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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, 2024

or

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

For the transition period from _____ to _____

Commission file number 000-49908

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

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

Registrant's Telephone Number, including area code: (360) 980-8524

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
None.	**None.**	**None.**

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

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

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

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

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

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

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

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and ask price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter: $156,180 thousand as of November 30, 2023.

As of July 31, 2024, the registrant had 1,214,900 thousand shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Document	**Parts Into Which Incorporated**
Portions of the Proxy Statement for the 2024 Annual Meeting of Stockholders	**Part III**

CYTODYN INC.
FORM 10-K FOR THE YEAR ENDED MAY 31, 2024
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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," "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 may include, among others, statements about leronlimab, its ability to provide positive health outcomes, the Company's ability to implement a successful operating strategy for the development of leronlimab and thereby create shareholder value, the ability to obtain regulatory approval of the Company's drug products for commercial sales, and the strength of the Company's leadership team. The Company's forward-looking statements are not guarantees of performance, and actual results could vary materially from those contained in or expressed by such statements due to risks and uncertainties, including: (i) the regulatory determinations of leronlimab's safety and effectiveness to treat the diseases and conditions for which we are studying the product by the U.S. Food and Drug Administration (the "FDA") and, potentially, drug regulatory agencies in various other countries; (ii) the Company's ability to raise additional capital to fund its operations; (iii) the Company's ability to meet its debt and other payment obligations; (iv) the Company's ability to recruit and retain key employees; (v) the Company's ability to enter into partnership or licensing arrangements with third parties; (vi) 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 applications for approval of the Company's drug product; (vii) the Company's ability to achieve approval of a marketable product; (viii) the design, implementation and conduct of the Company's clinical trials; (ix) the results of any such clinical trials, including the possibility of unfavorable clinical trial results; (x) the market for, and marketability of, any product that is approved; (xi) 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; (xii) regulatory initiatives, compliance with governmental regulations and the regulatory approval process; (xiii) legal proceedings, investigations or inquiries affecting the Company or its products; (xiv) general economic and business conditions; (xv) changes in foreign, political, and social conditions; (xvi) stockholder actions or proposals with regard to the Company, its management, or its board of directors; and (xvii) various other matters, many of which are beyond the Company's control.

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. (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), a novel humanized monoclonal antibody targeting the C-C chemokine receptor type 5 ("CCR5"). The pre-clinical and early clinical development of PRO 140 was led by Progenics through 2011. The Company acquired the asset from Progenics in October 2012. In November 2018, the United States Adopted Names Council adopted "leronlimab" as the official nonproprietary name for PRO 140. The Company has conducted clinical trials of leronlimab as a viral entry inhibitor for human immunodeficiency virus ("HIV"), believed to competitively bind to the N-terminus and second extracellular loop of the CCR5 receptor. For immunology, the CCR5 receptor is believed to be implicated in immune-mediated illnesses such as Metabolic dysfunction-associated steatohepatitis ("MASH"), formerly known as nonalcoholic steatohepatitis ("NASH"). The CCR5 receptor may also be present on cells that undergo malignant transformation and in the tumor microenvironment. Studies of leronlimab have also been conducted in MASH and solid tumors in oncology, in addition to HIV, where CCR5 is believed to play an integral role.

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

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

Business Overview

The Company is a clinical stage biotechnology company focused on the clinical development and potential commercialization of its product candidate, leronlimab, which is being studied for oncology and inflammation, as well as other potential indications, including but not limited to HIV and MASH.

Our current business strategy is the clinical development of leronlimab, which may include the following:

1. Conducting a Phase II study of leronlimab in patients with relapsed/refractory microsatellite stable colorectal cancer;
2. Conducting a Phase II study exploring leronlimab and its effects on inflammation; and
3. Continuing our work researching and developing a new or modified long-acting version of leronlimab.

Other programs that may be pursued include steatosis and liver fibrosis associated with MASH, either alone or as a combination therapy; and for metastatic triple-negative breast cancer with current standard of care, and/or exploring other trials with current standard of care and other cancer and immunologic indications.

We will need significant additional funding to execute the business strategy described above, including conducting additional pre-clinical studies and clinical trials, in furtherance of our efforts to obtain FDA approval to commercialize leronlimab. In addition to traditional fundraising the Company will pursue non-dilutive financing opportunities, such as license agreements and co-development or strategic partnerships, to help implement its strategy.

As further discussed in Part II, Item 8, Note 2, *Summary of Significant Accounting Policies - Inventories,* and Note 3, *Inventories, net,* in this Form 10-K, the Company previously capitalized procured or produced pre-launch inventories in preparation for product launches. As of May 31, 2024, the Company has written-off the full $99.2 million

of previously capitalized pre-launch inventories. Although these inventories have been written-off from an accounting perspective, they can be used in certain clinical contexts and could possibly be sold commercially upon regulatory approval if the shelf-lives can be extended as a result of the performance of on-going and future stability tests.

Recent Corporate Developments

On November 9, 2023, at the Company's annual meeting, our stockholders voted in favor of an amendment to the Company's Certificate of Incorporation to increase the total number of shares of common stock authorized for issuance from 1,350,000,000 shares to 1,750,000,000 shares.

On January 10, 2024, the Company entered into an agreement with an executive services firm to engage Mitchell Cohen to provide financial and accounting services to the Company as an independent contractor. On January 19, 2024, the Company's Board of Directors approved the appointment of Mr. Cohen as the Company's Interim Chief Financial Officer effective February 1, 2024. Mr. Cohen also serves as the Company's principal financial officer and principal accounting officer.

On January 26, 2024, the Company entered into an employment agreement with Jacob P. Lalezari, M.D., under which he is serving as the Company's Chief Executive Officer, effective as of January 26, 2024. Dr. Lalezari previously served as the Company's Interim CEO beginning November 17, 2023. Dr. Lalezari is responsible for leading the Company's corporate and product development, with a focus on short-term clinical development and related fundraising.

On April 3, 2024, the Company and Samsung BioLogics Co., Ltd. ("Samsung") executed an agreement (the "Letter Agreement"), wherein the parties reached agreement for an orderly process for winding down services and a restructuring of the amount payable by the Company to Samsung (the "Total Balance"). The Letter Agreement resolves the Company's obligations under the Master Services Agreement and related ancillary agreements first entered into between Samsung and the Company in or around April 2019 (collectively, the "Agreement").

The Total Balance due as restructured under the Letter Agreement is $43,821,231.32. Except for a single $250,000 payment due on or before December 31, 2024, the entirety of the Total Balance is conditional, and will only be due and payable, upon the Company achieving a qualifying "Revenue" event, as defined in the Letter Agreement. Under the Letter Agreement, the Company agreed to pay 20% of its qualifying Revenue generated in each calendar year, if any, with such payments to be applied to reduce the Total Balance until it is repaid in full. Interest will not accrue on the Total Balance throughout the prospective repayment period. For additional information on the Samsung relationship, please see Part II, Item 8, Note 10, *Commitments and Contingencies - Commitments with Samsung BioLogics Co., Ltd. ("Samsung")*.

On June 27, 2024, the Audit Committee of the Board of Directors of CytoDyn Inc. (the "Company") engaged Marcum LLP ("Marcum") and appointed the firm as the Company's independent registered public accounting firm, effective immediately, to perform audit services for the Company's fiscal year ended May 31, 2024, and review services for the quarters ending August 31, 2024, November 30, 2024, and February 28, 2025. The appointment of Marcum followed the Audit Committee's dismissal of BF Borgers CPA PC ("BF Borgers"), the Company's prior independent accounting firm, on May 3, 2024.

On July 2, 2024, the Company and Amarex Clinical Research, LLC ("Amarex"), the Company's former clinical research organization ("CRO"), entered into an agreement settling a lawsuit filed by the Company in October 2021 (the "Settlement Agreement").

The terms of the Settlement Agreement include: (i) the payment by Amarex of $12,000,000 to the Company, of which $10,000,000 was paid on execution of the Settlement Agreement and the balance will be paid on or before July 2, 2025; (ii) the release of the Company's surety bond posted in the lawsuit and the return of the Company's cash collateral in the amount of $6,500,000 provided as security to the surety; (iii) the crediting of all amounts claimed by Amarex as due and payable for its CRO services, totaling approximately $14,000,000, reducing the Company's outstanding balance to zero, with no funds required to be paid by the Company; and (iv) a mutual release of claims, resolving all legal claims between the parties.

Background: Leronlimab as a CCR5 Antagonist

CytoDyn is 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 known as chemokines. Chemokines are key orchestrators of cell trafficking by directing immune cells to the sites of inflammation. At the site of an inflammatory reaction, chemokines are released. These chemokines bind to the CCR5 receptor and cause the migration of T-cells to these sites, promoting further inflammation. The CCR5 receptor is also the co-receptor needed for the most common strains of HIV to infect healthy T-cells.

The mechanism of action ("MOA") of leronlimab has the potential to modulate the movement of T-cells to inflammatory sites, which could be beneficial by diminishing overactive 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.

Leronlimab prevents CCR5 tropic strains of HIV, which are the great majority of circulating viruses, from using the CCR5 receptor as a gateway to enter healthy cells. Pre-clinical research has also shown that leronlimab blocks calcium channel signaling of the CCR5 receptor when present on the cancer cell surface. This research suggests that calcium channel signaling of the CCR5 receptor is a crucial component to the spread of metastatic cancer. The CCR5 receptor has been identified as a potential therapeutic target in a variety of settings, including HIV, graft-versus-host disease ("GvHD"), MASH, Alzheimer's disease, cancer metastasis, 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 to provide benefit in a variety of clinical settings.

Leronlimab and Cancer

Research indicates that the CCR5 receptor works as a potential "GPS" system for cancer cells that promotes the spread of 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. However, it is metastatic disease and not the primary tumor that is the cause of death in most cancer patients.

Research has shown that CCR5 expression is increased in a number of solid tumors including breast, colon, prostate, and pancreatic cancer among others. Increased CCR5 expression has also been identified as an indicator of increased risk of progression in several cancers. Research has hypothesized that CCR5 may play a variety of roles in the progression of 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. The second is that blocking the CCR5 receptor on a group of immunosuppressive immune cells known as Regulatory T cells (Tregs) could turn on anti-tumor fighting properties thereby restoring immune function. A third observation is that blocking the interaction of CCR5 with a chemokine known as RANTES (also known as CCL5) has a potentially synergistic effect with chemotherapy in controlling cancer progression. Fourth, animal studies revealed a significant decrease in angiogenesis or new blood vessel formation following administration of leronlimab. Such new blood vessel formation is critically important for the growth of tumors. And lastly, it is hypothesized that leronlimab exerts an effect on tissue macrophages in the tumor microenvironment to repolarize these cells into anti-tumor fighting cells.

Glioblastoma Multiforme ("GBM") Pre-Clinical Development

In December 2023, the Company entered into a partnership with Albert Einstein College of Medicine and Montefiore Medical Center, located in New York. The Company will be providing leronlimab to support a pre-clinical study evaluating the efficacy of leronlimab independently and in combination with temozolomide in treating glioblastoma multiforme, also known as grade IV astrocytoma ("GBM") in infected humanized mice. The study will involve three groups of humanized mice: one control group, one group that will receive only leronlimab, and another group that will receive a combination of leronlimab and temozolomide. The primary objective of this study is to evaluate the effect of leronlimab on the primary tumor growth and occurrence of metastases on CCR5+ and CCR5- cells in humanized mice. Upon completion of the study, the academic institutions will provide the Company with a research report outlining the study results, and they will have the right to publish and present the study results. GBM is the most

common type of primary malignant brain tumor and is aggressive and fast-growing. This study is expected to take place in the 2024 calendar year.

Metastatic Triple-Negative Breast Cancer Pre-Clinical Development

In late November 2018, CytoDyn 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 previously reported that a pre-clinical research study with leronlimab reduced the incidence of human breast cancer metastasis in a mouse xenograft model for cancer through six weeks with leronlimab by more than 98%. The temporal equivalency of this six-week study in mice may be up to six years in humans. In May 2019, the FDA granted Fast Track designation for leronlimab for use in combination with carboplatin to treat patients with CCR5+ positive mTNBC.

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

This trial evaluated the feasibility of leronlimab in combination with carboplatin in patients with CCR5+ mTNBC. This trial advanced from Phase 1b/2 to Phase 2. The Phase 2 trial was a single arm study to test the hypothesis that the combination of intravenous carboplatin and maximum tolerated dose of subcutaneous leronlimab will increase progression free survival. This study also evaluated the change in Circulating Tumor Cells as a potential prognostic marker for clinical 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 and publication of the study results is pending.

Metastatic Triple-Negative Breast Cancer Compassionate Use Study

This was a single-arm, compassionate use study of 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, and publication of the results is pending.

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

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

Leronlimab and HIV

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

We continue to believe leronlimab is positioned to add value to the HIV market, as an alternative, or in addition to current therapies, which are failing primarily due to patient non-compliance, which causes drug resistance. Several

factors give rise to patient non-compliance issues, such as toxicity and side effects, coupled with the need for a strict daily dosing regimen. In 26 clinical studies previously conducted, leronlimab was generally well tolerated. In addition, there were no dose-limiting toxicities or patterns of drug-related toxicities observed during these trials. We believe the results of these trials establish that leronlimab's antiviral activity is potent, rapid, prolonged, and dose-dependent. 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 primarily as a subcutaneous injection once per week. We believe that if leronlimab is approved by the FDA for use in HIV, it could 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 co-morbidities;
- Patients with difficulty adhering to daily drug regimens;
- Patients who poorly tolerate existing therapies; and
- Patients with compromised organ function, such as hepatoxicity or renal insufficiency.

