliarese
Title: Chief Financial Officer

FORM OF EXERCISE

To be executed upon exercise of Warrant (please print)

The undersigned hereby irrevocably elects to exercise the right, represented by this Warrant Number A-1889 certificate, to _____ shares of common stock, $0.001 par value per share ("Common Stock") of CytoDyn Inc. (the "Company") and herewith tenders payment for such shares of Common Stock to the order of the Company the amount of $0.50 per share in accordance with the terms hereof. The undersigned requests that a certificate for such shares of Common Stock be registered in the name of _____ whose address is _____. If said number of shares of Common Stock is less than all of the shares of Common Stock purchasable hereunder, the undersigned requests that a new Warrant Certificate representing the remaining balance of the shares of Common Stock be registered in the name of _____, whose address is _____, and that such Warrant Certificate be delivered to _____, whose address is _____.

Representations of the undersigned.

a) The undersigned acknowledges that the undersigned has received, read and understood the Warrant and agrees to abide by and be bound by its terms and conditions.

b) (i) The undersigned has such knowledge and experience in business and financial matters that the undersigned is capable of evaluating the Company and the proposed activities thereof, and the risks and merits of this prospective investment.

[ ] YES [ ] NO

(ii) If "No", the undersigned is represented by a "purchaser representative," as that term is defined in the Securities Act of 1933, as amended (the "Securities Act") and Regulation D thereunder.

[ ] YES [ ] NO

c) (i) The undersigned is an "accredited investor," as that term is defined in the Securities Act and Rule 501 of Regulation D thereunder.

[ ] YES [ ] NO

(ii) If "Yes," the undersigned comes within the following category of that definition (check one and complete the blanks as applicable):

[ ] 1. The undersigned is a natural person whose present net worth (or whose joint net worth with his or her spouse), excluding the value of the undersigned's primary residence, exceeds $1,000,000. For purposes of calculating the undersigned's present net worth, the undersigned has included the following as liabilities: (i) any indebtedness that is secured by the undersigned's primary residence in excess of the estimated fair market value of the undersigned's

primary residence at the time of the sale of the shares, and (ii) any incremental debt secured by the undersigned's primary residence that was incurred in the 60 days before the sale of the shares, other than as a result of the acquisition of the undersigned's primary residence.

[ ] 2. The undersigned is a natural person who had individual income in excess of $200,000 in each of the last two years or joint income with the undersigned's spouse in excess of $300,000 during such two years, and the undersigned reasonably expects to have the same income level in the current year.

[ ] 3. The undersigned holds in good standing a Series 7, 65 or 82 license. [ ] 4.

The undersigned is an officer or director of the Company.

[ ] 5. The undersigned is a corporation or partnership not formed for the specific purpose of acquiring the securities offered, with total assets in excess of $5,000,000.

[ ] 6. The undersigned is a trust with total assets in excess of $5,000,000 whose purchase is directed by a person with such knowledge and experience in financial and business matters that such person is capable of evaluating the merits and risks of the prospective investment.

[ ] 7. The undersigned is an entity, all of whose equity owners are accredited investors under paragraphs 1, 2, 3, 4, 5 or 6, above.

d) The undersigned understands that the shares purchased hereunder have not been registered under the Securities Act, in reliance upon the exemption from the registration requirements under the Securities Act pursuant to Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D thereunder; and, therefore, that the undersigned must bear the economic risk of the investment for an indefinite period of time since the securities cannot be sold, transferred or assigned to any person or entity without compliance with the provisions of the Securities Act.

Submitted by: Accepted by CytoDyn Inc.:

By:_____ By:_____ Date:_____

Date:_____ SS/Tax ID:_____

Tax ID: _____ Telephone:_____

Email: _____

(Signature must conform in all respects to name of holder as specified on the face of the Warrant Certificate.)

Exhibit 21

SUBSIDIARIES

Name	Jurisdiction of Incorporation or Organization
CytoDyn Operations Inc.	Delaware

Exhibit 23

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation in this Registration Statement on Form S-8 (Nos. 333-206813, 333-223884, 333-237490 and 333-249179) of our report dated September 13, 2023, relating to the consolidated financial statements of CytoDyn Inc., appearing in CytoDyn Inc.'s Annual Report on Form 10-K for the year ended May 31, 2023. Our report on the consolidated financial statements contains an explanatory paragraph regarding substantial doubt as to CytoDyn Inc.'s ability to continue as a going concern and a critical audit matter regarding unfulfilled commitments with Samsung BioLogics Co., Ltd (Note 10). We also consent to the reference to us under the heading "Experts" in such Registration Statement.

/s/ Macias Gini & O'Connell LLP

San Jose, California
September 13, 2023

Exhibit 31.1

Certification of Principal Executive Officer

I, Antonio Migliarese, certify that:

1. I have reviewed this Annual Report on Form 10-K of CytoDyn Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:
    a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
    b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report, based on such evaluation; and
    d. disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the registrant's most-recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and
5. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):
    a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and
    b. any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: September 13, 2023

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

Exhibit 31.2

Certification of Chief Financial Officer

I, Antonio Migliarese, certify that:

1. I have reviewed this Annual Report on Form 10-K of CytoDyn Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:
    a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
    b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report, based on such evaluation; and
    d. disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the registrant's most-recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and
5. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):
    a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and
    b. any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: September 13, 2023

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

Exhibit 32

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350

In connection with the Annual Report of CytoDyn Inc. (the "Company") on Form 10-K for the fiscal year ended May 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned certify, pursuant to 18 U.S.C. § Section 1350, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Antonio Migliarese

Antonio Migliarese
Interim President and Chief Financial Officer
Date: September 13, 2023

A signed original of this written statement required by Section 906 has been provided to CytoDyn Inc. and will be retained by CytoDyn Inc. and furnished to the Securities and Exchange Commission or its staff upon request.