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, 2022

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	**83-1887078**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1111 Main Street, Suite 660 Vancouver, Washington	**98660**
(Address of principal executive offices)	**(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. Yes ☒ No □

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: $841,543,090 as of November 30, 2021.

As of July 31, 2022, the registrant had 810,720,424 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Document	**Parts Into Which Incorporated**
Portions of the Proxy Statement for the 2022 Annual Meeting of Stockholders	**Part III**

CYTODYN INC.
FORM 10-K FOR THE YEAR ENDED MAY 31, 2022
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 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, 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; 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. (together with its wholly owned subsidiaries, the "Company", also referred to as "CytoDyn", "we," "our," or "us" in this Form 10-K) 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 in this Form 10-K), a novel humanized monoclonal antibody targeting the CCR5 receptor. 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; refer to Part II, Item 8, Note 10, *Commitments and Contingencies - PRO 140 Acquisition and Licensing Arrangements* of this Form 10-K for additional information. In November 2018, the United States Adopted Names Council adopted "leronlimab" as the official nonproprietary name for PRO 140. Leronlimab is being investigated as a viral entry inhibitor for Human Immunodeficiency Virus ("HIV") and is 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 inflammation such as NASH. Leronlimab is also being studied in oncology, as well as other therapeutic indications, including COVID-19, where monoclonal antibody C-C chemokine receptor type 5 ("CCR5") is believed to play a 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 8-K, 10-K, and 10-Q that we file with the United States Securities and Exchange Commission (the "SEC"), as soon as reasonably practicable, after such materials are electronically filed with or furnished to the SEC. We do not intend to incorporate any content from our website into this Form 10-K. The consolidated financial statements include the accounts of CytoDyn Inc. and its wholly owned subsidiaries, CytoDyn Operations Inc. and Advanced Genetic Technologies, Inc. ("AGTI"), a dormant entity.

CytoDyn's core areas of clinical development are HIV, nonalcoholic steatohepatis ("NASH"), and solid tumors in oncology. The current areas of clinical focus in HIV are the multi-drug resistant HIV population, creating a long-acting formulation of leronlimab, and HIV cure 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. The areas of clinical development and focus are under review by our executive management.

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 highly active antiretroviral therapy ("HAART") for highly treatment-experienced HIV patients. 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. The deficiencies cited by the FDA included administrative deficiencies, omissions, corrections to data presentation and related analyses, and request for clarification regarding the manufacturing processes. The Company is working with consultants to cure the cited BLA deficiencies. In November 2021, the Company resubmitted the non-clinical and chemistry, manufacturing, and controls ("CMC") sections of the BLA and is currently reevaluating the feasibility and timelines over which it expects to complete the clinical section. As of March 2022, the FDA had commenced its review of the CMC section.

To facilitate our clinical research plans designed to accelerate and maximize the leverage of our multi-pathway approach to identifying and evaluating multiple opportunities for clinical indications, we engaged various contract research organizations ("CROs") to provide comprehensive regulatory and clinical trial management services. The clinical trial programs required a significant amount of capital to complete. The Company is in dispute with one of its former CROs, and, in the context of litigation with it, we obtained an order requiring the CRO to release the Company's clinical data related to the BLA, which the CRO had been withholding, further delaying our ability to complete the HIV BLA. Further, the order granted us the right to perform an audit of the CRO's services.

On March 31, 2022, the Company announced that the FDA had placed a full clinical hold on its COVID-19 program and a partial clinical hold on its HIV program in the United States. Under each of these clinical holds, no new clinical studies may be initiated until the clinical hold is resolved. The partial clinical hold on the HIV program allowed patients who were enrolled in the extension trials to transition to other available therapeutics. Under the full clinical hold on the COVID-19 program, no new clinical studies may be initiated until the clinical hold is resolved. The Company previously notified the FDA that it was pausing its COVID-19 trials in Brazil. We voluntarily withdrew the Investigational New Drug Application ("IND") for COVID-19 in the United States.

We are in the process of evaluating the data obtained from our former CRO, results of the audit, and implications of the HIV partial clinical hold. We will update the status and strategy of our anticipated resubmission of the clinical section of the BLA once we complete our evaluation.

There are currently no approved therapies for NASH and current 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 of patients to reduce HIV viral load, steatosis, and fibro-inflammation. We are currently focused on the following potential strategies:

1. Strengthening our pharmacovigilance program enabling us to remove the FDA clinical holds placed on our HIV and COVID-19 programs to allow us to conduct future clinical studies.
2. Advancing our NASH program to a Phase 2b or Phase 2b/3 trial for steatosis and liver fibrosis associated with NASH.
3. Exploring a study for patients with HIV and NASH.
4. Contining our Phase 2 program for metastatic triple-negative breast cancer with current standard of care, explore a Phase 2 colon cancer trial with current standard of care, and explore other solid tumor indications.
5. Continuing our work to evaluate the feasibility and timelines for the HIV BLA resubmission and explore other cancer and immunologic indications for leronlimab, continue our work on developing a long-acting version of leronlimab, and pursue proof of concept studies for HIV cure using leronlimab and AAV vectors.
6. Reviewing our strategy for our COVID-19 program.

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 HIV pre-exposure prophylaxis ("PrEP") if a longer acting version of subcutaneous leronlimab is successfully developed. This longer acting version could also be potentially 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 twenty-six 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 is the basis for our BLA submission with the FDA. We also commenced a rollover study for HIV, as combination therapy, designed for patients who 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 in March 2022, these patients were transitioned to current standard of care.

Leronlimab and NASH

As discussed earlier, 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. 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.

In October 2019, the FDA allowed us to proceed with a Phase 2 study to evaluate whether leronlimab may control the effects of liver fibrosis associated with NASH. This trial was originally designed to be a 60 patient, multi-center, randomized, double-blind, placebo-controlled Phase 2 clinical study of the safety and efficacy of leronlimab in adult patients with NASH. It was converted to an exploratory trial with an open label 350mg arm. The first patient was enrolled in December 2020. Leronlimab 700mg did not reduce mean change in PDFF and cT1 from baseline to week 14 versus placebo and did not meet its primary or secondary endpoints. Leronlimab 350mg significantly reduced mean change in PDFF and cT1 from baseline to week 14 versus placebo. Despite increased fibro-inflammation, in patients with moderate and severe cT1 values at baseline, leronlimab 350mg still showed significantly reduced cT1 from baseline to week 14 versus placebo.

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.

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. We have conducted the following trials:

Phase 2 Trial for Triple-Negative Breast Cancer

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.

Compassionate Use Study of Leronlimab in Triple Negative Breast Cancer

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.

Emergency IND Use Study of Leronlimab in Breast Cancer

One patient was administered leronlimab with stage 4 HER2+ breast cancer with metastasis to liver, lung, and brain. The patient received her first dose in November 2019 and remained on study drug until spring 2022.

Basket Trial for CCR5+ Locally Advanced or Metastatic Solid Tumors

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. If CytoDyn decides 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.

In calendar 2021, the Company initiated a Phase 2 investigative trial for post-acute sequelae of SARS COV-2 ("PASC"), also known as COVID-19 Long-Haulers, which was completed in July 2021. It is currently estimated that between 10%-30% of those infected with COVID-19 develop long-term sequelae. Common symptoms include fatigue, cognitive impairment, sleep disorders, and shortness of breath. This trial evaluated the effect of leronlimab on clinical symptoms and laboratory biomarkers to further understand the pathophysiology of PASC. This small investigative trial of 56 patients was not designed to show statistically significant differences due to the small sample size of the patients, but we believe potentially clinically meaningful improvements in the leronlimab-treated arm compared to the placebo-treated arm were observed for several symptoms. Preliminary results from the trial suggested leronlimab improved a majority of clinical symptoms. We observed increases in CCR5 expression from one expression in leronlimab responders but not placebo or leronlimab non-responders. These findings suggest an unexpected alternative mechanism of abnormal immune downmodulation, normalized by leronlimab. Plans to pursue additional clinical trials to evaluate leronlimab's effect on immunological dysregulation in COVID-19 and other post-viral syndromes are under strategic review.

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, and 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 will start to expire in 2023, the leronlimab concentrated protein formulation will start to expire in 2031, certain methods of using leronlimab for treatment of HIV-1 will start to expire in 2026, certain methods of using small-molecule CCR5 antagonists for treatment of cancer metastasis will start to expire in 2032, 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 will start to expire in 2042.

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 Part I, Item 1A, *Risk Factors* of this Form 10-k 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 at least a 12-year market and data exclusivity period measured from the first date of FDA licensure, during which period no other applications referencing leronlimab will be approved by FDA. Further, no other applications referencing leronlimab will be accepted by FDA for a 4-year period measured from the first date of FDA licensure. Accordingly, this period of regulatory exclusivity is expected to provide at least a 12-year term of protection against competing products shown to be biosimilar or interchangeable with leronlimab. Similar data exclusivity or data protection periods of between five (5) to ten (10) years are provided in at least Australia, Canada, Europe, Japan, and New Zealand. 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, 2022 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]	3	15	2023-2032	1	5
Methods of treatment by indication (e.g., HIV-1; COVID-19; GvHD) [2]	4	8	2022-2041	14	38
Methods of treatment – Cancer involving leronlimab (PRO 140 and/or anti-CCR5 small molecules) [2]	2	13	2032-2033	4	9
Mouse Model[2]	-	-	-	1	1

(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, and may be affected by subsequent, discoveries and test results, availability of financial resources, and other factors, and 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, pricing 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, or 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 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 the public health or safety.

On February 4, 2020, the Secretary determined that COVID-19 represents a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and, subsequently, declared on March 27, 2020, that circumstances exist to justify the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, subject to the terms of specific EUAs as issued by the FDA. The declaration has been renewed to extend through October 13, 2022.

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 FY2022 this application fee is approximately $3.1 million), and the sponsor of an approved BLA is also subject to an annual program fee, currently more than $350,000 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 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 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. Additionally, the following states have passed laws governing data privacy specifically: California, Virginia, Colorado, Connecticut, and Utah. Each of these laws contain exceptions for certain health data, but 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). California and Colorado are conducting rulemaking proceedings to develop implementing regulations for their laws, which could affect the laws' scope and the cost to comply with them.

The laws in Virginia, Colorado, Connecticut, and Utah will take effect in 2023 and the respective attorneys general will enforce them. California's law is already in effect but certain amendments to that law will take effect in 2023. Currently, the California Attorney General is charged with enforcing California's data privacy law, but there is a limited private right of action in the event of certain data breaches, which gives plaintiffs the ability to seek statutory damages. In 2023, a new dedicated privacy regulator in California (the California Privacy Protection Agency) will take over enforcement.

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 Part II, Item 8, Note 10, *Commitments and Contingencies - PRO 140 Acquisition and Licensing Arrangements* of this Form 10-K for additional information.

Manufacturing

We do not own or operate manufacturing facilities to produce leronlimab. As such, we must depend on third-party manufacturing organizations and suppliers for all of our clinical trial quantities of leronlimab, in addition to previously manufactured supplies of commercial grade leronlimab. We continue to explore alternative manufacturing sources, to

ensure that we have access to sufficient manufacturing capacity in order to meet potential demand 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.

As discussed earlier, the Company received a Refusal to File letter from the FDA regarding its BLA submission for leronlimab, and also announced that the FDA placed a full clinical hold on its COVID-19 program and a partial clinical hold on its HIV program in the United States. All manufacturing and CMC activities have been paused until the Company addresses deficiencies to allow the clinical hold to be removed, and later BLA to be approved.

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

Research and Development Costs

The Company's research and development expenses totaled approximately $27.0 million, $53.4 million and $52.6 million for the fiscal years ended May 31, 2022, 2021 and 2020, respectively.

Employees and Human Capital Resources

As of August 15, 2022, we had 23 full-time employees, as well as several independent consultants assisting us with the Company's regulatory 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 award stock options to selected employees under our stock 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, let alone maintain, profitability.

- The amount of financing we require will depend on a number of 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 capitalized pre-launch inventories prior to receiving FDA approval and have charged-off a portion of them due to their expected expiration based on the shelf-life relative to the date we expect to obtain regulatory approval. If either the FDA approval or market acceptance post-approval do not occur at all or on a timely basis prior to shelf-life expiration, we will be required to write-off additional or all pre-launch inventories, which would materially and adversely affect our financial condition, ability to raise additional financing, and stock price.

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.
- The loss or transition of any member of our senior management team or any other key employee could 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 by those agencies could divert management's focus and have a material adverse effect on our reputation and financial condition.

Risks Related to Development and Commercialization of Our Drug Candidates

- 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, 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 not able 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 experience significant delays in doing so, our business could be substantially 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 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 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 our product candidate, and/or to produce supplies for us with such delay causing us to impair our ability to complete our clinical trials 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 would have a significant 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 allows for 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 any cash dividends to be paid 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.

We must raise substantial additional funds in the near term to meet our payment obligations and fund our operations. The financial capital may not be available on acceptable terms or at all. In addition, as of May 31, 2022, we had only approximately 65.4 million shares of common stock available for issuance in new financing transactions. If we fail 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 our ability to remove clinical holds placed on us by the FDA, resubmission of our BLA application, analysis of clinical trial data for purposes of responding to FDA requirements and preparing additional regulatory submissions, additional clinical trials, regulatory and compliance activities, and legal defense activities. Any such delay or inability to pursue our planned activities could adversely affect our business, financial

condition, and stock price. 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. Our current drug candidate, leronlimab, is in various stages of development for multiple indications. We expect to incur losses for the foreseeable future, with no or only minimal revenues as we continue 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 a number of 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 submission, 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 Progenics, Lonza, and AbbVie,
- 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, 2022. 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 capitalized pre-launch inventories prior to receiving FDA approval and have charged-off a portion of them due to their expected expiration based on the shelf-life relative to the date we expect to obtain regulatory approval. If either the FDA approval or market acceptance post-approval do not occur at all or on a timely basis prior to shelf-life expiration, we will be required to write-off additional or all pre-launch inventories, which would materially and adversely affect our financial condition, ability to raise additional financing, and stock price.

Pre-launch inventories consist of raw materials and work-in-progress related to our product candidate leronlimab, the costs of which were capitalized prior to receiving FDA marketing approval. In addition, market acceptance of our product could fall short of our expectations due to introduction of a competing product, physicians being unwilling or unable to prescribe leronlimab to their patients, or if our target patient population is reluctant to try leronlimab as a new therapy. Pre-launch inventories consist of costs of raw materials and work-in-progress related to our product candidate leronlimab. Our planned BLA resubmission will require updating the analyses of clinical data previously provided to the FDA, which could result in a significant delay in obtaining approval. If the FDA approval is significantly delayed, the salability of our product may be affected due to the shelf-life of our pre-launch inventory and may require write-off of a significant portion of the carrying value of our pre-launch inventories, which would have a material adverse effect on our results of operations and financial condition.

During the fourth fiscal quarter of 2022, the Company concluded that certain inventories no longer qualify 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 is due to delays experienced from the originally anticipated BLA approval date from the FDA. Although these inventories are no longer being capitalized as pre-launch inventories for GAAP accounting purposes, the inventories written-off for 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 qualify for capitalization. Specifically, the Company evaluated its raw materials 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 reserve 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 comprising 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, as of May 31, 2022. Refer to Note 3, *Inventories, net* for additional information.

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 business depends on the skills, performance, and dedication of our officers and key scientific and technical advisors, and 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, which may affect their ability to provide services to us in a timely manner. We may need to recruit additional directors, executive management employees, and advisors, particularly scientific and technical personnel, which will require additional financial resources. 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. In order to successfully recruit and retain qualified employees, we will likely 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. 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.

The loss of a member of our senior management team or other key employee could adversely affect our business.

We have experienced significant turnover among our senior executives. 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 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 can be no assurance we will continue to be successful in attracting or retaining qualified personnel in the future.

Our success depends significantly on the continued 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 could harm 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 10-K for that fiscal year. As discussed in more detail in Item 9A of this Form 10-K, management determined that there was a material weakness in our internal control over financial reporting for periods beginning with the second fiscal quarter of 2021, and that our controls and procedures were ineffective at May 31, 2022. Any failure to maintain our controls or operation of these controls, could 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, COVID-19 has led to increased remote work by our employees, contractors, and other corporate partners. 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, and 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 of Directors, 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* of this Form 10-K for further information.

We are subject to the oversight by the SEC and other regulatory agencies. Investigations by those agencies could 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 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 COVID-19, 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. Certain of our executives have received subpoenas concerning similar issues and may be interviewed by the DOJ or SEC in the future. We are cooperating fully with these non-public, fact-finding investigations. In addition, we have received a Warning Letter from the FDA in which FDA asserted, among other matters, that statements made by our former CEO and President in a video interview created a misleading impression regarding the safety and efficacy of leronlimab. The Company is working closely with the FDA to resolve this matter and take the proper corrective actions. 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* of this Form 10-K for further information.

Risks Related to Development and Commercialization of Our Drug Candidates

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.

During fiscal 2022, Samsung communicated to us regarding alleged breaches of our agreements with Samsung relating to past due balances totaling approximately $38.1 million. 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 to be in breach of our agreements with Samsung. Failure to reach mutual agreement 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* of this Form 10-K for additional 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 the Progenics Purchase Agreement, the PDL License, and the Lonza Agreement, we must pay to Progenics, AbbVie, and Lonza significant milestone payments, license fees for "system know-how" technology, and royalties related to leronlimab. 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 any 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. For more information, refer to Part II, Item 8, Note 10, *Commitments and Contingencies* of this Form 10-K.

If we are not able 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. Success in early phases of pre-clinical and clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. A failure of one or more of our clinical trials may occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent our ability to receive regulatory approval or commercialize leronlimab, or any future drug candidate. 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 of a BLA 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 a BLA is approved. Regulatory authorities in other jurisdictions impose similar requirements. Of the large number of drugs in development, only a small percentage result in the submission of BLA to the FDA and even fewer are eventually 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, including the following:

- the FDA or comparable foreign regulatory authorities or institutional review boards ("IRBs") may disagree with the 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, the European Medicines Agency ("EMA"), or other comparable foreign regulatory authorities for marketing approval,
- the dosing of our drug candidate in a particular clinical trial may not be at an optimal level,
- 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 comparable 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 comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

As discussed in Part I, Item I, *Business*, the Company received a Refusal to File letter from the FDA regarding its BLA submission for leronlimab as a combination therapy with highly active antiretroviral therapy ("HAART") for highly treatment-experienced HIV patients. The Company also announced that the FDA placed a full clinical hold on its COVID-19 program and a partial clinical hold on its HIV program in the United States. Failure to obtain regulatory approval for leronlimab for the foregoing or any other reasons will prevent us from commercializing such product candidate as a prescription product, and our ability to generate revenue will be materially impaired. We cannot guarantee that regulators will agree with our assessment of the results of our clinical trials or that such trials will be considered by regulators to have shown safety or efficacy of our product candidate. The FDA, EMA and other regulators have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional clinical trials, or pre-clinical or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. 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. If we experience any delays in obtaining approval or if we fail to obtain approval of our product candidate, the commercial prospects for our product candidate may be harmed, and our ability to generate revenues will be materially 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 experience significant delays in doing so, our business could be substantially 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 the CROs we have hired to manage our clinical studies and the resulting data, as well as that of our collaborators and other third-party contractors,
- 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 Pharmaceuticals, Inc.,

- 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 any marketing approval,
- 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 experience delays as a result of any of these factors or otherwise, our business could be substantially harmed. If we are unable to obtain adequate coverage and reimbursement for leronlimab, or if healthcare reform or other proposals affect the availability of coverage and reimbursement for leronlimab, our business could 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, there are current treatments that are quite effective at controlling the effects of HIV and we expect that new developments by other companies and academic institutions in the areas of HIV treatment will continue. Similarly, 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 the 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. When we conduct clinical trials, we contract with third party full service CROs to manage our trials. As a result, we are 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 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 our product candidate, and/ or to produce supplies for us with such delay causing us to impair our ability to complete our clinical trials 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 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, in consultation with our collaborators, where applicable, design the clinical trials for our product candidate, leronlimab, but we rely on CROs and other third parties to perform many of the functions in managing, monitoring and otherwise carrying out many of these trials. 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 our ongoing and any future clinical trials, we are responsible for ensuring that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. Moreover, the FDA and foreign regulatory agencies require us 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, our clinical trials 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, it could lead to 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 – Amarex Dispute* for additional information.

As we stated earlier, we do not have capability or resources to manufacture, store, market or sell our current product candidate, and we do not own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidate; further, we have no plans to build our own clinical or commercial scale manufacturing capabilities. Therefore we relied, and anticipate to continue to do so in the future, upon third-party manufacturers to perform these services for us. Reliance on third-party manufacturers entails risks such as reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement because of factors beyond our control, failure of the third party to accept orders to supply raw materials, and the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities. In addition, all entities involved in the preparation of product candidates for clinical trials or commercial sale, including any contract manufacturers, are subject to extensive regulation which require that our product candidate be manufactured according to current good manufacturing practices (the "cGMP"), or similar foreign standards. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. We or our contract manufacturers must supply all necessary documentation in support of a BLA on a timely basis and must adhere to the FDA's current Good Laboratory Practice and cGMP regulations enforced through its facilities inspection program. Failure by our third-party manufacturers to comply with cGMP or failure to scale-up manufacturing processes as needed, including any failure to deliver sufficient quantities of product candidate in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of our product candidate. In addition, such failure could be the basis for action by the FDA to withdraw approvals for any product candidate previously granted to us and for other regulatory action, including recall or seizure, fines, imposition of operating restrictions, total or partial suspension of production or injunctions. Any significant delay in the supply of a product candidate or the raw material components thereof for an ongoing clinical trial or potential commercial launch due to the need to replace a third-party manufacturer could considerably delay completion of future clinical trials, product testing and potential regulatory approval of our product candidate. Any manufacturing problem or the loss of a contract manufacturer could be disruptive to our operations. Further, if we or our third-party manufacturers fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new product, or revocation of a pre-existing approval. If we are unable to arrange for third-party manufacturing sources, or to do so on commercially reasonable terms, we may not be able to complete development of our product candidate or to market it. Any unanticipated disruption of our relationship with a contract manufacturer could delay shipment of our products and increase our manufacturing and storage costs. Refer to Part II, Item 8, Note 10, *Commitments and Contingencies – Commitments with Samsung BioLogics Co., Ltd.*

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.

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 the 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 would have a significant 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, 2021 through May 31, 2022, the market price of our common stock has fluctuated from a high of $2.46 per share to a low of $0.24 per share, and our stock price reached a 52-week high of $2.46 on September 22, 2021. 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 allows for 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 of Directors 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 the 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,
- 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, 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 cash dividends to be paid 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* of this Form 10-K.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

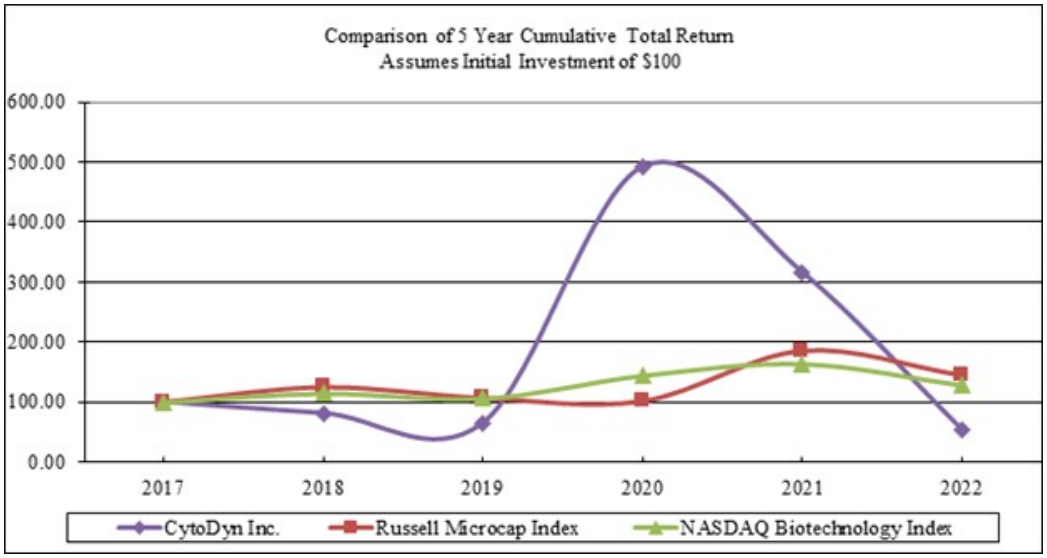
Part II

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.

The stock performance graph has been prepared assuming that $100 was invested on June 1, 2017 in our common stock. The stock price performance reflected in the graph may not be indicative of future price performance.



Holders

The number of record holders of our common stock on July 31, 2022 was approximately 993.

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, 2022, the Company had an accumulated deficit of approximately $766.1 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* for additional information.

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 financial condition, operations, plans, objectives and performance 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, Item 1A, *Risk Factors* of this Form 10-K.

Overview

The Company is a biotechnology company focused on the clinical development and potential commercialization of its product candidate, leronlimab (PRO 140), which is being studied for the treatment of HIV infection, NASH, oncology and other immunological indications. Our current business strategy is to seek the removal of the partial and full clinical holds recently imposed by the US FDA in March 2022, evaluate feasibility and timelines for the resubmission of our BLA for leronlimab as a combination therapy for highly treatment-experienced HIV patients, and to seek to further develop leronlimab for other HIV-related indications. We also seek to advance our clinical development of leronlimab for various forms of cancer, including metastatic triple negative breast cancer ("mTNBC") and other solid tumors, as well as to continue to evaluate NAFLD and NASH, and concurrently to explore other potential immunologic indications for leronlimab.

As further discussed in Part II, Item 8, Note 2, *Summary of Significant Accounting Policies - Inventories,* Note 3, *Inventories, net,* and Note 10*, Commitments and Contingencies*, the Company capitalized procured or produced pre-launch inventories in preparation for product launches. The Company considers anticipated future sales, shelf-lives, and expected approval date 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 may 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. In determining whether pre-approval inventory remains salable, the Company considers a number of factors, including potential delays in obtaining regulatory approval, the introduction of competing products that may negatively impact the demand for our product, the likelihood that physicians would be willing to prescribe leronlimab to their patients, and whether the target patient population would be willing to try leronlimab as a new therapy.

Fiscal 2022 Overview

Fiscal 2022 was a transitional year for the Company which included:

- Notification that the FDA had placed our HIV and COVID-19 programs on partial and full clinical holds, respectively;
- Successfully avoiding an attempted proxy contest seeking to replace the Company's Board of Directors;
- Strengthening the Company's Board of Directors and Scientific Advisory Board through the addition of highly-qualified and experienced members;
- Leadership transitions including the termination of the Company's former President and CEO in January 2022 and the hiring of a biotech veteran as its new President in July 2022;
- Completion of COVID-19 Long-Haulers, NASH, and oncology studies;
- Entering into a research agreement with a leading US cancer research institution;
- Resubmission of two of the three sections of the HIV BLA;
- Acceptance of five articles into various scientific journals;
- Strengthening our pharmacovigilance program, in part in response to the clinical holds placed on the Company by the FDA;
- Settlement of an ongoing legal disputes with the Company's former CMO and the 2020 shareholder derivative suit; and
- Completion of a number of private offerings to continue to fund the Company's progress.

Clinical and corporate development highlights are provided below.

HIV BLA and Clinical Developments

The remaining BLA section to be completed and submitted remains in progress as of the date of this report. The Company is in a dispute with its former contract research organization ("CRO"); the Company obtained an order requiring the CRO to release the Company's clinical data related to the BLA, which the CRO had been withholding, thereby preventing the Company from completing necessary clinical data submissions to the FDA. The order granted the Company access to the data and the right to perform an audit of the CRO's services. In March 2022, the FDA notified the Company that it had placed a partial clinical hold on the Company's HIV program; the Company was not enrolling any new patients in the trials placed on hold. The partial clinical hold on the HIV program impacted patients currently enrolled in HIV extension trials. The affected patients have been transitioned to other available therapeutics. No clinical studies can be initiated or resumed until the partial clinical hold is resolved, which may affect our ability to resubmit the BLA. The Company's efforts are focused on activities that will allow us to resolve the partial clinical hold and resume the BLA resubmission process. The Company will update the status of its anticipated resubmission of the clinical section of the BLA once it determines a date for resubmission.

Earlier in fiscal 2022, the Company completed the following:

- In June 2021, an animal study was published in Nature Communications regarding the use of leronlimab for HIV PrEP.
- In July 2021, the Company submitted its dose justification draft report to the FDA in connection with the resubmission of its BLA.
- In August 2021, the Company received guidance from the FDA with regard to its previously submitted HIV BLA draft dose justification report.
- In October 2021, the FDA accepted a revised rolling review timeline for resubmitting the BLA, allowing for contemporaneous review by the FDA for sections as they are submitted.
- In November 2021, the Company resubmitted two of the three integral sections of the BLA for review by the FDA, the non-clinical and manufacturing sections.

NASH Clinical Developments

There is currently no approved drug for NASH, and 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 and is exploring potential business opportunities to continue the investigation of leronlimab in the NASH indication and HIV patients with NASH. In October 2019, the FDA granted clearance to CytoDyn to proceed with a Phase 2 study to test whether leronlimab may control the effects of liver fibrosis associated with NASH. This trial was converted to an exploratory trial with an open label 350mg arm. The first patient was enrolled in December 2020. Leronlimab 700mg did not reduce mean change in PDFF and cT1 from baseline to week 14 versus placebo and did not meet its primary or secondary endpoints. Leronlimab 350mg significantly reduced mean change in PDFF and cT1 from baseline to week 14 versus placebo. Despite increased fibro-inflammation, in patients with moderate and severe cT1 values at baseline, leronlimab 350mg showed significantly reduced cT1 from baseline to week 14 versus placebo.

Cancer Clinical Developments

During 2021, the Company reported results from mTNBC patients who had failed at least two lines of previous therapy in the Compassionate Use program, our Phase 1b/2 clinical trial, and our Basket trial. The data were insufficient to support resubmission of a Breakthrough Therapy designation request without additional data. The Company is identifying the next steps in clinical development and potential business opportunities to continue the development of this indication, including potentially facilitating research in leronlimab's role in oncology at various academic institutions.

Earlier in fiscal 2022, the Company completed the following:

- In July 2021, the Company's Phase 1b clinical trial for mTNBC advanced to Phase 2 of the trial.

- In August 2021, the Company's final mTNBC report indicated an increase in 12-month overall survival and 12-month modified progression-free survival in certain patients.
- In October 2021, the Company signed a research agreement with a leading cancer research institution, the University of Texas MD Anderson Cancer Center, to evaluate the potential synergistic therapeutic efficacy of leronlimab in combination with immune checkpoint blockade.
- In January 2022, the FDA notified the Company that its mTNBC data did not demonstrate a substantial improvement over existing mTNBC therapies in the limited number of patients provided; therefore, it could not grant Breakthrough Therapy designation. The FDA indicated that the Company may submit a new request with additional clinical evidence that demonstrates a substantial improvement in second-line treatment of mTNBC over existing therapies.

COVID-19 Clinical Developments

In March 2022, the FDA notified the Company it had placed a full clinical hold on the Company's COVID-19 program. The Company was not conducting any COVID-19 trials in the United States at the time the hold was placed, and elected to voluntarily withdraw the respective IND. The Company will need to resolve the clinical hold and submit another IND before initiating any future COVID-19 trials in the United States. Further, the Company had elected to pause its Brazil COVID-19 trials pending results from its previously scheduled data safety monitoring board ("DSMB") meeting in early April 2022. In April 2022, the DSMB for the Brazilian COVID-19 clinical trials met and recommended that the Brazilian COVID-19 trials, previously paused by the Company, may continue based on the review of the interim patient safety data from the clinical trials. The Company is in the process of considering strategic alternatives prior to commencing the enrollment of new patients in the Brazilian trials.

Earlier in the year, the Company completed the following:

- In June 2021, the Company received its first purchase order from Chiral Pharma Corporation ("Chiral") to treat critically ill COVID-19 patients in the Philippines under a Compassionate Special Permit ("CSP"). This order was fulfilled in August 2021. In September 2021, the Company received two additional purchase orders from Chiral in the aggregate amount of approximately $0.2 million to continue to treat critically ill COVID-19 patients in the Philippines under a CSP. These orders were shipped during the quarter ended November 30, 2021.
- In July 2021, the Company was granted a patent by the U.S. Patent and Trademark Office for methods of treating COVID-19.
- In August 2021, the Company received clearance from Brazil's ANVISA to commence its Phase 3 trial for severe COVID-19 patients. The trial was conducted in up to 35 clinical sites with 612 patients. The first patient was treated in this trial in September 2021. Also in September 2021, the Company received clearance from Brazil's ANVISA to commence its pivotal Phase 3 trial in critically ill COVID-19 patients. The first patient was treated in this trial in October 2021.

Corporate Developments

In January 2022, the Board of Directors terminated the employment of Nader Z. Pourhassan, Ph.D. as President and CEO of the Company; he is also no longer a member of the Board of Directors. A committee of three Board members was appointed to initiate the search for a new CEO culminating in the appointment of Cyrus Arman, Ph.D., MBA as President effective July 9, 2022. Antonio Migliarese, the Company's Chief Financial Officer, was appointed interim President and served in that role until July 9, 2022.

During February 2022, the Board of Directors approved the continued appointments to the Scientific Advisory Board ("SAB") of Dr. Hope Rugo (oncology), Dr. Mazen Noureddin (hepatology), Dr. Jonah Sacha (HIV), Dr. Norman Gaylis (rheumatology), and Dr. Eric Mininberg (oncology), as well as new SAB members Dr. Otto Yang (infectious diseases/immunology), Dr. Kabir Mody (oncology), Dr. Paul Edison (neuroscience/neuroinflammation), and Dr. Gero Hutter (hematology, oncology and transfusion medicine).

In March 2022, the Board of Directors appointed Karen J. Brunke, Ph.D. as a director of the Company. Dr. Brunke has over 30 years of scientific, operational, clinical, senior executive, and corporate development experience with large and small biotechnology companies.

Results of operations for the fiscal years ended May 31, 2022, 2021 and 2020

Fluctuations in Operating Results

The Company's operating results may fluctuate significantly depending on the outcomes of clinical trials, patient enrollment and/or completion rates in clinical trials, entering into new clinical trial protocols, and their related effect on research and development expenses, regulatory and compliance activities, activities related to preparation and resubmission of the HIV BLA, general and administrative expenses, professional fees, and legal proceedings and the related outcomes. As a predominantly non-revenue generating company, we require a significant amount of additional capital to continue to operate; therefore, we regularly conduct offerings to raise capital, which can create various forms of non-cash interest expense or expense related to amortization of issuance costs. Additionally, we periodically negotiate settlement of debt payment obligations in exchange for equity securities of the Company, and enter into private warrant exchanges which may create a non-cash charge upon extinguishment of debt and/or inducement expense. Our ability to continue to fund operations will depend on our ability to raise additional capital. Refer to Part 1, Item 1A, *Risk Factors* of this Form 10-K, *Liquidity and Capital Resources*, and *Going Concern* sections below.

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

	Years ended May 31,			2022/2021 Change		2021/2020 Change	
	2022	2021	2020	$	%	$	%
(in thousands, except for per share data)		(Restated) [1]	(Revised) [1]				
Revenue	$ 266	$ —	$ —	$ 266	100	$ —	—
Cost of goods sold	53	—	—	53	100	—	—
Gross margin	213	—	—	213	100	—	—
Operating expenses:							
General and administrative	44,303	34,320	19,973	9,983	29	14,347	72
Research and development	27,043	53,403	52,640	(26,360)	(49)	763	1
Amortization and depreciation	781	1,797	2,034	(1,016)	(57)	(237)	(12)
Intangible asset impairment charge	—	10,049	—	(10,049)	(100)	10,049	100
Inventory write-off	73,490	5,027	—	68,463	1,362	5,027	100
Total operating expenses	145,617	104,596	74,647	41,021	39	29,949	40
Operating loss	(145,404)	(104,596)	(74,647)	(40,808)	39	(29,949)	40
Interest and other expense:							
Interest on convertible notes	(5,417)	(4,387)	(7,330)	(1,030)	23	2,943	(40)
Amortization of discount on convertible notes	(2,958)	(3,591)	(1,645)	633	(18)	(1,946)	118
Amortization of debt issuance costs	(87)	(65)	(404)	(22)	34	339	(84)
Loss on induced conversion	(37,381)	(39,131)	—	1,750	(4)	(39,131)	100
Finance charges	(9,029)	(145)	(431)	(8,884)	6,127	286	(66)
Inducement interest expense	(6,691)	(13,922)	(23,437)	7,231	(52)	9,515	(41)
Legal settlement	(3,853)	(10,628)	(22,500)	6,775	(64)	11,872	(53)
Change in fair value of derivative liabilities	—	—	(9,542)	—	—	9,542	(100)
Total interest and other expense	(65,416)	(71,869)	(65,289)	6,453	(9)	(6,580)	10
Loss before income taxes	(210,820)	(176,465)	(139,936)	(34,355)	19	(36,529)	26
Income tax benefit	—	—	—	—	—	—	—
Net loss	$ (210,820)	$ (176,465)	$ (139,936)	$ (34,355)	19	$ (36,529)	26
Basic and diluted:							
Loss per share	$ (0.31)	$ (0.30)	$ (0.33)	$ (0.01)	4	$ 0.03	(9)
Weighted average common shares outstanding	676,900	587,590	421,078	89,310	15	166,512	40

(1) See Note 2, *Revision of Financial Statements,* and Note 14, *Restatement.*

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

We recognized revenue of approximately $266.4 thousand and cost of goods sold of approximately $52.8 thousand in the fiscal year ended May 31, 2022; none in fiscal year 2021. 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 yet 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. For additional information about revenue recognition and our inventories policies, refer to Note 2, *Summary of Significant Accounting Policies, Revenue Recognition* and *Inventories* to the consolidated financial statements of this Form 10-K.

There were no revenues or cost of goods sold recognized in the fiscal years ended May 31, 2021 and 2020.

General and administrative expenses

General and administrative expenses consisted of the following:

	Years ended May 31,			2022/2021 Change		2021/2020 Change	
(in thousands)	2022	2021	2020	$	%	$	%
Salaries, benefits, and other compensation	$ 6,336	$ 13,161	$ 5,488	$ (6,825)	(52)%	$ 7,673	140 %
Stock-based compensation	6,263	10,429	6,548	(4,166)	(40)	3,881	59
Legal fees	21,993	5,548	1,441	16,445	296	4,107	285
Other	9,711	5,182	6,496	4,529	87	(1,314)	(20)
Total general and administrative	$ 44,303	$ 34,320	$ 19,973	$ 9,983	29 %	$ 14,347	72 %

G&A expenses totaled approximately $44.3 million and $34.3 million during the fiscal years ended May 31, 2022 and 2021, respectively, representing an increase of approximately $10.0 million, or 29% over the previous fiscal year. The increase in G&A expenses over the 2021 fiscal year was primarily due to legal and consulting fees and increased insurance premiums, offset by decreases in salaries, benefits, and stock-based compensation. The increase in legal fees was related to the proxy contest and related lawsuits, SEC and DOJ investigations, the Pestell employment dispute, and the Amarex dispute.