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

Leronlimab and MASH

As previously noted, CytoDyn believes that the CCR5 receptor is a crucial component in inflammatory responses. Some disease processes that could potentially benefit from CCR5 blockade include transplantation rejection, neuroinflammation, chronic inflammation, cancer, and Metabolic Dysfunction-Associated Steatohepatitis (MASH). 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 Metabolic Dysfunction-Associated Steatotic Liver Disease (MAFLD) into MASH. MAFLD is an inflammatory disease caused by the build-up of fat in hepatocytes (steatosis). In severe cases, MAFLD progresses into MASH. MASH is a chronic liver disease characterized by the presence of hepatic inflammation and fibrosis. Patients with advanced fibrosis due to MASH are at significantly higher risk of liver-related mortality. It is estimated that 30% to 40% of adults in the United States have MAFLD, while 3% to 12% of adults in the United States have MASH. If left untreated, MASH may progress to hepatocellular carcinoma and is expected to become the leading cause of liver transplantation. Further, liver disease is one of the leading causes of non-AIDS-related death in HIV patients. The Company is identifying the next steps in clinical development to continue the investigation of leronlimab in the MASH indication.

In MASH, liver homeostasis is impaired due to an accumulation of toxic lipids which can activate both Kupffer cells (KCs) and tissue-resident macrophages, resulting in the production of fibrogenic cytokines and chemoattractant chemokines such as transforming growth factor-beta (TGF-β) and monocyte chemoattractant protein1 (MCP1). Not only do these cytokines/chemokines promote differentiation of hepatic stellate cells (HSCs) into myofibroblasts (the primary source for fibrillary collagens), but they also amplify the immune response by recruiting additional cells into the damaged area. Recruitment of extra-hepatic inflammatory cells to the site of hepatic injury is typically mediated by interactions between cytokines/chemokines and their receptors. It has also been shown that patients with MASH also have high levels of CCR5 and the associated ligand, CCL5, thus demonstrating a potential role of CCR5 and its ligands in liver fibrosis.

MASH Pre-Clinical Development

The potential for leronlimab in the treatment of MASH was demonstrated in a pre-clinical model of fatty liver disease. Immunodeficient, NOD-SCID Gamma (NSG) mice were fed a high fat, MASH-inducing diet, transplanted with human stem cells to repopulate the deficient immune system, and treated with leronlimab. Sixteen (16) male NOD.Cg-*Prkdcscid Il2rgtm1Wjl/SzJ*, commonly known as the NOD *scid* IL2 receptor gamma knockout mice (NSG), were first humanized by intravenous inoculation with normal human umbilical cord blood cells (105). After 5 weeks on normal mouse chow, mice were successfully humanized, demonstrating >25% human CD45 cells in peripheral blood. Mice were switched to high fat (52%) high cholesterol (1.25%) diet (FPC diet: fructose, palmitate, cholesterol, trans-fat; Envigo-Teklad TD.160785). Leronlimab and control antibody (normal human IgG, Sigma) were administered i.p. at a dose of 2mg i.p. twice weekly, n=8 mice/group. The results showed that leronlimab inhibited fatty liver development, a key characteristic of early-stage MASH, such that treatment of humanized NSG mice with leronlimab caused a three-fold reduction in hepatic steatosis compared to control in an animal model of high fructose, high palmitate, high cholesterol diet.

MASH Phase 2a Exploratory Study

The Company has reported clinical data from patients with MASH from the CDI-MASH01 trial which was designed as a multi-center Phase 2a study and was subsequently converted into an exploratory study to evaluate the dose, efficacy, and safety of leronlimab at 350 mg and 700 mg, versus placebo. The study also included an expansive biomarker program designed to inform future clinical trials and to more fully understand leronlimab's mechanism of action within the MASH setting. CDI-MASH01 was conducted in two parts. Part 1 of the study was designed to assess the efficacy of leronlimab 700 mg (n=22) in improving measurements of liver steatosis and liver fibro-inflammation in adult patients diagnosed with MASH compared to placebo (n=28). Part 2 was subsequently added to assess leronlimab 350 mg in improving these same measurements in adult patients diagnosed with MASH (n=22). In Part 1 of the study, eligible subjects were randomized 1:1 to one of the two study arms to receive either leronlimab 700mg (Group A), or placebo (Group B), given once per week (±1day) at the study site for up to 13 weeks during the treatment period. In Part 2 of the study, eligible subjects were enrolled using the same inclusion and exclusion criteria to Part 1 and received open-label leronlimab 350 mg given once per week (±1day) at the study site for up to 13 weeks during the treatment period. The primary efficacy objective was percent change from baseline in hepatic fat fraction, as assessed by magnetic resonance imaging-derived proton density fat fraction (MRI-PDFF) at week 14. The secondary efficacy objective was absolute change from baseline in fibro-inflammatory activity in the liver as assessed by MRI-corrected T1 imaging (MRI-cT1) at week 14. MRI-cT1 is obtained by multiparametric magnetic resonance imaging of the liver and is a quantitative metric for assessing a composite of liver inflammation and fibrosis, expressed in milliseconds (msec). MRI-PDFF is being studied as an imaging surrogate endpoint for the fat density in the liver. MRI-cT1 is being studied as an imaging surrogate endpoint for hepatic fibro-inflammation. This is a critical unmet need in the MASH space, as many agents have been unable to show reductions in fibro-inflammation despite reductions in hepatic steatosis.

All analyses performed are being treated as exploratory. Treatment with leronlimab was well tolerated in both Part 1 and Part 2 compared to placebo. In Part 1 of the study, leronlimab 700 mg did not reduce mean change in PDFF and cT1 from baseline to week 14 vs. placebo. In Part 2, leronlimab 350 mg reduced mean change in PDFF and cT1 from baseline to week 14 vs. the placebo group from Part 1, despite increased degree of baseline fibro-inflammation. In the combined group of patients with moderate (≥ 875 msec) and severe (≥ 950 msec) cT1 values at baseline, leronlimab 350 mg reduced cT1 from baseline to week 14 vs. placebo. The study has been completed and publication of the results is pending.

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 disease 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 SARS-CoV2 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 potential effects of leronlimab on the immune system and the results from over 60 Emergency Investigation New Drug ("EIND") authorizations provided by the FDA, the Company conducted and completed two clinical trials in the United States for COVID-19 starting in fiscal 2020 and ending in fiscal 2022. Subsequently, the Company paused two additional clinical COVID trials in Brazil which commenced during fiscal 2022. Further, the Company withdrew its COVID-19 IND with the FDA, and the FDA put the COVID-19 program on a full clinical hold in March 2022. If CytoDyn were to continue to pursue the COVID-19 indication, we believe that subgroup analyses from our previous trials may inform the design of future clinical trials investigating leronlimab for the treatment of COVID-19.

Pre-Clinical Development of Long-Acting CCR5 Antagonist

In March 2023, the Company entered into a joint development agreement with a third-party generative AI drug discovery and development company to develop one or more longer-acting molecules. The Company believes working with a partner with AI capabilities will result in the expedited development of a modified, longer-acting therapeutic, and could lead to greater acceptance by patients due to the requirement for less frequent injections. The services provided by the third party may yield extended intellectual property protection, thereby increasing the value of the Company's patent portfolio. In December 2023, the Company received various iterations of potential long-acting therapeutics, on which the Company will be performing assays to determine the suitability and feasibility of the long-acting therapeutic candidates for further development.

If successful, such a modified therapeutic would require less frequent injections for patients on drug, furthering the convenience and overall marketability of the product. Working with a company with established AI-capabilities allows for a robust development path for this modified, longer-acting therapeutic for the Company. This joint development initiative remains in progress at this time and the Company will provide further updates when appropriate.

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 known as 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.

Patents, Proprietary Technology and Data Exclusivity

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

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

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

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

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

Patents and data exclusivity are different concepts, protect different subject matter, arise from different efforts, and have different legal effects over different time periods. Information with respect to our current patent portfolio as of May 31, 2024 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	16	2024-2032	3	3
Methods of treatment by indication (e.g., HIV-1; COVID-19; GvHD) [2]	3	—	2036-2040	3	5
Methods of treatment – Cancer, MASH (formerly, NASH)	—	—	2032-2033	3	30

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

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

Government Regulation

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

Licensure and Regulation of Biological Products in the United States

In the United States, the FDA regulates human drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and in the case of biological products, also under the Public Health Service Act, or the PHSA, and their implementing regulations. The failure to comply with the applicable U.S. requirements may result in FDA refusal to

approve any pending applications or delays in development and may subject an applicant to administrative or judicial sanctions, such as issuance of warning letters, or the imposition of fines, civil penalties, product recalls, product seizures, total or partial suspension of production or distribution, and injunctions and/or civil or criminal prosecution brought by the FDA and the U.S. Department of Justice or other governmental entities.

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

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

Pre-clinical Studies

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

The IND and IRB Processes

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

impose a clinical hold or partial clinical hold. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin.

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

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

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

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

Expanded Access

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

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

initiation, conduct, or completion of clinical investigations that could support marketing approval of the product or otherwise compromise the potential development of the product.

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

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

Human Clinical Trials in Support of an NDA or BLA

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

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

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

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

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

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

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

Expedited Programs for Serious Conditions

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

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

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

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

Emergency Use Authorizations

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

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

Review and Approval of BLAs

Assuming successful completion of the required clinical testing, the results of the pre-clinical studies and clinical trials, along with information relating to the product's chemistry, manufacturing, and controls and proposed labeling, are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety, potency, and purity of the investigational product to the satisfaction of the FDA. The fee required for the submission of an NDA or BLA under the Prescription Drug User Fee Act, or PDUFA, is substantial (for example, for FY2024 this application fee is approximately $4.0 million), and the sponsor of an approved BLA is also subject to an annual program fee, approximately $0.4 million per program. These fees are typically adjusted annually, but exemptions and waivers may be available under certain circumstances.

The FDA conducts a preliminary review of all BLAs within 60 days of receipt and informs the sponsor by the 74th day after the FDA's receipt of the submission whether an application is sufficiently complete to permit substantive review. In the event that the FDA determines that a BLA does not satisfy this standard, it will issue a Refuse to File ("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 ("REMS"), if it determines that a REMS is necessary to ensure that the benefits of the product outweigh its risks and to assure the safe use of the biological product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS and the FDA will not approve the BLA without a REMS.

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

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

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

Reference Product Exclusivity for Biological Products

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

Under the BPCIA, a manufacturer may submit an application for a product that is "biosimilar to" or "interchangeable with" a previously approved biological product or "reference product." For the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and the

proposed biosimilar product in terms of safety, purity, and potency. For the FDA to approve an interchangeable biological product, the agency must find that the biological product is biosimilar to the reference product, can be expected to produce the same clinical results as the reference product, and "for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch." Upon licensure by the FDA, an interchangeable biosimilar may be substituted for the reference product without the intervention of the healthcare provider who prescribed the reference product, although the substitutability of drug and biological products are determined at the state level.

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

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

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

Orphan Drug Designation and Exclusivity

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

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

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

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

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

demonstrate clinical superiority in order to receive orphan drug exclusivity for a product that is considered the same drug as a previously approved product for the same rare disease or condition.

Patent Term Restoration and Extension

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

Post-approval Requirements

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

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

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

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

We rely, and expect to continue to rely, on third parties to produce clinical (and, in the future, commercial) supplies of our product candidate in accordance with cGMP regulations. These manufacturers must comply with cGMP

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

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information, imposition of post-market clinical trials requirement to assess new safety risks or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

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

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

Other U.S. Healthcare Laws and Regulations

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

- federal false claims, false statements, and civil monetary penalties laws prohibiting, among other things, any person from knowingly presenting, or causing to be presented, a false claim for payment of government funds or knowingly making, or causing to be made, a false statement to get a false claim paid;
- federal healthcare program anti-kickback law, which prohibits, among other things, persons from offering, soliciting, receiving, or providing remuneration, directly or indirectly, to induce either the referral of an

individual for, or the purchasing or ordering of, a good or service for which payment may be made under federal healthcare programs such as Medicare and Medicaid;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which, in addition to privacy protections applicable to healthcare providers and other entities, prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- FDCA, which among other things, strictly regulates marketing, prohibits manufacturers from marketing such products prior to approval or for off-label use, and regulates the distribution of samples;
- federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;
- federal transparency law, which requires pharmaceutical companies to report certain payments to healthcare providers;
- state laws and regulations analogous to the above; and
- laws and regulations prohibiting bribery and corruption such as the Foreign Corrupt Practices Act ("FCPA"), which, among other things, prohibits U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations or foreign government-owned or affiliated entities, candidates for foreign public office, and foreign political parties or officials thereof.

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

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

U.S. Privacy Law

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

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

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

Registrational Clinical Trials Process

Described below is the traditional registrational drug development track.

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

were conducted and completed by or on behalf of Progenics by certain principal investigators prior to our acquisition of PRO 140.

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

Phase 3 studies are expanded controlled clinical studies. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained in Phase 2 and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit/risk relationship of the drug. Phase 3 studies also provide an adequate basis for extrapolating the results to the general population and transmitting that information in the physician labeling. Phase 3 studies usually involve significantly larger groups of patients, and considerable additional expense. We were required to pay significant fees to third parties upon the first patient dosing in a Phase 3 trial of leronlimab, and we may be required to make additional fee payments to third parties upon the completion of additional milestones. Refer to Part II, Item 8, Note 10, *Commitments and Contingencies - PRO 140 Acquisition and Licensing Arrangements,* for further information.

Manufacturing

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

We previously engaged 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 also contracted with suitable CMO(s) 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 continue to rely on active CMO relationships for all of our developmental and commercial needs. As noted above under "Recent Corporate Developments", we terminated our relationship with Samsung in April 2024 and currently maintain one active CMO relationship. We will continue to evaluate the need for any additional CMO services and/or relationships, as well as the potential use of our remaining pre-launch inventories described under the heading "Business Overview" above.

Research and Development Costs

The Company's research and development expenses totaled approximately $7.2 million and $2.6 million for the fiscal years ended May 31, 2024, and 2023, respectively.

Properties

We lease the space at which our principal executive offices are located at a monthly cost of approximately $15.6 thousand. We do not own or lease any other properties.

Employees and Human Capital Resources

As of August 15, 2024, we had nine full-time employees, as well as a number of independent consultants, including our interim Chief Financial Officer and other individuals assisting us with the Company's regulatory, quality, and medical matters. Our research and development team is geographically dispersed throughout the United States. CytoDyn is committed to pay equity regardless of gender or race/ethnicity. We invest in our workforce by offering competitive salaries and benefits. We may award stock options or other stock-based awards to selected employees and consultants under our equity incentive plan. We also offer various benefits to all eligible employees, including health care coverage

and a 401(k) plan. None of our employees are subject to a collective bargaining agreement. We consider our relationship with our employees to be good. There can be no assurance, however, that we will be able to identify or hire and retain additional employees or consultants on acceptable terms in the future.

Item 1A. RISK FACTORS

Our business is subject to numerous risks and uncertainties, including those highlighted in this section, which 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 Part II, 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 low and we do not expect to receive substantial, if any, revenues for the foreseeable future, such that we will need to raise additional financing to fund our ongoing operations and manage our payment obligations, which financing continues to be difficult to secure in light of the low trading price of our common stock.
- We are a clinical stage biotechnology company with a history of significant operating losses; we expect to continue to incur operating losses, and we may never achieve profitability.
- The amount of financing we require will depend on various factors, many of which are beyond our control. Our results of operations, financial condition, and stock price are likely to be adversely affected if we are unable to obtain additional funding on improved terms compared to previous financings.
- Our future cash requirements may differ significantly from our current estimates.
- Our auditors have issued a going concern opinion, and we will not be able to achieve our objectives and will have to cease operations if we cannot find adequate financing.
- We have written off the value of our pre-launch inventories of leronlimab and related raw materials, the costs of which were previously capitalized, and may be unable to use all or a portion of those inventories in the development of our product candidate.

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

- The recruitment and retention of skilled directors, executives, employees and consultants may be difficult and expensive, may result in dilution to our stockholders, and any failure to attract and retain such individuals may adversely affect our drug development and commercialization activities.
- The loss, temporary loss, or transition of members of our senior management team or any other key employees may adversely affect our business.
- If we are unable to maintain an effective 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.
- The class-action litigation filed against us could harm our business, and insurance coverage may not be sufficient to cover all related costs and damages.
- We are subject to oversight by the SEC, FDA, and other regulatory agencies. Investigations and proceedings by those agencies may divert management's focus and have a material adverse effect on our reputation and financial condition.
- We face risks and uncertainties related to litigation and other claims.

Risks Related to Development and Commercialization of Our Drug Candidate

- Certain agreements and related license agreements require us to make significant milestone, royalty, and other payments, which will require additional financing and, in the event we do commercialize leronlimab, will decrease the revenues we may ultimately receive on sales. To the extent that such milestone, royalty and other payments are not timely made, the counterparties to such agreements in certain cases have repurchase and termination rights thereunder with respect to leronlimab.
- If we are unable to obtain all required regulatory approvals for leronlimab, we will not be able to commercialize our primary product candidate, which would materially and adversely affect our business, financial condition, and stock price.
- We are substantially dependent on the success of leronlimab. If we, either alone or with collaborators, are unable to complete the clinical development of, obtain and maintain marketing approval for, or successfully commercialize leronlimab, including with respect to adequate coverage and reimbursement, or if we continue to experience significant delays in doing so, our business will be 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 limited number of internal research and development personnel, making us dependent on consulting relationships and strategic alliances with industry partners.
- We may continue to rely on third parties, such as CROs and third-party manufacturers, to conduct clinical trials for our product candidate, leronlimab, and to produce our pre-clinical and clinical product candidate supplies. Such third parties are subject to significant regulation. A failure by such third parties to perform their obligations properly and successfully to us, or failure of manufacturers on which we rely to meet regulatory requirements, may result in our inability to obtain regulatory approvals for or commercialize our product candidate.

Risks Related to Our Intellectual Property Rights

- Our success depends 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 resources on litigation and exposing our own intellectual property portfolio to challenge.

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

Risks Related to Ownership of Our Common Stock

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

Risks Related to Our Financial Position and Need for Additional Capital

Our cash reserves are low and we do not expect to receive substantial, if any, revenues for the foreseeable future, such that we will need to raise additional financing to fund our ongoing operations and manage our payment obligations, which financing continues to be difficult to secure in light of the low trading price of our common stock.

As of July 31, 2024, we had an unrestricted cash balance of approximately $26.3 million and no reserved cash balance. We must continue to raise additional funds in the near term to meet our payment obligations and fund our operations. Additional funding may not be available on acceptable terms or at all. In addition, as of July 31, 2024, we had approximately 202.2 million shares of common stock unreserved for other purposes and available for issuance in new financing transactions. Our outstanding accounts payable and accrued liabilities totaled approximately $16.7 million on July 31, 2024. If we are not able to raise additional funds on a timely basis, we may be forced to delay, reduce the scope of, or eliminate one or more of our planned operating activities, including: conducting a Phase II study of leronlimab in patients with relapsed/refractory microsatellite stable colorectal cancer; conducting a Phase II study evaluating the effects of leronlimab on chronic immune activation and inflammation; pursuing research and development of longer-acting molecules; evaluating whether to conduct a combination pre-clinical study or monotherapy Phase 2b/3 clinical trial in MASH; and evaluating other opportunities for pre-clinical and clinical studies and publishing data from previously conducted studies. Any delay or inability to pursue our planned activities likely will adversely affect our business, financial condition, and stock price. The continued low trading price of our common stock (with a closing price of $0.14 per share on July 31, 2024) presents a significant challenge to our ability to raise additional funds. If we deplete our cash reserves, we may have to discontinue our operations and liquidate our assets.

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

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

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

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

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

If any of these factors cause our funding needs to be greater than expected, our continued 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, 2024. A going concern paragraph in an audit opinion means that there is substantial doubt that we can continue as an ongoing business for the 12 months from the date the consolidated financial statements are issued. If we are unable to continue as an ongoing business, we might have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements. In addition, the inclusion of an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern and our lack of cash resources may materially adversely affect our share price and our ability to raise new capital or to enter into critical contractual relations with third parties. There is no assurance that we will be able to adequately fund our operations in the future.

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

Pre-launch inventories consist of costs of raw materials and work-in-progress related to our product candidate leronlimab. As of May 31, 2024, our inventories had been written off in full for accounting purposes. Although a portion of the inventories that were written off continue to be physically maintained and currently may be eligible for use in certain clinical contexts, we may be unable to use all of these inventories in the development of our product candidate.

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

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

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

The loss, temporary loss, or transition of members of our senior management team or any other key employees may adversely affect our business.

During the past 24 months, we have experienced significant turnover among our senior executives, and currently have only three executive officers. Jacob Lalezari, M.D., our current Chief Executive Officer, entered into an employment agreement with us in January 2024 that can be terminated by either party at any time. Mitchell Cohen, our current Interim Chief Financial Officer, was appointed effective February 1, 2024, pursuant to an agreement with Rapid Deployment LLC d/b/a InterimExecs, under which he serves as an independent contractor. The agreement may be terminated at any time by either party upon 30 days' advance notice in writing. The Board plans to initiate a search for a long-term Chief Financial Officer as soon as practicable in collaboration with Mr. Cohen. If we are successful in recruiting one or more additional individuals to executive positions, the complexity inherent in integrating a new key member of the senior management team with existing senior management may limit the effectiveness of any such successor or otherwise adversely affect our business. Leadership transitions and any disruptions that result are inherently difficult to manage and may cause uncertainty or a disruption to our business or increase the likelihood of turnover of other key officers and employees. Further, we may incur significant expenses related to any executive transitions. Finding suitable replacements for senior management and other key employees can be difficult, and there is no assurance we will be successful in attracting or retaining qualified personnel.

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

If we are unable to maintain an effective 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. Failure to maintain our controls or operation of these controls may harm our operations, decrease the reliability of our financial reporting, and cause us to fail to meet our financial reporting obligations, which could adversely affect our business and reduce our stock price.

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

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

Risks Related to Legal Proceedings

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

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

The 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 securities class action lawsuits filed against the Company in March 2021 have exhausted certain coverage allowances under the Company's D&O insurance applicable to the relevant time period. This litigation, whether or not successful, may require us to incur substantial costs, which could harm our business and financial condition. During the

course of litigation, negative public announcements regarding the results of hearings, motions, or other interim proceedings or developments may occur, 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 – Securities Class Action Lawsuits* in this Form 10-K for further information.

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

We are subject to the regulation and oversight by the 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. On December 20, 2022, the DOJ announced the unsealing of a criminal indictment charging both our former CEO, Nader Z. Pourhassan, and Kazem Kazempour, CEO of Amarex, our former CRO. That same day, the SEC announced charges against both Mr. Pourhassan and Mr. Kazempour for alleged violations of federal securities laws. The Company is cooperating fully with the DOJ and SEC investigations. We are unable to predict the effect of any governmental investigations on our business, financial condition, or reputation. In addition, publicity surrounding any investigation, even if ultimately resolved favorably, could have a material adverse effect on our business. Refer to Part II, Item 8, Note 10, *Commitments and Contingencies – Legal Proceedings* in this Form 10-K for further information.

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

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

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

Risks Related to Development and Commercialization of Our Drug Candidate

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

Under agreements we have with Progenics Pharmaceuticals, Inc. ("Progenics") and Lonza Sales AG ("Lonza"), as well as a Development and License Agreement (the "PDL License") between Protein Design Labs (now AbbVie Inc. ("AbbVie")) and Progenics, we are required to pay significant milestone payments, license fees for "system know-how"

technology, and royalties related to leronlimab upon the occurrence of specified events. To make these milestone and license payments, we will need to raise additional funds. In addition, our royalty obligations will reduce the economic benefits to us of future sales, if any. To the extent that such milestone payments and royalties are not timely made, under their respective agreements, Progenics has certain repurchase rights relating to the assets sold to us, and AbbVie has certain termination rights relating to our license of leronlimab under the PDL License. Refer to Part II, Item 8, Note 10, *Commitments and Contingencies – PRO 140 Acquisition and Licensing Arrangements* in this Form 10-K for further information.

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

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

- the FDA or comparable foreign regulatory authorities or institutional review boards ("IRBs") may disagree with the future design or implementation of our clinical trials,
- we may not be able to provide acceptable evidence of the safety and efficacy of our drug candidate,
- the results of our clinical trials may not be satisfactory or may not meet the level of statistical or clinical significance required by the FDA or foreign regulatory authorities for marketing approval,
- patients in our clinical trials may suffer adverse effects for reasons that may or may not be related to our drug candidate,
- the data collected from clinical trials may not be sufficient to support the submission of an application for marketing approval in the United States or elsewhere,
- the FDA or foreign regulatory authorities may not approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies, and
- the approval policies or regulations of the FDA or foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

We cannot guarantee that regulators will agree with our assessment of the results of our past or future clinical trials or that such trials will be considered by regulators to have shown safety or efficacy of our product candidate. The FDA has substantial discretion in the approval process and may refuse to accept any application or may require additional clinical trials or pre-clinical or other studies. Additionally, we have limited experience in filing the applications necessary to gain regulatory approvals and expect to continue to rely on consultants and our CROs to assist us in this process. Securing FDA approval requires the submission of pre-clinical, clinical, and/or pharmacokinetic data, information about product manufacturing processes and inspection of facilities, and supporting information for each therapeutic indication to establish a product candidate's safety and efficacy for each indication. Our drug candidate may prove to have undesirable or unintended side effects, toxicities, or other characteristics that may preclude us from obtaining regulatory approval or prevent or limit commercial use with respect to one or all intended indications. Failure to obtain regulatory approval for leronlimab will prevent us from commercializing it as a prescription product, and our ability to generate revenue will be seriously impaired.

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

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

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

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

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

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

- develop drug candidates and market drugs that increase the levels of safety or efficacy that our product candidate will need to show 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 greater financial resources than we do. Our competitors also have greater experience in:

- developing drug and other product candidates,

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

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

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

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

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

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

Risks Related to Our Dependence on Third Parties

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

We have few employees dedicated to quality control and CMC activities. We rely and intend to continue to rely on third parties to supplement many of these critical functions. If we commence additional clinical trials, we will contract

with third-party, full-service CROs to manage our trials. As a result, we are likely to be dependent on consultants and strategic partners in our development activities, and it may be administratively challenging for us to monitor and coordinate these relationships. If we do not appropriately manage our relationships with third parties, we may not be able to successfully manage development, testing, and preparation of regulatory filings for our product or commercialize any approved product, which would have a material and adverse effect on our business, financial condition, and stock price.

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

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

Risks Related to Our Intellectual Property Rights

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

Due to evolving legal standards relating to the patentability, validity, and enforceability of patents covering pharmaceutical inventions and the claim scope of patents, our ability to enforce our existing patents and to obtain and enforce patents that may issue from any pending or future patent applications is uncertain and involves complex legal, scientific, and factual questions. To date, no consistent policy has emerged regarding the breadth of claims allowed in biotechnology and pharmaceutical patents. We have pending patents for certain indications for our core product candidate and continue to seek patent coverage for various potential therapeutic applications for leronlimab. However, we cannot be sure that any patents will issue from any pending or future patent applications owned by or licensed to us. Even if patents do issue, we cannot be sure that the claims of these patents will be held valid or enforceable by a court of law, will provide us with any significant protection against competing products, or will afford us a commercial advantage over competitive products. If one or more products resulting from our product candidate is approved for sale by the FDA and we do not have adequate intellectual property protection for those products, competitors could duplicate

them for approval and sale in the United States without repeating the extensive testing required of us or our partners to obtain FDA approval, once our data exclusivity period has expired.