G&A expenses totaled approximately $34.3 million and $20.0 million during the fiscal years ended May 31, 2021 and 2020 respectively, representing an increase of approximately $14.3 million, or 72% over the preceding fiscal year. The increase in G&A expenses over the 2020 fiscal year was primarily due to employee compensation and related expenses, increased non-cash stock-based compensation, and higher professional services fees.

Research and development expenses

R&D expenses consisted of the following:

	Years ended May 31,			2022/2021 Change		2021/2020 Change	
(in thousands)	2022	2021	2020	$	%	$	%
Clinical	$ 20,347	$ 36,728	$ 29,553	$ (16,381)	(45)%	$ 7,175	24 %
Non-clinical	986	2,201	2,999	(1,215)	(55)	(798)	(27)
CMC	4,995	13,537	19,392	(8,542)	(63)	(5,855)	(30)
License and patent fees	715	937	696	(222)	(24)	241	35
Total research and development	$ 27,043	$ 53,403	$ 52,640	$ (26,360)	(49)%	$ 763	1 %

R&D expenses totaled approximately $27.0 million during the fiscal year ended May 31, 2022, a decrease of approximately $26.4 million, or 49%, compared to the preceding fiscal year. The decrease year over year was primarily due to lower clinical trial expenses resulting from clinical trials predominantly being administered and completed in prior year related to US COVID-19, oncology, and NASH, the pausing of the Brazilian COVID-19 trials, and the closing of HIV extension studies due to clinical holds placed on the Company by the FDA. The future trend of R&D expenses is dependent on the timing of BLA resubmission and the FDA approval, if any, the timing of FDA clearance from clinical hold, if any, of our pivotal trial protocol for leronlimab as a monotherapy for HIV patients, the future clinical development of oncology and NASH indications, the outcome of pre-clinical studies for several other cancer indications, and potential outcomes of the Brazilian COVID-19 trials. Additionally, the Company concluded the majority of its CMC activities related to the HIV BLA during fiscal 2021, thus resulting in a significant expense decrease in fiscal 2022 as compared to the preceding year.

R&D expenses totaled approximately $53.4 million during the fiscal year ended May 31, 2021, an increase of approximately $0.8 million, or 1%, over the fiscal year ended May 31, 2020. The 2021 increase over 2020 was primarily

attributable to higher clinical trial expenses, partially offset by decreases in non-clinical and CMC expenses. The increase in clinical trial costs were attributable to clinical trials related to COVID-19, oncology and immunology indications.

Amortization and depreciation expenses and Intangible asset impairment charge

Amortization and depreciation expense totaled approximately $0.8 million for the fiscal year ended May 31, 2022, a decrease of approximately $1.0 million, or 57% from the preceding year. The decrease was attributable to the intangible write-off of a proprietary algorithm intangible asset during the fiscal year ended May 31, 2021 and the ProstaGene noncompete intangible asset becoming fully amortized as of November 30, 2021, resulting in decreased amortization expense of intangibles.

Amortization and depreciation expense totaled approximately $1.8 million for the fiscal year ended May 31, 2021, a decrease of approximately $0.2 million, or 12% from the prior year. The decrease was attributable to the intangible write-off of a proprietary algorithm intangible asset, resulting in decreased amortization of intangibles.

For the fiscal years ended May 31, 2022 and 2020, the Company recorded no intangible asset impairment charges. The charge recorded in fiscal year 2021 was attributable to the impairment of the net carrying value of the proprietary algorithm the Company acquired in connection with the acquisition of the assets of ProstaGene, LLC in November 2018, and which was recorded as intangible asset in the Company's consolidated balance sheets.

Inventory write-off

During the fourth fiscal quarter of 2022, the Company concluded that certain inventories no longer qualify 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 is due to delays experienced from the originally anticipated BLA approval date from the FDA. Although these inventories are no longer being capitalized as pre-launch inventories for GAAP accounting purposes, the inventories written-off for 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 qualify for capitalization. Specifically, the Company evaluated its raw materials 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 reserve 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 comprising 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, as of May 31, 2022.

The Company recorded an inventory write-off based on its expected expiration dates of $5.0 million in fiscal 2021. Refer to Part II, Item 8, Note 3*, Inventories, net* in this Form 10-K for additional information.

Interest and other expense

Interest and other expenses consisted of the following:

	Years ended May 31,			2022/2021 Change		2021/2020 Change	
	2022	2021	2020	$	%	$	%
(in thousands)		(Restated) [1]	(Revised) [1]				
Interest on convertible notes payable	$ 5,417	$ 4,387	$ 7,330	$ 1,030	23 %	$ (2,943)	(40)%
Amortization of discount on convertible notes	2,958	3,591	1,645	(633)	(18)	1,946	118
Amortization of debt issuance costs	87	65	404	22	34	(339)	(84)
Loss on induced conversion	37,381	39,131	—	(1,750)	(4)	39,131	100
Finance charges	9,029	145	431	8,884	6,127	(286)	(66)
Inducement interest expense	6,691	13,922	23,437	(7,231)	(52)	(9,515)	(41)
Legal settlement	3,853	10,628	22,500	(6,775)	(64)	(11,872)	(53)
Change in fair value of derivative liabilities	—	—	9,542	—	—	(9,542)	(100)
Total interest and other expense	$ 65,416	$ 71,869	$ 65,289	$ (6,453)	(9)%	$ 6,580	10 %

(1) See Note 2, *Revision of Financial Statements,* and Note 14, *Restatement.*

Interest and other expense totaled approximately $65.4 million for the fiscal year ended May 31, 2022, a decrease of approximately $6.5 million, or 9%, from the preceding year. For the fiscal year ended May 31, 2022, we recognized non-cash losses on the induced conversion of convertible notes with common stock of approximately $37.4 million, a decrease of approximately $1.8 million, or 4%, from the preceding fiscal year. The losses resulted from separately and independently negotiated exchange agreements to satisfy certain note payment obligations in which certain debt was agreed to be settled in exchange for shares issued at a price less than the closing price for the effective date of the respective transactions. Inducement interest expense related to warrant inducements for the fiscal year ended May 31, 2022, totaled $6.7 million, a decrease of approximately $7.2 million, or 52%, from fiscal year ended May 31, 2021. During fiscal year ended May 31, 2021, the Company entered into fewer warrant inducement transactions as compared to the preceding year, resulting in a decreased inducement expense. During fiscal year 2022, the Company issued a total of 10.2 million shares of common stock, including additional shares as an inducement for warrant holders to exercise warrants; by comparison the Company issued a total of 36.2 million shares in connection with private warrant exchanges in the fiscal year ended May 31, 2021.

During the year, we also recorded $2.4 million of estimated finance charges related to open amounts due to Samsung. Additionally, we recorded approximately $6.6 million of non-cash finance charges related to 15 million warrants issued under a surety bond backstop agreement as a finance charge in the accompanying consolidated statement of operations. Refer to Note 7, *Equity Awards*, and Note 10, *Commitments and Contingencies - Commitments with Samsung BioLogics Co., Ltd. ("Samsung")*, respectively, of this Form 10-K for additional information. There were no comparable expenses in the preceding fiscal year. We also recorded $3.9 million of legal settlement charges related to settlement of a dispute with a placement agent and settlement of the Pestell employment dispute. Refer to Part II, Item 8, Note 10, *Commitments and Contingencies* for additional information.

Interest and other expense totaled approximately $71.9 million for the fiscal year ended May 31, 2021, an increase of approximately $6.6 million, or 10%, from fiscal year ended May 31, 2020. The increase mainly relates to an increase in loss on the induced conversion of convertible notes, offset by decreases in change in fair value of derivative liabilities, legal settlement expense, and inducement interest. For the fiscal year ended May 31, 2021, we did not realize a change in fair value of derivative liabilities as compared to the prior year, as the originating instruments were all exercised and settled during the 2020 fiscal year. The originating underlying instruments were certain warrants that originated in September 2016 and two convertible note instruments originated in June 2018 and January 2019 containing contingent cash settlement provisions, which gave rise to a derivative liability. For each reporting period, the Company determined the fair value of the derivative liability and recorded a corresponding non-cash benefit or non-cash charge, due to a decrease or increase, respectively, in the calculated derivative liability.

Legal settlements for the fiscal year ended May 31, 2021, of $10.6 million related to cash damages awarded to plaintiffs in legal proceedings against the Company. Legal settlements (non-cash) for the fiscal year ended May 31,

2020, of $22.5 million related to the issuance of shares of common stock in settlement of a claim filed by the holder of the January 2019 note alleging that the note holder was owed additional shares upon conversion of the note.

Inducement interest expense related to warrant inducements for the fiscal year ended May 31, 2021, totaled $13.9 million, a decrease of approximately $9.5 million, or 41%, from fiscal year ended May 31, 2020. During fiscal year ended May 31, 2021, the Company entered into fewer warrant inducement transactions as compared to the preceding year, resulting in decreased inducement expense. During fiscal year 2021, the Company issued a total of approximately 35.8 million shares of common stock, and approximately 0.4 million additional shares as an inducement for warrant holders to exercise warrants, for a total of approximately 36.2 million shares related to warrant inducements. In fiscal year 2020, the Company issued a total of 65.9 million shares in connection with private warrant exchanges. During fiscal year 2022, the Company identified an error in how non-cash inducement interest expense was calculated in previous reporting periods dating back to fiscal year 2018, resulting in a revision of previously reported inducement interest expense amounts. Refer to Part II, Item 8, Note 2, *Summary of Significant Accounting Policies - Revision of Financial Statements* of this Form 10-K for the discussion.

During the preparation and audit of the annual financial statements as of and for the fiscal year ended May 31, 2022, the Company concluded that a material error was identified in how the Company was accounting for common stock issued to settle certain convertible note obligations dating back to fiscal year 2021. The Company had been accounting for these transactions in accordance with debt extinguishment accounting. However, although the contractual terms did not explicitly describe the transactions as induced conversions, the transactions should be accounted for as induced conversions rather than extinguishments of debt and are therefore subject to induced conversion accounting. The error resulted in an understatement of the previously reported non-cash loss on induced conversions and additional paid-in capital. The errors had no impact on operating loss, cash, net cash used in or provided by operating, financing, and investing activities, assets, liabilities, commitments and contingencies, total stockholders' (deficit) equity, number of shares issued and outstanding, basic and diluted weighted average common shares outstanding, and number of shares available for future issuance for any of the affected periods. Refer to Part II, Item 8, Note 14, *Restatement* for additional information. For the fiscal year ended May 31, 2021, we recognized non-cash losses on the induced conversion of convertible notes of approximately $39.1 million. We did not recognize any non-cash losses on induced conversion of convertible notes in fiscal year ended May 31, 2020. The losses resulted from separately and independently negotiated exchange agreements to satisfy certain note payment obligations in which certain debt was agreed to be settled in exchange for shares issued at a price less than the closing price for the effective date of the respective transactions.

Liquidity and Capital Resources

As of May 31, 2022, we had a total of approximately $4.2 million in cash and approximately $123.2 million in short-term liabilities consisting primarily of approximately $42.2 million representing the current portion and accrued interest of convertible notes payable and approximately $76.8 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 accommodative and we do not currently anticipate significant delays in our business initiatives schedule due to 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 position of approximately $4.2 million at May 31, 2022 decreased by approximately $29.7 million compared to the balance of approximately $33.9 million at May 31, 2021. During the fiscal year ended May 31, 2022, we funded our operations by obtaining a total of approximately $48.0 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)	Years ended May 31, 2022	2021	2020	2022/2021 Change $	2021/2020 Change $
Net cash (used in) provided by:					
Net cash used in operating activities	$ (77,723)	$ (117,573)	$ (68,804)	$ 39,850	$ (48,769)
Net cash used in investing activities	$ —	$ (122)	$ (41)	$ 122	$ (81)
Net cash provided by financing activities	$ 48,011	$ 137,346	$ 79,670	$ (89,335)	$ 57,676

Cash used in operating activities decreased by approximately $39.9 million during the fiscal year ended May 31, 2022 primarily due to changes in our net loss, working capital fluctuations and changes in our non-cash expenses, all of which are highly variable. Cash used in operating activities totaled approximately $117.6 million during the fiscal year ended May 31, 2021, which reflects an increase of approximately $48.8 million over the approximately $68.8 million in fiscal year 2020. The increase in net cash used in operating activities was due to increased pre-launch inventories, and net loss, offset in part by the intangible asset impairment charge, increased accounts payables and accrued liabilities, and increased non-cash loss on induced conversion of debt, when compared to the changes in the prior year.

Cash used in investing activities did not change significantly between the fiscal years.

Cash provided by financing activities decreased by approximately $89.3 million which was primarily attributable to decreased funding in fiscal 2022 through convertible debt and decreased proceeds from warrant exercises, offset by proceeds from the sale of common stock and warrants during the fiscal year 2022. Cash provided by financing activities totaled approximately $137.3 million during the fiscal year ended May 31, 2021 representing an approximate $57.7 million increase in net cash provided by financing activities when compared to the previous fiscal year. The increase in net cash provided from financing activities was primarily attributable to an increase in proceeds from convertible debt issuances and an increase in proceeds from warrant inducement transactions.

Pre-launch inventories

During the fourth fiscal quarter of 2022, the Company concluded that certain inventories no longer qualify 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 is due to delays experienced from the originally anticipated BLA approval date from the FDA. Although these inventories are no longer being capitalized as pre-launch inventories for GAAP accounting purposes, the inventories written-off for 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 qualify for capitalization. Specifically, the Company evaluated its raw materials 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 reserve 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 comprising 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, as of May 31, 2022. Refer to Part II, Item 8, Note 3, *Inventories, net* for additional information.

Convertible debt

April 2, 2021 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 2023. 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, 2022, the outstanding balance of the April 2, 2021 Note, including accrued interest, was $11.9 million.

April 23, 2021 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 2023. Beginning six months after the issuance date, the noteholder may request monthly redemptions of up to $7.0 million. As of May 31, 2022, the outstanding balance of the April 23, 2021 Note, including accrued interest, was $30.3 million.

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

Common stock

We have 1,000.0 million authorized shares of common stock. The table below summarizes intended uses of common stock.

(in millions)	As of May 31, 2022
Issuable upon:	
Warrants exercise	88.2
Convertible preferred stock and undeclared dividends conversion	32.5
Outstanding stock options exercise or vesting of outstanding RSUs	17.8
Reserved for issuance pursuant to future stock-based awards under equity incentive plan	3.9
Reserved and issuable upon conversion of outstanding convertible notes	12.0
Reserved for private placement of common stock and warrants through placement agent	60.6
Total shares reserved for future uses	215.0
Common stock outstanding	719.6

As a result, as of May 31, 2022, we had approximately 65.4 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, 2022, 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,* and Note 10, *Commitments and Contingencies* 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 an accrual had not 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

FDA Refusal to File Letter re 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. The FDA informed the Company the BLA did not contain certain information and data needed to complete a substantive review and therefore, the FDA would not file the BLA. The deficiencies cited by FDA included administrative deficiencies, omissions, corrections to data presentation and related analyses, and clarifications regarding the manufacturing processes. The Company is working with consultants to cure the BLA deficiencies noted and will resubmit the BLA as soon as practical. In November 2021, the Company resubmitted the non-clinical and CMC sections of the BLA and is currently reevaluating when it expects to complete the clinical section. As of March 2022, the FDA had commenced its review of the CMC section. The Company is in dispute with its former contract research organization ("CRO"), as described in Note 10, *Commitments and Contingencies – Legal Proceedings* to this Form 10-K. Recently, in the context of the litigation, the Company obtained an order requiring the CRO to release the Company's clinical data related to the BLA, which the CRO had been withholding. Further, the order granted the Company the right to perform an audit of the CRO's services. Additionally, the FDA recently placed the HIV program on a partial clinical hold, which may affect the ability to resubmit the BLA. The Company is in the process of evaluating the data, results of the audit, and implications of the partial clinical hold. The Company will provide an updated strategy once it completes its evaluation, the impact those results may have on the BLA and an updated strategy timeline.

FDA Warning Letter re COVID-19 Misbranding of Investigational Drug

In January 2022, the Company received a Warning Letter from the United States FDA alleging that its former CEO and President, Dr. Nader Pourhassan, 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 has not yet been established, and that the related clinical trial data was mischaracterized in the video. The FDA further alleged the video misbrands leronlimab under section 502(f)(1) of the FD&C Act and in violation of section 301(a) of the FD&C Act, as the claims in the video make 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. The Company is working closely with the FDA to resolve this matter and take the proper corrective actions.

FDA Partial Clinical Hold re HIV and Full Clinical Hold re COVID-19 Letters

In March 2022, the United States 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. The partial clinical hold on the HIV program impacts patients currently enrolled in extension trials. These patients have transitioned to other available therapeutics and no clinical studies can be initiated or resumed until the partial clinical hold is resolved. CytoDyn is working closely with the FDA to resolve the partial clinical hold as soon as possible. Under the full clinical hold on the COVID-19 program, no new clinical studies may be initiated until the clinical hold is resolved.

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 $210.8 million for the year ended May 31, 2022 and has an accumulated deficit of $766.1 million as of May 31, 2022. As of May 31, 2022, 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 our efforts to complete the resubmission of our BLA and other development and commercialization initiatives or to adequately fund legal proceedings, 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 the date of this filing, the Company has approximately 65.4 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 those of common shares. 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. In February 2022, in exchange for warrants, the Company entered into a backstop arrangement with an accredited investor whereby the Company pledged its patents and the investor agreed to indemnify the issuer of the surety bond in the Amarex dispute with respect to the Company's obligations under the surety bond. 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* of this Form 10-K for the discussion.

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.

Inventories

We capitalize inventories procured or produced in preparation for product launches sufficient to support estimated initial market demand. 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 we have determined that it is probable that these capitalized costs will provide some 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 the compilation of the regulatory application. We closely monitor the status of the product within the regulatory review and approval process, including all relevant communication with regulatory authorities. If we are 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, the related inventory may no longer qualify for capitalization.

We value inventory at the lower of cost or net realizable value using the average cost method. Inventories currently consist of raw materials, bulk drug substance, and drug product in unlabeled vials to be used for commercialization of the Company's biologic, leronlimab, which is in the regulatory approval process. Inventory purchased in preparation for product launches is evaluated for recoverability by considering the likelihood that revenue will be obtained from the future sale of the related inventory, in light of 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 has become obsolete, or has a cost in excess of its expected net realizable value, and inventory quantities in excess of expected requirements. In assessing the lower of cost or net realizable value to pre-launch inventory, the Company relies on independent analysis provided by third parties knowledgeable of the range of likely commercial prices comparable to current comparable commercial product.

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.

During the fourth fiscal quarter of 2022, the Company concluded that certain inventories no longer qualify 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 is due to delays experienced from the originally anticipated BLA approval date from the FDA. Although these inventories are no longer being capitalized as pre-launch inventories for GAAP accounting purposes, the inventories written-off for 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 qualify for capitalization. Specifically, the Company evaluated its raw materials 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 reserve 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 comprising 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, as of May 31, 2022. Refer to Part II, Item 8, Note 3, *Inventories, net* 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. Based on limited historical experience of forfeitures, 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, BLA 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 Form 10-K 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, 2022, we had $4.2 million in 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 2022 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

To the Board of Directors and Stockholders
CytoDyn Inc.

Opinion on the Consolidated Financial Statements

We have audited, before the effects of the adjustments for the correction of the error described in Note 14, *Restatement*, the accompanying consolidated balance sheet of CytoDyn Inc. (the Company) as of May 31, 2021 and the related consolidated statements of operations, changes in stockholders' (deficit) equity, and cash flows for the two years then ended, and the related notes (collectively referred to as the consolidated financial statements). In our opinion, except for the error described in Note 14, *Restatement*, the 2021 consolidated financial statements present fairly, in all material respects, the financial position of the Company as of May 31, 2021, and the results of its operations and its cash flows for the two years then ended in conformity with accounting principles generally accepted in the United States of America.

We were not engaged to audit, review, or apply any procedures to the adjustments of the correction of the error described in Note 14, *Restatement* and accordingly, we do not express an opinion or any form of assurance about whether such adjustments are appropriate and have been properly applied. Those adjustments were audited by Macias Gini & O'Connell LLP. (The 2021 consolidated financial statements before the effects of the adjustments discussed in Note 14, *Restatement* have been withdrawn and are not presented herein.)

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 significant net losses and has an accumulated deficit through May 31, 2021, 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 consolidated 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 the 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 consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the 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.

/s/ Warren Averett, LLC

We served as the Company's auditor from 2007 through 2021.
Birmingham, Alabama

July 30, 2021, except for the effect of the revision discussed in Note 2, as to which the date is January 10, 2022

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
CytoDyn Inc.
Vancouver, Washington

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of CytoDyn Inc. (the "Company") as of May 31, 2022, and the related statements of operations, changes in stockholders' (deficit) equity, and cash flows for the year 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, 2022, and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

We also have audited the adjustments described in Note 14, *Restatement* that were applied to restate the 2021 consolidated financial statements to correct an error. In our opinion, such adjustments are appropriate and have been properly applied. We were not engaged to audit, review, or apply any procedures to the 2021 consolidated financial statements of the Company other than with respect to the adjustments and, accordingly, we do not express an opinion or any other form of assurance on the 2021 consolidated financial statements taken as a whole.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of May 31, 2022, based on criteria established in 2013 Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated August 15, 2022 expressed an adverse opinion.

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 $210,820,000 for the year ended May 31, 2022 and has an accumulated deficit of approximately $766,131,000 through May 31, 2022, 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.

Restatement of fiscal year 2021 Consolidated Financial Statements

As discussed in Note 14, *Restatement* to the consolidated financial statements, the consolidated financial statements as of December 31, 2021 and for the year then ended have been restated to correct misstatements.

Basis for Opinion

These consolidated financial statements are the responsibility of the entity's management. Our responsibility is to express an opinion on the entity's consolidated financial statements based on our audit. 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 the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit 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 consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audit 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 consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides 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 consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Evaluation of the Reserve and Write-off against Pre-Launch Inventory and Determination of alternate future use for Residual Raw Materials

Critical Audit Matter Description

As explained in Note 2, *Summary of Significant Accounting Policies* to the consolidated financial statements, the Company has capitalized pre-launch inventories procured or produced for product launches sufficient to support estimated initial demand. Typically, capitalization of such pre-launch inventory begins when the results of the clinical trial have reached a status sufficient for regulatory approval and the Company has determined that the capitalized costs will provide future economic benefits. Anticipated future sales, shelf lives, and expected approval dates are all factors when evaluating the realizability of capitalized pre-launch inventory. Evaluating the adequacy of the Company's reserve against pre-launch inventory, the write-off of certain components, as well as the alternate future use of residual raw materials was challenging because it involved a higher degree of management judgment.

How the Critical Audit Matter was Addressed in the Audit

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

- External confirmation of inventories held by others.
- Performing physical inventory count observation procedures
- Review of manufacturing contracts and inquiries of management who oversee research and development efforts.
- Testing the accuracy and completeness of the underlying data used in the estimate, including testing the methodology utilized to calculate the reserve and write-offs.
- Evaluating the factors used by management to determine if the pre-launch inventory should continue to be capitalized before regulatory approval.
- Evaluating the adequacy of reserves against pre-launch inventory.
- Evaluating the alternate use criteria for residual raw materials.

Identification, bifurcation and evaluation of derivatives in hybrid equity linked instrument and induced conversion of debt

Critical Audit Matter Description

As described in Note 6, *Convertible Instruments and Accrued Interest* to the consolidated financial statements, the Company entered into security purchase agreements pursuant to which the Company issued secured convertible promissory notes with two-year terms. In addition, as described in Note 7, *Equity Awards* to the consolidated financial statements, the Company entered into several transactions that included the issuance of equity and warrants. We identified the accounting for these financing transactions, including the evaluation for potential embedded derivatives, classification of the warrants, as well as the subsequent accounting and extinguishment/induced of these equity linked instruments, as a critical audit matter. The application of the accounting guidance applicable to these transactions, including the evaluation for potential embedded derivatives, and the classification of the related warrants is complex, and therefore, applying such guidance to the contract terms is complex and requires significant judgment. Auditing these elements involved especially complex auditor judgment due to the nature of the terms of the financings and warrants, their extinguishment/induced accounting, and the significant effort required to address these matters, including the extent of specialized skills and knowledge needed.

How the Critical Audit Matter was Addressed in the Audit

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

- Inspecting the agreements associated with each transaction and evaluating the completeness and accuracy of the Company's technical accounting analysis and application of the relevant accounting literature.
- Utilizing personnel with specialized knowledge and skills in valuations and technical accounting to assist in assessing management's analysis of the security purchase agreements and warrants, including the evaluation for potential embedded derivatives, and classification of warrants including: (i) evaluating the contracts to identify relevant terms that affect the recognition in the consolidated financial statements, and (ii) assessing the appropriateness of conclusions reached by management.
- Re-calculating inducement expense to validate accuracy related to current and prior period adjustments related to correcting misstatements and verifying all periods impacted are correctly restated.

/s/ Macias Gini & O'Connell LLP

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

San Jose, California

August 15, 2022

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
CytoDyn Inc.
Vancouver, Washington

Opinion on Internal Control over Financial Reporting

We have audited CytoDyn Inc.'s (the "Company") internal control over financial reporting as of May 31, 2022, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO criteria"). In our opinion, the Company did not maintain, in all material respects, effective internal control over financial reporting as of May 31, 2022, based on the COSO criteria.

We do not express an opinion or any other form of assurance on management's statements referring to any corrective actions taken by the Company after the date of management's assessment.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated balance sheet of the Company as of May 31, 2022, the related consolidated statements of operations, changes in stockholders' (deficit) equity, and cash flows for the year then ended, and the related notes (collectively referred to as the "consolidated financial statements") and our report dated August 15, 2022 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Item 9A. Controls and Procedures. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit of internal control over financial reporting in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A material weakness is a deficiency, or a 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 consolidated financial statements will not be prevented or detected on a timely basis. Material weaknesses regarding management's failure to design and maintain controls over the following have been identified and described in management's assessment:

- The failure to identify errors related to evaluation of complex accounting issues for which alternative accounting treatments exist constitutes a material weakness in the Company's internal control over financial reporting. This material weakness is deemed to be caused by lack of review of equity transactions to allow to consider alternative accounting treatments, and an insufficient number of financial reporting and accounting personnel with the knowledge, experience, or training appropriate with the Company's financial reporting requirements.
- The Company failed to perform an adequate risk assessment, did not adequately design, and did not fully document information technology (IT) general controls in the areas of user access, program change management, operations over certain IT systems that support the company's financial reporting processes, including controls to respond to the Complementary User Entity Controls assumed in the design and implementation of third-party service organizations controls. We concluded that in aggregate, these failures constitute a material weakness in the Company's internal control over financial reporting.

These material weaknesses were considered in determining the nature, timing, and extent of audit tests applied in our audit of the fiscal year 2022 consolidated financial statements, and this report does not affect our report dated August 15, 2022 on those consolidated financial statements.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Macias Gini & O'Connell LLP

San Jose, California

August 15, 2022

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

	May 31, 2022	May 31, 2021 (Restated) [1]
Assets		
Current assets:		
Cash	$ 4,231	$ 33,943
Prepaid expenses	5,198	616
Prepaid service fees	1,086	1,543
Total current assets	10,515	36,102
Inventories, net	17,929	93,479
Operating leases right-of-use asset	536	712
Property and equipment, net	73	134
Intangibles, net	132	1,653
Total assets	$ 29,185	$ 132,080
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 67,974	$ 65,897
Accrued liabilities and compensation	8,861	19,073
Accrued interest on convertible notes	5,974	2,007
Accrued dividends on convertible preferred stock	3,977	2,647
Operating leases	134	175
Convertible notes payable, net	36,241	62,747
Total current liabilities	123,161	152,546
Operating leases	422	552
Total liabilities	123,583	153,098
Commitments and Contingencies (Note 10)		
Stockholders' (deficit) equity:		
Preferred stock, $0.001 par value; 5,000 shares authorized:		
Series B convertible preferred stock, $0.001 par value; 400 shares authorized; 19 and 79 shares issued and outstanding at May 31, 2022 and May 31, 2021, respectively	—	—
Series C convertible preferred stock, $0.001 par value; 8 authorized; 7 and 8 issued and outstanding at May 31, 2022 and May 31, 2021, respectively	—	—
Series D convertible preferred stock, $0.001 par value; 12 authorized; 9 issued and outstanding at May 31, 2022 and May 31, 2021, respectively	—	—
Common stock, $0.001 par value; 1,000,000 shares authorized; 720,028 and 626,123 issued, and 719,585 and 625,680 outstanding at May 31, 2022 and May 31, 2021, respectively	720	626
Additional paid-in capital	671,013	532,031
Accumulated deficit	(766,131)	(553,675)
Treasury stock, $0.001 par value; 443 at May 31, 2022 and May 31, 2021	—	—
Total stockholders' deficit	(94,398)	(21,018)
Total liabilities and stockholders' equity	$ 29,185	$ 132,080

(1) See Note 2, *Revision of Financial Statements,* and Note 14, *Restatement.*

See accompanying notes to consolidated financial statements.

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

	Years ended May 31,		
	2022	2021 (Restated) [1]	2020 (Revised) [1]
Revenue	$ 266	$ —	$ —
Cost of goods sold	53	—	—
Gross margin	213	—	—
Operating expenses:			
General and administrative	44,303	34,320	19,973
Research and development	27,043	53,403	52,640
Amortization and depreciation	781	1,797	2,034
Intangible asset impairment charge	—	10,049	—
Inventory write-off	73,490	5,027	—
Total operating expenses	145,617	104,596	74,647
Operating loss	(145,404)	(104,596)	(74,647)
Interest and other expense:			
Interest on convertible notes	(5,417)	(4,387)	(7,330)
Amortization of discount on convertible notes	(2,958)	(3,591)	(1,645)
Amortization of debt issuance costs	(87)	(65)	(404)
Loss on induced conversion	(37,381)	(39,131)	—
Finance charges	(9,029)	(145)	(431)
Inducement interest expense	(6,691)	(13,922)	(23,437)
Legal settlement	(3,853)	(10,628)	(22,500)
Change in fair value of derivative liabilities	—	—	(9,542)
Total interest and other expense	(65,416)	(71,869)	(65,289)
Loss before income taxes	(210,820)	(176,465)	(139,936)
Income tax benefit	—	—	—
Net loss	$ (210,820)	$ (176,465)	$ (139,936)
Basic and diluted:			
Loss per share	$ (0.31)	$ (0.30)	$ (0.33)
Weighted average common shares outstanding	676,900	587,590	421,078

(1) See Note 2, *Revision of Financial Statements,* and Note 14, *Restatement.*

See accompanying notes to consolidated financial statements.

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

	Preferred stock		Common stock		Treasury stock		Additional paid-in capital	Accumulated deficit	Total stockholders' (deficit) equity
	Shares	Amount	Shares	Amount	Shares	Amount	(Revised) [1]	(Revised) [1]	(Revised) [1]
Balance May 31, 2019	95	$ —	329,555	$ 330	159	$ —	$ 225,177	$ (234,420)	$ (8,913)
Issuance of stock for note payable repayment	—	—	22,967	23	—	—	10,799	—	10,822
Note conversion and extension fees	—	—	8,232	8	—	—	3,891	—	3,899
Registered direct offering	—	—	38,856	39	—	—	12,627	—	12,666
Offering costs related to registered direct offering	—	—	—	—	—	—	(378)	—	(378)
Warrant exercises	—	—	42,024	42	—	—	20,458	—	20,500
Relative fair market value associated with warrants exercised	—	—	—	—	—	—	11,949	—	11,949
Public warrant tender offers	—	—	45,376	45	—	—	11,855	—	11,900
Offering costs related to public warrant tender offers	—	—	—	—	—	—	(1,059)	—	(1,059)
Inducement interest expense—tender offers and debt conversions	—	—	—	—	—	—	2,713	—	2,713
Private warrant exchanges	—	—	20,529	20	—	—	6,001	—	6,021
Offering costs related to private warrant exchanges	—	—	—	—	—	—	(197)	—	(197)
Inducement interest expense—private warrant exchanges	—	—	—	—	—	—	20,724	—	20,724
Preferred stock offerings	14	—	—	—	—	—	13,409	—	13,409
Offering costs related to preferred stock offering	—	—	—	—	—	—	(437)	—	(437)
Exercise of option to repurchase common stock	—	—	—	—	—	—	(8)	—	(8)
Dividends accrued on preferred stock	—	—	—	—	—	—	—	(945)	(945)
Legal fees in connection with equity offerings	—	—	—	—	—	—	(16)	—	(16)
Stock issued for services	—	—	2,620	3	—	—	(3)	—	—
Stock issued for bonuses and tendered for income tax	—	—	380	—	127	—	154	—	154
Stock option exercises	—	—	8,723	9	—	—	5,594	—	5,603
Stock-based compensation	—	—	—	—	—	—	6,548	—	6,548
Legal settlement	—	—	—	—	—	—	22,500	—	22,500
Net loss for May 31, 2020	—	—	—	—	—	—	—	(139,936)	(139,936)
Balance May 31, 2020	109	$ —	519,262	$ 519	286	$ —	$ 372,301	$ (375,301)	$ (2,481)

(1) See Note 2, *Revision of Financial Statements,* and Note 14, *Restatement.*

See accompanying notes to consolidated financial statements.

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

	Preferred stock		Common stock		Treasury stock		Additional paid-in capital	Accumulated deficit	Total stockholders' (deficit) equity
	Shares	Amount	Shares	Amount	Shares	Amount	(Restated) [1]	(Restated) [1]	(Restated) [1]
Issuance of stock for convertible note repayment	—	$ —	24,154	$ 24	—	$ —	$ 96,914	$ —	$ 96,938
Issuance of legal settlement shares	—	—	4,000	4	—	—	(4)	—	—
Stock option exercises	—	—	2,591	3	—	—	1,835	—	1,838
Stock issued for incentive compensation and tendered for income tax	—	—	323	—	157	—	828	—	828
Stock issued for private offering	—	—	667	1	—	—	999	—	1,000
Conversion of Series B convertible preferred stock to common stock	(13)	—	131	—	—	—	—	—	—
Private warrant exchanges	—	—	37,054	37	—	—	17,519	—	17,556
Offering costs related to private warrant exchanges	—	—	—	—	—	—	(495)	—	(495)
Warrant exercises	—	—	37,941	38	—	—	18,611	—	18,649
Inducement interest expense related to private warrant exchanges	—	—	—	—	—	—	13,922	—	13,922
Dividends accrued and paid on preferred stock	—	—	—	—	—	—	—	(1,909)	(1,909)
Stock-based compensation	—	—	—	—	—	—	9,601	—	9,601
Net loss for May 31, 2021	—	—	—	—	—	—	—	(176,465)	(176,465)
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
Conversion of Series B and C convertible preferred stock to common stock	(61)	—	3,200	3	—	—	(3)	—	—
Private warrant exchanges	—	—	7,920	8	—	—	5,382	—	5,390
Offering costs related to stock issuance	—	—	—	—	—	—	(5,316)	—	(5,316)
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	—	—	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)

(1) See Note 2, *Revision of Financial Statements,* and Note 14, *Restatement.*

See accompanying notes to consolidated financial statements.

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

	Years ended May 31,		
	2022	2021 (Restated) [1]	2020 (Revised) [1]
Cash flows from operating activities:			
Net loss	$ (210,820)	$ (176,465)	$ (139,936)
Adjustments to reconcile net loss to net cash used in operating activities:			
Amortization and depreciation	781	1,797	2,034
Amortization of debt issuance costs	87	65	404
Amortization of discount on convertible notes	2,958	3,591	1,645
Legal settlements	3,663	—	22,500
Finance charges related to surety bond backstop agreement	6,585	—	—
Loss on induced conversion	37,381	39,131	—
Inducement interest expense and non-cash finance charges	6,691	13,922	23,437
Interest expense associated with accretion of convertible notes payable	—	—	6,615
Change in fair value of derivative liabilities	—	—	9,542
Inventory write-offs	73,490	5,027	—
Stock-based compensation	6,239	10,429	6,548
Intangible asset impairment charge	—	10,049	—
Changes in operating assets and liabilities:			
Decrease (increase) in inventories	2,060	(79,359)	(19,147)
Decrease in miscellaneous receivables	—	—	91
(Increase) decrease in prepaid expenses	(4,125)	1,228	(1,577)
(Decrease) increase in accounts payable and accrued expenses	(2,713)	53,012	19,040
Net cash used in operating activities	(77,723)	(117,573)	(68,804)
Cash flows from investing activities:			
Furniture and equipment purchases	—	(122)	(41)
Net cash used in investing activities	—	(122)	(41)
Cash flows from financing activities:			
Proceeds from warrant transactions	5,390	17,060	—
Proceeds from sale of common stock and warrants, net of issuance costs	41,195	1,000	12,666
Proceeds from warrant exercises	1,036	19,428	38,422
Proceeds from sale of preferred stock, net of offering costs	—	—	13,409
Exercise of option to repurchase shares held in escrow	—	—	(8)
Payment on convertible notes	—	(950)	(2,185)
Release of restricted cash held in trust for warrant tender offer	—	(10)	(844)
Proceeds from stock option exercises	390	1,839	5,602
Payment of payroll withholdings related to tender of common stock for income tax withholding	—	(778)	(89)
Proceeds from convertible notes payable, net	—	100,000	15,000
Payment of conversion offering costs	—	—	(2,303)
Dividend declared and paid on Series B Preferred Stock	—	(243)	—
Net cash provided by financing activities	48,011	137,346	79,670
Net change in cash and restricted cash	(29,712)	19,651	10,825
Cash and restricted cash, beginning of period	33,943	14,292	3,467
Cash and restricted cash, end of period	$ 4,231	$ 33,943	$ 14,292
Cash and restricted cash consisted of the following:			
Cash	$ 4,231	$ 33,943	$ 14,282
Restricted cash	—	—	10
Total cash and restricted cash	$ 4,231	$ 33,943	$ 14,292

(1) See Note 2, *Revision of Financial Statements,* and Note 14, *Restatement.*

See accompanying notes to consolidated financial statements.

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

	Years ended May 31,		
	2022	2021 (Restated) [1]	2020 (Revised) [1]
Supplemental disclosure:			
Cash paid for interest	$ 63	$ 147	$ 243
Non-cash investing and financing transactions:			
Issuance of common stock for principal and interest of convertible notes	$ 31,000	$ 57,807	$ 15,092
Accrued dividends on convertible Series C and D Preferred Stock	$ 1,636	$ 1,666	$ 944
Cashless exercise of warrants	$ 1	$ 11	$ —

(1) See Note 2, *Revision of Financial Statements,* and Note 14, *Restatement.*

See accompanying notes to consolidated financial statements.