If we are sued for infringing on third-party intellectual property rights, it will be costly and time-consuming, and an unfavorable outcome would have a significant adverse effect on our business. We may also undertake infringement or other legal proceedings against third parties, causing us to spend 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 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 expensive and time-consuming and would distract management's attention. Also, in an infringement or misappropriation proceeding, a court may decide that one or more of our patents is invalid, unenforceable, or both, in which case third parties may be able to use our technology without paying license fees or royalties. Even if the validity of our patents is upheld, a court may refuse to stop the other party from using the technology at issue on the ground that the other party's activities are not covered by our patents.

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

Inventions discovered in the course of performance of contracts with third parties may become jointly owned by our strategic partners and us, in some cases, and the exclusive property of one of us, in other cases. Under some circumstances, it may be difficult to determine who owns a particular invention or whether it is jointly owned, and

disputes could arise regarding ownership or use of those inventions. Other disputes may also arise relating to the performance or alleged breach of our agreements with third parties. Any disputes could be costly and time-consuming, and an unfavorable outcome could have a significant adverse effect on our business.

Risks Related to Ownership of Our Common Stock

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

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

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

The market price of our common stock has historically experienced and may continue to experience significant volatility. From June 1, 2023, through July 31, 2024, the market price of our common stock has fluctuated from a high of $0.42 per share to a low of $0.13 per share. The volatile nature of our common share price may cause investment losses for our stockholders. In addition, the market price of stock in small capitalization biotech companies is often driven by investor sentiment, expectation, and perception, all of which may be independent of fundamental, objective, and intrinsic valuation metrics or traditional financial performance metrics, thereby exacerbating volatility. In addition, our common stock is quoted on the OTCQB of the OTC Markets marketplace, which may increase price quotation volatility and could limit liquidity, all of which may adversely affect the market price of our shares.

Since our inception, we have been insolvent and have required debt and equity financing to maintain operations. We expect our debt service obligations and our need for additional funding to finance operations will cause additional 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 satisfy our 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 downward pressure on our stock price. In addition, the exercise of our outstanding warrants and stock options for shares of our common stock, which we have encouraged from time to time through public or private warrant exchange offers, including in July 2024, will result in further dilution of 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 to induce them to invest in our company. The issuance of these senior securities may adversely affect the holders of our common stock as a result of preferential dividend and liquidation rights over the common stock and dilution of the voting power of the common stock.

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

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

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

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

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

- allow us to designate and issue shares of preferred stock, without stockholder approval, which could adversely affect the rights, preferences, and privileges of the holders of our common stock and could make it more difficult or less economically beneficial to acquire or seek to acquire us,
- provide that special meetings of stockholders may be called only by the Board acting pursuant to a resolution approved by the affirmative majority of the entire Board, and
- do not include a provision for cumulative voting in the election of directors. Under cumulative voting, a minority stockholder holding a sufficient number of shares may be able to ensure the election of one or more directors. The absence of cumulative voting may have the effect of limiting the ability of minority stockholders to effect changes in the composition of our Board.

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

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

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

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 1C. CYBERSECURITY

We have established processes for assessing, identifying and managing cybersecurity risks, which are built into our information technology function and are designed to safeguard our information assets and operations from internal and external cyber threats, including protecting employee and patient information from unauthorized access to or attacks on our networks and systems. These processes include physical, procedural and technical safeguards, response plans, regular tests on our systems, incident simulations and routine reviews of our policies and procedures to identify risks and enhance our practices. We also employ processes to identify material risks from cybersecurity threats associated with our use of third-party service providers.

We have engaged external parties, including risk management consultants and computer security firms, to enhance our cybersecurity oversight. In an effort to deter and detect cyber threats, we periodically provide training programs to our employees on issues related to privacy and data protection, cybersecurity risks, and the importance of reporting all incidents immediately. Topics include identifying phishing, password protection, securing confidential data, and mobile security. In addition, we use technology-based tools to mitigate cybersecurity risks and to bolster our employee-based cybersecurity programs. We also perform annual vulnerability assessments, conducted by independent, third-party cybersecurity firms.

Additionally, as part of our overall risk mitigation strategy, the Company obtains certain insurance policies. However, such insurance may not be sufficient in type or amount to cover us fully against claims related to security breaches, cyber-attacks and other related breaches.

The Audit Committee of our Board of Directors provides direct cybersecurity risk oversight. Our management provides timely disclosure and related updates to the Audit Committee regarding potential cybersecurity threats, incidents and general risks.

Our management periodically evaluates information provided by its consultants on evolving cybersecurity risks and, based on its assessment of the processes the Company has put in place, does not believe there are currently any known risks from cybersecurity threats that are reasonably likely to materially affect us or our business strategy, results of operations, or financial condition.

Item 2. PROPERTIES

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

Item 3. LEGAL PROCEEDINGS

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

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Part II

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

Market Information

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

Holders

The number of record holders of our common stock on July 31, 2024 was approximately 1,000.

Dividends

Holders of our common stock are entitled to receive dividends if declared by our Board. While we have no contractual restrictions or restrictions in our governing documents on our ability to pay dividends, other than the preferential rights provided to the holders of our outstanding preferred stock, we have never paid cash dividends to holders of common stock and do not anticipate paying any in the foreseeable future as we retain earnings, if any, for use in our operations.

Also, under Section 170 of the Delaware General Corporation Law (the "DGCL"), we are permitted to pay dividends only out of capital surplus or, if none, out of net profits for the fiscal year in which the dividend is declared or net profits from the preceding fiscal year. As of May 31, 2024, the Company had an accumulated deficit of approximately $891.5 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 5, *Convertible Instruments and Accrued Interest* in this Form 10-K for additional information.

Unregistered Sales of Equity Securities

Issuances of Shares in Convertible Note Exchange Transactions

In July 2024, the Company and the holder of its April 23, 2021 Note, in partial satisfaction of the holder's redemption rights, entered into an exchange agreement pursuant to which a portion of the original note was partitioned into a new note with an aggregate principal amount of $0.5 million. The new note was exchanged concurrently with issuance of a total of approximately 3.9 million shares of common stock. The Company relied on the exemption provided by Section 3(a)(9) of the Securities Act in connection with the exchange transactions.

Warrant Tender Offer

On July 19, 2024, the Company closed a tender offer in which warrants to purchase approximately 127.1 million shares of common stock were exercised at a $0.09387 exercise price, resulting in gross proceeds of approximately $11.9 million and net proceeds of approximately $10.5 million. The Company also issued approximately 25.4 million shares of common stock as bonus shares in the tender offer. The Company relied on the exemption provided by Section 4(a)(2) of the Securities Act and Rule 506 thereunder in connection with the exercise of the warrants for shares of common stock and issuance of bonus shares in the tender offer.

Item 6. [Reserved]

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

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

Overview

The Company is a clinical stage biotechnology company focused on the clinical development and potential commercialization of its product candidate, leronlimab, which is being studied for oncology and inflammation, as well as other potential indications, including but not limited to HIV and MASH.

Our current business strategy is the clinical development of leronlimab, which may include the following:

1. Conducting a Phase II study of leronlimab in patients with relapsed/refractory microsatellite stable colorectal cancer;
2. Conducting a Phase II study exploring leronlimab and its effects on inflammation; and
3. Continuing our work researching and developing a new or modified long-acting version of leronlimab.

Other programs that may be pursued include steatosis and liver fibrosis associated with MASH, either alone or as a combination therapy; and for metastatic triple-negative breast cancer with current standard of care, and/or exploring other trials with current standard of care and other cancer and immunologic indications.

We will need significant additional funding to execute the business strategy described above, including conducting additional pre-clinical studies and clinical trials, in furtherance of our efforts to obtain FDA approval to commercialize leronlimab. In addition to traditional fundraising the Company will pursue non-dilutive financing opportunities, such as license agreements and co-development or strategic partnerships, to help implement its strategy.

Fiscal 2024 Overview

Actions taken by the Company during fiscal 2024 included:

- Hiring of Dr. Jacob Lalezari as Chief Executive Officer;
- Hiring of Mitchell Cohen as interim Chief Financial Officer;
- Revamping our clinical strategy to focus on oncology, inflammation, and furthering the development of a modified, longer-acting molecule, potentially for use in the HIV population among other potential applications;
- Entering into several strategic partnerships with academic institutions to further the development of leronlimab on a cost-effective basis;
- Resolution of our dispute with Samsung BioLogics Co., Ltd. on terms favorable to the Company;
- Resolution of our dispute with Amarex Clinical Research LLC on terms favorable to the Company;
- Furthering the development of a long-acting modified therapeutic; and
- Closing multiple financing transactions to provide funding for the Company's business operations and initiatives.

Removal of Clinical Hold on HIV program

In March 2022, the FDA notified the Company that it had placed a partial clinical hold on the Company's HIV program. The FDA's hold letter requested that the Company provide the agency with an aggregate analysis of cardiovascular events across all leronlimab clinical programs, a Safety Surveillance Plan, an aggregate safety data analysis, an updated Investigator's Brochure, annual reports, a benefit-risk assessment, and a general investigational plan. In November 2023, the Company submitted a response to the FDA's clinical hold letter addressing comments received through previous incomplete response communications and an informal meeting with the agency primarily related to the benefit-risk assessment for the intended HIV population and a proposed new HIV clinical trial protocol.

The Company received a letter from the FDA in December 2023 notifying the Company that: (i) the "partial hold" implemented by the FDA in March 2022 had been lifted; and (ii) a new "full hold" had been applied as it related to the newly proposed clinical trial protocol submitted in November 2023 alongside the Company's complete response to the partial clinical hold. The Company submitted its revised protocol to the FDA in January 2024.

On February 27, 2024, the Company received confirmation from the FDA that its clinical hold on leronlimab had been lifted. The Company now intends to pursue its plans for the further development of leronlimab as a therapy described above. The Company believes its proposed inflammation study will allow the Company to further establish leronlimab's mechanism of action in a cost-effective manner.

Cancer program developments

In December 2023, the Company entered into a partnership with Albert Einstein College of Medicine and Montefiore Medical Center, located in New York. The Company is providing leronlimab to support a pre-clinical study evaluating the efficacy of leronlimab independently and in combination with temozolomide in treating glioblastoma multiforme, also known as grade IV astrocytoma ("GBM"), in infected humanized mice. The study will involve three groups of humanized mice: one control group, one group that will receive only leronlimab, and another group that will receive a combination of leronlimab and temozolomide. The primary objective of this study is to evaluate the effect of leronlimab on the primary tumor growth and occurrence of metastases on CCR5+ and CCR5- cells in humanized mice. Upon completion of the study, the academic institutions will provide the Company with a research report outlining the study results, and they will have the right to publish and present the study results. GBM is the most common type of primary malignant brain tumor and is aggressive and fast-growing. This study is expected to take place in the 2024 calendar year.

MASH program developments

The Company continues to evaluate whether to perform a pre-clinical study in MASH that would be significantly less capital-intensive than a human clinical trial and could generate potentially valuable data leading to partnerships or other potential non-dilutive financing opportunities.

Settlement Agreement with Samsung BioLogics Co., Ltd.

On April 3, 2024, the Company and Samsung executed a side letter agreement (the "Letter Agreement"), wherein the parties reached agreement for an orderly process for winding down services and a restructuring of the amount payable by the Company to Samsung (the "Total Balance"). The Total Balance due to Samsung, as restructured under the Letter Agreement, is now approximately $43.8 million. Except for a single $250,000 payment due on or before December 31, 2024, the entirety of the Total Balance is conditional, and will only be due and payable, upon the Company achieving a qualifying "Revenue" event, as that term is defined in the Letter Agreement. Under the Letter Agreement, the Company has agreed to pay 20% of its qualifying Revenue generated in each calendar year, if any, with such payments to be applied to reduce the Total Balance until it is repaid in full. Interest will not accrue on the Total Balance throughout the prospective repayment period. Refer to Part II, Item 8, Note 10, *Commitments and Contingencies* in this report for additional information.

Settlement Agreement with Amarex Clinical Research LLC

On July 2, 2024, the Company and Amarex Clinical Research, LLC ("Amarex"), the Company's former clinical research organization ("CRO"), entered into an agreement settling a lawsuit filed by the Company in October 2021 (the "Settlement Agreement").The terms of the Settlement Agreement include: (i) the payment by Amarex of $12,000,000 to the Company, of which $10,000,000 was paid on execution of the Settlement Agreement and the balance will be paid on or before July 2, 2025; (ii) the release of the Company's surety bond posted in the lawsuit and the return of the Company's cash collateral in the amount of $6,500,000 provided as security to the surety; (iii) the crediting of all amounts claimed by Amarex as due and payable for its CRO services, totaling approximately $14,000,000, against the Company's outstanding balance, reducing the balance to zero, with no funds required to be paid by the Company; and (iv) a mutual release of claims, resolving all legal claims between the parties.

Long-acting CCR5 antagonist developments

In March 2023, the Company entered into a joint development agreement with a third-party generative artificial intelligence ("AI") drug discovery and development company to develop one or more longer-acting molecules. The Company believes working with a partner with AI capabilities will result in the expedited development of a modified, longer-acting therapeutic, and could lead to greater acceptance by patients due to the requirement for less frequent injections. The services provided by the third party may yield extended intellectual property protection, thereby increasing the value of the Company's patent portfolio. In December 2023, the Company received various iterations of potential long-acting therapeutics, on which the Company will be performing assays to determine the suitability and feasibility of the long-acting therapeutic candidates for further development.

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

Results of operations for the fiscal years ended May 31, 2024, and 2023

Fluctuations in Operating Results

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

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

(in thousands, except for per share data)	Years ended May 31, 2024	2023	Change $	Change %
Operating expenses:				
General and administrative	$ 10,789	$ 17,136	$ (6,347)	(37)%
Research and development	7,240	2,632	4,608	175
Depreciation	29	43	(14)	(33)
Amortization	—	132	(132)	(100)
Inventory charge	—	20,633	(20,633)	(100)
Total operating expenses	18,058	40,576	(22,518)	(55)
Operating loss	(18,058)	(40,576)	22,518	55
Interest and other expenses:				
Interest on convertible notes	(4,659)	(4,624)	(35)	(1)
Amortization of discount on convertible notes	(1,076)	(2,126)	1,050	49
Amortization of debt issuance costs	(572)	(69)	(503)	(729)
Issuance costs for private placement of shares and warrants through placement agent	(2,819)	(9,678)	6,859	71
Loss on induced conversion	(6,680)	(5,312)	(1,368)	(26)
Finance charges	(2,367)	(8,689)	6,322	73
Loss on note extinguishment	(13,374)	—	(13,374)	(100)
Loss on derivatives	(236)	(8,750)	8,514	97
Total interest and other expenses	(31,783)	(39,248)	7,465	19
Loss before income taxes	(49,841)	(79,824)	29,983	38
Income tax benefit	—	—	—	—
Net loss	$ (49,841)	$ (79,824)	$ 29,983	38 %
Basic and diluted:				
Weighted average common shares outstanding	969,509	836,528	132,981	16
Loss per share	$ (0.05)	$ (0.10)	$ 0.05	50 %

General and administrative expenses

G&A expenses consisted of the following:

(in thousands)	Years ended May 31, 2024	2023	Change $	Change %
Salaries, benefits, and other compensation	$ 2,507	$ 4,114	$ (1,607)	(39)%
Stock-based compensation	2,415	4,222	(1,807)	(43)
Legal fees	2,089	2,805	(716)	(26)
Insurance	1,850	2,399	(549)	(23)
Other	1,928	3,596	(1,668)	(46)
Total general and administrative	$ 10,789	$ 17,136	$ (6,347)	(37)%

The decreases in G&A expenses for the fiscal year ended May 31, 2024, compared to the prior fiscal year, were primarily due to reductions in other, stock-based compensation, salaries, benefits, and other compensation, and legal fees. The decrease in other expenses was primarily the result of a reduction in audit-related fees. The decreases in stock-based compensation and salaries, benefits, and other compensation were primarily related to headcount reductions in an effort by the Company to preserve cash and align resources with corporate priorities. The decrease in legal fees was primarily due to decreased fees related to the SEC and DOJ investigations, offset by less fees covered by the Company's insurance carrier(s) and increased fees related to the Amarex litigation.

Research and development expenses

R&D expenses consisted of the following:

(in thousands)	Years ended May 31, 2024	2023	Change $	Change %
Clinical	$ 1,898	$ (92)	$ 1,990	(2,163)%
Non-clinical	493	136	357	263
CMC	3,867	1,687	2,180	129
License and patent fees	982	901	81	9
Total research and development	$ 7,240	$ 2,632	$ 4,608	175 %

The increase in R&D expense in the fiscal year ended May 31, 2024, compared to the prior fiscal year, was primarily related to an increase in CMC and clinical expenses. The increase in CMC expenses primarily relate to storage costs related to inventory. The increase in clinical expenses was primarily related to a credit balance in the prior year due to a reduction in CRO costs for the Brazilian COVID-19 trials, resulting in vendor credits, and Brazilian COVID-19 CRO close-out costs incurred in the current period, offset by decreases in costs related to the HIV program partial clinical hold, and studies completed, paused, or closed in the prior year.

The future trend of our R&D expenses is dependent on the costs of any future clinical trials, our decision-making and timing of which indications on which to focus our future efforts toward the development and study of leronlimab, which may include pre-clinical and clinical studies for oncology, MASH and HIV related indications, as well as efforts to develop a long-acting new or modified therapeutic, the timing and outcomes of such efforts, and the timing of the final close-out of closed studies.

Inventory charge

The decrease in the inventory charge for the fiscal year ended May 31, 2024, compared to the same period in the prior year was attributable to the full inventory write-off in the prior year because the pre-launch inventories no longer qualified for inventory capitalization following the withdrawal of the Company's BLA submission to the FDA. See Part II, Item 8, Note 3, *Inventories, net*, for additional information.

Interest and other expense

Interest and other expenses consisted of the following:

	Years ended May 31,		Change	
(in thousands)	**2024**	**2023**	**$**	**%**
Interest on convertible notes payable	$ (4,659)	$ (4,624)	$ (35)	1 %
Amortization of discount on convertible notes	(1,076)	(2,126)	1,050	(49)
Amortization of debt issuance costs	(572)	(69)	(503)	729
Issuance costs for private placement of shares and warrants through placement agent	(2,819)	(9,678)	6,859	71
Loss on induced conversion	(6,680)	(5,312)	(1,368)	26
Finance charges	(2,367)	(8,689)	6,322	(73)
Loss on note extinguishment	(13,374)	—	(13,374)	(100)
Loss on derivatives	(236)	(8,750)	8,514	(97)
Total interest and other expenses	$ (31,783)	$ (39,248)	$ 7,465	(19)%

The decrease in interest and other expenses for the fiscal year ended May 31, 2024, compared to the prior fiscal year, was primarily due to decreases in non-cash loss on derivatives, issuance costs for private placement of shares and warrants through placement agent, and finance charges, partially offset by increases in loss on note extinguishment and loss on induced conversion. The decrease in loss on derivatives is due to the issuance of fewer liability-classified warrants in the current period. The decrease in issuance costs for private placement of shares and warrants through placement agent is due to smaller PIPE transactions in the current fiscal year compared to the prior fiscal year. The decrease in finance charges is due to the Company's taking ownership of the surety bond in the fourth quarter of the prior fiscal year. The increase in loss on note extinguishment resulted from the Company retiring outstanding convertible debt by converting notes outstanding to common stock and warrants, and due to the final closing price of the related private placements being lower than the initial closing price. The increase in loss on induced conversion resulted from the Company settling a larger balance of the outstanding convertible debt with common stock in the current fiscal year compared to the prior fiscal year.

Refer to Part II, Item 8, Note 5, *Convertible Instruments and Accrued Interest* and Note 13, *Subsequent Events* in this report for additional information.

Liquidity and Capital Resources

As of May 31, 2024, we had a total of approximately $3.1 million in cash, $6.7 million in restricted cash, and approximately $84.2 million in short-term liabilities consisting primarily of approximately $45.0 million representing the principal of and accrued interest on convertible notes payable, net of unamortized debt discount, and approximately $32.4 million in accounts payable and accrued liabilities and compensation. We will continue to incur operating losses and the Company will require a significant amount of additional capital in the future as we continue to seek approval to commercialize leronlimab. Despite the Company's negative working capital position, vendor relations remain relatively accommodative given liquidity constraints. We cannot be certain, however, that future funding will be available to us when needed on terms that are acceptable to us, or at all. We sell securities and incur debt when the terms of such agreements are deemed favorable to both parties under then current circumstances and as necessary to fund our current and projected cash needs.

Cash

The Company's cash and restricted cash position of approximately $3.1 million and $6.7 million, respectively, on May 31, 2024, increased by approximately $0.6 million and increased by $0.2 million, respectively, compared to the cash balance of approximately $2.5 million and restricted cash balance of approximately $6.5 million on May 31, 2023.

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

(in thousands)	Years ended May 31, 2024	Years ended May 31, 2023	Change $
Net cash (used in) provided by:			
Net cash used in operating activities	$ (10,982)	$ (25,110)	$ 14,128
Net cash provided by/ used in investing activities	$ —	$ —	$ —
Net cash provided by financing activities	$ 11,748	$ 29,927	$ (18,179)

Cash used in operating activities

Net cash used in operating activities totaled approximately $11.0 million during the fiscal year ended May 31, 2024, representing an improvement of approximately $14.1 million compared to the prior year. The decrease in the net amount of cash used was primarily attributable to decreased G&A, and working capital fluctuations, all of which are highly variable, and which led to a significant decrease in our net loss. Refer to *General and administrative* above for further discussion.

Cash provided by financing activities

Net cash provided by financing activities totaled approximately $11.7 million, a decrease of approximately $18.2 million compared to the prior year. The decrease in net cash provided was primarily the result of raising less funds from private placements of common stock and warrants, and a decrease in cash received from warrant transactions and exercises.

Pre-launch inventories

The Company previously capitalized pre-launch inventories that were subsequently charged-off in October 2022 for GAAP accounting purposes due to no longer qualifying for pre-launch inventory capitalization resulting from the withdrawal of the BLA submission. Work-in-progress and finished drug product inventories continue to be physically maintained, can be used for clinical trials, and can be sold commercially upon regulatory approval if the shelf-lives can be extended as a result of the performance of on-going stability tests. Raw materials continue to be maintained so that they can be used in the future if needed. For additional information, refer to Part II, Item 8, Note 3, *Inventories, net*.

Convertible debt

April 2, 2021 Convertible Note

On April 2, 2021, we issued a convertible note with a principal amount of $28.5 million resulting in net cash proceeds of $25.0 million, after $3.4 million of debt discount and $0.1 million of offering costs. The note accrues interest daily at a rate of 10% per annum, contains a stated conversion price of $10.00 per share, and matures in April 2025. The April 2, 2021 Note required monthly debt reduction payments of $7.5 million for the six months beginning in May 2021, which could also be satisfied by payments on other notes held by the noteholder or its affiliates. Beginning six months after the issuance date, the noteholder may request monthly redemptions of up to $3.5 million. As of May 31, 2024, the outstanding balance of the April 2, 2021 Note, including accrued interest, was approximately $7.5 million.

April 23, 2021 Convertible Note

On April 23, 2021, we issued a convertible note with a principal amount of $28.5 million resulting in net cash proceeds of $25.0 million, after $3.4 million of debt discount and $0.1 million of offering costs. The note accrues interest daily at a rate of 10% per annum, contains a stated conversion price of $10.00 per share, and matures in April 2025. Beginning six months after the issuance date, the noteholder may request monthly redemptions of up to $7.0 million. As of May 31, 2024, the outstanding balance of the April 23, 2021 Note, including accrued interest, was approximately $38.0 million.

Refer to Part II, Item 8, Note 5, *Convertible Instruments and Accrued Interest* and Note 13, *Subsequent Events* in this report for additional information.

Common stock

We have 1,750.0 million authorized shares of common stock. The table below summarizes intended uses of common stock.

(in millions)	As of May 31, 2024
Issuable upon:	
Warrant exercises	361.4
Convertible preferred stock and undeclared dividends conversion	37.0
Outstanding stock option exercises	25.8
Reserved for issuance pursuant to future stock-based awards under equity incentive plan	12.5
Reserved and issuable upon conversion of outstanding convertible notes	12.0
Total shares reserved for future uses	448.7
Common stock outstanding	1,058.6

As a result, as of May 31, 2024, we had approximately 242.7 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.

Refer to Part II, Item 8, Note 13, *Subsequent Events* in this report for additional information.

Off-Balance Sheet Arrangements

As of May 31, 2024, 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 5, *Convertible Instruments and Accrued Interest,* Note 10, *Commitments and Contingencies* and Note 13, *Subsequent Events* included in Part II, Item 8 of this Form 10-K.

Legal Proceedings

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

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

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 $49.8 million for the fiscal year ended May 31, 2024, and had an accumulated deficit of $891.5 million as of May 31, 2024. 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 had 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 pursuing other development and commercialization initiatives, and obtaining adequate funding to cover the costs of the legal proceedings in which we are involved, all of which individually or in combination could materially impede our ability to achieve profitability. The Company's failure to raise additional capital could also affect our relationships with key vendors and disrupt 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 development activities and its working capital needs primarily from the sale of equity and debt securities. As of July 31, 2024, the Company had only approximately 202.2 million shares of common stock, authorized for issuance under its certificate of incorporation, as amended, and available for future uses. The sale of equity and convertible debt securities to raise additional capital is likely to result in dilution to stockholders and those securities may have rights senior to the common stock. If the Company raises funds through the issuance of additional preferred stock, convertible debt securities, or other debt or equity financing, the related transaction documents could contain covenants restricting its operations.

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

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

New Accounting Pronouncements

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

Critical Accounting Estimates

We prepare our consolidated financial statements in accordance with U.S. generally accepted accounting principles, which require our management to make estimates that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the balance sheet dates, as well as the reported amounts of revenues and expenses during the reporting periods. To the extent that there are material differences between these estimates and actual results, our financial condition or results of operations would be affected. We base our estimates on our own historical experience and other assumptions that we believe are reasonable after taking account of our circumstances and expectations for the future based on available information. We evaluate these estimates on an ongoing basis.

We consider an accounting estimate to be critical if: (i) the accounting estimate requires us to make assumptions about matters that were highly uncertain at the time the accounting estimate was made, and (ii) changes in the estimate that are reasonably likely to occur from period to period or use of different estimates that we reasonably could have used in the current period, would have a material impact on our financial condition or results of operations. There are items within our financial statements that require estimation but are not deemed critical, as defined above.

For a detailed discussion of our significant accounting policies and related judgments and estimates used in preparation of the consolidated financial statements, accounting policies and related judgments, see Part II, Item 8, Note 2, *Summary of Significant Accounting Policies,* in this Form 10-K.

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, 2024, we had $3.1 million in cash and $6.7 million in restricted cash.

Common Stock Price Volatility

The Compensation Committee of the Board of Directors has historically granted stock incentive awards to management and employees in the form of stock options. Stock-based compensation expense is recognized for stock options over the requisite service period using the fair value of these grants as estimated at the awards grant date using the Black-Scholes pricing model and the market value of our publicly traded common stock on the date of grant. In addition to the market value of our common stock, one of the inputs into this model that significantly impacts the fair value of the options is the expected volatility of our common stock over the estimated life of the option. We estimate expected volatility by using the most recent historical experience. Since November 2019, our common stock has experienced periods of high trading volatility. Grants of stock options and warrants during the fiscal year ended May 31, 2024, 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.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of

CytoDyn, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of CytoDyn, Inc. (the "Company") as of May 31, 2024, the related consolidated statements of operations, changes in stockholders' deficit and cash flows for the year ended May 31, 2024, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of May 31, 2024, and the results of its operations and its cash flows for the year ended May 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has a significant working capital deficiency, has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our 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 financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit 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 audit 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 audit provides a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the 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 financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Marcum LLP

We have served as the Company's auditor since 2024.