CYTODYN INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
AS OF MAY 31, 2022

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 (also referred to as "PRO 140" throughout this Form 10-K), a novel humanized monoclonal antibody targeting the CCR5 receptor. The Company is studying leronlimab in human immunodeficiency virus ("HIV"), non-alcoholic steatohepatitis ("NASH"), oncology, and other immunological applications such as coronavirus disease ("COVID-19").

Leronlimab is being investigated as a viral entry inhibitor for 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 HIV, NASH, oncology, and other therapeutic indications such as COVID-19 where CCR5 is believed to play an integral role.

The Company has pursued the regulatory approval of leronlimab in hopes that commercial sales will be obtained based on positive data from its Phase 2b/3 clinical trial for leronlimab as a combination therapy with highly active antiretroviral therapy ("HAART") for highly treatment-experienced HIV patients, as well as information gathered from meetings with the U.S. Food and Drug Administration ("FDA") related to its Biologic License Application ("BLA") for this indication. 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. The FDA informed the Company 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. The deficiencies cited by the FDA included administrative deficiencies, omissions, corrections to data presentation and related analyses, and clarifications regarding the manufacturing processes. The Company, with assistance of consultants, is in the process of curing the BLA deficiencies noted. In November 2021, the Company resubmitted the non-clinical and chemistry, manufacturing, and controls ("CMC") sections of the BLA. As of March 2022, the FDA had commenced its review of the CMC section.

As described in Note 10, *Commitments and Contingencies - Legal Proceedings*, the Company is in dispute with its former contract research organization ("CRO"). In the context of the litigation, the Company obtained an order requiring the CRO to release the Company's clinical data related to the BLA, which the CRO had been withholding. Further, the order granted the Company the right to perform an audit of the CRO's services.

Additionally, in March of 2022, the FDA placed the HIV program on a partial clinical hold, which may affect our ability to resubmit the BLA. The Company is in the process of evaluating the data, results of the audit, and implications of the partial clinical hold. The Company will update the feasibility and status of its anticipated resubmission of the clinical section of the BLA once it completes its evaluation.

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. and Advanced Genetic Technologies, Inc. ("AGTI"); AGTI is a dormant entity. All 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 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.

Revision of Financial Statements

During the preparation of the quarterly financial statements as of and for the period ended November 30, 2021, the Company identified an error in how non-cash inducement interest expense was calculated in previous reporting periods dating back to fiscal year 2018. The original inducement expense model was designed to calculate non-cash inducement interest expense specific to inducements that modified the warrant term (e.g., extension of the term or modification of exercise price) without settling the instrument. However, starting in fiscal year 2018, inducements were primarily structured to result in a settlement of the warrant, not merely a modification of a warrant that would remain outstanding for some period. The error was identified when the model started to calculate a gain on substantially all inducements, which was inconsistent with the economics of the arrangements. The error resulted in an understatement of non-cash inducement interest expense and additional paid-in capital.

The Company assessed the materiality of the misstatement in accordance with Accounting Standards Codification ("ASC") 250, *Accounting Changes and Error Corrections*, as well as SEC Staff Accounting Bulletins No. 99, *Materiality*, and No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*, and concluded that the misstatement was not material to the Company's consolidated financial statements for the prior periods and, accordingly, that amendments of previously filed reports were not required. However, the Company determined that the impact of the corrections would be too significant to record in the quarter ended November 30, 2021. As such, the revisions for the correction are reflected in the accompanying balance sheet, the statements of operations, changes in stockholders' (deficit), and statement of cash flows. The errors had no impact on operating loss, cash, net cash used in or provided by operating, financing, and investing activities, assets, liabilities, commitments and contingencies, total stockholders' (deficit) equity, number of shares issued and outstanding, basic and diluted weighted average common shares outstanding, and number of shares available for future issuance for any period presented.

The following tables present a summary of the impact of corrections by financial statement line item for the fiscal years presented:

	As of and For the Year Ended May 31, 2020		
(in thousands, except per share amount)	**Previously Reported**	**Adjustments**	**Revised**
Inducement interest expense	$ (7,904)	$ (15,533)	$ (23,437)
Total interest and other expense	$ (49,756)	$ (15,533)	$ (65,289)
Loss before income taxes	$ (124,403)	$ (15,533)	$ (139,936)
Net loss	$ (124,403)	$ (15,533)	$ (139,936)
Basic and diluted loss per share	$ (0.30)	$ (0.03)	$ (0.33)
Additional paid-in capital [1]	$ 351,711	$ 20,590	$ 372,301
Accumulated deficit [1]	$ (354,711)	$ (20,590)	$ (375,301)

	As of and For the Year Ended May 31, 2021		
(in thousands, except per share amount)	**Previously Reported**	**Adjustments**	**Revised[2]**
Inducement interest expense	$ (11,366)	$ (2,556)	$ (13,922)
Total interest and other expense	$ (50,078)	$ (2,556)	$ (52,634)
Loss before income taxes	$ (154,674)	$ (2,556)	$ (157,230)
Net loss	$ (154,674)	$ (2,556)	$ (157,230)
Basic and diluted loss per share	$ (0.27)	$ —	$ (0.27)
Additional paid-in capital [1]	$ 489,650	$ 23,146	$ 512,796
Accumulated deficit [1]	$ (511,294)	$ (23,146)	$ (534,440)

(1) *Previously Reported* accumulated deficit includes adjustments of $15,533, $4,532, and $525 for the fiscal years ended May 31, 2020, 2019 and 2018, respectively.

(2) Also refer to Note 14, *Restatement* for additional information in regards to restated amounts presented in the fiscal year ended May 31, 2021, and quarterly information within the fiscal year May 31, 2022.

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 $210.8 million, $176.5 million, and $139.9 million for the years ended May 31, 2022, 2021, and 2020, respectively, and has an accumulated deficit of $766.1 million as of May 31, 2022. These factors, among others, raise substantial doubt about the Company's ability to continue as a going concern.

The consolidated financial statements do not include any adjustments relating to the recoverability of assets and classification of liabilities that might be necessary should the Company be unable to continue as a going concern. The Company's continuation as a going concern is dependent upon its ability to obtain additional operating capital, complete 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 continues to engage in significant 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 and approval, and clinical trials. 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 largely from the sale of equity and debt securities, combined with additional funding from other traditional 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 U.S. 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 and updated each period to reflect current information, such as the status of our analysis of the clinical trial results and 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 market and other relevant, appropriate assumptions. Significant estimates include, but are not limited, to those relating to capitalization of pre-launch inventories including reserves and write-offs for excess and obsolete inventories, stock-based compensation, commitments and contingencies, assumptions used to value warrants including warrant modifications and inducements, and research and development expenses. 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 $4.0 million and $33.7 million at May 31, 2022 and May 2021, respectively.

The Company records cash received from fundraising activities before the closing of the transaction as restricted cash in its consolidated balance sheets.

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. The Company recognized an impairment charge of approximately $10.0 million for the year ended May 31, 2021; none for the years ended May 31, 2022 and 2020. Refer to Note 4, *Intangible Assets, net*, for additional information.

Inventories

Previously Expensed Inventories

The Company recorded revenue 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 comprise of 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 EUA for COVID-19 which required substantial commercial scale inventories to be created. The Company's pre-launch inventories consist 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 the 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 revaluation 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.

During the fourth fiscal quarter of 2022, the Company concluded that certain inventories no longer qualify 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 is due to delays experienced from the originally anticipated BLA approval date from the FDA. Although these inventories are no longer being capitalized as pre-launch inventories for GAAP accounting purposes, the inventories written-off for 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 qualify for capitalization. The Company recorded an inventory charge in the amount of $73.5 million for fiscal 2022. Refer to Note 3, *Inventories, net* for additional 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 is accounted for as one performance obligation. The Company does not offer discounts or rebates.

The transaction price is 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 is allocated to the one performance obligation. Therefore, upon delivery of the product quantity equal to the quantity requested in the purchase order, there are 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 is 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 is generally obtained 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 are 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 statement 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, 2021 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, 2021 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, 2022, 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.

The Company did not have any assets or liabilities measured at fair value using the fair value hierarchy as of May 31, 2022 and 2021.

Leases

Leases are included in operating lease right-of-use ("ROU") assets, current portion of lease liabilities in 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. Based on limited historical experience of forfeitures, 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 6*, Convertible Instruments and Accrued Interest* 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 2022 and 2021 tax years. The net tax expense for the years ended May 31, 2022 and 2021 was zero. As of May 31, 2022 and May 2021, the Company has a full valuation allowance as management does not consider it more than likely than not that the benefits from the net deferred taxes will be realized.

Recent Accounting Pronouncements

In December 2019, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") No. 2019-12, *Simplifying the Accounting for Income Taxes (Topic 740)*. The objective of the standard is to improve areas of U.S. GAAP by removing certain exceptions permitted by ASC 740 and clarifying existing guidance to facilitate consistent application. The Company adopted ASU 2019-12 on June 1, 2021. The adoption did not impact the Company's consolidated financial statements. In October 2020, the FASB issued ASU 2020-10, *Codification Improvements*. The amendments in this update improve consistency by amending the codification to include all disclosure guidance in the appropriate disclosure sections and clarifies application of various provisions in the codification by amending and adding new headings, cross referencing to other guidance, and refining or correcting terminology. ASU 2020-10 is effective for annual periods beginning after December 15, 2020 for public business entities. The transition method utilized for the amendments related to franchise taxes that are partially based on income were applied on a retrospective basis. All other amendments of the adoption of ASU 2019-12 are applied on a prospective basis. The adoption of this standard on June 1, 2021 did not have a material impact on the Company's consolidated financial statements.

The Company adopted ASU 2019-12 effective the year ending May 31, 2022. The adoption of the ASU requires the Company to disclose the impact of the change on the Company's consolidated financial statements as well as the transition method selected for each topic that will be affected. The transition method utilized for the amendments related to franchise taxes that are partially based on income will be applied on a retrospective basis. All other amendments of the adoption of ASU 2019-12 will be applied on a prospective basis. As of May 31, 2022 and 2021, the adoption of ASU 2019-12 did not have material impact on the income taxes of the Company.

Accounting Standards Not Yet Adopted

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 which 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 2020-06 is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted no earlier than the fiscal year beginning after December 15, 2020. The Company adopted ASU No. 2020-06 effective June 1, 2022 and does not believe the impact of adoption to be material, if any, to the Company's consolidated financial statements.

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). 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 ASU became effective for the Company on June 1, 2022. The Company is currently evaluating the effect of this ASU on the Company's consolidated financial statements and related disclosures.

Note 3. Inventories, net

Inventories, net of reserves, were as follows:

(in thousands)	As of May 31, 2022	2021
Raw materials	$ 16,264	$ 28,085
Work-in-progress	1,665	65,394
Total inventories, net	$ 17,929	$ 93,479

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 the 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. Also, as one of the stages 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 assigned shelf-life at that time, it may no longer be used and is considered to be expired. Further, 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, 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.

During the fourth fiscal quarter of 2022, the Company concluded that certain inventories no longer qualify 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 is due to delays experienced from the originally anticipated BLA approval date from the FDA. Although these inventories are no longer being capitalized as pre-launch inventories for GAAP accounting purposes, the inventories written-off for 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 qualify 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 reserve 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 comprising 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, as of May 31, 2022.

During the fourth fiscal quarter of 2022, the Company completed its validation of the resins' properties based on the number of cycles they have been used for, and the remaining number of manufacturing cycles they may be used for; the Company did not identify any resins that failed suitability validation. As of May 31, 2022, the remaining lifetime of resins ranges between 37 and 62 cycles. The Company will continue to present its resins inventory based on the remaining shelf-lives until a new shelf-life is assigned based on the results of usability testing.

The table below summarizes inventory that had been previously capitalized and subsequently written off for accounting purposes. Work-in-progress and finished drug product inventories 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 tests.

		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**
2023	0 to 12	$ 3,658	-	1,421	$ 5,079	$ 1,824	$ -	$ 6,903
2024	13 to 24	682	16,264	1,590	18,536	1,665	-	20,201
2025	25 to 36	2,099	-	-	2,099	-	29,142	31,241
2026	37 to 48	731	-	-	731	-	32,344	33,075
Thereafter	49 or more	-	-	-	-	-	-	-
Inventories, gross		7,170	16,264	3,011	26,445	3,489	61,486	91,420
Write-off		(7,170)	-	(3,011)	(10,181)	(1,824)	(61,486)	(73,491)
Inventories, net		$ -	16,264	-	$ 16,264	$ 1,665	$ -	$ 17,929

Note 4. Intangible Assets, net

Intangible assets were as follows:

	As of May 31,	
	2022	**2021**
Leronlimab (PRO 140) patent	$ 3,500	$ 3,500
ProstaGene, LLC intangible asset acquisition, net of impairment	—	2,926
Website development costs	20	20
Gross carrying value	3,520	6,446
Accumulated amortization, net of impairment	(3,388)	(4,793)
Total intangible assets, net	$ 132	$ 1,653

Amortization expense related to the intangible assets for the fiscal years ended May 31, 2022, May 31, 2021, and May 31, 2020 was approximately $0.7 million, $1.8 million and $2.0 million, respectively. The Company recorded an impairment charge of approximately $10.0 million related to the ProstaGene, LLC intangible asset acquisition during the year ended May 31, 2021; none in the fiscal years ended May 31, 2022 and 2020. The aggregate future amortization expense as of May 31, 2022 is estimated at $132.0 thousand in the fiscal year 2023; none beyond fiscal 2023.

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 arbitration hearing concerning a claim by ProstaGene for approximately 3.1 million shares of common stock that the Company withheld for damages incurred by the Company in connection with the purchase of the proprietary algorithm as part of the 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 the Pestell Employment Dispute, 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 period ended May 31, 2022. Refer to Note 10, *Commitments and Contingencies – Legal Matters* in this Form 10-K.

As of May 31, 2022, the Company recorded and amortized $3.5 million of intangible assets in the form of patents attributable to the leronlimab acquisition. As of May 31, 2021 and 2020, the Company recorded and amortized $4.6 million of intangible assets attributable to leronlimab and ProstaGene patents. The Company estimates the remaining useful life of its intangible assets to be less than a year.

Note 5. Accounts Payable and Accrued Liabilities

As of May 31, 2022 and 2021, the accounts payable balance was approximately $68.0 million and $65.9 million, respectively. The Company had two vendors that accounted for approximately 57% and 17%, and 72% and 14%, of the total balance of accounts payable as of each respective period.

The components of accrued liabilities were as follows:

	As of May 31,	
(in thousands)	2022	2021
Compensation and related expense	$ 1,504	$ 4,005
Legal fees and settlement	2,006	11,008
Clinical expense	3,727	1,462
Other liabilities	1,624	2,598
Total accrued liabilities	$ 8,861	$ 19,073

As of May 31, 2022, the entire accrued legal fees and settlement balance related to legal fees. As of May 31, 2021, the balance of accrued legal settlement and fees was comprised of $10.6 million related to legal settlements, with the remaining amount related to accrued legal fees.

Note 6. Convertible Instruments and Accrued Interest

Convertible Preferred Stock

	As of May 31,					
	2022			2021		
(in thousands)	Series B	Series C	Series D	Series B	Series C	Series D
Undeclared dividends	$ 10	$ -	$ -	$ 18	$ -	$ -
Accrued dividends	$ -	$ 2,014	$ 1,963	$ -	$ 1,530	$ 1,117
Shares of common stock	20	4,028	3,926	36	3,060	2,234

Under the Company's Certificate of Incorporation, the Company has the right to elect to pay dividends on its outstanding preferred stock in shares of the Company's common stock. 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 are accrued as of May 31, 2022. 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, 2022, the Company had an accumulated deficit of approximately $766.1 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 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.

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 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 Convertible Preferred Stock, $0.001 par value per share, and in preference to any payment or distribution to any holders of the Series B Convertible 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 $0.50 (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:

	As of May 31,						
	2022			2021			
(in thousands)	April 2, 2021 Note	April 23, 2021 Note	Total	November 2020 Note	April 2, 2021 Note	April 23, 2021 Note	Total
Convertible notes payable outstanding principal	$ 9,819	$ 28,500	$ 38,319	$ 13,500	$ 28,500	$ 28,500	$ 70,500
Less: Unamortized debt discount and issuance costs	(512)	(1,566)	(2,078)	(1,204)	(3,232)	(3,317)	(7,753)
Convertible notes payable, net	9,307	26,934	36,241	12,296	25,268	25,183	62,747
Accrued interest on convertible notes	2,599	3,375	5,974	1,258	447	302	2,007
Outstanding convertible notes payable, net and accrued interest	$ 11,906	$ 30,309	$ 42,215	$ 13,554	$ 25,715	$ 25,485	$ 64,754

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

(in thousands)	November 2020 Note	April 2, 2021 Note	April 23, 2021 Note	Total
Outstanding balance at May 31, 2021	$ 13,554	$ 25,715	$ 25,485	$ 64,754
Amortization of issuance discount and costs	98	1,197	1,750	3,045
Interest expense	192	2,152	3,073	5,417
Fair market value of shares exchanged for repayment	(18,495)	(23,578)	-	(42,073)
Difference between market value of common shares and reduction of principle	4,651	6,421	-	11,072
Outstanding balance at May 31, 2022	$ -	$ 11,907	$ 30,308	$ 42,215

Long-term Convertible Note – March 2020 Note

During the preparation and audit of the annual financial statements as of and for the fiscal year ended May 31, 2022, the Company concluded that a material error was identified in how the Company was accounting for common stock issued to settle certain convertible note obligations dating back to fiscal year 2021. The Company had been accounting for these transactions in accordance with debt extinguishment accounting. However, although the contractual terms did not explicitly describe the transactions as induced conversions, the transactions should be accounted for as induced conversions rather than extinguishments of debt and are therefore subject to induced conversion accounting. The error resulted in an understatement of the non-cash loss on induced conversion and additional paid-in capital. The Company recorded an adjustment to loss on convertible debt induced conversion of approximately $3.1 million in the fiscal year ended May 31, 2021. Refer to Note 14, *Restatement* for additional information.

Long-term Convertible Note – July 2020 Note

During the preparation and audit of the annual financial statements as of and for the fiscal year ended May 31, 2022, the Company concluded that a material error was identified in how the Company was accounting for common stock issued to settle certain convertible note obligations dating back to fiscal year 2021. The Company had been accounting for these transactions in accordance with debt extinguishment accounting. However, although the contractual terms did not explicitly describe the transactions as induced conversions, the transactions should be accounted for as induced conversions rather than extinguishments of debt and are therefore subject to induced conversion accounting. The error

resulted in an understatement of the non-cash loss on convertible induced conversion and additional paid-in capital. The Company recorded an adjustment to loss on convertible induced conversion of approximately $14.1 million in the fiscal year ended May 31, 2021. Refer to Note 14, *Restatement* for additional information.

Long-term Convertible Note – November 2020 Note

On November 10, 2020, the Company entered into a securities purchase agreement pursuant to which the Company issued a secured convertible promissory note with a two-year term to an institutional accredited investor in the initial principal amount of $28.5 million (the "November 2020 Note"). 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 accrued at an annual rate of 10% on the outstanding balance, with the outstanding balance convertible 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 November 2020 Note. The November 2020 Note was secured by all the assets of the Company, excluding the Company's intellectual property.

In addition, the Company was obligated to make monthly payments to reduce the outstanding balance of the note. During the year ended May 31, 2021 and subsequent to the issuance of the November 2020 Note, the Company and the institutional investor entered into separately negotiated agreements whereby portions of the November 2020 Note were partitioned into new notes, and the November 2020 Note was reduced by the balance of the new notes. The new notes were exchanged concurrently with issuance for shares of the Company's common stock.

On June 11, 2021, June 21, 2021, and June 30, 2021, in partial satisfaction of the June 2021 debt redemption amount on the November 2020 Note, the Company and the investor entered into separately negotiated exchange agreements, pursuant to which the November 2020 Note was partitioned into new notes (the "June 2021 Partitioned Notes") with a principal balance of $6.0 million. The Company and the holder of the November 2020 Note agreed to defer the remaining $1.5 million of the June 2021 debt redemption amount. The outstanding balance of the November 2020 Note was reduced by the June 2021 Partitioned Notes, and the Company and the investor exchanged the June 2021 Partitioned Notes for approximately 4.2 million shares of the Company's common stock.

On July 14, 2021 and July 27, 2021, in partial satisfaction of the July 2021 debt reduction amount, the Company and the November 2020 Note holder entered into exchange agreements, pursuant to which the November 2020 Note was partitioned into new notes (the "July 2021 Partitioned Notes") with a principal amount of $4.0 million. The Company and the holder of the November 2020 Note agreed to defer the remaining $3.5 million of the July 2021 debt redemption amount. The outstanding balance of the November 2020 Note was reduced by the July 2021 Partitioned Notes. The Company and the investor exchanged the July 2021 Partitioned Notes for approximately 3.2 million shares of common stock.

On August 4, 2021, August 16, 2021, and August 30, 2021, in partial satisfaction of the August 2021 debt reduction amount, the Company and the November 2020 Note holder entered into exchange agreements, pursuant to which the remaining principal and accrued balance of the November 2020 Note was partitioned into new notes (the "August 2021 Partitioned Notes") with a principal amount of $4.9 million. The Company and the holder of the November 2020 Note agreed to defer the remaining $2.6 million of the August 2021 debt reduction amount. The Company and the investor exchanged the August 2021 Partitioned Notes for approximately 4.4 million shares of common stock. Following the redemption, the obligation under the November 2020 Note was fully satisfied.

The Company accounted for the restructured partitioned notes and exchange settlements as induced conversion and, accordingly, recorded an aggregate loss on convertible debt induced conversion of $4.7 and $6.4 million in the years ended May 31, 2022 and 2021, respectively; none in fiscal year ended May 31, 2020.

During the preparation and audit of the annual financial statements as of and for the fiscal year ended May 31, 2022, the Company concluded that a material error was identified in how the Company was accounting for common stock issued to settle certain convertible note obligations dating back to fiscal year 2021. The Company had been accounting for these transactions in accordance with debt extinguishment accounting. However, although the contractual terms did not explicitly describe the transactions as induced conversions, the transactions should be accounted for as induced conversions rather than extinguishments of debt and are therefore subject to induced conversion accounting. The error resulted in an understatement of the non-cash loss on induced conversion and additional paid-in capital. The Company

recorded an adjustment to loss on induced conversion of approximately $13.9 million and $2.0 million in the fiscal years ended May 31, 2022 and May 31, 2021, respectively. Refer to Note 14, *Restatement* for additional information.

Long-term 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 with the holder of the November 2020 Note in the initial principal amount of $28.5 million (the "April 2, 2021 Note"). 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 incorporated by reference. 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 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 end of November 2021, at discretion of the noteholder, to reduce the outstanding balance of the April 2, 2021 Note by $7.5 million per month. Payments under the November 2020 Note and 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.

In September 2021, the Company and the holder of the April 2, 2021 Note agreed to defer the $7.5 million September 2021 debt redemption amount.

On October 5, 2021 and October 21, 2021, in partial satisfaction of the October 2021 debt reduction amount, the Company and the April 2, 2021 Note holder entered into exchange agreements, pursuant to which the April 2, 2021 Note was partitioned into new notes (the "October 2021 Partitioned Notes") with a principal amount of $5.0 million. The Company and the holder of the April 2, 2021 Note agreed to defer the remaining October 2021 debt redemption amount of $2.5 million. The outstanding balance of the April 2, 2021 Note was reduced by the October 2021 Partitioned Notes. The Company and the investor exchanged the October 2021 Partitioned Notes for approximately 3.9 million shares of common stock.

On November 2, 2021 and November 16, 2021, in partial satisfaction of the outstanding principal amount, the Company and the April 2, 2021 note holder entered into exchange agreements, pursuant to which the April 2, 2021 Note was partitioned into new notes (the "November 2021 Partitioned Notes") with a principal amount of $4.0 million. The Company and the investor exchanged the November 2021 Partitioned Notes for approximately 4.2 million shares of common stock.

On December 7, 2021 and December 29, 2021, in partial satisfaction of the outstanding principal amount, the Company and the April 2, 2021 note holder entered into exchange agreements, pursuant to which the April 2, 2021 Note was partitioned into new notes (the "December 2021 Partitioned Notes") with a principal amount of $4.0 million. The Company and the investor exchanged the December 2021 Partitioned Notes for approximately 4.8 million shares of common stock.

On January 19, 2022, in partial satisfaction of the outstanding principal amount, the Company and the April 2, 2021 Note holder entered into an exchange agreement, pursuant to which the April 2, 2021 Note was partitioned into a new note (the "January 2022 Partitioned Note") with a principal amount of $2.5 million. The Company and the investor exchanged the January 2022 Partitioned Note for approximately 5.4 million shares of common stock.

On February 18, 2022, in partial satisfaction of the outstanding principal amount, the Company and the April 2, 2021 Note holder entered into an exchange agreement, pursuant to which the April 2, 2021 Note was partitioned into a new note (the "February 2022 Partitioned Note") with a principal amount of $3.2 million. The Company and the investor exchanged the February 2022 Partitioned Note for approximately 7.0 million shares of common stock.

The Company accounted for the restructured partitioned notes and exchange settlements as induced conversion, and, accordingly, recorded an aggregate loss on convertible debt induced conversion of $6.4 million in the year ended May 31, 2022; none in fiscal years ended May 31, 2021 and 2020.

During the preparation of the annual financial statements as of and for the period ended May 31, 2022, the Company's auditor identified an error in how the Company was accounting for common stock issued to settle certain convertible note obligations dating back to fiscal year 2021. The Company was accounting for these transactions in accordance with debt extinguishment accounting, not conversion inducement accounting. However, these transactions are considered to be an induced conversion rather than an extinguishment of debt although not explicitly stated. The error resulted in an understatement of the non-cash loss on induced conversion and additional paid-in capital. The Company recorded an adjustment to loss on induced conversion of approximately $12.4 million in the fiscal year ended May 31, 2022. Refer to Note 14, *Restatement* for additional information.

Long-term Convertible Note – April 23, 2021 Note

On April 23, 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 to an institutional accredited investor affiliated with the holder of the November 2020 and April 2, 2021 Notes in the initial principal amount of $28.5 million (the "April 23, 2021 Note"). 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 incorporated by reference.

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 30 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 are parties to the Backstop Agreement. The noteholders also waived similar rights relating to the issuances of approximately 13 million shares of common stock and shares underlying warrants to investors between February and March 2022, in private placements conducted by the Company. Refer to Note 7, *Equity Awards* for additional information.

The Company fully satisfied its obligations under a number of notes previously outstanding in fiscal years 2021 and 2020; there were no outstanding balances associated with these notes as of May 31, 2022.

Note 7. Equity Awards

Stock option and warrant activity is presented in the table below:

(in thousands, except per share data)	Number of shares	Weighted average exercise price	Weighted average remaining contractual life in years	Aggregate intrinsic value
Options and warrants outstanding at May 31, 2020	130,561	$ 0.65	5.79	$ 896
Granted	7,036	$ 3.82		
Exercised	(75,735)	$ 0.59		
Forfeited, expired, and cancelled	(1,088)	$ 1.66		
Options and warrants outstanding at May 31, 2021	60,774	$ 0.95	4.37	$ 68,061
Granted	50,205	$ 0.72		
Exercised	(5,677)	$ 0.71		
Forfeited, expired, and cancelled	(14,597)	$ 1.36		
Options and warrants outstanding at May 31, 2022	90,705	$ 0.77	4.06	$ 352
Options and warrants outstanding and exercisable at May 31, 2022	82,918	$ 0.69	3.61	$ 352

	Years ended May 31,		
(in thousands)	2022	2021	2020
Option and warrant exercises:			
Number of options and warrants exercised	5,677	75,735	101,853
Cash received	$ 6,816	$ 38,327	$ 44,024
Aggregate intrinsic value	$ 5,815	$ 298,891	$ 112,145

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:

	Years ended May 31,		
	2022	2021	2020
Expected Volatility	94.3% - 122.0 %	80.3% - 127.8 %	0.0% - 92.8 %
Weighted-Average Volatility	104.89 %	84.86 %	52.29 %
Expected Dividends	- %	- %	- %
Expected Term (In years)	1.5 - 6.0	2.5 - 6.0	0.9 - 10.0
Risk-Free Rate	1.67 %	0.45 %	1.46 %

In fiscal year ended May 31, 2022, 2021, and 2020, stock-based compensation expense related to equity instruments totaled $6.2 million, $8.8 million, and $6.5 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 and warrants vested during the same periods was approximately $3.9 million, $4.7 million, and $3.3 million, respectively. As of May 31, 2022, there was approximately $6.5 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 1.18 years. Stock-based compensation expense for the year ended May 31, 2022 included approximately $1.6 million of forfeitures of unvested equity awards related to the termination of the Company's former CEO.

For the year ended May 31, 2022, approximately $6.6 million of stock-based compensation expense related to 15 million warrants issued under the Backstop Agreement is recorded as a finance charge in the accompanying consolidated statement of operations.

Equity Incentive Plan

As of May 31, 2022, the Company had one active equity incentive plan, the *CytoDyn Inc. Amended and Restated 2012 Equity Incentive Plan* (the "2012 Plan"), and one inactive equity incentive plan, the *CytoDyn Inc. 2004 Stock Incentive Plan* (the "2004 Plan") under which certain previously issued awards remain outstanding (together referred to as the "Incentive Plans"). 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, 2022, the 2012 Plan covered a total of 56.3 million shares of common stock.

By action taken on February 21, 2022, and May 23, 2022, the Board released 15.0 million and 7.0 million shares of common stock, respectively, from reservation under the 2012 Plan to permit their use for general purposes, leaving approximately 3.9 million shares available for future stock-based grants under the 2012 Plan as of May 31, 2022. As of May 31, 2022, the Board also made a determination to waive the "evergreen provision" that would have automatically increased the number of shares subject to the 2012 Plan effective June 1, 2022, by an amount equal to 1% of the total outstanding shares on May 31, 2022. The Board has called a special meeting of stockholders to be held on August 31, 2022, to vote on an amendment to the Company's Certificate of Incorporation to increase the total number of shares of common stock authorized for issuance by 350 million shares. If the proposal is approved by the stockholders, the Board intends to restore the 22 million shares reserved for future awards under the 2012 Plan.

Stock Options and Other Equity Awards

During the fiscal year ended May 31, 2022, the Company granted stock options, covering a total of approximately 3.0 million shares of common stock to non-executive employees and consultants, with exercise prices ranging between $0.43 and $2.23 per share. These stock option awards vest annually over three years, with a ten-year term and grant date fair values ranging between $0.33 and $1.71 per share. During the same period, the Company also issued approximately 0.5 million shares of common stock in connection with the exercise of stock options. The stated exercise prices ranged from $0.63 to $1.06 per share which resulted in aggregate gross proceeds of approximately $0.4 million to the Company. As of May 31, 2022 and 2021, approximately 9.9 million and 12.8 million vested stock options and approximately 7.5 million and 5.8 million unvested stock options were outstanding, respectively.

In January 2020, the Company awarded approximately 11.7 million performance shares to certain of its directors and executive officers outside of the 2012 Plan ("January 2020 Performance Shares") with awards vesting and be settled in shares of common stock of the Company if the Company achieved FDA Breakthrough Therapy designation for cancer within six months of the award date, among other things. The awards were forfeited on July 28, 2020 when the performance conditions were not met.

In July 2020, the Company awarded approximately 0.3 million shares of common stock to Nader Z. Pourhassan, Ph.D., Chief Executive Officer at that time, of which approximately 0.2 million were tendered back to the Company to cover income tax withholding requirements. The Company recorded approximately $1.6 million in stock compensation expense.

In September 2020, the Company issued to its executives non-qualified stock options covering 3.35 million shares of common stock, time-vesting restricted stock units ("RSUs") covering 1.12 million shares of common stock, and performance-based stock units ("PSUs") covering 4.35 million shares of common stock. The RSUs vest equally over three years, and the PSUs vest over the fiscal year ending May 31, 2021 only if certain performance conditions set forth in the awards are met. The options vest equally over three years. The issuance of common stock underlying the PSUs granted for performance in fiscal year ending May 31, 2021 are subject to the Compensation Committee's determination if certain performance conditions set forth in the awards are met.

During the fiscal year ended May 31, 2022, the Company issued approximately 0.4 million shares of common stock to executives in connection with the time-based vesting of RSUs granted in June Additionally, the Company issued approximately 0.4 million shares of common stock in connection with the vesting of PSUs awarded in June 2020. The PSUs are subject to the Compensation Committee's determination of the level of achievement of performance conditions set forth in the respective award agreements. Of the 4.35 million of original PSU awards, approximately 3.9 million PSUs were forfeited. Further, certain members of management received a total of approximately 0.2 million shares of fully vested shares of common stock in lieu of a portion of their cash bonus for services in fiscal year 2021.

In order to preserve cash resources, in April 2022, the Board of Directors approved the issuance to 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 year ended May 31, 2022, a total of 317,441 shares of common stock were issued pursuant to this cash preservation program. The number of shares issued was based on the closing price of the common stock on each payroll date.

Private Offerings of Shares of Common Stock and Warrants Directly by the Company

In private placements to accredited investors conducted directly by the Company during the period from August 2021 through April 2022, the Company issued a total of approximately 26.7 million shares of common stock, together with warrants, to purchase a total of approximately 8.9 million shares of common stock. The warrants have a five-year term and are immediately exercisable. The securities were issued with a combined purchase price of between $0.40 and $1.80 per fixed combination of one share of common stock and one quarter of one warrant to purchase one share of common stock. The total proceeds were $23.6 million. Together with the common stock offering through a placement agent described below, in which the Company issued 11.4 million shares of common stock, the Company issued 38.1 million shares of common stock in the year ended May 31, 2022.

In connection with the private placements to accredited investors described above, certain accredited investors who participated in previous private placements purchased 8.8 million shares of common stock, together with warrants with exercise prices ranging from $0.40 to $1.00 per share, to purchase a total of approximately 4.1 million shares of common stock. In connection with these purchases, the Company modified agreements related to issuances in the previous private placement, effectively lowering the purchase price of common shares, lowering the exercise price of the underlying warrants, and increasing the warrant coverage on the common stock purchased, resulting in the issuance of an additional 2.3 million shares of common stock and 0.9 million warrants with exercise prices of $0.45 to $1.00 per share. As the result of these modifications, the Company recorded inducement interest expense of approximately $1.5 million in the year ended May 31, 2022.

Additionally, during the fiscal year ended May 31, 2022, the Company entered into privately negotiated warrant exchange agreements with certain accredited investors, pursuant to which the investors purchased shares of common stock at exercise prices ranging from $0.45 to $1.00 per share. The Company issued approximately 3.5 million shares of common stock under the original warrants, as well as additional shares as an inducement to equity holders to exercise their warrants, for a total of approximately 7.9 million shares of common stock. In connection with these transactions, the Company recognized $5.2 million of inducement interest expense in the year ended May 31, 2022. The total proceeds were $5.4 million.

In February 2022, the Company issued to a third-party consultant, as consideration for services, a warrant to purchase 25,000 shares of common stock at an exercise price of $1.04 per share and with a term expiring on December 6, 2031. The warrant is fully vested as to 15,000 shares with the remainder vesting on December 6, 2022, subject to forfeiture if the consultant ceases to provide services to the Company prior to that date. The Company recognized $14 thousand in stock-based compensation related to this award in the year ended May 31, 2022.

Legal Settlement Issuances

During the fiscal year ended May 31, 2022, the Company settled a dispute with a placement agent in part by the issuance of warrants covering 1.6 million shares of common stock that expire in seven years and have a stated exercise price of $0.40 per share. The expense is presented as part of the legal settlement expense in the accompanying consolidated statement of operations and consists of a $0.2 million cash payment and $1.7 million of non-cash expense related to the issuance of warrants.

Private Warrant Exchanges

During the fiscal year ended May 31, 2021, the Company also entered into private warrant exchanges in which certain accredited investors purchased shares of common stock at a reduced warrant exercise price ranging from $0.21 to $0.90 per share as compared to the original stated exercise prices ranging from $0.30 to $1.50 per share. The Company issued a total of approximately 35.8 million shares of common stock upon the exercise of exchanged warrants, and approximately 0.4 million additional shares as an inducement to exercise warrants, for a total of approximately 36.2 million shares. Of these shares, 34.9 million shares were issued in exchange for 32.6 million warrants to purchase common stock. Aggregate gross proceeds from the private warrant exchanges were approximately $16.2 million, after

total offering costs of approximately $0.5 million. In connection with these transactions, the Company recognized approximately $14.0 million in non-cash inducement interest expense.

For the year-ended May 31, 2022 the Company recorded non-cash inducement interest expense of approximately $6.7 million in connection with the private warrant exchanges. For the fiscal year-ended May 31, 2021 the Company recorded non-cash inducement interest expense totaling approximately $13.9 million in connection with the private warrant exchanges.

Private Placement of Warrants under Surety Bond Backstop Agreement

On February 14, 2022, the Company entered into a Surety Bond Backstop Agreement (the "Backstop Agreement") with an accredited investor in his individual capacity and as trustee of a revocable trust, as well as certain other related parties (collectively, the "Indemnitors"). Pursuant to 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 Clinical Research, LLC ("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 15,000,000 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 15,000,000 shares, to be exercisable only if the Indemnitors are 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 are 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 will bear interest at 10% per annum and are 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 year ended May 31, 2022.

Pursuant to an amendment to the Backstop Agreement executed on July 18, 2022 (the "Backstop Amendment"), (i) the obligation of the Indemnitors to indemnify the Surety was extended from August 13, 2022 to November 15, 2022, (ii) each of the 4-Good Warrants has a five-year term from the date of issuance and an exercise price of $0.20 per share (reduced from $0.30 per share), (iii) the Make-Whole Warrant was amended to be fully exercisable immediately, (iv) the deadline for the Company to use its commercially reasonable efforts to file a Registration Statement on Form S-3 with the Securities and Exchange Commission (the "SEC") that is intended to register for resale the shares underlying the 4-Good Warrants was extended to December 31, 2022, (v) the Indemnitors and 4-Good agreed to waive the requirement to reserve for issuance the shares subject to the Make-Whole Warrant pending stockholder approval of an increase in the authorized shares of common stock and (vi) upon the exercise in full of the 4-Good Warrants, the Company agreed to take reasonable steps to cause the Indemnitors to be released from their indemnity obligations by an amount equal to the exercise proceeds.