Hartford, CT
August 15, 2024

Report of Independent Registered Public Accounting Firm (PCAOB ID 324)

To the Board of Directors and Stockholders

CytoDyn Inc.

Vancouver, Washington

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of CytoDyn, Inc. (the "Company") as of May 31, 2023, the related consolidated statements of operations, changes in stockholders' deficit 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, 2023, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

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

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

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting for the fiscal year ended May 31, 2023. As part of our audit, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting.

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

Critical Audit Matters

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

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

Critical Audit Matter Description

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

How the Critical Audit Matter was Addressed in the Audit

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

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

/s/ Macias Gini & O'Connell LLP

We served as the Company's auditor from 2022 to 2023.

San Jose, California

September 13, 2023

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

	May 31, 2024	May 31, 2023
Assets		
Current assets:		
Cash	$ 3,110	$ 2,541
Restricted cash	6,704	6,507
Prepaid expenses	463	1,167
Prepaid service fees	538	590
Total current assets	10,815	10,805
Other non-current assets	321	487
Total assets	$ 11,136	$ 11,292
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 29,561	$ 62,725
Accrued liabilities and compensation	2,810	6,669
Accrued interest on convertible notes	15,227	10,598
Accrued dividends on convertible preferred stock	6,791	5,308
Convertible notes payable, net	29,793	34,417
Derivative liability - equity instruments	—	79
Total current liabilities	84,182	119,796
Notes payable, net	—	714
Operating leases	141	283
Other liabilities (Note 10)	43,571	—
Total liabilities	127,894	120,793
Commitments and Contingencies (Note 10)		
Stockholders' deficit:		
Preferred stock, $0.001 par value; 5,000 shares authorized:		
Series B convertible preferred stock, $0.001 par value; 400 authorized; 19 issued and outstanding at May 31, 2024 and May 31, 2023	—	—
Series C convertible preferred stock, $0.001 par value; 8 authorized; 6 issued and outstanding at May 31, 2024 and May 31, 2023	—	—
Series D convertible preferred stock, $0.001 par value; 12 authorized; 9 issued and outstanding at May 31, 2024 and May 31, 2023	—	—
Common stock, $0.001 par value; 1,750,000 shares authorized; 1,059,002 and 919,053 issued, and 1,058,559 and 918,610 outstanding at May 31, 2024 and May 31, 2023, respectively	1,059	919
Treasury stock, $0.001 par value; 443 shares at May 31, 2024 and May 31, 2023	—	—
Additional paid-in capital	773,714	731,270
Accumulated deficit	(891,531)	(841,690)
Total stockholders' deficit	(116,758)	(109,501)
Total liabilities and stockholders' deficit	$ 11,136	$ 11,292

See accompanying notes to consolidated financial statements.

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

	Years ended May 31,	
	2024	2023
Operating expenses:		
General and administrative	$ 10,789	$ 17,136
Research and development	7,240	2,632
Depreciation	29	43
Amortization	—	132
Inventory charge	—	20,633
Total operating expenses	18,058	40,576
Operating loss	(18,058)	(40,576)
Interest and other expenses:		
Interest on convertible notes	(4,659)	(4,624)
Amortization of discount on convertible notes	(1,076)	(2,126)
Amortization of debt issuance costs	(572)	(69)
Issuance costs for private placement of shares and warrants through placement agent (Note 6)	(2,819)	(9,678)
Loss on induced conversion	(6,680)	(5,312)
Finance charges	(2,367)	(8,689)
Loss on note extinguishment	(13,374)	—
Loss on derivatives	(236)	(8,750)
Total interest and other expenses	(31,783)	(39,248)
Loss before income taxes	(49,841)	(79,824)
Income tax benefit	—	—
Net loss	$ (49,841)	$ (79,824)
Basic and diluted:		
Weighted average common shares outstanding	969,509	836,528
Loss per share	$ (0.05)	$ (0.10)

See accompanying notes to consolidated financial statements.

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

	Preferred stock		Common stock		Treasury stock		Additional paid-in capital	Accumulated deficit	Total stockholders' (deficit) equity
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance May 31, 2022	35	$ —	720,028	$ 720	443	$ —	$ 671,013	$ (766,131)	$ (94,398)
Issuance of stock for convertible note repayment	—	—	17,260	17	—	—	3,983	—	4,000
Loss on induced conversion	—	—	—	—	—	—	5,312	—	5,312
Warrants issued in Note offering	—	—	—	—	—	—	114	—	114
Stock issued for compensation	—	—	2,751	3	—	—	982	—	985
Stock issued for private offerings	—	—	157,390	157	—	—	37,067	—	37,224
Offering costs related to stock issuance	—	—	—	—	—	—	(1,760)	—	(1,760)
Conversion of Series C preferred stock to common stock	(1)	—	1,136	1	—	—	(1)	—	—
Private warrant exchanges, net of offering costs	—	—	13,094	13	—	—	2,794	—	2,807
Warrant exercises	—	—	1,898	2	—	—	437	—	439
Make-whole shares related to private warrant exchange	—	—	23	—	—	—	—	—	—
Deemed dividend paid in common stock due to down round provision, recorded in additional paid-in capital	—	—	5,154	6	—	—	(6)	—	—
Preferred stock dividends accrued and paid in common stock upon conversion	—	—	319	—	—	—	(1,331)	—	(1,331)
Reclassification of warrants from liability to equity	—	—	—	—	—	—	8,756	—	8,756
Stock-based compensation	—	—	—	—	—	—	3,290	—	3,290
Finance charges related to warrant issuance for surety bond backstop agreement	—	—	—	—	—	—	4,885	—	4,885
Reclassification of prior period preferred stock dividends	—	—	—	—	—	—	(4,265)	4,265	—
Net loss for May 31, 2023	—	—	—	—	—	—	—	(79,824)	(79,824)
Balance May 31, 2023	34	$ —	919,053	$ 919	443	$ —	$ 731,270	$ (841,690)	$ (109,501)

See accompanying notes to consolidated financial statements.

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

	Preferred stock		Common stock		Treasury stock		Additional paid-in capital	Accumulated deficit	Total stockholders' (deficit) equity
	Shares	Amount	Shares	Amount	Shares	Amount			
Issuance of stock for convertible note repayment	—	$ —	34,309	$ 34	—	$ —	$ 5,216	$ —	$ 5,250
Loss on induced conversion	—	—	—	—	—	—	6,680	—	6,680
Warrants issued in Note offering	—	—	—	—	—	—	359	—	359
Note conversion	—	—	24,410	24	—	—	7,126	—	7,150
Stock issued for compensation	—	—	2,608	3	—	—	487	—	490
Stock issued for private offerings	—	—	75,622	76	—	—	21,621	—	21,697
Discount related to private offering modification	—	—	—	—	—	—	137	—	137
Warrant exercises	—	—	3,000	3	—	—	297	—	300
Preferred stock dividends accrued	—	—	—	—	—	—	(1,483)	—	(1,483)
Reclassification of warrants from liability to equity	—	—	—	—	—	—	79	—	79
Stock-based compensation	—	—	—	—	—	—	1,925	—	1,925
Net loss for May 31, 2024	—	—	—	—	—	—	—	(49,841)	(49,841)
Balance May 31, 2024	34	$ —	1,059,002	$ 1,059	443	$ —	$ 773,714	$ (891,531)	$ (116,758)

See accompanying notes to consolidated financial statements.

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

	Years ended May 31,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (49,841)	$ (79,824)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization and depreciation	29	175
Amortization of debt issuance costs	572	69
Issuance costs for private placement of shares and warrants through placement agent	2,819	9,678
Amortization of discount on convertible notes	1,076	2,126
Loss on derivatives	236	8,750
Loss on induced conversion	6,680	5,312
Non-cash finance charges	—	4,885
Loss on note extinguishment	13,374	—
Change in fair value of derivative liabilities	—	6
Inventory charge	—	20,633
Stock-based compensation	2,415	4,275
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	893	1,902
Accounts payable, and accrued expenses, and other liabilities	10,765	(3,097)
Net cash used in operating activities	(10,982)	(25,110)
Cash flows from investing activities:		
Net cash Provided by/used in investing activities	—	—
Cash flows from financing activities:		
Proceeds from warrant transactions, net of offering costs	—	2,807
Proceeds from sale of common stock and warrants, net of issuance costs	9,137	25,786
Proceeds from warrant exercises	300	439
Proceeds held in trust	300	—
Proceeds from convertible note and warrant issuances, net of issuance costs	2,011	895
Net cash provided by financing activities	11,748	29,927
Net change in cash and restricted cash	766	4,817
Cash and restricted cash at beginning of period	9,048	4,231
Cash and restricted cash at end of period	$ 9,814	$ 9,048
Cash and restricted cash consisted of the following:		
Cash	$ 3,110	$ 2,541
Restricted cash	6,704	6,507
Total cash and restricted cash	$ 9,814	$ 9,048
Supplemental disclosure:		
Cash paid for interest	$ 45	$ 19
Non-cash investing and financing transactions:		
Derivative liability associated with warrants	$ 102	$ 8,750
Issuance of common stock for principal of convertible notes	$ 5,250	$ 4,000
Accrued dividends on Series C and D convertible preferred stock	$ 1,483	$ 1,490
Dividend paid in common stock on Series B and C convertible preferred stock conversions	$ —	$ 159
Warrants issued to placement agent	$ 1,783	$ 7,640
Warrants issued for surety bond backstop agreement	$ —	$ 4,885
Deemed dividend on common stock issued due to down round provision, recorded in additional paid-in capital	$ —	$ 5,417
Note conversion to common stock and warrants	$ 3,302	$ —

See accompanying notes to consolidated financial statements.

CYTODYN INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
AS OF MAY 31, 2024

Note 1. Organization

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

The Company is currently working to further establish leronlimab via clinical development of its effects on chronic inflammation, oncology, and a number of other potential exploratory indications. Historically, the Company has investigated leronlimab as a viral entry inhibitor for treatment of HIV, believed to competitively bind to the N-terminus and second extracellular loop of the CCR5 receptor. For immunology, the CCR5 receptor is believed to be implicated in immune-mediated illnesses such as MASH. Leronlimab is being or has been studied in MASH, solid tumors in oncology, COVID-19, Long-COVID, and other HIV indications where CCR5 is believed to play an integral role in the pathogenesis of disease.

Note 2. Summary of Significant Accounting Policies

Principles of Consolidation

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

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 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 $49.8 million and $79.8 million for the fiscal years ended May 31, 2024, and 2023, respectively, and has an accumulated deficit of approximately $891.5 million as of May 31, 2024. These factors, among others, including the various matters discussed in Note 10, *Commitments and Contingencies,* 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 continuance as a going concern is dependent upon its ability to obtain additional operating capital, complete the development of its product candidate, leronlimab, obtain approval to commercialize leronlimab from regulatory agencies, continue to outsource manufacturing of leronlimab, and ultimately generate revenues and attain profitability. The Company plans to continue to engage in research and development activities related to leronlimab and a new or modified longer-acting therapeutic for multiple indications and expects to incur significant research and development expenses in the future, primarily related to its regulatory compliance, including performing additional pre-clinical and clinical studies in various indications, and seeking regulatory approval for its product candidate for commercialization. These research and development activities are subject to significant risks and uncertainties. The Company intends to finance its future development activities and its working capital needs primarily from the sale of equity and debt securities, combined with additional funding from other sources. However, there can be no assurance that the Company will be successful in these endeavors.

Use of Estimates

The preparation of the consolidated financial statements in accordance with accounting principles generally accepted in the United States ("U.S. GAAP" or "GAAP") requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, and the disclosure of contingent assets and liabilities at the date of consolidated financial statements, and the reported amounts of revenue and expenses during the reporting period. Estimates are assessed each period and updated to reflect current information, such as the status of our analysis of the

results of our clinical trials and/or discussions with the FDA, which could have an impact on the Company's significant accounting estimates and assumptions. The Company's estimates are based on historical experience and on various other assumptions that are believed to be reasonable under the circumstances. Significant estimates include, but are not limited to, those relating to stock-based compensation, the assumptions used to value warrants and warrant modifications. Actual results could differ from these estimates.

Cash and Restricted Cash

Cash is maintained at federally insured financial institutions and, at times, balances may exceed federally insured limits. The Company has never experienced any losses related to cash balances. Balances in excess of federally insured limits were approximately $2.9 million of the cash balance and approximately $6.7 million of the restricted cash balance at May 31, 2024. Balances in excess of federally insured limits were approximately $2.3 million of the cash balance and approximately $5.5 million of the restricted cash balance at May 31, 2023.

As of May 31, 2024, the Company recorded approximately $6.7 million of restricted cash. The restricted cash balance is related to cash held as collateral in connection with a surety bond that was posted as required in the litigation with Amarex Clinical Research, LLC ("Amarex") and will remain as restricted cash until the litigation is resolved. On July 2, 2024, the legal matter was resolved and the surety bond was released to the Company, in full, as part of the settlement agreement.

Inventories

Capitalized Pre-launch Inventories

Pre-launch inventories comprised raw materials required to commercially produce leronlimab and substantially completed commercially produced leronlimab in anticipation of commercial sales of the product upon potential regulatory approval as a combination therapy for HIV patients in the United States, and potential emergency use authorizations for COVID-19. The Company's pre-launch inventories consisted of (1) raw materials purchased for commercial production, (2) work-in-progress materials which consist of bulk drug substance, which is the manufactured drug stored in bulk storage, and (3) drug product, which is the manufactured drug in unlabeled vials. The consumption of raw materials during production is classified as work-in-progress until saleable. Once it is determined to be in saleable condition, following regulatory approval, inventory is classified as finished goods. Inventories, net of write-offs had a zero balance for the fiscal years ended May 31, 2024 and 2023.

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 no longer qualifies for capitalization.

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

As one stage of the manufacturing process, the Company produces work-in-progress materials which consist of bulk drug substance, which is the manufactured drug stored in bulk storage. The initial shelf-life of bulk drug substance is established based on periodically performed stability studies and is set at four years from the date of manufacturing. Bulk drug substance is subject to deep freeze stability studies performed on a periodic basis in accordance with the established stability protocols. If drug substance meets suitability criteria beyond the initial shelf-life, its shelf-life is

extended by another four years. Regardless of the number of stability studies performed, if drug substance continues to meet prespecified suitability parameters it may be used in manufacturing; if drug substance fails to meet suitability criteria beyond its assigned shelf-life at that time, 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 and are treated and tested for suitability. Once resins are used in the manufacturing process, their shelf-life is measured by a validated predetermined number of manufacturing cycles they are usable for, conditional on appropriate storage solution under controlled environment between production campaigns, as well as by performing pre-production usability testing. Before a manufacturing campaign, each resin is tested for suitability. Regardless of the number of cycles, if a resin fails to meet prespecified suitability parameters it may not be used in manufacturing; likewise, even if the resin meets suitability criteria beyond the lifetime cycles, it may no longer be used. The cost of the resins used in a manufacturing campaign is allocated to the cost of the drug product in vials.

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

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

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 payment amount 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, 2024, the carrying value of the Company's assets and liabilities approximate their fair value due to the short-term maturity of the instruments. Debt is reported at amortized cost in the consolidated balance sheets which approximate fair value. The remaining financial instruments are reported in the consolidated balance sheets at amounts

that approximate current fair values. The fair value hierarchy specifies three levels of inputs that may be used to measure fair value as follows:

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

In accordance with the prescribed accounting guidance, the Company measured the fair value of the liability classified warrants using the fair value hierarchy during the fiscal years ended May 31, 2024, and 2023.

Leases

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

Stock-Based Compensation

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

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

Debt

The Company historically issued promissory notes at a discount and incurred direct debt issuance costs. Debt discount and issuance costs are netted against the debt and amortized over the life of the promissory note.

Warrants

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance included in ASC 480, *Distinguishing Liabilities from Equity* and ASC 815, *Derivatives and Hedging*. The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, whether the warrants meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding. Warrants that meet all of the criteria for equity classification are required to be recorded as a component of additional paid-in capital at the time of issuance. For issued

or modified warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded at their initial fair value on the date of issuance and remeasured each balance sheet date thereafter.

Offering Costs

The Company periodically incurs direct incremental costs associated with the sale of shares of common stock and warrants to purchase shares of common stock; refer to Note 6*, Private Placements of Common Stock and Warrants* for additional information. The costs are recorded as a component of equity upon receipt of the proceeds if the security is classified as equity when the sale occurs or expensed as issuance costs if the security is classified as a liability when the sale occurs.

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 2024 and 2023 tax years. The net tax expense for the fiscal years ended May 31, 2024, and 2023, was zero. As of May 31, 2024, and 2023, the Company has a full valuation allowance as management does not consider it more likely than not that the benefits from the deferred tax assets will be realized.

Basic and Diluted Net Loss Per Share

The Company calculates basic net loss per share by dividing the net loss by the weighted-average number of common shares outstanding during the period, without consideration of potential dilutive securities. Diluted net loss per share is computed by dividing the net loss by the sum of the weighted-average number of common shares outstanding during the period plus the dilutive effects of potentially dilutive securities outstanding during the period. Potentially dilutive securities include warrants to purchase shares of common stock and stock options. The Company has generated a net loss for all periods presented, therefore diluted net loss per share is the same as basic net loss per share since the inclusion of potentially dilutive securities would be anti-dilutive.

Recent Accounting Pronouncements

In July 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-03, *"Presentation of Financial Statements (Topic 205), Income Statement - Reporting Comprehensive Income (Topic 220), Distinguishing Liabilities from Equity (Topic 480), Equity (Topic 505), and Compensation - Stock Compensation (Topic 718)*: A*mendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 120, SEC Staff Announcement at the March 24, 2022 EITF Meeting, and Staff Accounting Bulletin Topic 6.B, Accounting Series Release 280 - General Revision of Regulation S-X: Income or Loss Applicable to Common Stock"* ("ASU 2023-03"). This ASU amends various paragraphs in the accounting codification pursuant to the issuance of Commission Staff Bulletin ("SAB") number 120. ASU 2023-03 does not provide any new guidance and is immediately effective. ASU 2023-03 did not have a material impact on the consolidated financial statements.

In October 2023, the FASB issued ASU 2023-06, *Disclosure Improvements – Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative.* The amendments clarify or improve disclosure and presentation requirements on various disclosure areas, including the statement of cash flows, earnings per share, debt, equity, and derivatives. The amendments will align the requirements in the FASB ASC with the SEC's regulations. The amendments in this ASU will be effective on the date the related disclosures are removed from Regulation S-X or

Regulation S-K by the SEC and will not be effective if the SEC has not removed the applicable disclosure requirement by June 30, 2027. Early adoption is prohibited. The Company is currently evaluating the impact of the amendments on its financial statement disclosures.

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* ("ASU 2023-07"). The standard is intended to improve annual and interim reportable segment disclosure requirements regardless of the number of reporting units, primarily through enhanced disclosure of significant expenses. The amendment requires public entities to disclose significant segment expenses that are regularly provided to the CODM and included with each reported measure of segment profit and loss. The standard is effective for annual periods beginning after December 15, 2023. Early adoption is permitted and the amendments in this update should be applied retrospectively to all periods presented. ASU 2023-07 did not have a material impact on the consolidated financial statements.

On December 14, 2023, the FASB issued ASU No. 2023-09, *Improvements to Income Tax Disclosures*, which requires disclosure of disaggregated income taxes paid, prescribes standard categories for the components of the effective tax rate reconciliation, and modifies other income tax-related disclosures. The ASU is effective for annual periods beginning after December 15, 2024, and allows for adoption on a prospective basis, with a retrospective option. The Company is currently evaluating the effect of this update on its consolidated financial statements and related disclosures.

Note 3. Inventories, net

Inventories, net of write-offs had a zero balance for the fiscal years ended May 31, 2024 and 2023.

During the first quarter of fiscal year 2023, the Company reviewed purchase commitments made by its manufacturing partner, Samsung, under the master agreement between the Company and Samsung, and its vendors for specialized raw materials for which the Company made a prepayment in the amount of approximately $2.7 million in the third quarter of fiscal year 2022, which was recorded as prepaid expenses in the consolidated financial statements as of May 31, 2022.

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

Note 4. Accrued Liabilities

The components of accrued liabilities were as follows (in thousands):

	May 31, 2024	May 31, 2023
Compensation and related expense	$ 208	$ 335
Legal fees and settlement	7	168
Clinical expense	329	187
Accrued inventory charges and expenses	—	4,978
License fees	1,799	862
Lease payable	142	139
Investor proceeds held in escrow	300	—
Other liabilities	25	—
Total accrued liabilities	$ 2,810	$ 6,669

As of May 31, 2024 and 2023, the accrued legal fees and settlement balance was primarily related to legal fees.

Note 5. Convertible Instruments and Accrued Interest

Convertible Preferred Stock

The following table presents the number of potentially issuable shares of common stock, should shares of preferred stock and amounts of undeclared and accrued preferred dividends be converted to common stock.

	May 31, 2024			May 31, 2023		
(in thousands except conversion rate)	**Series B**	**Series C**	**Series D**	**Series B**	**Series C**	**Series D**
Shares of preferred stock outstanding	19	6	9	19	6	9
Common stock conversion rate	10:1	2,000:1	1,250:1	10:1	2,000:1	1,250:1
Total shares of common stock if converted	190	12,670	10,565	190	12,670	10,565
Undeclared dividends	$ 19	$ —	$ —	$ 15	$ —	$ —
Accrued dividends	$ —	$ 3,135	$ 3,656	$ —	$ 2,500	$ 2,808
Total shares of common stock if dividends converted	38	6,270	7,312	30	5,000	5,616

Under the Company's Amended and Restated Certificate of Incorporation, as amended (the "Certificate of Incorporation"), dividends on its outstanding shares of Series B Convertible Preferred Stock (the "Series B Preferred Stock") may be paid in cash or shares of the Company's common stock at the election of the Company. Dividends on outstanding shares of Series C Convertible Preferred Stock (the "Series C Preferred Stock") and Series D Convertible Preferred Stock (the "Series D Preferred Stock") are payable in cash or shares of common stock at the election of the holder. The preferred stockholders have the right to dividends only when and if declared by the Company's Board of Directors. Shares of common stock presented in the table above represent the number of shares that would have been issued had the dividend been paid in shares of the Company's common stock as of the end of each presented period; undeclared dividends of Series C Preferred Stock and Series D Preferred Stock are accrued as of May 31, 2024. 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, 2024, the Company had an accumulated deficit of approximately $891.5 million and had net loss in each fiscal year since inception and, therefore, is prohibited from paying any dividends, whether in cash, other property, or in shares of capital stock. Refer to the discussion below for additional information.

Series B Convertible Preferred Stock

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

Series C Convertible Preferred Stock

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

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

Series D Convertible Preferred Stock

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

Convertible Notes and Accrued Interest

The outstanding balance of convertible notes, the terms of which are described in more detail below, including accrued interest, were as follows:

	May 31, 2024			May 31, 2023			
(in thousands)	April 2, 2021 Note	April 23, 2021 Note	Total	April 2, 2021 Note	April 23, 2021 Note	Placement Agent Notes	Total
Convertible notes payable outstanding principal	$ 2,831	$ 27,369	$ 30,200	$ 6,081	$ 29,369	$ 1,000	$ 36,450
Less: Unamortized debt discount and issuance costs	(45)	(362)	(407)	(211)	(822)	(286)	(1,319)
Convertible notes payable, net	2,786	27,007	29,793	5,870	28,547	714	35,131
Accrued interest on convertible notes	4,634	10,593	15,227	3,804	6,789	5	10,598
Outstanding convertible notes payable, net and accrued interest	$ 7,420	$ 37,600	$ 45,020	$ 9,674	$ 35,336	$ 719	$ 45,729

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

(in thousands)	April 2, 2021 Note	April 23, 2021 Note	Placement Agent Notes	Short-Term Notes	Total
Outstanding balance at May 31, 2023	$ 9,674	$ 35,336	$ 719	$ —	$ 45,729
Consideration received	—	—	975	698	1,673
Amortization of issuance discount and costs	166	460	583	302	1,511
Interest expense	830	3,804	18	7	4,659
Fair market value of shares and warrants exchanged for repayment	(4,737)	(2,513)	(4,379)	(2,558)	(14,187)
Difference between market value of common shares and reduction of principal	1,487	513	2,084	1,551	5,635
Outstanding balance at May 31, 2024	$ 7,420	$ 37,600	$ —	$ —	$ 45,020

Convertible Note – April 2, 2021 Note

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

Interest accrues at an annual rate of 10% on the outstanding balance, with the rate increasing to the lesser of 22% per annum or the maximum rate permitted by applicable law upon occurrence of an event of default. In addition, upon any event of default, the investor may accelerate the outstanding balance payable under the April 2, 2021 Note; upon such acceleration, the outstanding balance will increase automatically by 15%, 10%, or 5%, depending on the nature of the event of default. The events of default are listed in Section 4 of the April 2, 2021 Note filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed on April 8, 2021, and listed as Exhibit 4.13 in Item 15 to this report. The April 2, 2021 Note is secured by all the assets of the Company, excluding the Company's intellectual property.

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

The investor may convert all or any part of the outstanding balance of the April 2, 2021 Note into shares of common stock at an initial conversion price of $10.00 per share upon five trading days' notice, subject to certain adjustments and volume and ownership limitations. In addition to standard anti-dilution adjustments, the conversion price of the April 2, 2021 Note is subject to full-ratchet anti-dilution protection, pursuant to which the conversion price will be automatically reduced to equal the effective price per share in any new offering by the Company of equity securities that have

registration rights, are registered, or become registered under the Securities Act, as amended. The April 2, 2021 Note provides for liquidated damages upon failure to deliver common stock within specified timeframes and requires the Company to maintain a share reservation of 6.0 million shares of common stock. The investor may redeem any portion of the note, at any time beginning six months after the issue date upon three trading days' notice, subject to a maximum monthly redemption amount of $3.5 million. The April 2, 2021 Note requires the Company to satisfy its redemption obligations in cash within three trading days of the Company's receipt of such notice. The Company may prepay the outstanding balance of the note, in part or in full, plus a 15% premium, at any time upon 15 trading days' notice.

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

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

During the fiscal year ended May 31, 2024, in satisfaction of redemptions, the Company and the April 2, 2021 Noteholder entered into six exchange agreements, pursuant to which the April 2, 2021 Note was partitioned into new notes (the "Partitioned Notes") with an aggregate principal amount of approximately $3.3 million, which was exchanged concurrently with the issuance of an aggregate amount of approximately 20.4 million shares of common stock. The outstanding balance of the April 2, 2021 Note was reduced by the Partitioned Notes to a principal amount of $2.8 million. The Company accounted for the Partitioned Notes and exchange settlement as an induced conversion, and, accordingly, in the fiscal years ended May 31, 2024 and 2023, the Company recorded a non-cash loss on convertible debt induced conversion of $4.7 million and $5.3 million, respectively.

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 April 2, 2021 Note in the initial principal amount of $28.5 million (the "April 23, 2021 Note"). The maturity date has been extended another two years to April 2025. See *April 2, 2021 and April 23, 2021 Note Extensions* below. The Company received consideration of $25.0 million, reflecting an original issue discount of $3.4 million and issuance costs of $0.1 million. The April 23, 2021 Note is secured by all the assets of the Company, excluding the Company's intellectual property.