Private Placement of Common Stock and Warrants through Placement Agent

During the fiscal year ended May 31, 2022, the Company conducted two private placements of common stock and warrants to accredited investors through a placement agent. The first private placement was completed on November 24, 2021, resulting in the issuance of a total of approximately 11.4 million shares, together with warrants to purchase a total of approximately 5.0 million shares. The securities were issued at a purchase price of $1.00 per fixed combination (unit) of one share of common stock and three-tenths of one warrant to purchase one share of common stock, for aggregate gross and net proceeds to the Company of approximately $11.4 million and $10.0 million, respectively. The Company paid the placement agent a cash fee equal to 12% of the gross proceeds of the offering, or approximately $1.4 million, as well as a one-time non-accountable expense fee of $50,000. The Company also issued warrants to the placement agent or its designees to purchase a total of 1.4 million shares, representing 12% of the total number of shares sold in the offering. The warrants are fully exercisable and have an exercise price of $1.00 per share and a 10-year term.

The second private placement conducted through a placement agent during the fiscal year ended May 31, 2022, began in April 2022 and was completed on June 24, 2022. As of May 31, 2022, the Company had sold a total of 34.6 million units, with each unit comprising 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, for gross proceeds of $8.8 million and net proceeds of $7.6 million. The warrants issued to investors in the private placement have a five-year term and an exercise price of 120% of the final unit price, or $0.30 per share, and are immediately exercisable. The Company agreed to pay the placement agent a cash fee in an amount equal to 13% of the gross proceeds of the offering, as well as a one-time non-accountable expense fee of $50,000, and to issue to the placement agent or its designees warrants with an exercise price of $0.255 per share and a 10-year term to purchase shares of common stock equal to 13% of the total number of shares, including shares subject to warrants, sold in the offering. The issuance of the warrants is subject to the approval by the Company's stockholders of an increase in authorized shares of common stock. The Board has called a special meeting of stockholders to be held on August 31, 2022, to vote on an amendment to the Company's Certificate of Incorporation to increase the total number of shares of common stock authorized for issuance by 350 million shares.

Also refer to Note 13, *Subsequent Events - Private Placement of Common Stock and Warrants through Placement Agent.*

Payment of Severance to Former Executive Officers in Common Stock

During the fiscal year ended May 31, 2022, the Board terminated the employment of our CEO and General Counsel. 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 be made to our General Counsel to be made through the issuance of shares of common stock. On March 25, 2022, the Company issued 908,418 shares to our former CEO in satisfaction of our obligation to make an initial lump sum payment equal to 12 months' salary, subject to tax withholding and other payroll deductions. As of May 31, 2022, a total of 155,612 shares had been issued to our former General Counsel in satisfaction of our obligation to pay $12,500 in severance each payroll period, net of tax withholding and other payroll deductions. The number of shares issued was based on the closing price of the Common Stock on each payroll date.

Warrants

During the fiscal year ended May 31, 2022, the Company issued approximately 1.4 million shares of common stock in connection with the exercise of an equal number of warrants. The stated exercise prices ranged from $0.45 to $1.35 per share, which resulted in aggregate gross proceeds of approximately $1.0 million. Additionally, during the fiscal year ended May 31, 2022, the Company issued approximately 0.2 million shares of common stock in connection with the cashless exercise of approximately 0.3 million warrants with stated exercise prices ranging from $0.40 to $0.83. In connection with various private warrant exchange agreements during the fiscal year ended May 31, 2022, the Company issued approximately 7.9 million shares of common stock in connection with the exercise of approximately 3.5 million warrants.

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:

(in thousands, except per share amounts)	Years ended May 31, 2022	2021 (Restated) [1]	2020 (Revised) [1]
Net loss	$ (210,820)	$ (176,465)	$ (139,936)
Less: Accrued preferred stock dividends	(1,628)	(1,687)	(708)
Net loss applicable to common stockholders	$ (212,448)	$ (178,152)	$ (140,644)
Basic and diluted weighted average common shares outstanding	676,900	587,590	421,078
Basic and diluted loss per share	$ (0.31)	$ (0.30)	$ (0.33)

(1) See Note 2, *Revision of Financial Statements*, and Note 14, *Restatement*.

Refer to Note 13, *Subsequent Events - Private Placement of Common Stock and Warrants through Placement Agent* for additional information regarding the number of shares issued subsequent to May 31, 2022.

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:

(in thousands)	As of May 31, 2022	2021	2020
Stock options, warrants, and unvested restricted stock units	106,002	82,386	131,361
Convertible notes	12,000	18,000	3,864
Convertible preferred stock	32,535	33,008	30,130

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, 2022, 2021, and 2020. Reconciliation of the federal statutory income tax rate of 21% to the effective income tax rate is as follows:

	Years ended May 31,		
	2022	2021	2020
Income tax provision at statutory rate:	21.0 %	21.0 %	21.0 %
Derivative loss	—	—	(1.6)
Non-deductible debt issuance costs	—	—	(0.1)
Non-deductible interest on convertible notes	(0.5)	(0.6)	(1.2)
Inducement interest expense	(0.7)	(1.5)	(1.3)
Other	1.1	—	(0.3)
Credit carry-forward released	(0.2)	(0.1)	(0.1)
Non-deductible loss on induced conversion	(3.7)	(2.6)	—
Non-deductible debt discount amortization	(0.3)	(0.6)	(0.3)
IRC section 162(m) limitation	(0.1)	(1.1)	(2.4)
Stock-based compensation in excess of ASC 718	0.0	1.7	3.2
Non-deductible expense on induced conversion of debt	(0.3)	(1.2)	(3.8)
Valuation allowance	(16.3)	(15.0)	(13.1)
Effective income tax rate	0.0 %	0.0 %	0.0 %

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

	As of May 31,	
	2022	2021
Net operating loss	$ 106,965	$ 74,258
Credits	2,063	2,063
ASC 718 expense on NQO's	6,057	5,510
Charitable contribution carry forward	14	14
Accrued vacation and payroll	68	87
ASC 842 lease accounting	—	(3)
Right of use asset	(112)	—
Lease liability	117	—
Inventory	2,138	146
Accrued expenses	89	874
Amortization	238	396
Fixed assets	1	—
Basis difference in acquired assets	—	(91)
Valuation allowance	(117,638)	(83,254)
Deferred tax asset, non-current	$ —	$ —
Non-current asset	117,638	83,254
Valuation allowance	(117,638)	(83,254)
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, 2022, 2021, and 2020, the Company had available net operating loss carry forwards of approximately $509.4 million, $352.0 million and $264.7 million, respectively, which expire beginning in 2023. The Company's income tax returns remain subject to examination by all tax jurisdictions for tax years ended May 31, 2019 through 2021.

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 and supply services for the commercial supply of leronlimab 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. 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 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, and was included in accounts payable as of February 28, 2022. Under the agreements, Samsung may be entitled to terminate its services if the parties cannot reach an agreement as to the past due balance. Management is 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 of time, and proposals by the Company of satisfaction of a portion of the Company's payment obligations in equity securities of the Company and postponing or cancelling the manufacturing of additional drug product provided for in the agreements. As of May 31, 2022, the Company had past due balances of approximately $38.1 million due to Samsung which were included in accounts payable.

As of May 31, 2022, the future commitments pursuant to these agreements are estimated as follows (in thousands):

Fiscal Year	Amount
2023	$ 34,638
2024	121,750
2025	76,400
2026 and thereafter	—
Total	$ 232,788

Commitments with Contract Research Organization ("CRO")

The Company entered, and continues to maintain agreements, into project work orders, as amended, for each of our clinical trials with a CRO and related laboratory vendors. Under the terms of these agreements, the Company prepaid execution fees for direct services costs, which are recorded as a current asset in the accompanying consolidated balance sheets. In the event the Company were to terminate any trial, it may incur financial penalties to be payable to the CRO.

Distribution and Licensing

In December 2019, the Company entered into 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.

On April 6, 2021, the Company entered into an exclusive supply and distribution agreement with Biomm S.A., a Brazilian pharmaceutical company, granting the exclusive right to distribute and sell leronlimab in Brazil upon Brazilian regulatory approval.

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. Therefore, if this arrangement continues, 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 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. During the fiscal years ended May 31, 2022 and 2021, we recognized $0.2 million and $0.3 million of operating lease costs.

The following table summarizes the presentation of the operating leases in our consolidated balance sheet at May 31, 2022 and 2021:

	As of May 31,	
(in thousands)	2022	2021
Assets		
Right of use asset	$ 536	$ 712
Liabilities		
Current operating lease liability	$ 134	$ 175
Non-current operating lease liability	422	552
Total operating lease liability	$ 556	$ 727

The minimum (base rental) lease payments reconciled to the carrying value of the operating lease liabilities as of May 31, 2022 are expected to be as follows (in thousands):

Fiscal Year	Amount
2023	$ 177
2024	182
2025	185
2026	208
Total operating lease payments	752
Less: imputed interest	(196)
Present value of operating lease liabilities	$ 556

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.

Shareholder Derivative Lawsuit under Section 16(b) of the Securities Exchange Act

On September 10, 2020, certain stockholders of the Company filed a derivative action in the U.S. District Court for the Western District of Washington against then CEO Nader Z. Pourhassan, Ph.D. The plaintiffs claimed that certain of Dr. Pourhassan's transactions in the Company's common stock violated Section 16(b) of the Securities Exchange Act of 1934. The Company was only a nominal defendant in the action, and the plaintiffs sought no relief against the Company. On March 12, 2021, the district court granted Dr. Pourhassan's motion to dismiss the plaintiffs' complaint with prejudice. The plaintiffs timely appealed that decision to the U.S. Court of Appeals for the Ninth Circuit. On April 8, 2022, the Court of Appeals affirmed the district court's ruling.

Pestell Employment Dispute

On May 19, 2022, the Company and its subsidiary CytoDyn Operations Inc. entered into a Settlement Agreement with Richard G. Pestell, M.D. Ph.D. ("Dr. Pestell"), its former Chief Medical Officer. The Settlement Agreement terminated a lawsuit brought by Dr. Pestell in the U.S. District Court for the District of Delaware in August 2019 denominated Pestell v. CytoDyn Inc., et al. (the "Lawsuit") that alleged breach of Pestell's employment agreement with the Company, and the Company's failure to release from escrow 8,342,000 shares of the Company's common stock (the

"Escrowed Stock"), issued in connection with the Company's 2018 acquisition of ProstaGene LLC, of which Dr. Pestell was a controlling owner. Under the Settlement Agreement, the Company agreed to: (1) relinquish all rights to, and remove all transfer restrictions from, the Common Stock; (2) transfer and assign to Dr. Pestell all rights, title and interest (if any) in and to certain intangible assets that had been acquired in the ProstaGene transaction; (3) grant to Dr. Pestell warrants with a three-year term to purchase 7,000,000 shares of Common Stock at an exercise price of $0.37 per share (the "Warrants"); and (4) include the shares issuable upon exercise of the Warrants in a registration statement to be filed by the Company with the SEC under the Securities Act of 1933, in connection with a private placement of shares of Common Stock and warrants as described in the Company's Current Report on Form 8-K filed with the SEC on May 12, 2022. Except as described above, the Warrants have substantially the same terms as the form of warrant filed as Exhibit 4.1 to the Company's Form 8-K filed on September 7, 2021. In addition, each of the parties agreed to dismiss the lawsuit and to release the other party from all claims, whether known or unknown as of May 19, 2022, other than the rights and obligations arising out of or in connection with the Settlement Agreement.

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 current and 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 Company and certain current and former officers 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. 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 current and former officers, certain current and former Board members, 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 Company executives have received subpoenas concerning similar issues and may be interviewed by the DOJ or SEC in the future. The SEC informed the Company that its inquiry should not be construed as an indication that any violations of law have occurred or that the SEC has any negative opinion of any person, entity or security. The Company is cooperating fully with these non-public, fact-finding investigations, and as of the date of this filing, the Company is unable to predict the ultimate outcome and cannot reasonably estimate the potential possible loss or range of loss, if any.

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 Clinical Research LLC ("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. The arbitration demand 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 demand 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. Amarex has counterclaimed alleging that CytoDyn has failed to pay invoices due under the contract between the parties. In light of the fact that this dispute is in 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.

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.

In November 2020, the Company sold approximately 0.7 million unregistered shares of common stock at a purchase price of $1.50 per share to Christopher P. Recknor, M.D., former Chief Operating Officer and current Sr. Director of R&D, who was a non-executive at the time of the transaction, for the aggregate amount of proceeds to the Company of $1.0 million. The transaction was approved by the Board.

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. As of May 31, 2022, the Company had approximately $0.3 million in accounts payable due to CARE and made payments of approximately $1.7 million and $0.9 million to CARE during the fiscal years ended May 31, 2022 and 2021.

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 the years ended May 31, 2022, 2021 and 2020, the Company incurred an expense of approximately $0.1 million, $0.7 million, and $0.1 million, respectively, for qualified non-elective contributions.

Note 13. Subsequent Events

Private Placement of Common Stock and Warrants through Placement Agent

During June 2022, approximately 50.7 million additional shares of common stock were sold in the second private placement conducted by the Company through a placement agent, for gross proceeds of $12.9 million and net proceeds of $11.3 million. Each unit comprised 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 warrants issued to investors in the private placement, which cover a total of 38.1 million shares, have a five-year term and an exercise price of 120% of the final unit price, or $0.30 per share, and are immediately exercisable. Refer to Note 7, *Equity Awards - Private Placement of Common Stock and Warrants through Placement Agent* for additional information.

Appointment of President

On June 27, 2022, the Company entered into an employment agreement with Cyrus Arman, Ph.D. (the "Employment Agreement"), under which he has been employed as the Company's President on an at-will basis beginning on July 9, 2022. Antonio Migliarese, who was appointed as interim President on January 24, 2022, ceased to be President on July 9, 2022, and will continue in his roles of Chief Financial Officer, Corporate Secretary and Treasurer, as well as serving as the Company's principal accounting officer.

Special Stockholders' Meeting

On July 8, 2022, the Company issued a notice for a special stockholders' meeting to be held on August 31, 2022, to seek approval of a proposal to increase the total number of authorized shares of common stock from 1,000,000,000 to 1,350,000,000 shares. The proposal to increase the number of shares of common stock authorized for issuance, if approved at the special meeting, will become effective, and the Company's authorized shares of common stock will be increased to 1,350,000,000 shares, upon the filing of the certificate of amendment with the Secretary of State of the State of Delaware. The Board believes that it is essential to the Company's continued operations to have additional authorized shares of common stock available for future issuance; the authorization of a pool of additional shares of common stock at the special meeting will provide the Company with ability to use these shares to meet the Company's business and financial needs without the expense and delay of another special stockholders' meeting. These needs include: (i) satisfaction of the Corporation's existing obligations to issue shares of common stock for which authorized shares are not currently available, (ii) future financings to raise the capital needed to operate the Company's business, including potential negotiations with third parties to satisfy the Company's existing payment obligations in shares of common stock rather than cash; (iii) possible acquisition or other strategic transactions or partnerships; (iv) future equity awards as compensation for employees, officers, directors, consultants and advisors, including equity incentives for

performance; and (v) other general corporate purposes. Although such issuances of additional shares would dilute existing stockholders, the Board believes that such transactions would increase the overall value of the Company to its stockholders. In addition, the Board believes the Company's success depends in part on its continued ability to attract, retain and motivate highly qualified management and clinical and scientific personnel and advisors, as well as independent directors with requisite skills and experience.

Issuance of Shares to Former Executive Officer and Former CEO

The Company issued to a former executive officer a total of 69,040 shares of common stock to satisfy its obligation to make severance payments for the payroll periods ended June 15, June 30, July 15, and July 31, 2022, net of payroll deductions and withholding taxes. Consistent with the terms of our former CEO's employment agreement, in August 2022, the Company issued 26,106 shares of common stock in satisfaction of the severance amount due for the month of July 2022. The number of shares issued was based on the closing price of the common stock on the applicable date.

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Note 14. Restatement

During the preparation and audit of the annual financial statements as of and for the fiscal year ended May 31, 2022, the Company concluded that a material error was identified in how the Company was accounting for common stock issued to settle certain convertible note obligations dating back to fiscal year 2021. The Company had been accounting for these transactions in accordance with debt extinguishment accounting. However, although the contractual terms did not explicitly describe the transactions as induced conversions, the transactions should be accounted for as induced conversions rather than extinguishments of debt and are therefore subject to induced conversion accounting. The error resulted in an understatement of the previously reported non-cash loss on induced conversion and additional paid-in capital.

The Company assessed the materiality of the misstatement in accordance with ASC 250, *Accounting Changes and Error Corrections*, as well as SEC Staff Accounting Bulletins No. 99, *Materiality*, and No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*, and concluded that the misstatement are material to the Company's consolidated financial statements for the prior periods and, accordingly, are restating previously filed reports. As such, the restatements for the correction are reflected in the accompanying balance sheets, the statements of operations, changes in stockholders' (deficit), and statement of cash flows. The financial statements being restated below are as of and for the periods ended November 30, 2020, February 28, 2021, May 31, 2021, August 31, 2021, November 30, 2021, and February 28, 2022. The errors had no impact on operating loss, cash, net cash used in or provided by operating, financing, and investing activities, assets, liabilities, commitments and contingencies, total stockholders' (deficit) equity, number of shares issued and outstanding, basic and diluted weighted average common shares outstanding, and number of shares available for future issuance for any of the affected periods.

Fiscal Year Ended May 31, 2021 - Consolidated Financial Statements

	As of and For the Year Ended May 31, 2021		
(in thousands, except per share amount)	**Previously Reported**	**Adjustments**	**Restated**
Loss on induced conversion [1]	$ (19,896)	$ (19,235)	$ (39,131)
Inducement interest expense [2]	$ (11,366)	$ (2,556)	$ (13,922)
Total interest expense and other expense	$ (50,078)	$ (21,791)	$ (71,869)
Loss before income taxes	$ (154,674)	$ (21,791)	$ (176,465)
Net loss	$ (154,674)	$ (21,791)	$ (176,465)
Basic and diluted loss per share	$ (0.27)	$ (0.03)	$ (0.30)
Additional paid-in capital [3]	$ 489,650	$ 42,381	$ 532,031
Accumulated deficit [3]	$ (511,294)	$ (42,381)	$ (553,675)

Fiscal Year Ended May 31, 2021 and 2022 - Interim Consolidated Financial Statements (Unaudited)

There was no impact on the quarter ended August 31, 2020.

(in thousands, except per share amount)	As of and For Three Months Ended November 30, 2020			As of and Six Months Ended November 30, 2020		
	Previously Reported	Adjustments	Restated	Previously Reported	Adjustments	Restated
Loss on induced conversion [1]	$ (4,169)	$ (2,555)	$ (6,724)	$ (4,169)	$ (2,555)	$ (6,724)
Inducement interest expense [2]	$ (3,758)	$ (459)	$ (4,217)	$ (7,103)	$ (459)	$ (7,562)
Total interest expense and other expense	$ (10,463)	$ (3,014)	$ (13,477)	$ (15,623)	$ (3,014)	$ (18,637)
Loss before income taxes	$ (34,966)	$ (3,014)	$ (37,980)	$ (65,798)	$ (3,014)	$ (68,812)
Net loss	$ (34,966)	$ (3,014)	$ (37,980)	$ (65,798)	$ (3,014)	$ (68,812)
Basic and diluted loss per share	$ (0.06)	$ (0.01)	$ (0.07)	$ (0.12)	$ (0.00)	$ (0.12)
Additional paid-in capital [3]	$ 414,463	$ 23,604	$ 438,067	$ 414,463	$ 23,604	$ 438,067
Accumulated deficit [3]	$ (421,587)	$ (23,604)	$ (445,191)	$ (421,587)	$ (23,604)	$ (445,191)

(in thousands, except per share amount)	As of and For Three Months Ended February 28, 2021			As of and For Nine Months Ended February 28, 2021		
	Previously Reported	Adjustments	Restated	Previously Reported	Adjustments	Restated
Loss on induced conversion [1]	$ (7,625)	$ 7,625	$ —	$ (11,794)	$ 5,070	$ (6,724)
Inducement interest expense [2]	$ (4,139)	$ (1,221)	$ (5,360)	$ (11,242)	$ (1,680)	$ (12,922)
Total interest expense and other expense	$ (13,200)	$ 6,404	$ (6,796)	$ (28,823)	$ 3,390	$ (25,433)
Loss before income taxes	$ (43,985)	$ 6,404	$ (37,581)	$ (109,783)	$ 3,390	$ (106,393)
Net loss	$ (43,985)	$ 6,404	$ (37,581)	$ (109,783)	$ 3,390	$ (106,393)
Basic and diluted loss per share	$ (0.08)	$ 0.01	$ (0.07)	$ (0.18)	$ (0.00)	$ (0.18)
Additional paid-in capital [3]	$ 449,579	$ 17,200	$ 466,779	$ 449,579	$ 17,200	$ 466,779
Accumulated deficit [3]	$ (465,983)	$ (17,200)	$ (483,183)	$ (465,983)	$ (17,200)	$ (483,183)

(in thousands, except per share amount)	As of and For the Three Months Ended August 31, 2021		
	Previously Reported	Adjustments	Restated
Loss on induced conversion [1]	$ (4,651)	$ (13,879)	$ (18,530)
Inducement interest expense [2]	$ (9)	$ (519)	$ (528)
Total interest expense and other expense	$ (9,302)	$ (14,398)	$ (23,700)
Loss before income taxes	$ (30,939)	$ (14,398)	$ (45,337)
Net loss	$ (30,939)	$ (14,398)	$ (45,337)
Basic and diluted loss per share	$ (0.05)	$ (0.02)	$ (0.07)
Additional paid-in capital [3]	$ 516,816	$ 56,779	$ 573,595
Accumulated deficit [3]	$ (542,653)	$ (56,779)	$ (599,432)

(in thousands, except per share amount)	As of and For Three Months Ended November 30, 2021			As of and For Six Months Ended November 30, 2021		
	Previously Reported	Adjustments	Restated	Previously Reported	Adjustments	Restated
Loss on induced conversion [1]	$ (3,312)	$ (3,473)	$ (6,785)	$ (7,963)	$ (17,352)	$ (25,315)
Total interest expense and other expense	$ (11,282)	$ (3,473)	$ (14,755)	$ (21,103)	$ (17,352)	$ (38,455)
Loss before income taxes	$ (36,604)	$ (3,473)	$ (40,077)	$ (68,062)	$ (17,352)	$ (85,414)
Net loss	$ (36,604)	$ (3,473)	$ (40,077)	$ (68,062)	$ (17,352)	$ (85,414)
Basic and diluted loss per share	$ (0.06)	$ (0.00)	$ (0.06)	$ (0.11)	$ (0.02)	$ (0.13)
Additional paid-in capital [2]	$ 589,971	$ 36,587	$ 626,558	$ 589,971	$ 36,587	$ 626,558
Accumulated deficit [2]	$ (603,353)	$ (36,587)	$ (639,940)	$ (603,353)	$ (36,587)	$ (639,940)

(in thousands, except per share amount)	As of and For Three Months Ended February 28, 2022			As of and For Nine Months Ended February 28, 2022		
	Previously Reported	Adjustments	Restated	Previously Reported	Adjustments	Restated
Loss on induced conversion [1]	$ (3,109)	$ (8,957)	$ (12,066)	$ (11,072)	$ (26,309)	$ (37,381)
Total interest expense and other expense	$ (12,931)	$ (8,957)	$ (21,888)	$ (34,034)	$ (26,309)	$ (60,343)
Loss before income taxes	$ (32,328)	$ (8,957)	$ (41,285)	$ (100,390)	$ (26,309)	$ (126,699)
Net loss	$ (32,328)	$ (8,957)	$ (41,285)	$ (100,390)	$ (26,309)	$ (126,699)
Basic and diluted loss per share	$ (0.05)	$ (0.01)	$ (0.06)	$ (0.15)	$ (0.04)	$ (0.19)
Additional paid-in capital [2]	$ 612,905	$ 45,544	$ 658,449	$ 612,905	$ 45,544	$ 658,449
Accumulated deficit [2]	$ (636,078)	$ (45,544)	$ (681,622)	$ (636,078)	$ (45,544)	$ (681,622)

(1) Amounts previously presented in *Loss on extinguishment of convertible notes* have been restated for fiscal year ended May 31, 2021 and each quarter within fiscal year 2021. The restated conversion inducement expense associated with the notes is presented in the *Loss on induced conversion* line item in the consolidated statement of operations.

(2) Immaterial revisions related to Inducement interest expense were made through the period ended November 30, 2021. *Previously Reported* amounts as of November 30, 2021 and February 28, 2022, for the three and six months ended November 30, 2021, and for the three and nine months ended February 28, 2022 reflect impact of those corrections. Refer to Note 2, *Revision of Financial Statements* for additional information.

(3) Adjustments amounts include $15,533, $4,532, and $525 for the fiscal years ended May 31, 2020, 2019 and 2018, respectively.

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

None.

Item 9A. Controls and Procedures.

We maintain controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in our Securities Exchange Act of 1934, as amended ("the Exchange Act") reports is accurately recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and that such information is accumulated and communicated to our management, including our Chief Financial Officer, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As previously disclosed in the Form 10-Q for the period ended November 30, 2021, we identified an error that resulted in revisions to additional paid-in capital and non-cash inducement interest expense beginning in fiscal year 2018 through the three months ended August 31, 2021. The error relates to a pre-existing model used to calculate non-cash inducement interest expense designed to calculate inducement interest expense specific to modification of a warrant term (e.g., extension of the term or modification of exercise price) without settling the instrument. However, starting in fiscal year 2018 and to date, inducements have been primarily structured to be a settlement of the warrant, not a modification.

Additionally, during the preparation and audit of the annual financial statements as of and for the fiscal year ended May 31, 2022, the Company concluded that a material error was identified in how the Company was accounting for common stock issued to settle certain convertible note obligations dating back to fiscal year 2021. The Company had been accounting for these transactions in accordance with debt extinguishment accounting. However, although the contractual terms did not explicitly describe the transactions as induced conversions, the transactions should be accounted for as induced conversions rather than extinguishments of debt and are therefore subject to induced conversion accounting. The error resulted in an understatement of the previously reported non-cash loss on induced conversion and additional paid-in capital.

Management’s assessment performed at end of year ended May 31, 2022 resulted in the following conclusions regarding the Company’s internal control over financial reporting.

- We concluded that the failure to identify errors related to evaluation of complex accounting issues for which alternative accounting treatments exist constitutes a material weakness in the Company’s internal control over financial reporting. This material weakness is deemed to be caused by lack of review of equity transactions to allow to consider alternative accounting treatments, and an insufficient number of financial reporting and accounting personnel with the knowledge, experience, or training appropriate with the Company’s financial reporting requirements.
- The Company failed to perform an adequate risk assessment, did not adequately design, and did not fully document information technology (IT) general controls in the areas of user access, program change management, operations over certain IT systems that support the company’s financial reporting processes, including controls to respond to the Complementary User Entity Controls assumed in the design and implementation of third-party service organizations controls. We concluded that in aggregate, these failures constitute a material weakness in the Company’s internal control over financial reporting.

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 statement will not be prevented or detected on a timely basis.

Our independent registered public accounting firm, Macias Gini & O’Connell LLP, who audited the consolidated financial statements included in this Form 10-K, issued an adverse opinion on the effectiveness of the Company’s internal control over financial reporting.

In connection with the identification of the material weaknesses in our internal control over financial reporting, we continue to evaluate, design and implement controls and procedures to address this weakness. We have entered into consulting arrangements for external resources and have hired additional personnel with accounting skills to strengthen internal control over financial reporting, specifically in the areas of technical accounting and financial reporting. We also plan to perform a risk assessment of our internal controls related to information technology systems, and plan to design

and place in operation controls tailored to address risks that we deem to be relevant to our Company. Further, we plan to document all of our control activities in this area, including controls to respond to the Complementary User Entity Controls assumed in the design and implementation of third-party service organizations. A material weakness in internal control over financial reporting is a matter that may require some period of time to correct. Other than the changes to date described above, there have not been any changes in our internal control over financial reporting during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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, 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 and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Our management, with the participation of our Principal Executive Officer and Principal Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of May 31, 2022 (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). 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 and Principal Financial Officer have concluded, based upon the evaluation described above that, as of May 31, 2022, our disclosure controls and procedures were not 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 and 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 acquisitions and dispositions 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 directors 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 and 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 ("COSO"). Based on this evaluation, our management concluded that our internal control over financial reporting were not effective as of May 31, 2022.

Changes in Internal Control Over Financial Reporting

During the quarter ended May 31, 2022, there have been 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.

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 2022 Annual Meeting of Stockholders under the captions *Proposal 1: Election of Directors, Information about our Executive Officers, Delinquent Section 16(a) Reports and Corporate Governance*, to be filed with the SEC within 120 days of the end of the Company's fiscal year May 31, 2022 (the "2022 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 (who is our Chief Executive Officer), principal financial officer and principal accounting officer (who is 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.

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 2022 Proxy Statement under the captions *Executive Compensation* 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 2022 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 2022 Proxy Statement under the captions *Related Person Transactions*, and *Meetings and Committees of the Board of Directors - 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 2022 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 years ended May 31, 2022 and 2021 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 April 7, 2022		10-Q	3.1	4/11/2022
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 Placement Agent Warrant (Private Offerings, as Amended)		10-K	4.11	7/27/2018
4.4	Form of Placement Agent Warrant (Registered Offerings, as Amended)		10-K	4.12	7/27/2018
4.5	Form of Warrant Agreement (Private Offerings)		8-K	4.1	9/4/2018
4.6	Form of Warrant Agreement (Registered Offerings)		8-K	4.1	4/5/2019
4.7	Form of Warrant Agreement (Series C Convertible Preferred Stock Offering)		8-K	4.1	4/20/2019
4.8	Form of Warrant Agreement (Series C Convertible Preferred Stock Offering)		8-K	4.1	10/22/2019
4.9	Form of Warrant Agreement (Series D Convertible Preferred Stock Offering)		8-K	4.1	2/3/2020
4.10	Form of Warrant to Purchase Common Stock (December 2018 Convertible Note Offering)		8-K	4.2	1/3/2019
4.11	Form of Warrant to Purchase Common Stock		8-K	4.1	1/31/2019
4.12	Form of Common Stock Purchase Warrant		8-K	4.1	8/29/2019
4.13	Form of Common Stock Purchase Warrant		8-K	4.1	12/27/2019
4.14	Warrant to Purchase Common Stock by and between CytoDyn Inc. and Iliad Research and Trading, L.P.		8-K	4.2	1/31/2019

4.15	Form of Convertible Promissory Note		8-K	4.1	6/27/2018
4.16	Form of Convertible Promissory Note (December 2018 Convertible Note Offering)		8-K	4.1	1/3/2019
4.17	Secured Convertible Promissory Note between CytoDyn Inc. and Streeterville Capital, LLC, dated April 2, 2021		8-K	4.1	4/8/2021
4.18	Secured Convertible Promissory Note between CytoDyn Inc. and Uptown Capital, LLC, dated April 23, 2021		8-K	4.1	4/29/2021
4.19	Form of Warrant		8-K	4.1	9/7/2021
4.20	Initial Warrant Issued under Surety Bond Backstop Agreement		8-K	4.1	2/17/2022
4.21	Make-Whole Warrant Issued under Surety Bond Backstop Agreement		8-K	4.2	2/17/2022
4.22	Warrant Issued to Richard G. Pestell	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#	Distribution and Supply Agreement between CytoDyn Inc. and American Regent, Inc.		10-K	10.16	8/14/2020

10.7#	Exclusive Supply and Distribution Agreement between CytoDyn Inc. and Biomm S.A., dated April 6, 2021	X			
10.8	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
10.9	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
10.10#	Master Services Agreement between CytoDyn Inc. and Samsung BioLogics Co., Ltd, dated April 1, 2019		10-K	10.11	8/14/2019
10.11	Form of Indemnification Agreement		10-Q	10.2	10/9/2018
10.12	Security Agreement between CytoDyn Inc. and Streeterville Capital, LLC, dated April 2, 2021		8-K	10.2	4/8/2021
10.13	Security Agreement between CytoDyn Inc. and Uptown Capital, LLC, dated April 23, 2021		8-K	10.2	4/29/2021
10.14*	CytoDyn Inc. Amended and Restated 2012 Equity Incentive Plan (the "2012 Plan")		10-K	10.42	8/14/2020
10.15*	Form of Stock Option Award Agreement for Executive Employees under the 2012 Plan		10-K	10.43	8/14/2020
10.16*	Form of Stock Option Award Agreement for Non-Employee Directors under the 2012 Plan		10-K	10.9	8/29/2013
10.17*	Form of Restricted Stock Unit Agreement under the 2012 Plan		8-K	10.1	6/19/2020
10.18*	Form of Stock Option Award Agreement for Employees granted under an arrangement not approved by the Registrant's shareholders		10-K	10.10	8/29/2013
10.19*	Form of Stock Option Award Agreement for Non-Employee Directors granted under an arrangement not approved by the Registrant's shareholders		10-K	10.11	8/29/2013
10.20*	Second Amended and Restated Employment Agreement by and between CytoDyn Inc. and Nader Pourhassan dated June 15, 2020		8-K	10.5	6/19/2020

10.21*	Consulting Agreement, dated July 15, 2019, between CytoDyn Inc. and Scott A. Kelly, M.D.		8-K	10.1	7/19/2019
10.22*	Consulting Agreement, dated July 15, 2019, between CytoDyn Inc. and David F. Welch, Ph.D.		8-K	10.2	7/19/2019
10.23*	Surety Bond Backstop Agreement dated February 14, 2022, among CytoDyn Inc. and certain parties named therein #		10-Q	10.1	4/11/2022
10.24*	Employment Agreement between CytoDyn Inc. and Antonio Migliarese, effective May 18, 2021		10-Q	10.3	10/12/2021
10.25*	Employment Agreement between CytoDyn Inc. and Cyrus Arman, effective July 9, 2022	X			
10.26	Amendment to Surety Bond Backstop Agreement		8-K	10.1	7/25/2022
10.27*	Separation Agreement and Release of Claims between CytoDyn Inc. and Nader Z. Pourhassan, Ph.D., effective March 8, 2022		10-Q	10.2	4/11/2022
10.28	Settlement Agreement dated May 19, 2022, between CytoDyn Inc. and Richard G. Pestell, M.D., Ph.D.	X			
21	Subsidiaries of the Registrant	X			
23.1	Consent of Warren Averett, LLC	X			
23.2	Consent of Macias Gini & O'Connell LLP	X			
31.1	Certification of Chief Executive Officer under Rule 13a-14(a)	X			
31.2	Certification of Chief Financial Officer under Rule 13a-14(a)	X			
32	Certification of Chief 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: August 15, 2022

CYTODYN INC.
(Registrant)

By: /s/ Cyrus Arman
Cyrus Arman, Ph.D.
President

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 August 15, 2022.

Principal Executive Officer:

/s/ Cyrus Arman
Cyrus Arman, Ph.D.
President

Principal Financial and Accounting Officer:

/s/ Antonio Migliarese
Antonio Migliarese
Chief Financial Officer

Directors:

/s/ Tanya Durkee Urbach
Tanya Durkee Urbach, Chair

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

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

/s/ Scott A. Kelly
Scott A. Kelly, M.D.

Exhibit 4.1

DESCRIPTION OF THE REGISTRANT'S CAPITAL STOCK

General

CytoDyn, Inc. (the "Company" or "we") is authorized to issue up to 1,005,000 shares of capital stock, including 1,000,000 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 July 31, 2022, we had 810,720,424 shares of common stock, 19,000 shares of Series B Preferred Stock (as defined below), 6,903 shares of Series C Preferred Stock (as defined below) and 8,452 shares of Series D Preferred Stock (as defined below) 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 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 certificate of incorporation, as amended, and bylaws, both of which are on file with the Securities and Exchange Commission ("SEC") as exhibits to previous SEC filings, for additional information. 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 of Directors acting pursuant to a resolution approved by the affirmative majority of the entire Board of Directors. 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 of Directors) 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 of Directors 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 of Directors 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 of Directors 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.

If we offer a specific series of preferred stock under this prospectus, we will describe the terms of the preferred stock in the prospectus supplement for such offering and will file a copy of the certificate establishing the terms of the preferred stock with the SEC. To the extent required, this description will include:

- the title and stated value;
- the number of shares offered, the liquidation preference per share and the purchase price;
- the dividend rate(s), period(s) and/or payment date(s), or method(s) of calculation for such dividends;
- whether dividends will be cumulative or non-cumulative and, if cumulative, the date from which dividends will accumulate;
- the procedures for any auction and remarketing, if any;
- the provisions for a sinking fund, if any;
- the provisions for redemption, if applicable;
- any listing of the preferred stock on any securities exchange or market;
- 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;
- a discussion of any material and/or special U.S. federal income tax considerations applicable to 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 of Directors 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 shares of common stock, valued at $0.50 per share. The holders of the Series B Preferred Stock can only convert their shares to shares of common stock 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 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 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 of Directors, 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). 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 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 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 $0.50 (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.

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

As described above, our Board of Directors 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 of Directors acting pursuant to a resolution approved by the affirmative majority of the entire Board of Directors.

Additional Warrants

As of July 31, 2022, we had issued and outstanding warrants to purchase up to approximately 156.9 million shares of common stock, exercisable at prices ranging from $0.255 per share to $3.73 per share.

Stock Options

As of July 31, 2022, we had issued and outstanding options to purchase up to approximately 17.3 million shares of common stock, exercisable at prices ranging from $0.39 per share to $6.15 per share.

Exhibit 4.22

Warrant Number A-1600

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

May 19, 2022

WARRANT TO PURCHASE COMMON STOCK OF

CYTODYN INC.

This is to certify that, in connection with the settlement of Civil Action No. 1:I 9-cv 01563-RTD as to which Richard G. Pestell, M.D., Ph.D., and CytoDyn Inc., a Delaware corporation (the "Company"), are parties, and for value received, Richard G. Pestell, or a proper assignee (the "Holder"), is entitled to purchase up to 7,000,000 shares ("Warrant Shares") of common stock, $0.001 par value per share (the "Common Stock"), of the Company, subject to the provisions of this Warrant. This Warrant shall be exercisable at $0.37 per share (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 three 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. 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:

(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 Indefinite! . 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: /s/ Antonio Migliarese
Name: Antonio Migliarese
Title: President and Chief Financial Officer

[Signature Page to Common Stock Purchase Warrant]

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-1600 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 $_____ 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. he 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/TaxID:	_____	Tax ID:	_____
Telephone:	_____		
Email:	_____		

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

Exhibit 10.7

CERTAIN IDENTIFIED INFORMATION MARKED BY [*] HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED

EXCLUSIVE SUPPLY AND DISTRIBUTION AGREEMENT

Entered into by and between

BIOMM S.A.

And

CYTODYN INC.

April 6, 2021

THIS EXCLUSIVE SUPPLY AND DISTRIBUTION AGREEMENT (the "***Agreement***") is made as of 6th of April, 2021 ("**Effective Date"**), by and between

CYTODYN INC. ("***CytoDyn***"), a corporation incorporated and legally existing under the laws of USA, with its principal office and place of business at 1111 Main Street, Suite 660, Vancouver, Washington 98660, hereby duly represented in accordance with its By-Laws, and

BIOMM S.A. ("***Biomm***"), a corporation incorporated and legally existing under the laws of Brazil, with headquarters at Regent Avenue, 705, Alphaville – Lagoa dos Ingleses, city of Nova Lima, State of Minas Gerais, enrolled with the CNPJ/MF under # 04.752.991/0001-10, hereby duly represented in accordance with its By-Laws,

CytoDyn and Biomm, individually, hereinafter referred to as "***Party***", and jointly, ***"Parties"***.

RECITALS

WHEREAS, CytoDyn is an American company that develops pharmaceutical products and intends to establish a distribution system in Brazil by qualified and specially trained partner that meets the established requirements;

WHEREAS, Biomm is a Brazilian pharmaceutical company engaged in the business of manufacturing and/or distributing pharmaceutical products in the Territory (as such term is defined below);

WHEREAS, CytoDyn has developed a drug substance and drug product, manufacturing process and the Intellectual Property Rights (as defined hereinafter) for the Product which, among other indications, is intended for COVID-19´s treatment (as defined hereinafter);

WHEREAS, CytoDyn has recently requested the Authorization For Emergency Use of **Vyrologix** before US FDA and other regulatory agencies;

WHEREAS, Brazilian National Health Surveillance Agency has recently allowed the Authorization For Emergency Use of products intended for COVID-19´s treatment, in order to immediately make

available certain pharmaceutical drugs that are able to control the current public health emergency arising from the pandemic;

WHEREAS, Biomm intends to supply the Product to private and/or public healthcare providers that use the Product solely to treat patients, including but not limited to the MOH ("Entities") as of now on an emergency basis, upon submission and approval of the Authorization For Emergency Use for the Product before ANVISA and, subsequently, on an ordinary basis;

WHEREAS, Biomm holds all necessary licenses and authorizations, at all government levels, to take the position of the Marketing Authorization Holder of the Product in the Territory;

WHEREAS, Biomm and CytoDyn have decided to join efforts to act immediately before ANVISA with the primary purpose of supplying the Product on an emergency basis to save as many lives as possible;

WHEREAS, Biomm and CytoDyn now desire to enter into this Agreement to provide the terms and conditions upon which CytoDyn supplies the Product on an exclusive basis for distribution and sale of **Vyrologix** in the Territory to private and/or public institutions.

AGREEMENT

NOW THEREFORE, in consideration for the covenants set forth below, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as set forth below.

1. CERTAIN DEFINITIONS.

1.1 "Affiliate" means, with respect to any Party, another entity or person which directly or indirectly, is controlled by, or controls, or is under common control with such Party, where, for purposes of this definition, the term "control" means ownership, directly or indirectly, of more than 50% of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or more than 50% of the equity interests in the case of any other type of legal entity, status as a general partner in any partnership, or any other arrangement whereby a Party controls or has the right to control the Board of Directors or equivalent governing body of a corporation or other entity, or if such level of ownership or control is prohibited in any country, any entity owning or controlling at the maximum control or ownership right permitted in the country where such entity exists.

1.2 "**ANVISA**" means the Brazilian National Health Surveillance Agency or Agência Nacional de Vigilância Sanitária.

1.3 "Approvals" has the meaning given to that term in Section 2.10.

1.4 "CMED" means Câmara de Regulação de Mercado de Medicamentos, the Brazilian interministerial chamber that approves prices of drug products in Brazil.

1.5 "Confidential Information" means any confidential or proprietary information of a Party disclosed to the other Party or generated in the course of this Agreement, including inventions, know-how, works of authorship, software, data, software tools, designs, schematics, plans or other information relating to any work in process, future development, engineering, manufacturing, marketing or business plan, or financial or personnel matters relating to either Party, its present or future products, sales, suppliers, customers, employees, investors or business.

1.6 "Current Good Manufacturing Practice" or **"cGMP"** means the methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the regulatory requirements of the United States Food and Drug Administration and as further defined in 21 C.F.R. Parts 210 and 211 and the guidance of the Center for Drug Evaluation and Research ("CDER") and the Center for Biologics Evaluation and Research ("CBER"), and the European Commission Directive 2003/94/EC of October 8, 2003.

1.7 "Definitive Product Registration" means ANVISA's formal approval (i.e., that is not on an emergency use basis) of the Product for treating any indications in humans, together with CMED´s price approval. for the Product.

1.8 "Authorization For Emergency Use" or "Authorization" means the authorization granted by ANVISA for emergency use of the Product intended for COVID-19 treatment, in order to immediately make available certain pharmaceutical drugs that are able to control de current public health emergency arising from the pandemic.

1.9 "**Distribution Price**" [*]

1.10 "**FDA**" means the United States Food and Drug Administration.

1.11 "Intellectual Property Rights" means any and all rights in and to discoveries, concepts, ideas, technical information, developments, specifications, methods, drawings, designs, flow charts, diagrams, models, formulae, procedures, processes, schematics, specifications, algorithms, apparatus, inventions, ideas, know-how, materials, techniques, methodologies, modifications, improvements, works of authorship and data (whether or not protectable under patent, copyright, trade secrecy or similar laws), including patents, utility models, and registered and unregistered designs, including mask works, copyrights, trade secrets, design history, manufacturing documentation, and any other form of protection afforded by law to inventions, models, designs, works of authorship, databases or technical information and applications and registrations with respect thereto.

1.12 "Marketing Authorization" means all necessary approvals issued by ANVISA for Territory required to develop, market, sell or have sold the Product in the Territory but excluding any CMED's pricing approval.

1.13 "Marketing Authorization Holder" or "MAH" means Biomm that holds the regulatory Approval to place the Product on the market in the Territory and is responsible for the medicinal product by obtaining the Marketing Authorization granted by the responsible regulatory authorities in the Territory.

1.14 "Non-Conforming Shipment" has the meaning set forth in Section 4.3(a).

1.15 "Packaging Specifications" means lay-out, including design and text, material specifications and other instructions of carton, label and insert defined by Biomm according to ANVISA´s regulations.

1.16 "Pharmacovigilance Agreement" means a separate agreement, executed in accordance with Section 6.5(b) of this Agreement, between the Parties that shall be incorporated herein by reference, and following its execution shall be attached hereto and made a part hereof, and which sets forth, among other things, the process and procedure for sharing adverse event information.

1.17 "**Purchase Price**" means [*]

1.18 "Product" means a subcutaneous injectable biopharmaceutical drug product that contains CytoDyn´s proprietary leronlimab product (a humanized monoclonal antibody targeting against the CCR5 receptor) as the only active pharmaceutical ingredient for treating COVID-19, **Vyrologix**, as further described in the applicable product specification.

1.19 "Purchase Order" means a purchase order that is issued by Biomm for the purpose of obtaining the Product under this Agreement.

1.20 "Quality/Technical Agreement" means a separate agreement, executed in accordance with Section 6.5(a) of this Agreement, between the Parties that shall be incorporated herein by reference, and following its execution shall be attached hereto and made a part hereof, and which sets forth, among other things, the quality control and quality assurance terms for the Product. In case of a discrepancy between this Agreement and the Quality /Technical Agreement, as to quality and technical matters the terms of the Quality/Technical Agreement shall govern.

1.21 "Subdistributor" has the meaning set forth in Section 2.8.

1.22 "Territory" means the country of Brazil.

2. PERFORMANCE OBLIGATIONS

2.1 Manufacture and Supply. CytoDyn shall manufacture and supply the Product in accordance with the Quality Agreement and all applicable laws and regulations. CytoDyn shall

perform its activities in accordance with professional standards and practices including, but not limited to cGMP.

2.2 Biomm shall provide CytoDyn, upon request and only for use in accordance with the terms of this Agreement, with any information that CytoDyn reasonably requires to perform its obligations under this Agreement.

2.3 CytoDyn shall pack the Products in accordance with the Packaging Specifications to be provided by Biomm according to Anvisa´s instructions.

2.4 Distribution

(a) Appointment. Subject to the terms and conditions of this Agreement, CytoDyn appoints Biomm as CytoDyn's exclusive distributor of the Product in the Territory during the Term. Biomm hereby accepts such appointment and agrees to diligently promote, market, distribute and sell the Product in the Territory during the Term.

(b) Exclusivity. During the Term, CytoDyn shall not supply the Product or the rights to import, distribute, resell or market the Product in the Territory, directly or indirectly, to any public or private entity in Brazil without Biomm´s consent and participation, and Biomm shall purchase all of its requirements of the Product from CytoDyn and not from any other third party without CytoDyn's prior written consent.

(c) Intent. The Parties' intention of this Agreement is to obtain Authorization(s) of the Product before ANVISA**,** with Biomm being the Marketing Authorization Holder in the Territory.

(d) Conditions Precedent. The Parties' respective rights, licenses and [*]

2.5 Application for Authorization. Biomm shall arrange a pre-submission [*]

2.6 Definitive Product Registration. For the Definitive Product Registration, the Parties undertakes to amend this Agreement to describe the specific regulatory and commercial terms, being right that Biomm will be the Marketing Authorization Holder of the Product in the Territory.

2.7 Restrictions. Biomm shall not directly or indirectly advertise, market, promote, sell, deliver, tender, solicit or fill orders for Product outside the Territory. Biomm shall not itself, or permit others to, modify, adapt, alter, reverse engineer or disassemble Product or create derivative works from the Product. Biomm shall not remove, alter, or obscure in any way any proprietary rights notices of CytoDyn (including patent markings, copyrights, trademarks or other attributions to CytoDyn) or any batch, lot or registration numbers on or within any Product, sample or documentation provided by CytoDyn to Biomm. Biomm shall not directly or indirectly sell Products to anyone except directly to the Entities. Biomm shall not make any representations, warranties, guarantees or statements to third parties regarding the specifications, features or efficacies of the Products that are additional to or inconsistent with any statements,

representations, warranties or guaranties regarding the Products without express authorization in writing by CytoDyn.

2.8 Subdistributors. Biomm shall not appoint pharmaceutical distributors to distribute the Product without CytoDyn's prior written consent.

2.9 Inspection.

(i) Biomm shall permit representatives of CytoDyn, after reasonable notice and during Biomm's normal business hours, to inspect Biomm's facilities and inventory of Product to confirm that Biomm is complying with all of its obligations under this Agreement, including that Biomm is meeting applicable quality control standards and is otherwise complying with the Quality/Technical Agreement, Approvals, and all laws, rules and regulations applicable to Biomm's storage, handling, promotion, marketing, sale and delivery of Product in the Territory.

(ii) CytoDyn shall permit representatives of Biomm, after reasonable notice and during CytoDyn's normal business hours, to inspect CytoDyn's production facility and that of its active pharmaceutical ingredient (API) supplier to prepare for ANVISA's inspection or other Biomm´s inspection as needed. CytoDyn shall also allow Biomm to access the dossier for the Product a reasonable period of time in advance of submitting it to ANVISA for registration.

2.10 Regulatory Filings. Biomm shall, at its own cost, with the assistance of CytoDyn, prepare the transfer, translation and interpretation of the relevant data and materials submitted to the FDA to the extent necessary to complete the relevant filings with the ANVISA and all applicable local regulatory agencies, and shall translate the proposed label and summaries of the clinical information for filing with the local healthcare regulatory authorities and all other applicable regulatory authorities in each country in the Territory, and shall take such other actions, at its own cost, as are necessary to obtain and maintain throughout the Term all governmental approvals, authorizations, licenses, permits, registrations and consents that are, or may in the future be, required for the Parties to perform under this Agreement ("***Approvals***"), including any government registration, reimbursement and marketing approvals, import and export registrations or licenses, customs clearances, currency authorizations and any certificates, authorizations or permits necessary to store, handle, transport, promote, market, distribute and sell Product in each country in the Territory. CytoDyn, at its own cost, shall delegate no less than two of its senior specialists in relation to the Product to assist Biomm with meetings, demonstrating the Product's relevant data and materials, and filings with all applicable local regulatory agencies. The development of any additional data and information of the Product necessary for Approvals in the Territory shall be CytoDyn's responsibility and cost. For clarity, the Approvals shall be held in Biomm's name, to the extent required by ANVISA.

2.11 Cooperation. Biomm shall cooperate with CytoDyn and provide CytoDyn with all necessary information, data and reasonable assistance in order for CytoDyn to efficiently and effectively achieve commercially reasonable regulatory results for the Products throughout the world. The Parties together with applicable third parties who are distributors, sellers or

manufacturers of the Products shall enter into a Pharmacovigilance Agreement to help facilitate the collection, sharing and reporting to applicable regulatory authorities of all safety and adverse event information relating to the Products. CytoDyn shall have the sole right to create and maintain, and shall be the sole owner of, a master drug safety database that shall cross-reference any adverse event relating to Product occurring anywhere in the world. Biomm shall maintain records of all Product-related complaints of any nature and reports of all adverse events that it receives with respect to Product in the Territory and shall submit to CytoDyn all data collected by it with respect to adverse events and all copies of complaints relating to the Product (with electronic copies of source documents) within the time period set forth in the Pharmacovigilance Agreement, but in no case later than 5 (five) business days after Biomm's receipt of the same. If requested by CytoDyn, Biomm shall cooperate with CytoDyn in a timely manner in any investigation or resolution of complaints involving the Product.

2.12 Regulatory Compliance. In performing its obligations hereunder each Party shall comply with all applicable federal, state, municipal, or local laws, rules, regulations, orders, decisions or permits of any relevant jurisdiction relating to matters including, but not limited to foreign corrupt practices, employment, safety, health, environmental standards and requirements, non-discrimination, equal employment opportunity, import/export and privacy protection. For greater certainty, in performing its obligations hereunder, Biomm shall not make any payments to a government official. Without limiting the foregoing, at all times during the Term Biomm shall comply with all requirements of the Approvals. Biomm shall keep CytoDyn informed of the regulatory requirements in the Territory and shall promptly notify CytoDyn in writing, and provide a copy to CytoDyn, of any correspondence, reports or other communication with respect to Product submitted to or received from any regulatory authority in the Territory. Biomm shall immediately notify CytoDyn in writing if Biomm suffers the loss or impairment of any Approval required for Biomm to import the Product into the Territory or to distribute, market, promote or sell the Product in the Territory or to otherwise perform its obligations under this Agreement. Likewise, CytoDyn shall immediately notify Biomm, as early as possible, in writing, if CytoDyn suffers or potentially suffers the loss or impairment of any license, permit or other authorization required for CytoDyn to manufacture and supply the Product.

2.13 Use of Trademarks. Subject to the terms of this Agreement, CytoDyn hereby grants to Biomm a non-exclusive, nontransferable, and nonassignable authorization to use the name and trademark, **Vyrologix**, and other trademarks, service marks, trade dress, and/or logos which are owned by, or licensed or assigned to, CytoDyn ("***CytoDyn Marks***") as agreed upon in advance by CytoDyn, solely to promote Product in a manner consistent with this Agreement. Except as set forth in the preceding sentence, Biomm shall not have, assert or acquire any right, title or interest in or to any CytoDyn Marks or any goodwill related thereto. Biomm shall provide CytoDyn with a sample of each proposed use of CytoDyn Marks and shall obtain CytoDyn's approval of such sample prior its use. Biomm shall use the CytoDyn Marks in the form provided and in conformance with any trademark usage policies provided, from time to time, by CytoDyn to Biomm. Biomm shall not adopt, use, or attempt to register any trademarks or trade names that are confusingly similar to the CytoDyn Marks.

2.14 Ownership of Intellectual Property Rights. The rights granted to Biomm under this Agreement do not constitute and shall not be construed as a grant or a license to Biomm of or under any of CytoDyn's Intellectual Property Rights. Biomm acknowledges and agrees that

CytoDyn has sole and exclusive right, title and interest in and to all Intellectual Property Rights covering, claiming or associated with the Product, including any improvements and modifications thereto, and in and to all goodwill associated therewith. CytoDyn shall exclusively own any and all data, information, results and analyses related to the Product and generated by either Party's performance under this Agreement and CytoDyn shall have the unrestricted right to use any and all such data, information, results and analyses for any purpose whatsoever.

3. PURCHASE ORDERS

3.1 Purchase Orders ("PO"). Biomm shall notify CytoDyn as soon as the [*]

3.2 [*]

3.3 All orders shall be evidenced by specific and separate Purchase Orders issued by Biomm to CytoDyn pursuant to this section. Purchase Orders for Product may be submitted by Biomm to CytoDyn in writing, or electronically pursuant to a mutually agreed upon process. All Purchase Orders shall only contain: (a) the quantities ordered; (b) the Purchase Price for Product as agreed between the Parties; (c) mutually agreed-to delivery dates; and (d) shipping instructions. Each Purchase Order shall be deemed to be a transaction issued under the terms of this Agreement between the Parties.

3.4 Purchase Price. Subject to the other provisions of this Agreement, CytoDyn shall [*]

3.5 Production and Delivery Capacity.

(a) [*]

(b) Notwithstanding anything to the contrary herein, if CytoDyn, at such time it knows or becomes aware that it is unable to secure the manufacturing capacity necessary to provide to Biomm the quantity of Product specified above, then CytoDyn shall promptly inform Biomm in writing and shall use commercially reasonable efforts to increase production capacity to meet Biomm's estimated quantity and delivery requirements.

4. DELIVERY AND ACCEPTANCE; RECALL

4.1 Time and Place of Delivery. CytoDyn shall deliver the Product FCA (Incoterms 2020) [*] to arrive within the timeframe specified, as set forth in the Purchase Orders as accepted by CytoDyn in accordance with Section 3.3.

(a) If CytoDyn fails to meet an accepted Purchase Order delivery date, it will pay a penalty established in the agreement signed between Biomm and Entities.

(b) CytoDyn shall deliver the Product in accordance with the shipment instructions specified in the Quality/Technical Agreement for long distance international transportation, including with temperature recorders. The Parties shall collaborate on cold chain validation between their respective premises, sharing the costs of such validation.

4.2 Shelf Life. As part of its obligation to deliver the Product to Biomm in accordance with the specifications, CytoDyn shall deliver to Biomm Products with not less than [*] such shelf life being determined based solely on CytoDyn's internal stability test data.

4.3 Inspection and Rejection.

(a) Biomm shall inspect each shipment of the Product upon its release of the goods (customs and ANVISA) and shall notify CytoDyn in writing of any claims for shortages or alleged failure of the Product to conform to the warranty set forth in Section 6.2 ("***Non-Conforming Shipment***") within 20 (twenty) days after receipt of such shipment, except if any special request is done by regulatory authorities; provided that, in the case of any latent or other defect which was not, and could not reasonably be expected to have been found by exercise of ordinary care in inspection ("***Latent Defect***"), Biomm shall notify CytoDyn of such Non-Conforming Shipment within 20 (twenty) days after Biomm discovers the Latent Defect. Biomm shall submit all such claims to CytoDyn in writing, setting forth in full the details, basis and amount of such claim, shall request a return goods authorization number and shall, if requested by CytoDyn and as soon as the regulatory authority allows Biomm to do so, return a sample of such Non-Conforming Shipment to CytoDyn freight collect and properly insured.

(b) If CytoDyn disputes Biomm's claim made as provided above, such dispute shall be resolved by an independent testing organization or consultant of recognized repute as mutually agreed upon by the Parties, which agreement shall not be unreasonably withheld or delayed by either Party. The determination of such organization or consultant shall be final and binding upon the Parties and the costs therefor shall be paid by the Party against whom the determination is made. If CytoDyn agrees with Biomm's claim or if the testing organization or consultant determines that any shipment of Product is a Non-Conforming Shipment and that the warranty has not been voided for any of the reasons set forth in Section 6.2, then the remedy for breach of warranty shall apply.

(c) In the event of a Non-Conforming Shipment notified to CytoDyn within the agreed time period, and if such Products are unusable and remain unusable by Biomm, the Parties shall negotiate in good faith whether CytoDyn will destroy such Products or replace such Products free of charge or credit to Biomm the net amount actually paid for any such Product, including, without limitation, all logistic expenses, taxes and duties. In the event the Parties decide to destroy Products, the costs for such destruction shall be borne by CytoDyn.

(d) Upon receiving a written claim from Biomm of any Non-Conforming Shipment and provided that CytoDyn agrees with Biomm's claim or if a testing organization or consultant determines that any shipment of Product is a Non-Conforming Shipment and provided that the warranty has not been voided, CytoDyn shall at CytoDyn's sole expense promptly (and in no event longer than 90 days) correct, at no cost to Biomm, any such non-conformity by replacement of the Product that did not conform to such warranty and shall provide technical assistance to Biomm to address the Product non-conformity issues. Any replacement shall be considered a new Product for purposes of this Section. Except for Biomm's right to indemnification as set forth in Section 7.a, the foregoing shall be CytoDyn's sole and exclusive liability, and Biomm's sole and exclusive remedy, for any failure of the Product to conform to the warranty above.

4.4 Documents. Each shipment of the Product shall be accompanied by accurate and complete documents including, but not limited to relevant certificates of analysis, certificates of compliance and packing list and a copy of the invoice duly hand signed.

4.5 Recall. Each Party shall promptly inform the other Party of any circumstances giving rise to a possible or actual recall or withdrawal of Product in the Territory (collectively referred to as a "***Recall***") or if any Recall is desirable or required by law or regulatory authority in the Territory. Thereafter, the Parties shall promptly discuss reasonably and in good faith whether to carry out a Recall in the Territory and, if so, the manner in which to carry out such Recall. Biomm shall initiate no communications regarding any Recall with the news media, customers, regulatory authorities or other third parties without the prior written approval of CytoDyn, except if and to the extent required by applicable law. CytoDyn shall have sole authority to implement a Recall, provided that Biomm shall be responsible for physically recovering the recalled Products in the Territory. Biomm shall carry out the Recall in coordination and consultation with CytoDyn, in the manner agreed by the Parties, and in a manner which enables CytoDyn to meet its regulatory requirements as expeditiously as possible and in such a way as to cause the least disruption of sales of the Product in the Territory and to preserve the goodwill and reputation of the Parties and the Product. All costs and expenses associated with a Recall shall be borne by: (a) CytoDyn, if the Recall results from acts or omissions of CytoDyn or any contract manufacturer retained by CytoDyn; or (b) Biomm, if the Recall results from acts or omissions of Biomm or any of its subdistributors.

4.6 Serialization. The Parties acknowledge and agree that all Products delivered to Biomm under this Agreement are not required to be and will not be serialized.

5. Invoices: Method of Payment

5.1 Invoices. At the time of each shipment, CytoDyn shall send an invoice to Biomm specifying the total amount due under the invoice, calculated as the Purchase Price times the quantity of Product contained in the shipment.

5.2 Payment. [*] Biomm shall pay to CytoDyn the amount owed to CytoDyn under Section 3.3.

5.3 Payment Method. All payments under this Agreement shall be made by bank wire transfer in immediately available funds to a U.S. account designated in writing by CytoDyn or by other mutually acceptable means.

5.3.1 Credit Protection. Thirty (30) days before each shipment, Biomm shall open, at an internationally well-known bank reasonably acceptable to CytoDyn, an international bank letter of credit "**LoC**" that: (i) designates CytoDyn as the beneficiary; (ii) allows CytoDyn to draw on the LoC after presenting this Agreement, an invoice that has become due pursuant to Section 5.2 and the corresponding airway bill, each containing the required information as the Parties agreed and specified in the LoC; (iii) whose authorized amount is at least equal to the amount payable by Biomm to CytoDyn under each individual Invoice Order; (iv) and otherwise complies with the Uniform Customs and Practice for Documentary Credits latest version and Supplement to the Uniform Customs and Practice for Documentary Credits for Electronic

Presentation (eUCP). To the extent that amounts drawn by CytoDyn in accordance with this Section 5.3.1 is less than the amounts actually owed by Biomm to CytoDyn under Section 3.3, the amounts drawn shall be set off against, but shall not be in lieu of, the amounts actually owed Biomm to CytoDyn under Section 3.3.

5.4 Interest. In the event that any payment due under this Agreement is not made when due, the payment shall accrue interest from the date due at a rate per annum equal to 1% above the U.S. Prime Rate (as set forth in the *Wall Street Journal*, Eastern U.S. Edition) for the date on which payment was due, calculated daily on the basis of a 365-day year, or similar reputable data source, limited to 5% of the amount due; provided that, in no event shall such rate exceed the maximum legal annual interest rate.

5.5 Taxes. Unless otherwise provided on the Purchase Order, in addition to the price stated on the face of the invoice, Biomm shall pay costs for all sales, use, value-added or excise taxes, assessments or other charges, including customs duties, fees and inland Brazil freight and insurance or other shipping and handling charges, regulatory costs, marketing and medical costs attributable to the sale, use, shipment, transportation, or delivery of the Product, according the FCA (Incoterms 2020) [*]

5.6 Audit. Biomm shall keep and retain complete and accurate records pertaining to the disposition of the Product and amounts payable under this Agreement for each calendar year or part thereof during the Term in sufficient detail to permit CytoDyn to confirm the accuracy of all payments made or due hereunder for a period of two (2) years following the applicable calendar year or part thereof. CytoDyn shall have the right to appoint an independent internationally recognized audit firm, reasonably acceptable to Biomm, to audit the books of account of Biomm in order to determine whether Biomm has properly reported and accounted for any fees or payments due to CytoDyn pursuant to this Agreement. The appointed audit firm may perform audits during regular business hours, not more than once in any calendar year during the Term and upon reasonable prior notice to Biomm. CytoDyn shall bear the audit fees, unless such third party auditor determines that the amount actually due CytoDyn, in the aggregate, exceeds the amounts paid or deemed paid by Biomm hereunder by one hundred thousand U.S. Dollars ($100,000), in which case Biomm shall bear the audit fees. The results of the audit shall be final and binding upon the Parties.

6. Representations And Warranties; Covenants

6.1 By CytoDyn represents and warrants that (i) as soon as possible it will submit the request of product registration of **Vyrologix** before U.S. FDA, (ii) it has the rights to the distribution and sale of the Product is not currently being negotiated with a third party, and (iii) the technology it has developed to produce the Products does not infringe third party's intellectual property rights.

6.2 CytoDyn represents and warrants that the manufacturing facilities and processes utilized for the manufacture, fill/finish and labeling of the Products comply with applicable government regulations, such as regulatory authorities' GMP certificate, among others.

6.3 CytoDyn represents and warrants that the Product provided hereunder shall be manufactured in compliance with cGMP, and, at the time of delivery, shall be free from defect, encumbrance or lien, and shall be delivered according to the terms of the relevant Purchase Order accepted by CytoDyn. The foregoing warranty is contingent upon normal and proper use of the Products in their intended applications. The foregoing warranty shall be void, and CytoDyn shall have no obligations or liability hereunder, with respect to any Products that are abused, damaged, altered, tampered with, modified or adulterated after delivery or are used, stored or handled after delivery in any manner other than as designed or intended under normal use, or if any breach of the foregoing warranty is due in whole or in part to any act or omission of Biomm or any subdistributor or other contractor, representative or agent of Biomm (including any mishandling of Product or any translations of Product labels, packaging, documentation or promotional material by Biomm).

6.4 By Biomm. Biomm represents, expressly warrants and covenants that it does not and shall not during the Term employ, contract with, or retain any person directly or indirectly to perform Biomm's obligations under this Agreement if such person is (i) debarred by either the U.S. Food and Drug Administration under 21 U.S.C. Section 335(a) or any equivalent law or regulation in the Territory, or (ii) disqualified as described in 21 C.F.R. Section 812.119, or any equivalent law or regulation in the Territory. If Biomm becomes aware of the debarment or disqualification of any person or entity performing, directly or indirectly, any of Biomm's obligations under this Agreement, Biomm agrees to notify CytoDyn immediately.

6.5 Covenants.

(a) Quality/Technical Agreement. As soon as practicable after the Effective Date, the Parties hereby agree to negotiate in good faith the execution of a Quality/Technical Agreement. Such Quality/Technical Agreement shall be mutually agreed to in writing prior to placement of any Purchase Order for the Product.

(b) Pharmacovigilance Agreement. The Parties hereby agree to negotiate in good faith the execution of a Pharmacovigilance Agreement. Such Pharmacovigilance Agreement shall be mutually agreed in writing prior to placement of any Purchase Order for the Product. Subject to applicable laws and regulations in the Territory. Biomm as the holder of the MAH ensures that will be ultimately responsible towards the regulatory authorities for all pharmacovigilance obligations.

(c) Competitive Products. CytoDyn acknowledges that Biomm will be free to sell other products intended for COVID-19´s treatment and for the other potential indications for the Product and that it is not considered a direct competitor to the Product.

(d) Compliance with Certain United States Laws. Biomm acknowledges that the Product and other materials made available to Biomm by CytoDyn hereunder may be subject to the export administration regulations of the United States Department of Commerce and other United States governmental regulations related to the export of technical data and equipment and products. Biomm agrees to comply with all such applicable regulations in connection with the distribution of the Product and performance of this Agreement. Biomm also agrees that it will comply with the requirements of the U.S. Foreign Corrupt Practices Act, as amended from time to

time, and will refrain from making any payments to third parties that would cause Biomm or CytoDyn to violate such laws. Biomm hereby agrees to indemnify and hold CytoDyn harmless from any breach by Biomm of this section.

7. Indemnification And Liability

7.a Mutual Indemnification. Each Party (the "***Indemnifying Party***") shall indemnify and hold harmless the other Party and its Affiliates, and their respective directors, employees, consultants and agents (the "***Indemnified Parties***") from and against any and all liabilities, losses, damages, costs, and other expenses (including attorneys' and expert witnesses' costs and fees) (***"Losses"***) incurred by the Indemnified Parties (or any of them) as a result of any claim, demand, action or proceeding by any third party (a ***"Claim"***) to the extent arising from or relating to any material breach of any representation, warranty, covenant, or obligation of the Indemnifying Party under this Agreement or any intentional misconduct or negligence by the Indemnifying Party or any of its employees, agents, or subcontractors (including, with respect to Biomm, any subdistributor), except to the extent such Losses result from the intentional misconduct or negligence of, any of the Indemnified Parties. Under any circumstances, CytoDyn shall be responsible for losses, damages, adverse effects, accidents or product liability of any kind whatsoever, whenever the same can be proved to have occurred because the undertaking by CytoDyn, as defective quality of the Product supplied by CytoDyn, and/or its components, package, leaflet, drug leaflet (printed directions for the use of the Product), etc, information to final consumers or other motive attributed by CytoDyn. Under any circumstances, Biomm shall be responsible for losses, damages, adverse effects, accidents or product liability of any kind whatsoever, whenever the same can be proved to have occurred because the undertaking by Biomm regarding the marketing, sale or distribution of the Product or other reasons attributed to Biomm.

7.1 Indemnification Procedures. In the event of any Claim for which any Indemnified Party is or may be entitled to indemnification hereunder, the Indemnified Party may, at its option, require the Indemnifying Party to defend such Claim at the Indemnifying Party's sole expense; provided, however, that the obligations of Section 7.a shall not apply to amounts paid in settlement of any claim, demand, action or other proceeding if such settlement is effected without the consent of the other Party, which consent shall not be withheld or delayed unreasonably.

7.2 Failure to Defend or Settle. If the Indemnifying Party fails or wrongfully refuses to defend or settle any Claims, then the Indemnified Party shall, upon written notice to the Indemnifying Party, have the right to defend or settle (and control the defense of) such Claims. In such case, the Indemnifying Party shall cooperate, at its own expense, with the Indemnified Party and its counsel in the defense and settlement of such Claims, and shall pay, as they become due, all costs, damages, and reasonable legal fees incurred therefore.

7.3 Liability. EXCEPT FOR A PARTY'S INDEMNIFICATION OBLIGATIONS, INCLUDING, WITHOUT LIMITATION, CYTODYN´S INDEMINIFICATION OBLIGATIONS ARISING FROM THIRD-PARTY CLAIMS FOR ADVERSE REACTIONS, OR ITS BREACH OF SECTION 11 (CONFIDENTIALITY), WHICH ARE NOT LIMITED BY ANY LIABILITY CAP: (I) IN NO EVENT WILL EITHER OF THE PARTIES BE LIABLE

TO THE OTHER FOR ANY INDIRECT OR CONSEQUENTIAL LOSS OR DAMAGES OR LOSS OF PROFITS IN RELATION TO, OR ARISING OUT OF THE OPERATION OR TERMINATION OF THIS AGREEMENT, EVEN IF SUCH LOSS, DAMAGE, OR LOSS OF PROFITS WAS OR SHOULD HAVE BEEN REASONABLY FORESEEABLE; AND (II) EACH PARTY'S TOTAL CUMULATIVE LIABILITY IN CONNECTION WITH THIS AGREEMENT, WHETHER IN CONTRACT OR TORT OR OTHERWISE, WILL NOT EXCEED THE AMOUNT PAID OR OWED BY BIOMM TO CYTODYN UNDER THIS AGREEMENT DURING THE TWELVE (12) MONTH PERIOD IMMEDIATELY PRECEDING THE INCIDENT GIVING RISE TO THE CLAIM.

8. Insurance Protection. Each Party shall obtain and maintain during the Term liability, comprehensive, and workers' compensation insurance with a reputable insurance company to help protect against those insurable risks that such Party may incur in connection with the performance of its obligations under this Agreement. Each Party shall provide, upon request, to the other Party any such policies of such insurance, and the premium receipt(s) and insurance certificate(s) therefore.

9. Trademark and Patent Litigation. Any litigation or administrative proceedings concerning trademarks, patent and/or patent applications in the name of CytoDyn or an Affiliate filed and protected in Brazil related to sale of the Product in the Territory shall be conducted and controlled by CytoDyn or its Affiliate. All costs and expenses related to such proceedings shall be borne by CytoDyn.

10. Term; Termination

10.1 Term. Unless terminated sooner as provided in Section 10.2, this Agreement shall enter into effect on the Effective Date and will remain in force until the Definitive Product Registration is granted. (the "***Term***").

10.2 Termination Events

(a) For Cause. Either Party shall have the right to terminate this Agreement if at any time the other Party has materially breached any of its obligations hereunder (and has not cured such breach after being given the reasonable opportunity to do so).

(b) Force Majeure. A Party shall have a right to terminate this Agreement in accordance with Section 12.12.

(c) Business Circumstances. A Party shall have the right to terminate this Agreement in the event of the other Party's liquidation, bankruptcy or state of insolvency.

(d) Regulatory Decisions. Without prejudice to Section 10.1 above, a Party may terminate this Agreement upon written notice to the other Party in the event that ANVISA makes a final, non-appealable decision to not approve the Authorization or withdraws approval of the Authorization.

(e) Biomm and CytoDyn Disqualification. Either of the Parties may terminate this Agreement effective immediately upon delivery of written notice to the other (i) if

a Party fails to secure or renew any license, permit, authorization, or other Approval for the conduct of its business or if any such license, permit, authorization, or Approval is revoked or suspended, or (ii) if a Party becomes legally disqualified for any reason from importing, exporting, distributing, promoting or selling the Product in the Territory or otherwise from performing its obligations under this Agreement.

10.3 Change of Control or Sale of Product´s rights. The Parties expressly acknowledge that this Agreement shall continue in force and all sections herein will remain applicable to the Parties and/or their successors in case of a change of control of any of the Parties and/or sale of the Product´s rights. In the event that a Party experiences a change of control, such Party shall give prior written notice to the other Party any time before the change of control or sale of Product´s rights. For the avoidance of any doubt, internal reorganizations change in board or senior management within CytoDyn or Biomm shall not be considered as a change of control.

10.4 Effects of Termination. Upon expiration of the Term or earlier termination of this Agreement, Biomm shall provide, in a prompt and timely manner, all cooperation and assistance to CytoDyn, and shall undertake all actions as are required or reasonably requested by CytoDyn, to facilitate the smooth transition of Biomm's obligations hereunder to CytoDyn or to CytoDyn's Affiliate, distributor or other designee and to enable CytoDyn or its designee to assume, with as little disruption as possible, the promotion, marketing, import, sale and distribution of Products in the Territory. Thereafter Biomm shall:

(a) cease all further activities related to the Products, including all promotion, marketing, distribution and sales of the Products in the Territory;

(b) cease all further use of, and promptly collect and return or, at CytoDyn's request, destroy all documents containing CytoDyn Marks or Confidential Information of CytoDyn, all promotional material, and other Product-related sales or sales training materials;

(c) transfer all Approvals to CytoDyn;

(d) pay any and all amounts due and payable to CytoDyn under this Agreement.

10.5 Survival. Section 2.14, Article 6, Article 7, Section 10.4 and Article 11 shall survive the expiration or termination of this Agreement.

11. CONFIDENTIALITY

11.1 Confidentiality Obligations. Each Party shall at all times, and notwithstanding any termination or expiration of this Agreement, hold in confidence and not disclose to any third party Confidential Information of the other Party, except as approved in writing by the other Party to this Agreement, and shall use the Confidential Information for no purpose other than the purposes expressly permitted by this Agreement. Each Party shall only permit access to Confidential Information of the other Party to those of its employees, consultants, agents, and attorneys having a need to know and who are bound by confidentiality obligations at least as restrictive as those contained herein. The obligations in this Section 11.1 shall terminate ten years from the date of expiration or termination of this Agreement.

11.2 Exceptions to Confidentiality Obligations. A Party's obligations under this Agreement with respect to any portion of the other Party's Confidential Information shall terminate when the Party that is subject to such obligations can document in writing that such information:

(a) entered the public domain through no fault of such Party;

(b) was in such Party's possession free of any obligation of confidence at the time it was communicated to such Party by the other Party;

(c) was rightfully communicated to such Party free of any obligation of confidence subsequent to the time it was communicated to such Party by the other Party; or

(d) was developed by employees or agents of such Party independently of and without reference to any information communicated to such Party by the other Party.

11.3 Authorized Disclosure. Notwithstanding anything to the contrary, a Party shall not be in violation of Section 11.1 with regard to a disclosure of the other Party's Confidential Information that is in response to a valid order by a court or other governmental body or necessary to comply with applicable law or governmental regulations, provided that if such Party is required to make any such disclosure of the other Party's Confidential Information it shall to the extent practicable give reasonable advance notice to the other Party of such disclosure requirement in order to permit the other Party to seek confidential treatment of or to limit the Confidential Information required to be disclosed.

11.4 Separate Confidential Disclosure Agreements. Any prior confidential disclosure agreements between the Parties are incorporated by reference to this Agreement. In case of a discrepancy between the terms of this Agreement and such prior agreements, the terms of the separate Agreement shall prevail. Notwithstanding the foregoing, the Parties from time to time may execute additional confidential disclosure agreements, as required by their respective SOPs, for the limited and specific purpose of conducting audits.

12. MISCELLANEOUS

12.1 Assignment. Except as expressly provided hereunder, neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred by either Party without the prior written consent of the other Party (which consent shall not be unreasonably withheld); provided, however, that either Party may assign this Agreement and its rights and obligations hereunder without the other Party's consent, to any Affiliate, and CytoDyn may, without the consent of Biomm, assign this Agreement and its rights and obligations hereunder in connection with the transfer or sale of all or substantially all of its assets or its line of business to which this Agreement relates or to the successor entity or acquirer in the event of CytoDyn's merger, consolidation, sale of stock or other change of control. Notwithstanding the foregoing, any assignment to an Affiliate shall not relieve the assigning Party of its responsibilities for performance of its obligations under this Agreement. The rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties. Any assignment not in accordance with this Agreement shall be void.

12.2 Relationship of the Parties. It is expressly agreed that CytoDyn and Biomm shall be independent contractors and that the relationship between the Parties shall not constitute a partnership, joint venture or agency of any kind. Neither Party shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party.

12.3 Amendment. Unless otherwise provided herein, this Agreement may not be changed, waived, discharged, or terminated orally, but instead only by a written document that is signed by the duly authorized officers of both Parties.

12.4 Waiver. No failure or delay by either Party in exercising any right, power, or privilege under this Agreement shall operate as a waiver thereof, nor shall any single or partial waiver thereof include any other or further exercise thereof or the exercise of any other right, power, or privilege.

12.5 Severability. Whenever possible, each provision of the Agreement shall be interpreted in such manner as to be effective and valid under applicable law, but if any term or provision of this Agreement is held to be prohibited by or invalid under applicable law, such provision shall be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of the Agreement and this Agreement shall be interpreted and construed as if such provision had never been contained herein.

12.6 Notices. All notices and statements to be given (which shall be in writing) and all payments to be made hereunder (other than payments required to be wired) shall be given or made at the respective addresses of the Parties as set forth above, unless notification of a change of address is given. All notices, payments (other than wired payments) and statements to be made hereunder shall be mailed by certified or registered mail, return receipt requested, or sent by overnight courier, or by facsimile or other electronic means. Any notice given pursuant to this Agreement by mail shall be considered effective three business days after mailing. Any notice sent by overnight courier shall be considered effective one day after mailing. The date of transmission of any notice sent by electronic means shall be deemed to be the date the notice or statement is transmitted.

12.7 Construction. The section headings of this Agreement are inserted for ease of reference only, and shall not be used to interpret, define, construe, or describe the scope or extent of any aspect of this Agreement. Unless otherwise expressly stated, when used in this Agreement the word “including” means “including but not limited to.” Each Party represents that it has had the opportunity to participate in the preparation of this Agreement and hence the Parties agree that the rule of construction that ambiguities be resolved against the drafting Party shall not apply to this Agreement.

12.8 No third party Beneficiaries. Unless expressly provided, no provisions of this Agreement are intended or shall be construed to confer upon or give to any person other than Biomm and CytoDyn any rights, remedies, or other benefits under or by reason of this Agreement.

12.9 Dispute Resolution. If a dispute arises under this Agreement, the Parties shall use reasonable efforts to attempt to resolve such dispute, including escalation of discussions to the appropriate level of management, prior to exercising any remedies that may exist before commencing an action against the other Party. Notwithstanding the foregoing, either Party may at any time seek equitable relief without first attempting to resolve a dispute under this Section 12.9 provided, however, that such Party notifies the other Party promptly after it files any such action.

12.10 Equitable Relief. Each Party acknowledges and agrees that any breaches or violations of Section 11 may cause the non-breaching Party irreparable damage for which the award of monetary damages would be inadequate. Consequently, the non-breaching Party may seek to enjoin the breaching Party from any and all acts in violation of any such provisions, which remedy shall be cumulative and not exclusive, and a Party may seek the entry of an injunction enjoining any breach or threatened breach of such provisions, in addition to any other relief to which the non-breaching Party may be entitled at law or in equity.

12.11 Governing Law. The Parties agree that they shall in good faith work towards implementation of this Contract and any dispute arising out of or in relation to this Contract shall be first attempted to be resolved amicably by mutual negotiations. This Agreement shall be governed by and interpreted under the laws of Delaware without regard to its conflict or choice of law provisions. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement. All dispute, controversy or claim arising out of or relation to this Agreement shall be finally settled by arbitration, to be conducted in accordance with the rules of the International Chamber of Commerce of USA or any re-enactment thereof. The arbitration proceedings and all documents under this Agreement shall be conduct in English. The decision of the arbitration court shall be final and binding and shall enforceable by any court having jurisdiction.

12.12 Force Majeure. Except for a Party's payment obligations, neither Party shall be liable to the other for any failure or delay in the performance of any of its obligations under this Agreement arising out of any event or circumstance beyond its reasonable control, including war, rebellion, pandemic, terrorism, civil commotion, strikes, lock-outs or industrial disputes; fire, explosion, earthquake, acts of God, flood, drought, or bad weather; or requisitioning or other act or order by any government, council, or constituted body. If such failure or delay occurs, then the affected Party shall give the other Party notice of the circumstances causing such failure or delay, and such Party shall be excused from the performance of such of its obligations that it is thereby disabled from performing for so long as it is disabled and for 60 days thereafter; provided, however, that such affected Party commences and continues to take reasonable and diligent actions to cure such failure or delay. Notwithstanding the foregoing, if a Party is disabled from the performance of any material obligation under this Agreement for a period of 120 days or more, then the other Party shall have the right to terminate this Agreement upon written notice to the other Party.

12.13 Attorneys' Fees. If any claim, action, or dispute arises between the Parties with respect to any matter covered by this Agreement that leads to a proceeding before a court of competent jurisdiction to resolve such claim, the Prevailing Party in such proceeding shall be entitled to receive from the other Party its reasonable attorneys' fees, expert witness fees, court

costs and other out-of-pocket costs incurred in connection with such proceeding, in addition to any other relief that it may be awarded. For purposes of this Section 12.13, the term "Prevailing Party" means that Party in whose favor any monetary or equitable award is made or in whose favor any dispute is resolved, regardless of any settlement offers.

12.14 Publicity. Neither Party shall disclose the fact that they are conducting business together or the existence of, or the provisions of, this Agreement to any other third party unless such disclosure is in response to a valid order by a court or other governmental body or necessary to comply with applicable governmental law or regulations provided. Notwithstanding the foregoing, each Party shall have the right to issue from time to time press releases that disclose the relationship of the Parties under this Agreement upon the prior agreement of the Parties, which agreement shall not be unreasonably withheld, delayed, or conditioned. Any press releases that are to be issued by either Party shall be in a form and substance as may be mutually agreed upon by the Parties, and shall reflect the requirements of the regulatory agencies for public companies.

12.15 Entire Agreement. This Agreement includes all schedules attached hereto and any Packaging Specifications that are executed by authorized representatives of the Parties, and constitutes the entire Agreement by and between the Parties as to the subject matter hereof. Except for the Confidentiality Agreement, which shall remain in effect, this Agreement supersedes and replaces in its entirety all prior agreements, understandings, letters of intent, and memoranda of understanding by and between the Parties hereto, in either written or oral form. No amendment or modification of this Agreement shall be valid unless set forth in writing referencing this Agreement and executed by authorized representatives of both Parties.

12.16 English Language. This Agreement has been prepared in the English language and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral or other communications between the Parties regarding this Agreement, or delivered pursuant to the terms of this Agreement, shall be in the English language. Any proceedings related to dispute resolution including, but not limited to legal, equitable, or alternative dispute resolution, shall be conducted in the English language.

[Signature page follows]

In Witness Whereof, the Parties hereto have this day caused this Agreement to be executed by their duly authorized officers.

CytoDyn Inc.	**Biomm S.A.**
By: /s/ Nader Pourhassan_____	By: _/s/ Heraldo Carvalho Marchezini____
Name: Nader Pourhassan, Ph.D.	Name: Heraldo Carvalho Marchezini
Title: President & CEO	Title: CEO
	By: _/s/ Luciano Vilela_____
	Name: Luciano Vilela
	Title: CTO

Witnesses:

1. /s/ Arian Colachis	2. /s/ Kelly Silveira Gomes Figueiroa
Name Arian Colachis	Name: Kelly Silveira Gomes Figueiroa
ID: General Counsel and Corporate Secretary	ID: OAB/MG 71710

SCHEDULE B
PHARMACOVIGILANCE AGREEMENT
[TO BE INSERTED UPON EXECUTION]

SCHEDULE C
QUALITY AGREEMENT
[TO BE INSERTED UPON EXECUTION**]**

Exhibit 10.8

CERTAIN IDENTIFIED INFORMATION MARKED BY [*] HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED

EXCLUSIVE SUPPLY AND DISTRIBUTION AGREEMENT

KNOW ALL PERSONS BY THESE PRESENTS:

This Exclusive Supply and Distribution Agreement ("**Agreement**"), made and entered into this 15th day of April, 2021 ("**Effective Date**"), by and between:

CHIRAL PHARMA CORPORATION with business address at P. Antonio St., cor F. Legaspi St., Ugong, Pasig, Metro Manila, a Philippines corporation

("**CPC**");

&

CytoDyn Inc. a Delaware corporation, with business address at 1111 Main Street, Suite 660, Vancouver, WA 98660 ("**CytoDyn**").

Collectively known as the "**Parties**"

WITNESSETH;

WHEREAS, CytoDyn is the owner of product Leronlimab ("Product").

WHEREAS, CPC has obtained and is continuing to obtain Compassionate Special Permit ("**CSP**") applications or Emergency Use Authorization **("EUA")** from the Food and Drug Administration of the Philippines ("**Philippines FDA**") to use Leronlimab to treat confirmed coronavirus disease 2019 ("**COVID-19**") patients in the Philippines.

NOW THEREFORE, the Parties hereto have agreed as follows:

1. APPOINTMENT

1.1 Appointment. Subject to and conditioned on CPC complying with all of its obligations under this Agreement, CytoDyn hereby appoints CPC as the exclusive distributor of the Product in the Territory during the period beginning on the Effective Date and ending on the first (1st) anniversary thereafter ("**Exclusivity Period**"). CPC hereby accepts such appointment and shall purchase all of its required quantities of Product from CytoDyn at the Purchase Price and distribute Product solely in the Territory and in accordance with the applicable CSP.

1.2 **"Product"** means Vyrologix ™ (350 mg), a subcutaneous injectable biopharmaceutical drug product that contains CytoDyn's Leronlimab (a humanized monoclonal antibody (also known as PRO 140)

targeting against the CCR5 receptor) as the only active pharmaceutical ingredient, as further described in the applicable product specification provided by CytoDyn ("**Specifications**"). "**Territory**" means the Republic of Philippines. "**Purchase Price**" means [*] U.S. Dollars ([*]) per vial of Product, CIF (Incoterms® 2020) Manila Ninoy Aquino International Airport in Manila, Philippines.

1.3 Supply Obligation. Subject to and conditioned on CPC complying with all of its obligations under this Agreement, CytoDyn will sell to CPC up to two hundred thousand (200,000) vials of Product at [*] per vial. During the Exclusivity Period, CytoDyn shall not supply the Product to any third party for sale, distribution or use in the Territory.

1.4 No Sub-distributors. Without CytoDyn's prior written approval, CPC shall not sell or distribute Product to any third party for further resale or distribution or subcontract any of CPC's obligations hereunder except to CPC's logistic partner Metro Drug Inc. Any such approval is conditioned on such third party complying with the obligations of CPC in this Agreement. Any such approval shall not relieve CPC of its obligations under this Agreement, and CPC shall be and remain fully responsible for the activities of all of sub-distributors or its subcontractors. Unless agreed otherwise in writing, CPC shall not exploit the Product outside the Territory in any way.

1.5 Restrictions. CPC shall use the Products (and shall ensure the Products be used) solely in accordance with the treatment protocols approved under the applicable CSPs or EUA. CPC shall not distribute, resell, reverse engineer, administer, or otherwise use or make available the Products to anyone in any way or for any purpose. CPC shall store and handle the Products in accordance with the handling and storage instructions as specified in labeling or as provided by CytoDyn from time to time.

1.6 Quality Agreement**.** The Parties shall negotiate in good faith and use commercially reasonable efforts to enter into the Quality Agreement promptly after the Effective Date. The Quality Agreement will set out the policies, procedures and standards by which the Parties will coordinate and implement the operation and quality assurance activities and regulatory compliance objectives contemplated under this Agreement with respect to Product. To the extent there are any inconsistencies or conflicts between this Agreement and the Quality Agreement, the terms and conditions of this Agreement shall control unless the Parties specifically agreed otherwise in writing.

1.7 Cooperation. Without limiting the foregoing, each of CytoDyn and CPC shall provide to each other in a timely manner all information which the other Party reasonably requests regarding the Product in order to enable the other Party to comply with all laws applicable to the Product in the Territory. Each of CytoDyn and CPC shall provide to the other or if applicable, directly to the applicable regulatory authorities, any assistance and all documents reasonably necessary to enable the other to carry out its obligations under this Agreement. In general, requests for cooperation should be responded to by the other Party within three (3) days and both should make responsible efforts to ensure cooperation is maintained to ensure completion of the given project.

2. SUPPLY OF PRODUCT

2.1 Purchase Orders. CPC shall place orders for a Product in writing (each a "**Purchase Order**"). Each Purchase Order shall be in the form acceptable to CytoDyn and shall specify (a) the quantities of Product ordered (which shall be at least [*] vials in each Purchase Order) and (b) the requested delivery date (provided that the delivery date is at least five (5) days after the date of CytoDyn's receipt of the first Purchase Order and within twenty (20) days after the date of CytoDyn's receipt of the succeeding Purchase Order. Purchase Orders shall not be made in any other form of document other than that prescribed by this Agreement unless the Parties mutually agree otherwise in writing. Any term or condition of a Purchase Order that is different from or contrary to the terms and conditions of this Agreement shall be void.

2.2 Purchase Order Acceptance. CytoDyn shall, within two (2) days of receipt of a Purchase Order, confirm in writing whether a given Purchase Order has been accepted. CytoDyn shall use commercially

reasonable efforts to accept all Purchase Orders received in accordance with this Agreement. Unless agreed otherwise in writing by both Parties, all Purchase Orders accepted by CytoDyn shall each be a "**Firm Order**" and non-cancelable by either Party, andCPC shall be obligated to pay for the Product supplied to CPC pursuant to an accepted Purchase Order.

2.3 Delivery. CytoDyn shall deliver each shipment of Product CIF (Incoterms® 2020) Manila Ninoy Aquino International Airport in Manila, Philippines. Delivery on each Firm Order will take place on or before the later of (i) the delivery date specified in the corresponding Purchase Order and (ii) at least 5 days after the date of CytoDyn's receipt of the first Purchase Order and within twenty (20) days after the date of CytoDyn's receipt of the succeeding Purchase Order. Notwithstanding anything to the contrary contained herein, CytoDyn shall have satisfied its obligations with respect to a Firm Order if (a) the actual delivery date is within plus or minus five (+/-5) days of the specified delivery date specified in the corresponding Purchase Order except for the first purchase order, and (b) if the actual quantity of Product delivered is within plus or minus five percent (+/-5%) of the accepted Purchase Order quantity specified in the accepted Purchase Order.

2.4 Acceptance; Rejection.

2.4.1. CytoDyn shall be responsible for Product test procedures for quality assurance, including Product storage and shipping requirements, before Product is released to CPC. With each delivery, CytoDyn shall provide a certificate of analysis and other documents (collectively, the "**COA**") as specified in the Quality Agreement and Philippine Regulatory Authorities and Bureau of Customs requirements.

2.4.2. CPC shall inspect each shipment of Product promptly upon receipt. CPC may reject any Product which does not conform to the Specifications, or the shipping and storage requirements for the Product, at the time of receipt at CPC's location. CPC shall make any such rejection in writing, within ten (10) days of the later of the receipt of the COA or the Product at the facility designated by CPC in the applicable Firm Order (the "**Stipulated Rejection Period**"), to CytoDyn, and shall specify the reasons for such rejection (the **"Rejection Notice"**).

2.4.3. If CPC has not delivered a Rejection Notice within the Stipulated Rejection Period, CPC shall be deemed to have accepted that shipment of Product. Once CPC has accepted or has been deemed to have accepted a shipment of Product, and CPC may not exercise any rights to subsequently reject such shipment.

2.5 Rejection Procedures.

2.5.1. After CytoDyn receives the Rejection Notice, it will evaluate process issues and the reasons given by CPC for the rejection. CytoDyn shall use commercially reasonable efforts to promptly notify CPC whether it agrees with the basis for CPC's rejection. If CytoDyn agrees with the basis for CPC's rejection, CytoDyn shall use commercially reasonable efforts to promptly replace, at no cost to CPC, such rejected Product.

2.5.2. If CytoDyn disagrees with the basis for CPC's rejection specified in the Rejection Notice: (i) CytoDyn shall use commercially reasonable efforts to promptly replace such rejected Product; and (ii) the Parties shall submit samples of the rejected Product to a mutually acceptable third party laboratory, which shall determine whether such Product meets the Specifications. The determination of the third-party laboratory shall be final and determinative. If the third-party laboratory determines that the rejected shipment meets the Specifications, the rejection by CPC is unjustified, and CPC shall promptly pay CytoDyn for any replacement Product and, if the Product can no longer be distributed, Purchase Price on the unjustifiably rejected Product. If the third-party laboratory determines that the rejected shipment does not meet the Specifications, CytoDyn shall not invoice CPC for the replacement Product. The Party against whom the third-party laboratory rules shall also bear the fees in connection with resolution of the disagreement.

2.5.3. Notwithstanding any of the other provisions in this Agreement and without limiting any other provision herein, CPC agrees that the remedies set forth in this Section 2.5 are CPC's sole and exclusive remedies with respect to the rejection of Product.

2.6 No serialization. The Parties acknowledge and agree that all Products delivered to CPC under this Agreement are not required to be and will not be serialized.

3. PAYMENT

3.1 Invoices. At the time of each shipment, CytoDyn shall send an invoice to CPC specifying the total amount due under the invoice, calculated as the Purchase Price times the quantity of Product contained in the shipment.

3.2 Payment. All payments due to Cytodyn shall be payable in US Dollars. CPC shall open an irrevocable import letter of credit to be issued by a local bank acceptable to CytoDyn and confirmed by a reputable international bank. The terms of payment shall be within [*] days credit from the date of delivery. Letter of credit should be received before the product shipment to CPC.

3.3 In the event that the Product obtains commercial approval in another market, it is understood by the Parties that the purchase price to CPC shall remain at par or less than other purchase contracts made by CytoDyn during the Term of this Agreement.

3.4 Any price increase after the Exclusivity Period should be fair and reasonable, following the prevailing market conditions and in accordance with all regulatory approvals.

4. INTELLECTUAL PROPERTY

CytoDyn shall retain all of its rights, title and interest in and to all industrial and intellectual property rights embodied in or which covers the Product, in each case which is owned, held, or licensed by it as of the Effective Date or thereafter or developed, created or discovered by it or on its behalf. Except as otherwise expressly provided in this Agreement, CPC has and shall have no right, title or interest in any intellectual property right relating to the Product.

5. REPRESENTATION & WARRANTY

5.1 By Each Party. Each Party represents and warrants that (i) it has the corporate authority to enter into this Agreement and to perform the respective obligations hereunder; (ii) this Agreement is a legal, valid and binding agreement enforceable in accordance with its terms; (iii) executing this Agreement and performing its respective obligations hereunder do not conflict with or violate any requirement of applicable laws, regulations or orders of governmental bodies; and do not conflict with, or constitute a default under, any contractual obligation of such Party; and (iv) its affiliates and its and their respective officers, directors and employees (a) have not been debarred and are not subject to a pending debarment, under applicable laws or by any government healthcare programs or procurement programs, (b) are not disqualified by any government or regulatory authorities from distributing pharmaceutical products, (c) are not subject to a pending disqualification proceeding, and (d) have not been convicted of a criminal offense related to the provision of healthcare products or services and are not subject to any such pending action.

5.2 By CytoDyn. CytoDyn represents and warrants that at the time of delivery the Products shall conform to the Specifications. CytoDyn further warrants that the Products are manufactured in compliance with the applicable current good manufacturing practices ("**cGMP**") standards, are fit for human use pursuant to the CSP, and are free from manufacturing defects, as well as guarantees

a minimum shelf-life of [*] months upon receipt of Products, such shelf life being determined based solely on CytoDyn's internal stability test data.

5.3 By CPC. CPC hereby represents and warrants that it has not and will not take any action that will render CytoDyn liable for any violation of US or foreign laws, including without limitation the FCPA, which prohibits the offering, giving or promising to offer or give, directly or indirectly, money or anything of value to any official of a government, political party or instrumentality thereof in order to assist CytoDyn in obtaining or retaining business. If CPC makes any payment or takes any action that CytoDyn reasonably believes would violate any such US or foreign laws, CytoDyn may terminate this Agreement immediately.

5.4 No Additional Warranties. CPC shall not make any representation or give any warranty in respect of the Products other than those authorized in writing by CytoDyn from time to time.

5.5 Insurance. In addition, each Party agrees to obtain commercially reasonable and customary insurance sufficient to cover its respective potential liabilities hereunder and provide each other a copy thereof.

6. LIABILITY AND CROSS-INDEMNIFICATIONS

6.1 Each Party shall indemnify and hold the other Party, its affiliates, and their respective officers, directors, employees and representatives, harmless from and against any third-party claims and liability, including liability for death or personal injury and reasonable attorney's fees, which results solely from breach of its obligations under this Agreement, its negligence or willful misconduct, or its violation of applicable laws.

6.2 The Party seeking indemnification for third party claims under Sections 6.1 shall promptly notify the other Party in writing of all matters which may give rise to the right to indemnification hereunder; failure to promptly give such written notice, to the extent prejudicial to the indemnifying Party's defense of such claims, shall relieve the indemnifying Party's obligation to the other Party under this Section 6.

7. ADVERSE REACTIONS, COMPLAINTS AND RECALLS

7.1 CPC and CytoDyn shall notify each other within twenty-four (24) hours by confirmed facsimile or email of any information concerning any serious or unexpected side effect, injury, toxicity, or sensitivity reaction, any unexpected incidents, or any adverse drug experience reports and the severity thereof associated with the Products, the use and sale thereof (collectively "**Adverse Events**"). To enable CytoDyn to comply with its regulatory reporting responsibilities, CPC shall use commercially reasonable efforts to deliver to CytoDyn all Adverse Event information received by CPC and all other information as required by CytoDyn by notice in writing to CPC.

7.2 CytoDyn and CPC shall each comply with Philippines FDA pharmacovigilance policy (i.e., Adverse drug experience reports).

7.3 Complaints with regard to the Products received by CPC will be promptly sent by facsimile or email to CytoDyn at: jflisak@cytodyn.com and CYDY_Team@cytodyn.com.

7.4 If, for any reason, it shall become necessary to trace back or recall any particular batch of the Products, or to identify the customer or customers to whom Products from such batch will have been delivered, CPC shall cooperate fully with CytoDyn in doing so in accordance with the procedure established for the said purpose. If the recall is due to manufacturing defects of the Products, all costs and expenses related to said recall shall be borne by Cytodyn.

7.5 The obligation relating to Section 7.2 and to the Pharmacovigilance Policy and its subsequent amendments shall survive for one (1) year after the expiry date of the last batch of Products marketed by CPC in the Territory.

7.6 The obligation relating to Products complaints under Section 7.3 shall survive until the expiry date of the last batch of Products marketed by CPC in the Territory.

7.7 The obligation relating to Products recall under Section 7.4 shall survive until the expiry date of the last batch of Products marketed by CPC in the Territory.

8. CONFIDENTIALITY

8.1 "**Confidential Information**" means all confidential or proprietary information relating to the business and affairs of CytoDyn or its affiliates that are disclosed by or on behalf of CytoDyn to CPC and all information derived therefrom, including without limitation financial information, business opportunities, information relating to pharmaceutical products of any nature in any form. CPC shall not make available Confidential Information to any third party; except that it shall be entitled to disclose to government authorities to the extent necessary for obtaining CSP, in accordance with accepted practices in the pharmaceutical industry.

8.2 CPC shall take all necessary steps to ensure that its employees who gain access to Confidential Information are bound in writing by terms similar to the terms of this Agreement, not to divulge Confidential Information, except that they may divulge it to the extent that CPC may do so in accordance with the provisions hereof.

8.3 CPC agrees that all Confidential Information that it receives from CytoDyn and/or its affiliates in connection with the Products are the sole property of CytoDyn and shall be used by it only in accordance with the terms and provisions of this Agreement.

8.4 CPC shall have no obligation to keep confidential and secret any part of the Confidential Information that is already known to it from any source other than by disclosure by, or which emanated originally from CytoDyn and/or its affiliates, as shown by written records, or which now or in future becomes known to the public or which is made known to CPC by a third party as a matter of right or when ordered by a competent court.

8.5 CPC's obligations under Section 8 shall survive for five (5) years after termination of this Agreement and indefinitely as to any trade secret.

9. TERMINATION

9.1 Term. This Agreement shall commence on the Effective Date and shall be valid for one (1) year thereafter, unless terminated earlier pursuant to Section 9.

9.2 Termination for Breach. A Party may terminate this Agreement upon prior written notice to the other Party for material breach of this Agreement by the other Party (which includes any failure by CPC to pay amounts when due to CytoDyn in accordance with the terms of this Agreement). Any notice of material breach shall specify the breach in reasonable detail. Unless otherwise provided in this Agreement, the termination shall be effective thirty (30) days after receipt of the written notice, unless the breaching Party cures the breach within that thirty (30) day notice period.

9.3 Termination for Convenience. Each Party may terminate this Agreement for convenience upon sixty (60) days' notice to the other Party.

9.4 Effects of Termination. Upon termination:

9.4.1. CPC shall (i) promptly return to CytoDyn, or, at CytoDyn's request, destroy (and certify such destruction in writing) all of CytoDyn's Confidential Information, and (ii) cease using Confidential Information in any way for any purpose.

9.4.2. CytoDyn shall within thirty (30) days from effective date of termination of this Agreement, repurchase all inventory of Products of marketable quality and having a remaining shelf life of at least fifty percent (50%) based on CytoDyn's Invoice date held by CPC. In the event that CytoDyn transfers the right to distribute to another distributor, then said distributor shall purchase all stocks of the products held by CPC, in good and marketable condition. In both cases, CytoDyn shall pay CPC for a price equivalent to the Products' landed cost plus 15%.

9.4.3. In the event Cytodyn decides not to repurchase, CPC may, where permitted by applicable laws, sell Product then in its inventory for a period of six (6) months thereafter ("**Selloff Period**"), all in accordance with the terms of this Agreement. Promptly after the expiration of the Selloff Period, CPC shall, at its cost, destroy any unsold Product remaining in its inventory and will provide appropriate evidence of such destruction to CytoDyn.

10. INDEPENDENT PARTY

This Agreement does not constitute either Party as agent or legal representative of the other Party for any purpose whatsoever. A Party is not granted any right or authority to assume or to create any obligation or responsibility, express or implied, on behalf of or in the name of the other Party, with regard to any manner or thing whatsoever, unless otherwise specifically agreed upon in writing.

11. ASSIGNMENT

CPC shall not assign, delegate or transfer its rights and obligations under this Agreement in whole or in part without prior written authorization from CytoDyn; any purported assignment, delegation or transfer in violation of the foregoing is void. CytoDyn may assign, delegate or transfer its rights and obligations under this Agreement in whole or in part.

12. FORCE MAJEURE

Each of the Parties hereto shall be excused from the performance of its obligations hereunder, other than the payment of money, in the event that such performance is prevented by force majeure, provided that each of the Parties shall use its best efforts to complete such performance by other means. For the purpose of this Agreement force majeure is defined as causes beyond the control of CPC or CytoDyn, including but not limited to, acts of God, acts, regulations or laws of any government, war, civil

commotion, destruction of production facilities or materials by fire, earthquake or storm, labor disturbances, epidemic and failure of public utilities or common carriers.

13. SEVERABILITY

Should any part or provision of this Agreement be held unenforceable or in conflict with the applicable laws or regulations of any applicable jurisdiction, the invalid or unenforceable part or provision shall, provided that it does not affect the essence of this Agreement, be replaced with a revision which accomplishes, to the extent possible, the original commercial purpose of such part or provision in a valid and enforceable manner, and the balance of this Agreement shall remain in full force and effect and binding upon the Parties hereto.

14. ENTIRE AGREEMENT

This Agreement constitutes the entire agreement between the Parties with respect to its subject matter and supersedes all prior agreements, arrangements, dealings or writings between the Parties. This Agreement may not be varied except in writing signed by the Parties' authorized representatives.

15. WAIVER

No waiver of any right, breach or default hereunder shall be considered valid unless in writing and signed by the Party giving such waiver, and no such waiver shall be deemed a waiver of any subsequent right, breach or default of the same or similar nature.

16. GOVERNING LAW

This Agreement shall be governed, interpreted and construed in accordance with the laws of the Republic of Singapore, without reference to the principles of conflicts of law. Any dispute, controversy or claim initiated by either Party arising out of, resulting from or relating to this Agreement (other than good-faith third party actions or proceedings filed or instituted in an action or proceeding by a third party against a Party) shall be finally resolved by binding arbitration conducted in the English language, in the Republic of Singapore, under the Arbitration Rules of the Singapore International Arbitration Centre ("**SIAC Rules**"), by a panel of one arbitrator appointed in accordance with the SIAC Rules. Notwithstanding the foregoing, either Party may, without waiving any right or remedy available to such Party, seek and obtain from any court of competent jurisdiction any interim or provisional relief that is necessary or desirable to protect the rights or property of such Party, pending the selection of the arbitrator hereunder or pending the arbitrator’s determination of any dispute, controversy or claim hereunder. The Parties undertake to use all reasonable best efforts in order to solve in an amicable manner any controversy arising in connection with this Agreement.

17. NOTICE

Unless otherwise stated in this Agreement, all requests and notices required or permitted to be given to the Parties hereto shall be given in writing, shall expressly reference the section(s) of this Agreement to which they pertain, and shall be delivered to the other Party, effective on receipt, at the appropriate address as set forth below or to such other addresses as may be designated in writing by the Parties from time to time during the term of this Agreement.

If to CPC:

Chiral Pharma Corporation, P. Antonio St., cor F. Legaspi St., Ugong, Pasig,
Metro Manila
Attention: Francis Wade Z. Gomez
Email: fzgomez@nmpc.com.ph

If to CytoDyn:

CytoDyn Inc., 1111 Main Street, Suite 660, Vancouver, WA 98660, USA
Attention: Chief Executive Officer
Email: npourhassan@cytodyn.com and CYDY_Team@cytodyn.com

Product complaints and quality issues: jflisak@cytodyn.com

18. COUNTERPARTS

This Agreement may be executed in counterparts, each of which shall be deemed to be an original and together shall be deemed to be one and the same agreement.

IN WITNESS WHEREOF, the Parties hereto have each caused this Agreement to be executed by their duly-authorized representatives as of the Effective Date.

CytoDyn Inc.	**Chiral Pharma Corporation**
/s/ Nader Pourhassan	/s/ Francis Wade Z. Gomez, IV
Nader Pourhassan Chief Executive Officer	**Francis Wade Z. Gomez, IV** President

Exhibit 10.9

CERTAIN IDENTIFIED INFORMATION MARKED BY [*] HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED

Amendment No.1 to Exclusive Supply and Distribution Agreement

This amendment (this "**Amendment**"), dated as of April 19, 2021, is entered by and between CytoDyn Inc., a Delaware corporation ("**CytoDyn"**) having a place of business at 1111 Main Street, Vancouver, Washington 98660, and Chiral Pharma Corporation, a Philippines corporation ("**CPC**") having a place of business at P. Antonio St., cor F. Legaspi St., Ugong, Pasig, Metro Manila, with respect to the following facts:

The parties entered into a certain Exclusive Supply and Distribution Agreement dated as of April 15, 2021 ("**Agreement**"). Capitalized terms not defined herein have their respective meanings in the Agreement. The parties now desire to amend the Agreement in certain respects on the terms and conditions set forth below. In consideration of the foregoing premises and the mutual covenants set forth below, the parties hereby amend the Agreement and otherwise agree as follows:

1. Amendments.

(a) A new Section 2.5.3 is added as follows:

Notwithstanding any of the other provisions in this Agreement and without limiting any other provision herein, CPC agrees that the remedies set forth in this Section 2.5 are CPC's sole and exclusive remedies with respect to the rejection of Product.

(b) The reference to section "3.2" is added and the section is amended as follows:

3.2 Payment. All payments due to CytoDyn shall be payable in US Dollars. With respect to each Purchase Order, CPC shall open an irrevocable import letter of credit ("**LoC**") and deliver such LoC to CytoDyn within five (5) working days (i.e., excluding Saturdays, Sundays or national holidays) in the Philippines after CytoDyn submits the Payment Invoice. Such LoC shall allow CytoDyn to draw on the LoC [*] days after delivering the shipment corresponding to the Payment Invoice and shall be (i) in the amount equal to the amount payable by CPC to CytoDyn under the corresponding Payment Invoice and (ii) issued by a well-known bank acceptable to CytoDyn and confirmed by a reputable international bank.

(c) A new Section 6.3 is added as follows:

6.3 EXCEPT FOR ITS INDEMNIFICATION OBLIGATIONS (INCLUDING PRODUCT LIABILITY), BREACH OF SECTION 8, OR ITS GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT: (i) CYTODYN OR ITS AFFILIATES WILL NOT BE LIABLE TO CPC FOR ANY INDIRECT, INCIDENTAL, PUNITIVE OR SPECIAL DAMAGES, INCLUDING LOSS OF PROFITS, GOODWILL OR REVENUE, DATA OR USE, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, ARISING OUT OF THIS AGREEMENT; and (ii) CYTODYN'S MAXIMUM LIABILITY UNDER THIS AGREEMENT SHALL NOT EXCEED THE

AMOUNT PAID BY CPC TO CYTODYN WITHIN NINETY (90) DAYS BEFORE THE EVENT GIVING RISE TO SUCH LIABILITY OCCURRED.

(d) Section 9.4.2 is amended to add "CytoDyn may decide to repurchase Products from CPC; in such event," to the beginning of this section.

(e) A new Section 9.4.4 is added as follows:

In the event of adverse regulatory ruling regarding use of leronlimab for Covid-19, CytoDyn shall within thirty (30) days from effective date of termination of this Agreement, repurchase all inventory of Products and CytoDyn shall pay CPC for a price equivalent to the Product's Purchase Price.

2. **Limited Effect**. Except as expressly provided in this Amendment, all of the terms and provisions of the Agreement are and will remain in full force and effect and are hereby ratified and confirmed by the parties. Without limitation, the amendments contained herein will not be construed as an amendment to or waiver of any other provision or exhibit of the Agreement or as a waiver of or consent to any further or future action on the part of either party that would require the waiver or consent of the other party. On and after the Amendment Effective Date, each reference in the Agreement to "this Agreement," "the Agreement," "hereunder," "hereof," "herein," or similar words, and each reference to the Agreement in any other agreements, documents, or instruments executed and delivered pursuant to, or in connection with, the Agreement will mean and be a reference to the Agreement, as amended by this Amendment.

This Amendment will be governed by and construed under the same laws that govern the Agreement. This Amendment may be executed in two or more counterparts, including counterparts delivered electronically, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

IN WITNESS WHEREOF, the parties have duly executed and delivered this Amendment as of the Amendment Date.

CYTODYN INC.	CHIRAL PHARMA CORPORATION
By /s/ Nader Pourhassan	By /s/ Francis Wade Z. Gomez, IV
Name Nader Pourhassan, Ph.D.	Name Francis Wade Z. Gomez, IV
Title President and Chief Executive Officer	Title President

Exhibit 10.10

CERTAIN IDENTIFIED INFORMATION MARKED BY [*] HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED

EXCLUSIVE SUPPLY AND DISTRIBUTION AGREEMENT

KNOW ALL PERSONS BY THESE PRESENTS:

This Exclusive Supply and Distribution Agreement ("**Agreement**"), made and entered into this 11th day of May, 2021 ("**Effective Date**"), by and between:

Macleods Phamaceuticals Ltd with registered office at 304, Atlanta Arcade, Marol Church Road, Opp. Hotel Leela, Andheri (East) Mumbai 400 059, an India corporation

("**MACLEODS**");

&

CytoDyn Inc. a Delaware corporation, with business address at 1111 Main Street, Suite 660, Vancouver, WA 98660 ("**CYTODYN**").

Collectively known as the "**Parties**"

WITNESSETH;

WHEREAS, CYTODYN is the owner of product Leronlimab.

WHEREAS, CYTODYN has represented that it is in the process to commercialise the product Leronlimab and is keen to partner with entities to distribute the same.

WHEREAS, MACLEODS has obtained and is continuing to obtain Compassionate Special Permit ("**CSP**") or Emergency Use Authorization ("**EUA**") from the India Central Drugs Standard Control Organization ("**CDSCO**") to treat confirmed coronavirus disease 2019 ("**COVID-19**") patients in India.

NOW THEREFORE, the Parties hereto have agreed as follows:

1. APPOINTMENT

1.1 Appointment. Subject to and conditioned on MACLEODS complying with all of its obligations under this Agreement, CYTODYN hereby appoints MACLEODS as the exclusive distributor of the Product in the Field in the Territory during the period beginning on the Effective Date and [*] anniversary thereafter ("**Exclusivity Period**"). MACLEODS hereby accepts such appointment and shall purchase all of its required quantities of Product from CYTODYN at the Purchase Price and distribute Product solely in the Territory for use in the Field, in each case in accordance with the applicable EUA.

1.2 **"Product"** means Vyrologix TM (350 mg), a subcutaneous injectable biopharmaceutical drug product that contains CYTODYN's Leronlimab (a humanized monoclonal antibody (also known as PRO 140) targeting against the CCR5 receptor) as the only active

pharmaceutical ingredient, as further described in the applicable product specification provided by CYTODYN ("**Specifications**"). **"Field"** means treating confirmed COVID-19 patients. **"Territory"** means India. **"Purchase Price"** means [*]

1.3 Supply Obligation. Subject to and conditioned on MACLEODS complying with all of its obligations under this Agreement, [*]. During the Exclusivity Period, CYTODYN shall not supply the Product to any third party for sale, distribution or use in the Field in the Territory.

1.4 Intentionally Omitted. Any such approval is conditioned on such third party complying with the obligations of MACLEODS in this Agreement. Any such approval shall not relieve MACLEODS of its obligations under this Agreement, and MACLEODS shall be and remain fully responsible for the activities of all of sub-distributors or its subcontractors. Unless agreed otherwise in writing, MACLEODS shall not exploit (i) the Product outside the Territory or the Field in any way.

1.5 Restrictions. MACLEODS shall use the Products (and shall ensure the Products be used) solely in accordance with the treatment protocols approved under the applicable CSP (as defined below) or EUA. MACLEODS shall not distribute, resell, reverse engineer, administer, or otherwise use or make available the Products to anyone in any way or for any purpose. MACLEODS shall store and handle the Products in accordance with the handling and storage instructions as specified in labeling or as provided by CYTODYN from time to time.

1.6 Quality Agreement**.** The Parties shall negotiate in good faith and use commercially reasonable efforts to enter into the Quality Agreement promptly after the Effective Date. The Quality Agreement will set out the policies, procedures and standards by which the Parties will coordinate and implement the operation and quality assurance activities and regulatory compliance objectives contemplated under this Agreement with respect to Product. To the extent there are any inconsistencies or conflicts between this Agreement and the Quality Agreement, the terms and conditions of this Agreement shall control unless the Parties specifically agreed otherwise in writing.

1.7 Cooperation. Without limiting the foregoing, each of CYTODYN and MACLEODS shall provide to each other in a timely manner all information which the other Party reasonably requests regarding the Product in order to enable the other Party to comply with all laws applicable to the Product in the Territory. Each of CYTODYN and MACLEODS shall provide to the other or if applicable, directly to the applicable regulatory authorities, any assistance and all documents reasonably necessary to enable the other to carry out its obligations under this Agreement. In general, requests for cooperation should be responded to by the other Party within three (3) days and both should make responsible efforts to ensure cooperation is maintained to ensure completion of the given project.

1.8 Regulatory Approval. MACLEODS will be responsible for applying and obtaining CSP or EUA for the treatment of patients with COVID-19 within the Territory. CYTODYN shall provide all the necessary documents, data, information, samples, presentation and help MACLEODS with necessary technical, scientific, expert advice, information and presentation at no cost to obtain regulatory approval for to import, market, promote, sell or distribution of product in the territory. MACLEODS will advise CYTODYN in advance about the requisite actions necessary and taken to comply with any such new application or renewal. Costs and expenses of renewal shall be borne by MACLEODS.

2. SUPPLY OF PRODUCT

2.1 Purchase Orders. MACLEODS shall place orders for a Product in writing (each a "**Purchase Order**"). Each Purchase Order shall be in the form acceptable to CYTODYN and shall specify (a) the quantities of Product ordered (which shall be at least [*] vials in each Purchase Order) and (b) the requested delivery date (provided that the delivery date is at least twenty

(20) days after the date of CYTODYN's receipt of the Purchase Order). Purchase Orders shall not be made in any other form of document other than that prescribed by this Agreement unless the Parties mutually agree otherwise in writing. Any term or condition of a Purchase Order that is different from or contrary to the terms and conditions of this Agreement shall be void.

2.2 Purchase Order Acceptance. CYTODYN shall, within five (5) days of receipt of a Purchase Order, confirm in writing whether a given Purchase Order has been accepted. CYTODYN shall use commercially reasonable efforts to accept all Purchase Orders received in accordance with this Agreement. Unless agreed otherwise in writing by both Parties, all Purchase Orders accepted by CYTODYN shall each be a "**Firm Order**" and non-cancelable by either Party, and MACLEODS shall be obligated to pay for the Product supplied to MACLEODS pursuant to an accepted Purchase Order.

2.3 Delivery. CYTODYN shall deliver each shipment of Product FCA at Chhatrapati Shivaji Maharaj International Airport in Mumbai, India; provided, however, that:

2.3.1. If the quantity of Product contained in any Purchase Order is less than [*] vials, then MACLEODS shall reimburse CYTODYN for [*] percent [*] of CYTODYN's out-of-pocket shipping and insurance expenses related to such deliveries.

2.3.2. Delivery on each Firm Order will take place on or before twenty (20) days after CYTODYN's receipt of the Purchase Order.

2.3.3. CYTODYN shall have satisfied its obligations with respect to a Firm Order if (a) the actual delivery date is within plus or minus five (+/-5) days of the specified delivery date specified in the corresponding Purchase Order, and (b) if the actual quantity of Product delivered is within plus or minus five percent (+/-5%) of the accepted Purchase Order quantity specified in the accepted Purchase Order.

2.4 Acceptance; Rejection.

2.4.1. CYTODYN shall be responsible for Product test procedures for quality assurance, including Product storage and shipping requirements, before Product is released to MACLEODS. With each delivery, CYTODYN shall provide a certificate of analysis and other documents (collectively, the "**COA**") as specified in the Quality Agreement.

2.4.2. CYTODYN shall notify in advance to MACLEODS of any variation or change that affects the formulation, design, packaging, specifications, or any notable change in the Products, change in the plant or production lines, to the extent the same may affect the process of importing and marketing of the Products.

2.4.3. MACLEODS shall inspect each shipment of Product promptly upon receipt. MACLEODS may reject any Product which does not conform to the Specifications, or the shipping and storage requirements for the Product, at the time of receipt at MACLEODS's location. MACLEODS shall make any such rejection in writing, within seven (7) days of the later of the receipt of the COA and the Product at the facility designated by MACLEODS in the applicable Firm Order (the "**Stipulated Rejection Period**"), to CYTODYN, and shall specify the reasons for such rejection (the **"Rejection Notice"**).

2.4.4. If MACLEODS has not delivered a Rejection Notice within the Stipulated Rejection Period, MACLEODS shall be deemed to have accepted that shipment of Product. Once MACLEODS has accepted or has been deemed to have accepted a shipment of Product, and MACLEODS may not exercise any rights to subsequently reject such shipment.

2.5 Rejection Procedures.

2.5.1. After CYTODYN receives the Rejection Notice, it will evaluate process issues and

the reasons given by MACLEODS for the rejection. CYTODYN shall use commercially reasonable efforts to promptly notify MACLEODS whether it agrees with the basis for MACLEODS' rejection. If CYTODYN agrees with the basis for MACLEODS' rejection, CYTODYN shall use commercially reasonable efforts to promptly replace, at no cost to MACLEODS, such rejected Product.

2.5.2. If CYTODYN disagrees with the basis for MACLEODS' rejection specified in the Rejection Notice: (i) CYTODYN shall use commercially reasonable efforts to promptly replace such rejected Product; and (ii) the Parties shall submit samples of the rejected Product to a mutually acceptable third party laboratory, which shall determine whether such Product meets the Specifications. The determination of the third-party laboratory shall be final and determinative. If the third-party laboratory determines that the rejected shipment meets the Specifications, the rejection by MACLEODS is unjustified, and MACLEODS shall promptly pay CYTODYN for any replacement Product and, if the Product can no longer be distributed, Purchase Price on the unjustifiably rejected Product. If the third-party laboratory determines that the rejected shipment does not meet the Specifications, CYTODYN shall not invoice MACLEODS for the replacement Product. The Party against whom the third-party laboratory rules shall also bear the fees in connection with resolution of the disagreement.

2.5.3. Notwithstanding any of the other provisions in this Agreement and without limiting any other provision herein, MACLEODS agrees that the remedies set forth in this Section 2.5 are MACLEODS's sole and exclusive remedies with respect to the rejection of Product.

2.6 No serialization. The Parties acknowledge and agree that all Products delivered to MACLEODS under this Agreement are not required to be and will not be serialized.

3. PAYMENT

3.1 Invoices. At the time of each shipment, CYTODYN shall send an invoice to MACLEODS specifying the total amount due under the invoice, calculated as the Purchase Price times the quantity of Product contained in the shipment.

3.2 Payment. Within [*] days after receiving each invoice, MACLEODS shall pay to CYTODYN the amount owed to CYTODYN under the invoice.

3.3 Shipping charge re-imbursement. All re-imbursement of shipping charges under Section 2.3.1 shall be made by bank wire transfer in immediately available funds to a U.S. account designated in writing by CYTODYN or by other mutually acceptable means.

3.4 Letter of Credit. At least 20 (20) days before the delivery date in each Firm Order, MACLEODS shall open, at an internationally known bank reasonably acceptable to CYTODYN, an international bank letter of credit "**LoC**" that: (i) designates CYTODYN as the beneficiary; (ii) allows CYTODYN to draw on the LoC after presenting this Agreement, an invoice that has become due pursuant to Section 3.2 and the corresponding airway bill, each containing the required information as the Parties agreed and specified in the LoC; (iii) whose authorized amount is equal to the amount payable by MACLEODS to CYTODYN under the invoice for the corresponding Firm Order; (iv) and otherwise complies with the Uniform Customs and Practice for Documentary Credits latest version and Supplement to the Uniform Customs and Practice for Documentary Credits for Electronic Presentation (eUCP). To the extent that amounts drawn by CYTODYN in accordance with this Section 3 is less than the amounts actually owed by MACLEODS to CYTODYN under Section 3.2, the amounts drawn shall be set off against, but shall not be in lieu of, the amounts actually owed MACLEODS to CYTODYN under Section 3.2.

4. INSPECTIONS AND COMMUNICATIONS

With respect to the Product Manufactured by CYTODYN, each Party shall promptly notify the other Party of any Regulatory Authorities' notices of violation or deficiency letters received and

promptly deliver to the other Party all related reports, data information and correspondence received from such Regulatory Authorities with respect to API(s)/API in the Product, any GMP issues relating thereto and any written response, information, data or correspondence delivered by such Party to the Regulatory Authority with respect to the API(s)/ Product and shall cooperate to the extent reasonably requested by the other Party in its response to the Regulatory Authorities.

5. INTELLECTUAL PROPERTY

CYTODYN shall retain all of its rights, title and interest in and to all industrial and intellectual property rights embodied in or which covers the Product, in each case which is owned, held, or licensed by it as of the Effective Date or thereafter or developed, created or discovered by it or on its behalf. Except as otherwise expressly provided in this Agreement, MACLEODS has and shall have no right, title or interest in any intellectual property right relating to the Product.

6. REPRESENTATION & WARRANTY

6.1 By Each Party. Each Party represents and warrants that (i) it has the corporate authority to enter into this Agreement and to perform the respective obligations hereunder; (ii) this Agreement is a legal, valid and binding agreement enforceable in accordance with its terms; (iii) executing this Agreement and performing its respective obligations hereunder do not conflict with or violate any requirement of applicable laws, regulations or orders of governmental bodies; and do not conflict with, or constitute a default under, any contractual obligation of such Party; and (iv) its affiliates and its and their respective officers, directors and employees (a) have not been debarred and are not subject to a pending debarment, under applicable laws or by any government healthcare programs or procurement programs, (b) are not disqualified by any government or regulatory authorities from distributing pharmaceutical products, (c) are not subject to a pending disqualification proceeding, and (d) have not been convicted of a criminal offense related to the provision of healthcare products or services and are not subject to any such pending action. In addition to the preceding The Parties represents and warrants each other that it has not and will not take any action which shall render the other party liable for any violation of any statute or guideline including but not limited to USFCPA, UKBA and Indian Prevention of Corruption Act, which prohibits offering, giving or promising to offer or give, directly or indirectly, money or anything of value to any official of a government, political party or instrumentality thereof in order to assist the other party in obtaining or retaining business. If any party makes any payment or takes any action that the other party reasonably believes would violate any such US or foreign laws, the other party may terminate this Agreement immediately.

6.2 By CYTODYN. CYTODYN represents and warrants that at the time of delivery the Products shall conform to the Specifications. CYTODYN further warrants that the Products are manufactured in compliance with the applicable current good manufacturing practices ("**cGMP**") standards, are fit for human use pursuant to the [equivalent CSP] and EUA, and are free from manufacturing defects, as well as guarantees a minimum shelf-life of [*] upon receipt of Products, such shelf life being determined based solely on CYTODYN's internal stability test data. CYTODYN represents and warrants and hold harmless MALEODS for any infringement of patent or trademark or any other third party rights infringement claims on MACLEODS arising from importing and/ or marketing and/or selling of the Products in the Territory by MACLEODS / MACLEODS affiliates.

6.3 No Additional Warranties. MACLEODS shall not make any representation or give any warranty in respect of the Products other than those authorized in writing by CYTODYN from time to time.

6.4 Insurance. In addition, each Party agrees to obtain commercially reasonable and customary insurance sufficient to cover its respective potential liabilities hereunder and provide each other a copy thereof.

7. LIABILITY AND CROSS-INDEMNIFICATIONS

7.1 Each Party shall indemnify and hold the other Party, its affiliates, and their respective officers, directors, employees and representatives, harmless from and against any third-party claims and liability, including liability for death or personal injury and reasonable attorney's fees, which results solely from breach of its obligations under this Agreement, its negligence or willful misconduct, or its violation of applicable laws.

7.2 The Party seeking indemnification for third party claims under Sections 6.1 shall promptly notify the other Party in writing of all matters which may give rise to the right to indemnification hereunder; failure to promptly give such written notice, to the extent prejudicial to the indemnifying Party's defense of such claims, shall relieve the indemnifying Party's obligation to the other Party under this Section 6.

7.3 EXCEPT FOR ITS INDEMNIFICATION OBLIGATIONS, BREACH OF SECTION 8, OR ITS GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT: (i) NEITHER PARTY WILL NOT BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, INCIDENTAL, PUNITIVE OR SPECIAL DAMAGES, INCLUDING LOSS OF PROFITS, GOODWILL OR REVENUE, DATA OR USE, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, ARISING IN ANY WAY OUT OF THIS AGREEMENT; and (ii) EACH PARTY MAXIMUM LIABILITY UNDER THIS AGREEMENT SHALL NOT EXCEED THE AMOUNT PAID BY MACLEODS TO CYTODYN WITHIN THIRTY (30) DAYS BEFORE THE EVENT GIVING RISE TO SUCH LIABILITY OCCURRED.

8. ADVERSE REACTIONS, COMPLAINTS AND RECALLS

8.1 MACLEODS and CYTODYN shall notify each other within twenty-four (24) hours by confirmed facsimile or email of any information concerning any serious or unexpected side effect, injury, toxicity, or sensitivity reaction, any unexpected incidents, or any adverse drug experience reports and the severity thereof associated with the Products, the use and sale thereof (collectively "**Adverse Events**"). To enable CYTODYN to comply with its regulatory reporting responsibilities, MACLEODS shall use commercially reasonable efforts to deliver to CYTODYN all Adverse Event information received by MACLEODS and all other information as required by CYTODYN by notice in writing to MACLEODS.

8.2 CYTODYN and MACLEODS shall each comply with CDSCO pharmacovigilance policy (i.e., Adverse drug experience reports).

8.3 Complaints with regard to the Products received by MACLEODS will be promptly sent by facsimile or email to CYTODYN at: jflisak@CYTODYN.com and CYDY_Team@CYTODYN.com.

9. CONFIDENTIALITY

9.1 "**Confidential** Information" means all confidential or proprietary information relating to the business and affairs of CYTODYN or its affiliates that are disclosed by or on behalf of CYTODYN to MACLEODS and all information derived therefrom, including without limitation financial information, business opportunities, information relating to pharmaceutical products of any nature in any form. MACLEODS shall not make available Confidential Information to any third party; except that it shall be entitled to disclose to government authorities to the extent necessary for obtaining [equivalent CSP] and EUA, in accordance with accepted practices in the pharmaceutical industry.

9.2 MACLEODS shall take all necessary steps to ensure that its employees who gain access to Confidential Information are bound in writing by terms similar to the terms of this

Agreement, not to divulge Confidential Information, except that they may divulge it to the extent that MACLEODS may do so in accordance with the provisions hereof.

9.3 MACLEODS agrees that all Confidential Information that it receives from CYTODYN and/or its affiliates in connection with the Products are the sole property of CYTODYN and shall be used by it only in accordance with the terms and provisions of this Agreement.

9.4 MACLEODS shall have no obligation to keep confidential and secret any part of the Confidential Information that is already known to it from any source other than by disclosure by, or which emanated originally from CYTODYN and/or its affiliates, as shown by written records, or which now or in future becomes known to the public or which is made known to MACLEODS by a third party as a matter of right or when ordered by a competent court.

9.5 MACLEODS's obligations under Section 9 shall survive for five (5) years after termination of this Agreement and indefinitely as to any trade secret.

10. TERMINATION

10.1 Term. This Agreement shall commence on the Effective Date and shall be valid for [*] years thereafter, unless terminated earlier pursuant to Section 9. The Parties may mutually agree in signed writing to extend the term of this Agreement or amend the scope of this Agreement.

10.2 Termination for Breach. A Party may terminate this Agreement upon prior written notice to the other Party for material breach of this Agreement by the other Party. Any notice of material breach shall specify the breach in reasonable detail. Unless otherwise provided in this Agreement, the termination shall be effective thirty (30) days after receipt of the written notice, unless the breaching Party cures the breach within that thirty (30) day notice period.

10.3 Termination for Convenience. Each Party may terminate this Agreement for convenience upon sixty (60) days' notice to the other Party.

10.4 Effects of Termination. Upon termination:

10.4.1. MACLEODS shall (i) promptly return to CYTODYN, or, at CYTODYN's request, destroy (and certify such destruction in writing) all of CYTODYN's Confidential Information, and (ii) cease using Confidential Information in any way for any purpose.

10.4.2. MACLEODS may, where permitted by applicable laws, sell Product then in its inventory until the expiry of the Product ("**Selloff Period**"), all in accordance with the terms of this Agreement. Promptly after the expiration of the Selloff Period, MACLEODS shall, at its cost, destroy any unsold Product remaining in its inventory and will provide appropriate evidence of such destruction to CYTODYN. Furthermore, CYTODYN may cancel any Firm Order accepted by CYTODYN before termination and requires delivery of Product after the date of termination.

11. INDEPENDENT PARTY

This Agreement does not constitute either Party as agent or legal representative of the other Party for any purpose whatsoever. A Party is not granted any right or authority to assume or to create any obligation or responsibility, express or implied, on behalf of or in the name of the other Party, with regard to any manner or thing whatsoever, unless otherwise specifically agreed upon in writing.

12. ASSIGNMENT

MACLEODS shall not assign, delegate or transfer its rights and obligations under this Agreement in whole or in part without prior written authorization from CYTODYN; any purported assignment, delegation or transfer in violation of the foregoing is void. CYTODYN may assign, delegate or transfer its rights and obligations under this Agreement in whole or in part.

13. FORCE MAJEURE

Each of the Parties hereto shall be excused from the performance of its obligations hereunder, other than the payment of money, in the event that such performance is prevented by force majeure, provided that each of the Parties shall use its best efforts to complete such performance by other means. For the purpose of this Agreement force majeure is defined as causes beyond the control of MACLEODS or CYTODYN, including but not limited to, acts of God, acts, regulations or laws of any government, war, civil commotion, destruction of production facilities or materials by fire, earthquake or storm, labor disturbances, epidemic and failure of public utilities or common carriers.

14. SEVERABILITY

Should any part or provision of this Agreement be held unenforceable or in conflict with the applicable laws or regulations of any applicable jurisdiction, the invalid or unenforceable part or provision shall, provided that it does not affect the essence of this Agreement, be replaced with a revision which accomplishes, to the extent possible, the original commercial purpose of such part or provision in a valid and enforceable manner, and the balance of this Agreement shall remain in full force and effect and binding upon the Parties hereto.

15. ENTIRE AGREEMENT

This Agreement constitutes the entire agreement between the Parties with respect to its subject matter and supersedes all prior agreements, arrangements, dealings or writings between the Parties. This Agreement may not be varied except in writing signed by the Parties' authorized representatives.

16. WAIVER

No waiver of any right, breach or default hereunder shall be considered valid unless in writing and signed by the Party giving such waiver, and no such waiver shall be deemed a waiver of any subsequent right, breach or default of the same or similar nature.

17. GOVERNING LAW

This Agreement shall be governed, interpreted and construed in accordance with the laws of the State of New Jersey, without to the principles of conflicts of law. Any dispute, controversy or claim initiated by either Party arising out of, resulting from or relating to this Agreement (other than good-faith third party actions or proceedings filed or instituted in an action or proceeding by a third party against a Party) shall be finally resolved by binding arbitration conducted in the English language, in Singapore, under the Arbitration Rules of Singapore International Arbitration Centre ("SIAC Rules") , by a panel of one arbitrator appointed in accordance with the SIAC Rules. Notwithstanding the foregoing, either Party may, without waiving any right or remedy available to such Party, seek and obtain from any court of competent jurisdiction any interim or provisional relief that is necessary or desirable to protect the rights or property of such Party, pending the selection of the arbitrator hereunder or pending the arbitrator’s determination of any dispute, controversy or claim hereunder. The Parties undertake to use all reasonable best efforts in order to solve in an

amicable manner any controversy arising in connection with this Agreement. The award of the arbitrator shall be final and binding.

18. NOTICE

Unless otherwise stated in this Agreement, all requests and notices required or permitted to be given to the Parties hereto shall be given in writing, shall expressly reference the section(s) of this Agreement to which they pertain, and shall be delivered to the other Party, effective on receipt, at the appropriate address as set forth below or to such other addresses as may be designated in writing by the Parties from time to time during the term of this Agreement.

If to MACLEODS:

Macleods Phrmaceuticals Ltd

304, Atlanta Arcade, Maroi Church Road, Opp. Hotel Leela, Andheri (East) Mumbai 400 059

Attention: Vijay Agarwal

Email: vijay@macleodspharma.com

If to CYTODYN:

CYTODYN Inc., 1111 Main Street, Suite 660, Vancouver, WA 98660, USA

Attention: Chief Executive Officer

Email: npourhassan@CYTODYN.com and CYDY_Team@CYTODYN.com

Product complaints and quality issues: jflisak@CYTODYN.com

19. COUNTERPARTS

This Agreement may be executed in counterparts, each of which shall be deemed to be an original and together shall be deemed to be one and the same agreement.

IN WITNESS WHEREOF, the Parties hereto have each caused this Agreement to be executed by their duly-authorized representatives as of the Effective Date.

CYTODYN Inc.	**MACLEODS PHARMACEUTICAL LTD.**
/s/ Nader Pourhassan	/s/ Vijay Agarwal
Nader Pourhassan Chief Executive Officer	**Vijay Agarwal** Business Development Director

SIDE LETTER TO EXCLUSIVE SUPPLY AND DISTRIBUTION AGREEMENT

[Dated and Effective as of May 11, 2021]

This side letter agreement ("Side Letter") is entered into by and among Macleods Pharmaceuticals Ltd, an India corporation (the "Macleods") and CytoDyn Inc., a Delaware corporation ("CytoDyn") with reference to the Exclusive Supply and Distribution Agreement, dated and effective as of May 11, 2021 by and between Macleods and CytoDyn (the "Agreement"). Macleods and CytoDyn are referred to herein collectively as the "Parties"

1. Shortly after execution of the Agreement, the Parties noticed an error in Section 1.4 of the Agreement, which the Parties intended to intentionally omit from the Agreement, but which was not deleted in error.

2. By their signatures below, the Parties wish to confirm that Section 1.4 of the Agreement should read as follows:

1.4 Intentionally Omitted.

3. All other terms and conditions of the Agreement remain unchanged.

IN WITNESS WHEREOF, the parties have executed this Side Letter as of the date first written above.

CYTODYN INC.	MACLEODS PHARMACEUTICALS LTD.
/s/ Nader Pourhassan	/s/ Vijay Agarwal
Nader Pourhassan	Vijay Agarwal
Chief Executive Officer	Business Development Director

Exhibit 10.25

EMPLOYMENT AGREEMENT

This EMPLOYMENT AGREEMENT (this "Agreement"), dated as of July 9, 2022 (the "Effective Date"), is by and between CYTODYN INC., a Delaware corporation (the "Company") and CYRUS ARMAN (the "Executive").

WITNESSETH:

WHEREAS, the Company desires to employ the Executive as its President for an initial six (6) month term, with the opportunity to extend for a longer term and advance to the position of Chief Executive Officer within that six (6) month timeframe, and the Executive desires to accept such employment, on the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the promises and the mutual covenants and agreements contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound hereby, agree as follows:

ARTICLE 1

EMPLOYMENT; TERMINATION OF PRIOR AGREEMENT; TERM OF AGREEMENT

Section 1.1 Employment and Acceptance. During the Term (as defined in Section 1.2), the Company shall employ the Executive, and the Executive shall accept such employment and serve the Company, in each case, subject to the terms and conditions of this Agreement.

Section 1.2 Term. The employment relationship hereunder shall be for the period (such period of the employment relationship shall be referred to herein as the "Term") commencing on the Effective Date and ending upon the termination of the Executive's employment hereunder by either party hereto pursuant to the terms of Section 4.1, Section 4.2, Section 4.3 or Section 4.4. In the event that the Executive's employment with the Company terminates, the Company's obligation to continue to pay, after the Termination Date (as defined in Section 4.3(b)), Base Salary (as defined in Section 3.1(a)), Annual Bonus (as defined in Section 3.1(c)) and other unaccrued benefits shall terminate, except as may be provided for in ARTICLE 4.

ARTICLE 2

TITLE; DUTIES AND OBLIGATIONS; LOCATION

Section 2.1 Title. The Company shall employ the Executive to render exclusive and full-time services to the Company. The Executive shall serve in the capacity of President for an initial six (6) month term, with the opportunity for advancement to the position of Chief Executive Officer thereafter provided certain benchmarks established by the Board are met.

Section 2.2 Duties. Subject to the direction and authority of the Board of Directors of the Company (the "Board"), the Executive shall have direct responsibility for the day-to-day operations of the Company. The Executive shall report to, and be subject to, the lawful direction of the Board. The Executive agrees to perform to the best of his ability, experience and talent, those acts and duties consistent with the position of President of the Company, as the Board shall from time to time direct.

Section 2.3 Compliance with Policies, etc. During the Term, the Executive shall be bound by, and comply fully with, all of the Company's applicable policies and procedures including, but not limited to, all terms and conditions set forth in the Company's employee handbook, compliance manual, codes of conduct and any other memoranda and communications applicable to the Executive pertaining to any policies, procedures, rules and regulations, as currently in effect and as may be amended from time to time. These policies and procedures include, among other things and without limitation, the Executive's obligations to comply with the Company's rules regarding confidential and proprietary information and trade secrets.

Section 2.4 Time Commitment. During the Term, the Executive shall use the Executive's best efforts to promote the interests of the Company (including its subsidiaries and other Affiliates), and shall devote all of the Executive's business time, ability and attention, to the performance of the Executive's duties for the Company and shall not, directly or indirectly, render any services to any other person or organization, whether for compensation or otherwise, except with the Board's prior written consent, provided that the foregoing shall not prevent the Executive from: (i) participating in charitable, civic, educational, professional, community or industry affairs; (ii) managing the Executive's passive personal investments; or (iii) serving on the board of directors, (or similar governing bodies) of not more than two (2) other corporations (or other business entities), that are not competitors of the Company, its subsidiaries or any of its other Affiliates (as determined by the Board), so long as, in each case, such activities

individually or in the aggregate do not materially interfere or conflict with the Executive's duties hereunder or create a potential business or fiduciary conflict (in each case, as determined by the Board).

Section 2.5 Location. The Executive's principal place of business for the performance of the Executive's duties under this Agreement shall be at the principal executive office of the Company (currently located in Vancouver, Washington), provided it is agreed that the Executive may work remotely from time to time at the sole discretion of the Board. Notwithstanding the foregoing, the Executive shall be required to travel as necessary to perform the Executive's duties hereunder.

ARTICLE 3

COMPENSATION AND BENEFITS; EXPENSES

Section 3.1 Compensation and Benefits. For all services rendered by the Executive in any capacity during the Term (including, without limitation, serving as an officer, director or member of any committee of the Company or any of its subsidiaries or other Affiliates), the Executive shall be compensated (subject, in each case, to the provisions of ARTICLE 4 below), as determined by the Compensation Committee, as follows:

(a) Base Salary. During the Term, the Company shall pay the Executive a base salary (the "Base Salary") approved by the Compensation Committee of the Board (the "Compensation Committee"), which shall be subject to customary withholdings and authorized deductions and be payable in equal installments in accordance with the Company's customary payroll practices in place from time to time. The Executive's Base Salary shall be subject to periodic adjustments as determined by the Compensation Committee. As used in this Agreement, the term "Base Salary" shall refer to Base Salary as may be adjusted from time to time.

(b) Annual Bonus. For each fiscal year ending during the Term (beginning with the fiscal year ending May 31, 2023, the Executive shall be eligible to receive an annual bonus (the "Annual Bonus") with a target amount equal to forty percent (40%) of the Base Salary earned by the Executive for such fiscal year (the "Target Annual Bonus"). The actual amount of each Annual Bonus will be based upon the level of achievement of the Company's corporate objectives and the Executive's individual objectives established by the Compensation Committee for the fiscal year with respect to which such Annual Bonus relates. The level of

achievement of the corporate objectives and the Executive's individual performance objectives for any fiscal year shall be determined by the Compensation Committee. Each Annual Bonus for a fiscal year, to the extent earned, will be paid in a lump sum at a time determined by the Company, but in no event later than March 15 of the calendar year immediately following the year in which such Annual Bonus was earned. Each Annual Bonus shall be payable, as determined by the Compensation Committee, either in cash in full or fifty percent (50%) in cash and (50%) in unrestricted shares under (and as defined in) the Company's 2012 Equity Incentive Plan (as it may be amended from time to time, the "2012 Plan"), or any successor equity compensation plan as may be in place from time to time (collectively with the 2012 Plan, the "Plan"), subject to the availability of shares under the Plan. The Annual Bonus shall not be deemed earned until the date that it is paid. Accordingly, in order for the Executive to receive an Annual Bonus, the Executive must be actively employed by the Company at the time of such payment. Any Annual Bonus paid to the Executive with respect to the fiscal year ending May 31, 2023 shall be prorated based on the number of days the Executive has been employed by the Company during the fiscal year ended May 31, 2023 based on a 365-day fiscal year.

(c) Long-Term Incentive Compensation. Contingent upon approval by the stockholders of an amendment to the Company's Certificate of Incorporation to increase the number of shares authorized for issuance and subject to vesting as outlined in the applicable award agreements, Executive will be awarded an initial grant of long-term incentive compensation totaling $1,500,000, which shall include $750,000 options based on grant date fair value as calculated on the Black-Scholes model, $375,000 Restricted Stock Units ("RSUs"), and $375,000 Performance Stock Units ("PSUs") calculated based on 100% of the trading price on the date of the grant. Vesting of PSUs will be tied to Executive's satisfactory achievement of the performance metrics approved by the Board. The RSUs will vest in four (4) equal annual installments.

(d) Equity Compensation. During the Term, and likewise subject to the terms and conditions established within the Plan and separate Award Agreements (as defined in the Plan), the Executive also shall be eligible to receive from time to time additional Options, Stock Appreciation Rights, Restricted Awards or Other Stock-Based Awards (as such capitalized terms are defined in the Plan), in amounts, if any, as determined by the Compensation Committee.

(e) Benefit Plans. The Executive shall be entitled to participate in all employee benefit plans and programs (excluding severance plans, if any) generally made available by the Company to senior leadership of the Company, to the extent permissible under the general terms and provisions of such plans or programs and in accordance with the provisions thereof. The Company may amend, modify or rescind any employee benefit plan or program and/or change employee contribution amounts to benefit costs without notice in its discretion.

(f) Paid Time Off. The Executive shall be entitled to paid time off in accordance with the Company's policies in effect from time to time for its senior management.

Section 3.2 Expense Reimbursement. Subject to the requirements contained in Section 5.17, the Company shall reimburse the Executive during the Term, in accordance with the Company's expense reimbursement policies in place from time to time, for all reasonable out-of-pocket business expenses incurred by the Executive in the performance of the Executive's duties hereunder. In order to receive such reimbursement, the Executive shall furnish to the Company documentary evidence of each such expense in the form required to comply with the Company's policies in place from time to time.

ARTICLE 4

TERMINATION OF EMPLOYMENT

Section 4.1 Termination Without Cause.

(a) The Company may terminate the Executive's employment hereunder at any time without Cause (other than by reason of death or Disability) upon written notice to the Executive.

(b) As used in this Agreement, "Cause" means: (i) a material act, or act of fraud, committed by the Executive that is intended to result in the Executive's personal enrichment to the detriment or at the expense of the Company or any of its Affiliates; (ii) the Executive is convicted of a felony; (iii) willful and continued failure by the Executive to perform the duties or obligations reasonably assigned to the Executive by the Board from time to time, which failure is not cured upon ten (10) days' prior written notice (unless such failure is not susceptible to cure, as determined in the reasonable discretion of the Board); or (iv) the Executive violates the Covenants Agreement (as defined in Section 5.1 below).

(c) If the Executive's employment is terminated pursuant to Section 4.1(a), the Executive shall, in full discharge of all of the Company's obligations to the Executive, be entitled to receive, and the Company's sole obligation to the Executive under this Agreement or otherwise shall be to pay or provide to the Executive, the following:

(i) the Accrued Obligations (as defined in Section 4.3(b)); and

(ii) subject to Section 4.5 and Section 4.6, either:

(1) If prior to completion of the initial six (6) months of employment, payments equal to six (6) months of the Executive's Base Salary at the rate in effect immediately prior to the Termination Date (less applicable withholdings and authorized deductions), to be paid in accordance with the Company's customary payroll practices, commencing on the first regular payroll date on or following the date that is sixty (60) days following such termination of employment (the "Severance Payments"); or

(2) After the initial six (6) months of full-time continuous employment, the Severance Payments shall consist of: (A) an additional one (1) month of salary at the Executive's Base Salary at the rate in effect immediately prior to the Termination Date (less applicable withholdings and authorized deductions) for each month of employment after the initial six (6) months, if the Executive's employment is extended after six (6) months provided the Severance Payments are capped at a total of twelve (12) months regardless of term of employment.

(d) Notwithstanding anything in Section 4.1(c) to the contrary, the Severance Payments may be made, as determined by the Compensation Committee, in whole or in part through the issuance of shares of the Company's common stock, in each case with a Fair Market Value (as defined in the Plan) equal to the amount to be paid on the applicable date.

(e) Unless the award agreement specifically provides otherwise, all stock options and other awards that the Executive has been granted under the Plan as of the date of this Agreement shall vest and, in the case of stock options or like awards, become exercisable, to the extent not already vested and (if applicable) exercisable, on the Termination Date, and (if applicable) shall remain exercisable following termination to the extent provided in the award agreement for such award.

Section 4.2 Termination Without Cause or for Good Reason Within 12 Months Following a Change in Control.

(a) Provided that the Executive has completed one hundred eighty (180) days of full-time continuous employment with the Company, if, within twelve (12) months following the occurrence of a Change in Control of the Company (as defined below), the Executive's employment hereunder is terminated without Cause (other than by reason of death or Disability) or the Executive resigns for Good Reason, the provisions of this Section 4.2 shall control instead of the provisions of Section 4.1.

(b) As used in this Agreement, "Change in Control" means:

(i) Any one person or entity, or more than one person or entity acting as a group (as defined in Treasury Regulation Section 1.409A-3), acquires ownership of stock of the Company that, together with stock previously held by the acquiror, constitutes more than fifty percent (50%) of the total fair market value or total voting power of the Company's stock. If any one person or entity, or more than one person or entity acting as a group, is considered to own more than fifty percent (50%) of the total fair market value or total voting power of the Company's stock, the acquisition of additional stock by the same person or entity or persons or entities acting as a group does not cause a Change in Control. An increase in the percentage of stock owned by any one person or entity, or persons or entities acting as a group, as a result of a transaction in which the Company acquires its stock in exchange for property, is treated as an acquisition of stock; or

(ii) A majority of the members of the Company's Board is replaced during any twelve (12) month period by directors whose appointment or election is not endorsed by a majority of the members of the Board prior to the date of appointment or election; or

(iii) Any one person or entity, or more than one person or entity acting as a group, acquires (or has acquired during the twelve (12) month period ending on the date of the most recent acquisition by that person or entity or persons or entities acting as a group) assets from the Company that have a total gross fair market value equal to at least forty percent (40%) of the total gross fair market value of all the Company's assets immediately prior to the acquisition or acquisitions. Gross fair market value means the value of the Company's assets, or the value of the assets being disposed of, without regard to any liabilities associated with these assets. Notwithstanding anything in this clause (iii) to the contrary, in no event shall a license of (or other similar transfer of rights in) leronlimab be a change in the ownership of a substantial portion of the Company's assets

In determining whether a Change in Control occurs, the attribution rules of Code Section 318 apply to determine stock ownership. The stock underlying a vested option is treated as owned by the individual who holds the vested option, and the stock underlying an unvested option is not treated as owned by the individual who holds the unvested option.

(c) As used in this Agreement, "Good Reason" means the occurrence of any of the following: (1) a material breach by the Company of the terms of this Agreement; (2) a material reduction in the Executive's Base Salary unless the reduction is generally applicable to substantially all similarly situated Company employees or is otherwise offset economically by increases in other compensation or replacement plans or programs; or (3) a material diminution in the Executive's authority, duties or responsibilities; provided, however, that the Executive must notify the Company within ninety (90) days of the occurrence of any of the foregoing conditions that the Executive considers it to be a "Good Reason" condition and provide the Company with at least thirty (30) days in which to cure the condition. If the Executive fails to provide this notice and cure period prior to the Executive's resignation, or resigns more than six (6) months after the initial existence of the condition, the Executive's resignation will not be deemed to be for "Good Reason."

(d) If the Executive's employment is terminated pursuant to Section 4.2(a) (i.e., the Executive's employment hereunder is terminated without Cause (other than by reason of death or Disability) within twelve (12) months following a Change in Control of the Company, or the Executive resigns for Good Reason within twelve (12) months following a Change in Control of the Company), the Executive shall, in full discharge of all of the Company's obligations to the Executive, be entitled to receive, and the Company's sole obligation to the Executive under this Agreement or otherwise shall be to pay or provide to the Executive, the following:

(i) the Accrued Obligations; and

(ii) subject to Section 4.5 and Section 4.6:

(A) the following payments (the "Enhanced Severance Payments") (i) a lump sum payment on the sixtieth (60th) day following the Termination Date (or the next business day thereafter, but in no event later that March 15 of the calendar year immediately following the Termination Date) in an amount equal to eight (8) months of the Executive's monthly Base Salary at the rate in effect immediately prior to the Termination Date (less

applicable withholdings and authorized deductions) and (ii) payments equal to ten (10) months of the Executive's monthly Base Salary at the rate in effect immediately prior to the Termination Date (less applicable withholdings and authorized deductions), to be paid on the first regular payroll date following the date that is two hundred seventy (270) days following the Termination Date. Notwithstanding the foregoing, in no event shall the portion of the Enhanced Severance Payments described in clause (ii) above exceed two times the lesser of (x) the sum of the Executive's annualized compensation based upon the Executive's annual salary in the year preceding the year in which the Executive's employment is terminated (adjusted for any increase during that year that was expected to continue indefinitely if the Executive's employment had not terminated) or (y) the applicable dollar limit under Section 401(a)(17) of the Internal Revenue Code for the calendar year in which the Executive's employment is terminated; and

(B) Unless the award agreement specifically provides otherwise, all stock options and other awards that the Executive has been granted under the Plan as of the date of this Agreement shall vest and, in the case of stock options or like awards, become exercisable, to the extent not already vested and (if applicable) exercisable, on the Termination Date, and (if applicable) shall remain exercisable following termination to the extent provided in the award agreement for such award.

For purposes of clarity, it is understood and agreed that the Enhanced Severance Payments set forth in this Section 4.2 shall be in lieu of (and not in addition to) the Severance Payments set forth in Section 4.1.

Section 4.3 Termination for Cause; Voluntary Termination.

(a) The Company may terminate the Executive's employment hereunder at any time for Cause upon written notice to the Executive. The Executive may voluntarily terminate the Executive's employment hereunder at any time for any reason or no reason as well, but is requested to provide ninety (90) days' prior written notice to the Company, if possible; provided, however, the Company reserves the right, upon written notice to the Executive, to accept the Executive's notice of resignation and to accelerate such notice and make the Executive's resignation effective immediately, or on such other date prior to the Executive's intended last day of work as the Company deems appropriate. It is understood and agreed that the Company's election to accelerate the Executive's notice of resignation shall not be deemed a termination by the Company without Cause for purposes of Section 4.1 or 4.2 of this Agreement

or otherwise or constitute Good Reason for purposes of Section 4.2 of this Agreement or otherwise.

(b) If the Executive's employment is terminated pursuant to Section 4.3(a), the Executive shall, in full discharge of all of the Company's obligations to the Executive, be entitled to receive, and the Company's sole obligation under this Agreement or otherwise shall be to pay or provide to the Executive, the following (collectively, the "Accrued Obligations"):

(i) the Executive's accrued but unpaid Base Salary through the final date of the Executive's employment by the Company (the "Termination Date"), payable in accordance with the Company's standard payroll practices;

(ii) the Executive's unused vacation as accrued in accordance with the Company's policies, if any);

(iii) expenses reimbursable under Section 3.2 above incurred on or prior to the Termination Date but not yet reimbursed; and

(iv) any amounts or benefits that are vested amounts or vested benefits or that the Executive is otherwise entitled to receive under any plan, program, policy or practice (with the exception of those, if any, relating to severance) on the Termination Date, in accordance with such plan, program, policy, or practice.

Section 4.4 Termination Resulting from Death or Disability.

(a) As the result of any Disability suffered by the Executive, the Company, upon five (5) days' prior notice to the Executive, may terminate the Executive's employment under this Agreement. The Executive's employment shall automatically terminate upon the Executive's death.

(b) "Disability" means a determination by the Company in accordance with applicable law that as a result of a physical or mental injury or illness, the Executive is unable to perform the essential functions of the Executive's job with or without reasonable accommodation for a period of (i) ninety (90) consecutive days; or (ii) one hundred twenty (120) days during any twelve (12) month period.

(c) If the Executive's employment is terminated pursuant to Section 4.4(a), the Executive or the Executive's estate, as the case may be, shall be entitled to receive, and the Company's sole obligation under this Agreement or otherwise shall be to pay or provide to the Executive or the Executive's estate, as the case may be, the Accrued Obligations.

Section 4.5 Release Agreement. In order to receive the Severance Payments set forth in Section 4.1 or to receive the Enhanced Severance Payments set forth in Section 4.2 (as applicable, and, in each case, if eligible), the Executive must timely execute (and not revoke) a separation agreement and general release (the "Release Agreement") in a customary form as is determined to be reasonably necessary by the Company in its good faith and reasonable discretion; provided, that the Company shall endeavor to provide the Executive with the form of Release Agreement within three (3) days following the Termination Date. The Severance Payments or the Enhanced Severance Payments, as applicable, are subject to the Executive's execution of such Release Agreement within twenty-one (21) days of the Executive's receipt of the Release Agreement and the Executive's non-revocation of such Release Agreement, if applicable.

Section 4.6 Post-Termination Breach. Notwithstanding anything to the contrary contained in this Agreement, the Company's obligations to provide the Severance Payments or the Enhanced Severance Payments, as applicable, will immediately cease if the Executive breaches any of the provisions of the Covenants Agreement, the Release Agreement or any other agreement the Executive has with the Company, or if any provision of those agreements is determined to be unenforceable, to any extent, by a court or arbitration panel, whether by preliminary or final adjudication.

Section 4.7 Removal from any Boards and Position. If the Executive's employment is terminated for any reason under this Agreement, the Executive shall be deemed (without further action, deed or notice) to resign (i) if a member, from the Board (or similar governing body) of the Company, any Affiliate of the Company or any other board to which the Executive has been appointed or nominated by or on behalf of the Company and (ii) from all other positions with the Company or any subsidiary or other Affiliate of the Company, including, but not limited to, as an officer of the Company and any of its subsidiaries or other Affiliates.

ARTICLE 5

GENERAL PROVISIONS

Section 5.1 Employee Inventions Assignment and Non-Disclosure Agreement. The Executive acknowledges and confirms that the Employee Inventions Assignment and Non-Disclosure Agreement executed by the Executive contemporaneously with this Agreement (the "Covenants Agreement"), the terms of which are incorporated herein by reference, remains

in full force and effect and binding on the Executive. The Covenants Agreement shall survive the termination of this Agreement and the Executive's employment by the Company for the applicable period(s) set forth therein.

Section 5.2 Expenses. Each of the Company and the Executive shall bear its/the Executive's own costs, fees and expenses in connection with the negotiation, preparation and execution of this Agreement.

Section 5.3 Key-Person Insurance. Upon the Company's request, the Executive shall cooperate (including, without limitation, taking any required physical examinations) in all respects in obtaining a key-person life insurance policy on the life of the Executive in which the Company is named as the beneficiary.

Section 5.4 Entire Agreement. This Agreement, the Indemnification Agreement between the Executive and the Company entered into contemporaneously with this Agreement, as it may be amended from time to time (the "Indemnification Agreement"), and the Covenants Agreement contain the entire agreement of the parties hereto with respect to the terms and conditions of the Executive's employment during the Term and activities following termination of this Agreement and the Executive's employment with the Company and supersede any and all prior agreements and understandings, whether written or oral, between the parties hereto with respect to the subject matter of this Agreement, the Indemnification Agreement, or the

Covenants Agreement. Each party hereto acknowledges that no representations, inducements, promises or agreements, whether oral or in writing, have been made by any party, or on behalf of any party, which are not embodied herein, or in the Covenants Agreement. The Executive acknowledges and agrees that the Company has fully satisfied, and has no further obligations to the Executive arising under, or relating to, any prior employment or consulting arrangement or understanding (including, without limitation, any claims for compensation or benefits of any kind) or otherwise. No agreement, promise or statement not contained in this Agreement, the Indemnification Agreement, or the Covenants Agreement shall be valid and binding, unless agreed to in writing and signed by the parties sought to be bound thereby.

Section 5.5 No Other Contracts. The Executive represents and warrants to the Company that neither the execution and delivery of this Agreement by the Executive nor the performance by the Executive of the Executive's obligations hereunder, shall constitute a default under or a breach of the terms of any other agreement, contract or other arrangement, whether

written or oral, to which the Executive is a party or by which the Executive is bound, nor shall the execution and delivery of this Agreement by the Executive nor the performance by the Executive of the Executive's duties and obligations hereunder give rise to any claim or charge against either the Executive, the Company or any Affiliate, based upon any other contract or other arrangement, whether written or oral, to which the Executive is a party or by which the Executive is bound. The Executive further represents and warrants to the Company that the Executive is not a party to or subject to any restrictive covenants, legal restrictions or other agreement, contract or arrangement, whether written or oral, in favor of any entity or person that would in any way preclude, inhibit, impair or limit the Executive's ability to perform the Executive's obligations under this Agreement, including, but not limited to, non-competition agreements, non-solicitation agreements or confidentiality agreements. The Executive shall defend, indemnify and hold the Company harmless from and against all claims, actions, losses, liabilities, damages, costs and expenses (including reasonable attorney's fees and amounts paid in settlement in good faith) arising from or relating to any breach of the representations and warranties made by the Executive in this Section 5.5.

Section 5.6 Notices. Any notice or other communication required or permitted hereunder shall be in writing and shall be delivered personally or sent by nationally recognized overnight courier service (with next business day delivery requested). Any such notice or communication shall be deemed given and effective, in the case of personal delivery, upon receipt by the other party, and in the case of a courier service, upon the next business day, after dispatch of the notice or communication. Any such notice or communication shall be addressed as follows:

If to the Company, to:	If to the Executive, to:
CytoDyn Inc. 1111 Main Street, Suite 660 Vancouver, Washington 98660 Attn: Chief Executive Officer	The address provided on Executive's current Form W-4 on file with the Company.

Section 5.7 Governing Law; Jurisdiction. This Agreement shall be governed by, and construed in accordance with, the laws of the state of Washington, without regard to principles of conflicts of law. Any and all actions arising out of this Agreement or Executive's employment by the Company or termination therefrom shall be brought and heard in the state and federal

courts of the state of Washington and the parties hereto hereby irrevocably submit to the exclusive jurisdiction of any such courts.

Section 5.8 Waiver. Either party hereto may waive compliance by the other party with any provision of this Agreement. The failure of a party to insist on strict adherence to any term of this Agreement on any occasion shall not be considered a waiver or deprive that party of the right thereafter to insist upon strict adherence to that term or any other term of this Agreement. No waiver of any provision shall be construed as a waiver of any other provision. Any waiver must be in writing.

Section 5.9 Severability. If any one or more of the terms, provisions, covenants and restrictions of this Agreement shall be determined by a court of competent jurisdiction to be invalid, void or unenforceable, the remainder of the terms, provisions, covenants and restrictions of this Agreement shall remain in full force and effect, and shall in no way be affected, impaired or invalidated. The parties will attempt to agree upon a valid and enforceable provision, which shall be a reasonable substitute for such invalid and unenforceable provision in light of the tenor of this Agreement, and, upon so agreeing, shall incorporate such substitute provision in this Agreement. In addition, if any one or more of the provisions contained in this Agreement shall, for any reason, be determined by a court of competent jurisdiction to be excessively broad as to duration, geographical scope, activity or subject, it shall be construed, by limiting or reducing it, so as to be enforceable to the extent compatible with then applicable law.

Section 5.10 Counterparts. This Agreement may be executed in any number of counterparts and each such duplicate counterpart shall constitute an original, any one of which may be introduced in evidence or used for any other purpose without the production of its duplicate counterpart. Moreover, notwithstanding that any of the parties did not execute the same counterpart, each counterpart shall be deemed for all purposes to be an original, and all such counterparts shall constitute one and the same instrument, binding on all of the parties hereto.

Section 5.11 Advice of Counsel. Both parties hereto acknowledge that they have had the opportunity to seek and obtain the advice of counsel before entering into this Agreement and have done so to the extent desired, and have fully read the Agreement and understand the meaning and import of all the terms hereof.

Section 5.12 Assignment. This Agreement shall inure to the benefit of the Company and its successors and assigns (including, without limitation, the purchaser of all or substantially all of its assets), and shall be binding upon the Company and its successors and assigns. This Agreement is personal to the Executive, and the Executive shall not assign or delegate the Executive's rights or duties under this Agreement; any such assignment or delegation shall be null and void.

Section 5.13 Agreement to Take Actions. Each party to this Agreement shall execute and deliver such documents, certificates, agreements and other instruments, and shall take all other actions, as may be reasonably necessary or desirable, in order to perform the Executive's or its obligations under this Agreement.

Section 5.14 No Attachment. Except as required by law, no right to receive payments under this Agreement shall be subject to anticipation, commutation, alienation, sale, assignment, encumbrance, charge, pledge, or hypothecation or to execution, attachment, levy or similar process or assignment by operation of law, and any attempt, voluntary or involuntary, to effect any such action shall be null, void and of no effect; provided, however, that nothing in this Section 5.14 shall preclude the assumption of such rights by executors, administrators or other legal representatives of the Executive or the Executive's estate and their assigning any rights hereunder to the person or persons entitled thereto.

Section 5.15 Source of Payment. Except as otherwise provided under the terms of any applicable Executive benefit plan, all payments provided for under this Agreement shall be paid in cash from the general funds of the Company. The Company shall not be required to establish a special or separate fund or other segregation of assets to assure such payments, and, if the Company shall make any investments to aid it in meeting its obligations hereunder, the Executive shall have no right, title or interest whatever in or to any such investments except as may otherwise be expressly provided in a separate written instrument relating to such investments. Nothing contained in this Agreement, and no action taken pursuant to its provisions, shall create or be construed to create a trust of any kind, or a fiduciary relationship, between the Company and the Executive or any other person. To the extent that any person acquires a right to receive payments from the Company hereunder, such right, without prejudice to rights which employees may have, shall be no greater than the right of an unsecured creditor

of the Company. The Executive shall not look to the owners of the Company for the satisfaction of any obligations of the Company under this Agreement.

Section 5.16 Tax Withholding. The Company or other payor is authorized to withhold from any benefit provided or payment due hereunder, the amount of withholding taxes due any federal, state or local authority in respect of such benefit or payment and to take such other action as may be necessary in the opinion of the Compensation Committee to satisfy all obligations for the payment of such withholding taxes. The Executive will be solely responsible for all taxes assessed against the Executive with respect to the compensation and benefits described in this Agreement, other than typical employer-paid taxes such as FICA, and the Company makes no representations as to the tax treatment of such compensation and benefits.

Section 5.17 409A Compliance. All payments under this Agreement are intended to comply with or be exempt from the requirements of Section 409A of the Code and regulations promulgated thereunder ("Section 409A"). As used in this Agreement, the "Code" means the Internal Revenue Code of 1986, as amended. To the extent permitted under applicable regulations and/or other guidance of general applicability issued pursuant to Section 409A, the Company reserves the right to modify this Agreement to conform with any or all relevant provisions regarding compensation and/or benefits so that such compensation and benefits are exempt from the provisions of Section 409A and/or otherwise comply with such provisions so as to avoid the tax consequences set forth in Section 409A and to assure that no payment or benefit shall be subject to an "additional tax" under Section 409A. To the extent that any provision in this Agreement is ambiguous as to its compliance with Section 409A, or to the extent any provision in this Agreement must be modified to comply with Section 409A, such provision shall be read in such a manner so that no payment due to the Executive shall be subject to an "additional tax" within the meaning of Section 409A(a)(1)(B) of the Code. If necessary to comply with the restriction in Section 409A(a)(2)(B) of the Code concerning payments to "specified employees," any payment on account of the Executive's separation from service that would otherwise be due hereunder within six (6) months after such separation shall be delayed until the first business day of the seventh (7th) month following the Termination Date, and the first such payment shall include the cumulative amount of any payments (without interest) that would have been paid prior to such date if not for such restriction. Each payment in a series of payments hereunder shall be deemed to be a separate payment for purposes of Section 409A. In

no event may the Executive, directly or indirectly, designate the calendar year of payment. All reimbursements provided under this Agreement shall be made or provided in accordance with the requirements of Section 409A, including, where applicable, the requirement that (i) any reimbursement is for expenses incurred during the Executive's lifetime (or during a shorter period of time specified in this Agreement), (ii) the amount of expenses eligible for reimbursement during a calendar year may not affect the expenses eligible for reimbursement in any other calendar year, (iii) the reimbursement of an eligible expense will be made on or before the last day of the calendar year following the year in which the expense is incurred, and (iv) the right to reimbursement is not subject to liquidation or exchange for another benefit. Notwithstanding anything contained herein to the contrary, the Executive shall not be considered to have terminated employment with the Company for purposes of Section 4.1 or 4.2 unless the Executive would be considered to have incurred a "separation from service" from the Company within the meaning of Treasury Regulation §1.409A-1(h). In no event whatsoever shall the Company be liable for any additional tax, interest or penalty that may be imposed on the Executive by Section 409A or damages for failing to comply with Section 409A.

Section 5.18 280G Modified Cutback.

(a) If any payment, benefit or distribution of any type to or for the benefit of the Executive, whether paid or payable, provided or to be provided, or distributed or distributable pursuant to the terms of this Agreement or otherwise (collectively, the "Parachute Payments") would subject the Executive to the excise tax imposed under Section 4999 of the Code (the "Excise Tax"), the Parachute Payments shall be reduced so that the maximum amount of the Parachute Payments (after reduction) shall be one dollar ($1.00) less than the amount which would cause the Parachute Payments to be subject to the Excise Tax; provided that the Parachute Payments shall only be reduced to the extent the after-tax value of amounts received by the Executive after application of the above reduction would exceed the after-tax value of the amounts received without application of such reduction. For this purpose, the after-tax value of an amount shall be determined taking into account all federal, state, and local income, employment and excise taxes applicable to such amount. Unless the Executive shall have given prior written notice to the Company to effectuate a reduction in the Parachute Payments if such a reduction is required, which notice shall be consistent with the requirements of Section 409A to avoid the imputation of any tax, penalty or interest thereunder, then the Company shall reduce or

eliminate the Parachute Payments by first reducing or eliminating any cash payments (with the payments to be made furthest in the future being reduced first), then reducing or eliminating accelerated vesting of stock options or similar awards, then by reducing or eliminating any other remaining Parachute Payments; provided, that no such reduction or elimination shall apply to any non-qualified deferred compensation amounts (within the meaning of Section 409A) to the extent such reduction or elimination would accelerate or defer the timing of such payment in manner that does not comply with Section 409A.

(b) An initial determination as to whether (x) any of the Parachute Payments received by the Executive in connection with the occurrence of a change in the ownership or control of the Company or in the ownership of a substantial portion of the assets of the Company shall be subject to the Excise Tax, and (y) the amount of any reduction, if any, that may be required pursuant to the previous paragraph, shall be made by an independent accounting firm selected by the Company (the "Accounting Firm") prior to the consummation of such change in the ownership or effective control of the Company or in the ownership of a substantial portion of the assets of the Company. The Executive shall be furnished with notice of all determinations made as to the Excise Tax payable with respect to the Executive's Parachute Payments, together with the related calculations of the Accounting Firm, promptly after such determinations and calculations have been received by the Company.

(c) For purposes of this Section 5.18, (i) no portion of the Parachute Payments the receipt or enjoyment of which the Executive shall have effectively waived in writing prior to the date of payment of the Parachute Payments shall be taken into account; (ii) no portion of the Parachute Payments shall be taken into account which in the opinion of the Accounting Firm does not constitute a "parachute payment" within the meaning of Section 280G(b)(2) of the Code; (iii) the Parachute Payments shall be reduced only to the extent necessary so that the Parachute Payments (other than those referred to in the immediately preceding clause (i) or (ii)) in their entirety constitute reasonable compensation for services actually rendered within the meaning of Section 280G(b)(4) of the Code or are otherwise not subject to disallowance as deductions, in the opinion of the auditor or tax counsel referred to in such clause (ii); and (iv) the value of any non-cash benefit or any deferred payment or benefit included in the Parachute Payments shall be determined by the Company's independent auditors based on Sections 280G

and 4999 of the Code and the regulations for applying those sections of the Code, or on substantial authority within the meaning of Section 6662 of the Code.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

EXECUTIVE:	COMPANY: CytoDyn Inc.
By: /s/ Cyrus Arman	By: /s/ Tanya Durkee Urbach
Name: Cyrus Arman	Name: Tanya Durkee Urbach
	Title: Board Chair

Exhibit 10.28

Execution Copy

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RICHARD G. PESTELL, M.D., PH.D.,

Plaintiff/Counterclaim Defendant, v.

CYTODYN INC., *et al.*,

Civil Action No. 1:19-cv-01563-RTD

Defendants/Counterclaims Plaintiffs.

SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into this 19th day of May 2022 (the "Effective Date") by and between Plaintiff Richard G. Pestell, M.D., PH.D ("Plaintiff" or "Dr. Pestell") on the one hand, and Defendants CytoDyn Inc. and CytoDyn Operations Inc. (collectively, "Defendants," the "Company" or "CytoDyn") on the other hand (each a "Party" and collectively, the "Parties"). By this Agreement, the Parties settle the above-captioned litigation (the "Litigation") pending in the United States District Court for the District of Delaware (the "District Court").

BACKGROUND

A. CytoDyn Inc. is a biotechnology company focused on developing a biologic drug called Leronlimab or PRO 140.

B. Dr. Pestell is a physician and scientist specializing in oncology. In 2011, Dr. Pestell founded ProstaGene LLC ("ProstaGene"), a biotechnology start-up focused on developing gene-based prostate cancer testing technology.

C. On August 27, 2018, CytoDyn, ProstaGene, and (solely with respect to certain sections) Dr. Pestell entered into a Transaction Agreement (the "Transaction Agreement"), pursuant to which CytoDyn agreed to purchase substantially all of the assets and rights, and to assume certain obligations and liabilities, associated with ProstaGene's business (the "ProstaGene Transaction").

D. In connection with the ProstaGene Transaction, Dr. Pestell entered into an Employment Agreement (the "Employment Agreement") with CytoDyn and joined CytoDyn's Board of Directors (the "Board").

E. Closing on the ProstaGene Transaction occurred on November 16, 2018, the Employment Agreement was effective as of that date, and Dr. Pestell became the Company's Chief Medical Officer.

F. Pursuant to the Transaction Agreement, CytoDyn's consideration included 27,000,000 common shares of CytoDyn Inc. stock (the "Acquisition Shares").

G. As an inducement for CytoDyn to enter into the Transaction Agreement, Dr. Pestell agreed to subject 8,342,000 of the Acquisition Shares distributed to Dr. Pestell by ProstaGene in accordance with ProstaGene's Amended and Restated Operating Agreement (the "8,342,000 Shares") to a Stock Restriction Agreement (the "Stock Restriction Agreement") dated November 16, 2018.

H. The Company terminated Dr. Pestell's employment on July 25, 2019.

I. On August 22, 2019, Dr. Pestell commenced the Litigation, in which he asserted claims for breach of the Employment Agreement, defamation, and declaratory judgment concerning his rights to the 8,342,000 Shares (collectively, the "Claims"). In response, CytoDyn asserted counterclaims against Dr. Pestell for breach of the Employment Agreement and related

agreements, as well as for a declaratory judgment in its favor concerning the 8,342,000 Shares (collectively, the "Counterclaims").

J. In accordance with a Stipulated Order entered in the Litigation (Document 87, filed 7/29/21), the parties entered into an Escrow Agreement dated August 3, 2021 (the "Escrow Agreement"), pursuant to which Delaware Trust Company serves as "Escrow Agent" for the 8,342,000 Shares pending a determination as to who—as between Dr. Pestell and the Company — is entitled to the 8,342,000 Shares.

K. The parties have agreed to settle and resolve the Litigation and all existing and potential disputes between them, upon the terms and conditions set forth in this Agreement.

NOW THEREFORE, the Parties, intending to be legally bound, hereby agree as follows:

1. Disposition of the 8,342,000 Shares.

1.1 Upon execution of this Agreement, the Parties will execute and deliver to the Escrow Agent a joint written instruction, in the form attached hereto as Exhibit A (the "Escrow Release"), authorizing, and directing the Escrow Agent to forthwith release and/or deliver the certificate evidencing the 8,342,000 Shares to Dr. Pestell for his sole and exclusive benefit.

1.2 CytoDyn hereby fully, finally, and forever waives, releases and relinquishes any and all claims, rights, title or interests in or to the 8,342,000 Shares.

1.3 CytoDyn agrees to instruct its transfer agent, and provide such documents required by the transfer agent (including opinions of counsel), in each case as is necessary for removal of all restrictive legends currently applied to the 8,342,000 Shares.

2. Transfer of Transferred Assets to Dr. Pestell.

2.1 Upon execution of this Agreement, CytoDyn shall execute and deliver to Dr. Pestell the Assignment and Assumption Agreement attached as Exhibit B (the "Assignment and

Assumption Agreement") that transfers and assigns to Dr. Pestell all of CytoDyn's right, title and interest (if any) in and to the assets listed in the Assignment and Assumption Agreement (collectively, the "Transferred Assets").

2.2 For a period of six (6) months from the Effective Date, Dr. Pestell shall make no public statements as to his ownership, possession or intended use of the Transferred Assets.

3. Grant of Warrants to Dr. Pestell.

The Company shall grant warrants (the "Warrants") to Dr. Pestell giving him the right to purchase 7,000,000 shares of CytoDyn common stock at an exercise price of $0.37, which is five cents ($.05) over the closing price of CytoDyn's common stock on the Effective Date. The Warrants shall be exercisable over a period of three (3) years. The Company shall use commercially reasonable efforts to (a) prepare and file with the Securities and Exchange Commission (the "SEC"), and cause the SEC to declare effective, within ninety (90) days following the final closing of the offering described in the Company's Form 8-K filed with the SEC on May 12, 2022, a registration statement under the Securities Act covering the resale of the stock receivable upon exercise of the Warrants and (b) keep such registration statement effective until at least two years after the Warrants are fully exercised. A copy of the Warrant grant is attached hereto as Exhibit C.

4. Press Release.

Promptly after execution of this Agreement, the Company shall issue a press release, in the form attached hereto as Exhibit D, announcing: (i) the settlement of the Litigation; (ii) that the Company regrets (a) Dr. Pestell's prior departure from the Company and (b) the public statements made by the Company's prior CEO about Dr. Pestell after such departure; and (iii) that Dr. Pestell

and the Company are exploring ways in which Dr. Pestell can reengage with the Company to help realize Leronlimab's potential in oncology.

5. Mutual Releases.

Dr. Pestell and CytoDyn hereby agree to dismiss all pending claims against each other with prejudice and fully, finally, forever, and irrevocably waive, discharge, and release each other from and against any and all actions, causes of action, contracts, agreements, obligations, liabilities, claims, suits, demands, and damages of every kind, nature, and description (whether contingent or matured, known or unknown, asserted or unasserted, and suspected or unsuspected, and whether arising under state statutory law, federal statutory law, state common law, federal common law or otherwise) that Dr. Pestell or CytoDyn or anyone claiming by, under or through either of them ever had, now have, or may in the future have against the other for or by reason of any matter, action, inaction, omission, statement, cause, or thing whatsoever, from the beginning of the world to the Effective Date, including but not limited to claims relating to or arising out of the Employment Agreement, the Confidential Information, Inventions And Noncompetition Agreement dated as of November 16, 2018 by and between the Company and Dr. Pestell (the "Covenants Agreement") (including the post-employment noncompetition obligations of Dr. Pestell under Section 4 of the Covenants Agreement), the Transaction Agreement, the ProstaGene Transaction, Dr. Pestell's prior employment with the Company, the Company's use of the Transferred Assets, and all claims that were at any time asserted or could have been asserted in the Litigation, including those asserted in the Claims and Counterclaims (collectively, the "Released Claims"), EXCLUDING, HOWEVER FROM THE SCOPE OF THIS RELEASE, the rights and obligations of the Parties arising out of or in connection with this Agreement, the Escrow Release and/or the Assignment and Assumption Agreement, and any obligations Dr. Pestell has with

respect to the maintenance of the confidentiality of CytoDyn proprietary and confidential information arising from the Covenants Agreement or otherwise, from the Effective Date forward.

6. Representations and Warranties.

Each Party hereby represents and warrants as to itself to the other Parties that: (a) the person(s) executing this Agreement, the Escrow Release and the Assignment and Assumption Agreement on behalf of such Party is duly authorized to do so and to bind such Party; (b) such Party has obtained all necessary approvals and/or consents required by applicable law and under its charter documents, and has the power and authority, to enter into, deliver and perform this Agreement, the Escrow Release and the Assignment and Assumption Agreement; (c) the execution, delivery and performance of this Agreement by such Party does not violate or conflict with such Party's charter documents or any agreement to which such Party is a party or any law or court order binding on such Party or any of its assets; (d) upon the execution and delivery of this Agreement by all the Parties, this Agreement shall constitute the binding and enforceable obligation of such Party; and (e) such Party has not assigned any interest in the Released Claims.

7. Tax Treatment.

7.1. The Parties shall treat the 8,342,000 Shares and the release from escrow for all tax purposes as purchase price paid by CytoDyn to ProstaGene in November 2018 pursuant to the Transaction Agreement and immediately distributed by ProstaGene to Dr. Pestell in accordance with ProstaGene's Amended & Restated Operating Agreement. Unless such action is required pursuant to a "determination" within the meaning of Section 1313(a) of the Internal Revenue Code of 1986, as amended (the "Code"), that the 8,342,000 Shares were compensation, CytoDyn shall not issue an Internal Revenue Service ("IRS") Form W-2, 1099 or similar tax forms to report the release of 8,342,000 Shares or the sale or transfer thereof as compensation to Dr. Pestell.

7.2 For all tax purposes, the Parties shall (a) treat the transfer of the Transferred Assets to be in respect of settlement of Dr. Pestell's claims for damages arising from CytoDyn's maintenance of the sale restrictions on the 8,342,000 Shares and (b) value the Transferred Assets at $10,000 ("Fair Market Value"). Unless such action is required pursuant to a "determination" within the meaning of Section 1313(a) of the Code, CytoDyn shall not issue an IRS Form W-2 to Dr. Pestell in respect of the Transferred Assets, but CytoDyn may issue an IRS Form 1099 to Dr. Pestell for the Transferred Assets in the amount of Fair Market Value.

7.3 The Parties shall treat the Warrants for all tax purposes as issued in settlement of Dr. Pestell's severance and employment compensation related claims. In this regard, the Parties agree that the Warrants are not taxable at the time of issuance and will generate taxable income, if at all, upon the earlier of a sale of the Warrants or each exercise of the Warrants. Unless such action is required pursuant to a "determination" within the meaning of Section 1313(a) of the Code, CytoDyn shall not an IRS Form W-2, 1099 or similar tax forms to Dr. Pestell in respect of the Warrants other than in connection with a sale or exercise of the Warrants.

7.4 If the IRS or other tax authority (each, a "Tax Authority") proposes to re-characterize any of the tax treatments set forth in Sections 7.1 through 7.3 (each such proposal and further correspondence from the Tax Authority in respect of such Proposal, a "Re-Characterization Proposal"), then CytoDyn shall: (a) promptly notify Dr. Pestell of such Re-Characterization Proposal and include with such notice all correspondence from the Tax Authority regarding such Re-Characterization Proposal; (b) keep Dr. Pestell reasonably informed of all material developments and events relating to such Re-Characterization Proposal (including promptly forwarding copies to Dr. Pestell of any related correspondence; (c) provide to Dr. Pestell all proposed responses to the Tax Authority related to each Re-Characterization Proposal (each, a

"Response") as far in advance of submitting the Response as is reasonably possible and reasonably implement Dr. Pestell's comments to each Response to the extent consistent with counsel's advice with the goal of prevailing on such issue (unless such comments are factually incorrect or take tax positions that are not supportable at a more likely than not level of authority); and (d) upon receipt of a fee deposit and agreement that Dr. Pestell will fund the costs associated with maintaining the tax controversy, not settle or enter into a closing agreement with the Tax Authority or consent to any re-characterization of any of the tax treatments set forth in Sections 7.1 through 7.3 except with the consent of Dr. Pestell (such consent not to be unreasonably conditioned, withheld or delayed). Notwithstanding the foregoing, Dr. Pestell may elect to assume and control the defense of each Re-Characterization Proposal at his own expense using counsel and tax professionals engaged directly by Dr. Pestell; provided that CytoDyn may continue to participate in (but not control) the defense of such Re-Characterization Proposal at its own expense using counsel and tax professionals of its choosing. Upon a final adverse determination, if any, which results in a re- characterization of any of the tax treatments set forth in Sections 7.1 through 7.3, Dr. Pestell will indemnify and hold CytoDyn harmless from and against any (i) taxes resulting from such re- characterization including any such taxes that the Tax Authority collects from CytoDyn but excluding the employer side of taxes payable pursuant to the Federal Insurance Contributions Act, as amended and (ii) penalties and interest resulting from such re-characterization.

8. Enforcement and Retention of Jurisdiction; Prevailing Party Counsel Fees.

In the Parties' request for dismissal of this action, they shall request that the District Court retain jurisdiction to enforce this Agreement. If a Party claims a material breach of this Agreement, the Party claiming material breach shall provide written notice to the allegedly breaching Party of the claimed material breach and provide fourteen (14) days to cure the alleged material breach. In

the event the Party claiming breach has not been satisfied that the other Party has cured the noticed breach within 14 days after providing such notice, then the Parties agree to the propriety of and waive objection to the commencement of expedited injunctive proceedings that may provide for, inter alia, specific performance (without waiving herein substantive objections or arguments to the merits of any such claim). A copy of the Stipulation of Dismissal to be executed by the Parties and filed in the Litigation is attached hereto as Exhibit E.

If litigation is commenced or prosecuted to enforce the terms of this Agreement pursuant to this section of this Agreement, the prevailing Party in any such legal action shall be entitled to reimbursement of reasonable attorneys' fees and costs incurred in prosecuting or defending any claim(s) relating to the enforcement of this Agreement, in addition to any other relief to which it may be entitled. For the sake of clarity, other than for attorneys' fees and expenses provided for in this Section of this Agreement pertaining to any action to enforce this Agreement, each Party agrees that it is responsible for its own fees and costs associated with the Litigation and this Agreement, including all attorneys' fees incurred as a result, and each agrees that it will not seek from any other Party reimbursement for such attorneys' fees or costs.

9. Miscellaneous.

9.1 Background Paragraphs**.** Background paragraphs A. – K. above are incorporated into this Agreement by reference and are not merely recitals.

9.2 Further Instruments/Assurances. The Parties acknowledge their intent to consummate this Agreement and the transactions contemplated herein and agree to cooperate to the extent reasonably necessary to effectuate and implement this Agreement, including, without limitation, executing any further documentation and taking such further action as may be reasonably necessary to effectuate or carry out this Agreement.

9.3 Choice of Law and Forum. This Agreement shall be governed by, and construed in

accordance with, the laws of the State of Delaware, without regard to its conflicts of law rules. The Parties hereby further agree that the District Court shall have exclusive jurisdiction and venue to enforce and award damages or other relief in any dispute that may arise from or relate to this Agreement. Should the District Court fail to have jurisdiction to enforce this Agreement at the time of any such dispute, then exclusive jurisdiction and venue shall vest in the state courts of the State of Delaware.

9.4 Joint Drafting. This Agreement shall be treated as jointly drafted by the Parties and shall not be construed in favor of or against any Party.

9.5 Time. Time is of the essence in the performance of the Parties' obligations hereunder.

9.6 Severability. If any provision of this Agreement or the application of such provision to any person or circumstance shall be held invalid, the remainder of this Agreement and the application of such provision to persons or circumstances other than those to which it is held invalid shall remain in effect and valid.

9.7 Waiver of Right to Jury Trial. THE PARTIES HEREBY KNOWINGLY AND VOLUNTARILY WAIVE THE RIGHT TO TRIAL BY JURY IN ANY ACTION, CLAIM, COUNTERCLAIM, CROSS-CLAIM, THIRD-PARTY CLAIM, DISPUTE, DEMAND, SUIT OR PROCEEDING ARISING OUT OF OR IN ANY WAY CONNECTED WITH THIS AGREEMENT AND THE TRANSACTIONS CONTEMPLATED HEREBY, AND AGREE THAT ANY SUCH ACTION, CLAIM, SUIT OR PROCEEDING SHALL BE TRIED BEFORE A JUDGE AND NOT BEFORE A JURY.

9.8 Successors and Assigns. This Agreement shall be binding on and inure to the benefit of each of the Parties and their respective heirs, legatees, executors, estates, legal representatives,

successors and assigns. This Agreement provides no rights to any third party except to the extent expressly set forth herein.

9.9 Entire Agreement. This Agreement is the complete and accurate expression of the

terms of the settlement between the Parties and supersedes all prior or contemporaneous written or oral term sheets, statements, or other representations or negotiations. In its entry into and performance of this Agreement, neither Party is relying on any statements, representations or warranties made by the other Party that are not expressly set forth herein or in the Assignment and Assumption Agreement.

9.10 No Admissions, Prevailing Party or Evidentiary Effect. Each Party denies and disclaims any wrongdoing or liability of any kind whatsoever, and/or the lack thereof, and enters into this Agreement solely for the purpose of avoiding further expense, uncertainty and inconvenience. No Party shall be deemed to be a prevailing party for any purpose. Neither this Agreement, nor the execution and acceptance of this Agreement, nor anything contained in this Agreement, shall constitute, be presumed, construed, or deemed to be, or shall be cited or used by any Party as an admission of any kind, or evidence as to the strength or merit or lack of merit of any claim of liability, fault, wrongdoing, misconduct or impropriety of any kind by any Party to this Agreement or any other person.

9.11 Amendment; Waiver. This Agreement may not be amended except by a written document duly executed and delivered by all Parties and no provision or obligation hereunder may be waived except by a written document duly executed by the Party bound by such waiver.

9.12 Counterparts. This Agreement may be executed in any number of counterparts, each of which, when executed and delivered, shall be deemed an original and all of which together

shall constitute one and the same Agreement. Signatures obtained by facsimile or email in PDF format or other electronic transmission shall be deemed to be original signatures.

9.13 Section Titles. Article, section, and subsection titles contained in this Agreement

shall be without substantive meaning or content of any kind whatsoever and are not a part of the agreement between the Parties.

WHEREFORE, the Parties have executed this Agreement as of the date first set forth above.

CYTODYN INC.

By: /s/ Antonio Migliarese

Name: Antonio Migliarese

Title: CFO & Interim President

CYTODYN OPERATIONS INC.

By: /s/ Antonio Migliarese

Name: Antonio Migliarese

Title: CFO & Interim President

/s/ Richard G. Pestell
RICHARD G. PESTELL, M.D., PH.D

Exhibit 21

SUBSIDIARIES

Name	Jurisdiction of Incorporation or Organization
CytoDyn Operations Inc.	Delaware
Advanced Genetic Technologies, Inc.	Florida

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-206813, 333-223884, 333-237490 and 333-249179) and Registration Statements on Form S-3 (Nos. 333-228991, 333-233526, 333-236198, and 333-258944) of our report dated July 30, 2021, except for the effect of the revision discussed in Note 2, as to which the date is January 10, 2022 with respect to the consolidated financial statements of CytoDyn Inc. included in this Annual Report on Form 10-K for the year ended May 31, 2022. 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.

/s/ Warren Averett, LLC

Birmingham, Alabama
August 15, 2022

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-206813, 333-223884, 333-237490 and 333-249179) and Registration Statements on Form S-3 (Nos. 333-228991, 333-233526, 333-236198, and 333-258944) of our reports dated August 15, 2022, with respect to the consolidated financial statements of CytoDyn Inc. and the effectiveness of internal control over financial reporting of CytoDyn Inc., included in this Annual Report on Form 10-K for the fiscal year ended May 31, 2022.

Our report on the consolidated financial statements contains two explanatory paragraphs regarding substantial doubt as to CytoDyn Inc.'s ability to continue as a going concern and its restatement of the fiscal year ended May 31, 2021 (Note 14).

/s/ Macias Gini & O'Connell LLP

San Jose, California
August 15, 2022

Exhibit 31.1

Certification of Chief Executive Officer

I, Cyrus Arman, 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: August 15, 2022

/s/ Cyrus Arman
Cyrus Arman, Ph.D.
President

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: August 15, 2022

/s/ Antonio Migliarese
Antonio Migliarese
Chief Financial Officer and Treasurer

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, 2022, 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/ Cyrus Arman	/s/ Antonio Migliarese
Cyrus Arman, Ph.D. President Date: August 15, 2022	Antonio Migliarese Chief Financial Officer Date: August 15, 2022

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.