Interest accrues at an annual rate of 10% on the outstanding balance of the April 23, 2021 Note, with the rate increasing to the lesser of 22% per annum or the maximum rate permitted by applicable law upon the occurrence of an event of default. In addition, upon any event of default, the investor may accelerate the outstanding balance payable under the April 23, 2021 Note; upon such acceleration, the outstanding balance will increase automatically by 15%, 10%, or 5%, depending on the nature of the event of default. The events of default are listed in Section 4 of the April 23, 2021 Note filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed on April 29, 2021, and listed as Exhibit 4.14 in Item 15 to this report.

The investor may convert all or any part of the outstanding balance into shares of common stock at an initial conversion price of $10.00 per share upon five trading days' notice, subject to certain adjustments and volume and ownership limitations specified in the April 23, 2021 Note. In addition to standard anti-dilution adjustments, the conversion price of the April 23, 2021 Note is subject to full-ratchet anti-dilution protection, pursuant to which the conversion price will be automatically reduced to equal the effective price per share in any new offering by the Company

of equity securities that have registration rights, are registered, or become registered under the Securities Act. The April 23, 2021 Note provides for liquidated damages upon failure to deliver common stock within specified timeframes and requires the Company to maintain a share reservation of 6.0 million shares of common stock.

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

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

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

During the fiscal year ended May 31, 2024, in satisfaction of redemptions, the Company and the April 23, 2021 Noteholder entered into four exchange agreements, pursuant to which the April 23, 2021 Note was partitioned into new notes (the "Partitioned Notes") with an aggregate principal amount of $2.0 million, which was exchanged concurrently with the issuance of an aggregate amount of approximately 13.9 million shares of common stock. The outstanding balance of the April 23, 2021 Note was reduced by the Partitioned Notes to a principal amount of $27.4 million. The Company accounted for the Partitioned Notes and exchange settlement as an induced conversion, and, accordingly, in the fiscal year ended May 31, 2024 the Company recorded a non-cash loss on convertible debt induced conversion of $1.9 million. No non-cash loss on convertible debt induced conversion related to the April 23, 2021 Note was recorded in the fiscal year ended May 31, 2023.

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 additional notes, and shares of common stock and warrants issued through a placement agent.

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

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

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

Placement Agent Notes

During the period April through June 2023, the Company entered into securities purchase agreements pursuant to which the Company issued secured promissory notes bearing interest at a rate of 6.0% and with an 18-month term to accredited investors through a placement agent ("Placement Agent Notes") for a total principal amount of approximately $2.3 million, of which $1.3 million was sold in June 2023. The Placement Agent Notes were secured by the net cash recovery, if any, by the Company in its dispute with Amarex and provided the investors with a right to convert the unpaid principal and accrued but unpaid interest into shares of common stock upon the occurrence of an event of default. The Placement Agent Notes had maturity dates during the fiscal year ending May 31, 2025.

In connection with the sale in June 2023, the Company issued warrants to investors to purchase approximately 1.3 million shares of common stock with a three-year term and an exercise price of $0.50 per share. The net proceeds from the sale of the Placement Agent Notes in June of approximately $1.1 million reflect issuance costs of approximately $0.2 million. The Company also issued warrants to purchase approximately 0.4 million shares of common stock to the placement agent with a ten-year term and an exercise price of $0.26 per share, which the Company accounted for as additional issuance costs related to the sale of Placement Agent Notes in June 2023. The Company allocated the proceeds between the liability-classified Placement Agent Notes and the equity-classified warrants based on their relative fair values.

During June 2023, an amendment was entered into with the investors of the Placement Agent Notes, which stated that the principal amount and accrued but unpaid interest on the notes would be converted into shares of common stock and warrants as of the first closing of a subsequent private placement of common stock and warrants through a placement agent. The deemed purchase price of a unit of one share plus one warrant was fixed at 90% of the lower of the intraday volume weighted average price ("VWAP") on the date of the first closing and last closing of the private placement, while the exercise price of the warrants was set at $0.306 per share, compared to $0.50 per share in the original private placement.

In July 2023, the first closing of the subsequent private placement of common stock and warrants through a placement agent occurred. Therefore, the Placement Agent Notes were converted into units with the same pricing as the private placement described below in Note 6, *Private Placements of Common Stock and Warrants – Private placements of common stock and warrants through placement agent*. The $2.1 million difference in fair value between the shares and warrants and the principal amount of the Placement Agent Notes was accounted for as a loss on note extinguishment. See Note 6, *Private Placements of Common Stock and Warrants* for additional information.

Short-term Notes

During November and December 2023, the Company issued unsecured promissory notes bearing interest at a rate of 10% to accredited investors under a securities purchase agreement through a placement agent ("Short-term Notes") for a total principal amount of $1.0 million. The Short-term Notes' maturity date was June 7, 2024. The Company also agreed to issue warrants at the final closing of the sale of Short-term Notes to purchase one share of common stock for each dollar of principal amount of Short-term Notes sold. The warrants have a five-year term and an exercise price of $0.35 per share. The net proceeds from the sale of the Short-term Notes of $0.9 million reflect issuance costs of approximately $0.1 million. The Company allocated the proceeds between the liability-classified Short-term Notes and the equity-classified warrants based on their relative fair values.

The Company also agreed to issue warrants to purchase shares of common stock to the placement agent with a ten-year term, with the number of warrants and the exercise price of the warrants to be determined by the share price on the final closing date of the sale of Short-term Notes. The Company accounted for the warrants to be issued to the placement agent as additional issuance costs. See Note 6, *Private Placements of Common Stock and Warrants* for additional information.

In December 2023, the principal amount and accrued but unpaid interest on the notes were converted into units consisting of shares of common stock and warrants as of the first closing of a private placement of common stock and warrants through a placement agent, with a conversion based on an amount equal to a 20% discount to the price at which the units were sold in the private placement. The $1.6 million difference in fair value between the shares and warrants and the principal amount of the Short-term Notes was accounted for as a loss on note extinguishment. See Note 6, *Private Placements of Common Stock and Warrants* for additional information.

Note 6. Private Placements of Common Stock and Warrants

Approval of increase in authorized common stock

On November 9, 2023, at the Company's annual stockholders' meeting, the Company's stockholders approved a proposal to increase the total number of authorized shares of common stock from 1.35 billion shares to 1.75 billion shares.

Liability classified warrants

From June 24, 2022 through August 31, 2022, the Company had insufficient authorized common stock to reserve for the shares underlying the Surety Backstop warrants and warrants issued to a placement agent in connection with the June 2022 offering. After approval by the Company's stockholders of an increase to the Company's authorized common stock, on August 31, 2022, sufficient shares were authorized to cover the shares underlying the warrants. Given that the Company did not have a sufficient number of authorized shares for the instruments at the time they were issued, the Company accounted for such warrants issued from June 24, 2022 through August 2022 as liability classified warrants consistent with ASC 815, *Derivatives and Hedging.*

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

During April and May 2023, the Company sold Placement Agent Notes through a placement agent. See Note 5, *Convertible Instruments and Accrued Interest – Placement Agent Notes*. The Company agreed to issue warrants to the placement agent as part of the issuance costs with an exercise price that was not determined until the final closing date. As the exercise price of the warrants was to be fixed based on the final terms of the offering, the Company accounted for the warrants as a liability-classified warrant beginning on the initial closing date until the final closing date. The value of the warrants on May 31, 2023, was recorded as a derivative liability on the balance sheet, and the change in the fair value of the warrants was recorded as a gain or loss on derivatives. On June 23, 2023, the final closing of the Placement Agent Notes occurred, and the fair value of the warrants became equity classified.

On July 31, 2023, the Placement Agent Notes were converted into units that had similar terms to units being offered in a private placement of shares and warrants through a placement agent that commenced in July 2023. See *Private placement of common stock and warrants through placement agent* below. As the unit price was not determinable until the final closing date of the subsequent private placement, the units related to the conversion of the Placement Agent Notes were recorded as a liability and at fair value. On October 23, 2023, the private placement was concluded, which finalized the unit purchase price at $0.16, and the fair value of the units became equity-classified.

During November 2023, in connection with the issuance of the Short-term Notes described in Note 5, *Convertible Instruments and Accrued Interest – Short-term Notes*, the Company agreed to issue warrants to the placement agent as part of the issuance costs, with the ultimate number of warrants and exercise price to be determined as of the final closing date. The value of the warrants was recorded as a derivative liability on the balance sheet until the final closing date in December 2023, and the change in the fair value of the warrants was recorded as a gain or loss on derivatives.

On December 29, 2023, the Short-term Notes were converted into units that had similar terms to units being offered in a private placement of shares and warrants through a placement agent. See *Private placement of common stock and warrants*

through placement agent below. As the unit price was not determinable until the final closing date of the subsequent private placement, the units related to the conversion of the Placement Agent Notes were recorded as a liability and at fair value. The change in the fair value of the units was recorded as a gain or loss on derivatives. On May 3, 2024, the private placement was concluded, which finalized the unit purchase price at $0.10, and the fair value of the units became equity-classified.

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

As of May 31, 2024, in accordance with ASC 815, *Derivatives and Hedging,* the Company reclassified warrants to equity when the warrants no longer qualified as liabilities. The Company recorded a loss on derivatives of approximately $0.2 million and $8.8 million in the fiscal years ended May 31, 2024 and 2023, respectively, due to a change in fair market value of the liability classified shares of common stock and warrants. The table below presents a reconciliation of the beginning and ending balances for liabilities measured at fair value as of May 31, 2022, and during the fiscal years ended May 31, 2023 and 2024:

(in thousands)	Liability Classified Warrants
Balance at May 31, 2022	$ —
Classified as liability	16,664
Reclassified as equity	(25,335)
Loss on derivative due to change in fair market value	8,750
Balance at May 31, 2023	79
Classified as liability	6,970
Reclassified as equity	(7,285)
Loss on derivative due to change in fair market value	236
Balance at May 31, 2024	$ —

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

The Company estimated the fair value of the warrant derivatives using the following assumptions:

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

	April Placement Agent warrants at May 31, 2023	Inputs at Liability Classification			Inputs at Equity Classification			
		July Note conversion warrants	November Placement Agent warrants	December Note conversion warrants	April Placement Warrants	July Note conversion warrants	November Placement Agent conversion warrants	December Note conversion warrants
Fair value of underlying stock	$ 0.26	$ 0.21	$ 0.18	$ 0.20	$ 0.27	$ 0.17	$ 0.30	$ 0.15
Risk free rate	3.64%	4.18%	4.42%	3.84%	3.74%	4.81%	4.14%	4.48%
Expected term (in years)	10.00	5.00	10.00	5.00	10.00	5.00	10.00	5.00
Stock price volatility	97.90%	124.55%	95.82%	124.25%	97.45%	124.70%	96.18%	124.04%
Expected dividend yield	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%

Private placement of common stock and warrants through placement agent

In July 2023, the Company commenced a private placement of units consisting of common stock and warrants to accredited investors through a placement agent. Each unit sold included a fixed combination of one share of common stock and one warrant to purchase one share of common stock. The purchase price per unit was $0.16, equal to 90% of the intraday VWAP of the common stock as of the last closing on September 27, 2023. From July through September 2023, the Company sold a total of approximately 21.5 million units for a total of approximately $3.0 million of proceeds, net of issuance costs. The Company classified the securities issued in the private placement as a liability until the final close, when it was reclassified as equity. As part of the offering, the Company issued approximately 21.5 million warrants to investors, with each such warrant having a five-year term and an exercise price of $0.50 per share. The warrants were immediately exercisable. In connection with the above, the Company paid the placement agent a total cash fee of approximately $0.4 million, equal to 12% of the gross proceeds of the offering, as well as a one-time fee for expenses of $5,000, and issued to the placement agent and its designees a total of approximately 3.2 million warrants with an exercise price of $0.16 per share and a ten-year term, representing 15% of the total number of shares of common stock sold in the offering.

Based on contractual payment terms, the private placement transactions above are considered convertible debt instruments prior to final settlement, and the option to enter a final closing that would lower the purchase price is considered a share-settled redemption feature. Therefore, the approximately $0.9 million of cash and non-cash issuance costs associated with such issuances were capitalized and subsequently recognized through the statement of operations as interest expense on the final closing date. As the VWAP of the final closing was lower than the VWAP on the initial closing, the share-settled redemption feature was triggered, and the Company recorded a $2.4 million non-cash loss on note extinguishment.

In addition, approximately $2.3 million of principal and interest of the Placement Agent Notes were converted into approximately 14.3 million units with the same terms as described above except for a warrant exercise price of $0.306. See Note 5, *Convertible Instruments and Accrued Interest – Placement Agent Notes*, and *Liability-classified equity instruments* above for additional information.

In December 2023, the Company commenced a private placement of units consisting of common stock and warrants to accredited investors through a placement agent. Each unit sold included a fixed combination of one share of common stock and one warrant to purchase one share of common stock. The purchase price per unit was $0.13 equal to 90% of the intraday VWAP of the common stock as of the last closing on May 3, 2024. From December 2023 through May 2024, the Company sold a total of approximately 52.6 million units for a total of approximately $5.9 million of proceeds, net of issuance costs. The Company classified the securities to be issued in the private placement as a liability until the final close when it was reclassified as equity. As part of the offering, the Company issued approximately 52.6 million warrants to investors, with each such warrant having a five-year term and an exercise price of $0.21 per share (reduced

from $0.35 per share as discussed below). The warrants were immediately exercisable when issued on the final closing date. In connection with the above, the Company paid the placement agent a total cash fee of approximately $0.9 million, equal to 13% of the gross proceeds of the offering, as well as a one-time fee for expenses of $5,000, and issued to the placement agent and its designees a total of approximately 7.9 million warrants with an exercise price of $0.13 per share and a ten-year term, representing 15% of the total number of shares of common stock sold in the offering.

Based on contractual payment terms, the private placement transactions above are considered convertible debt instruments prior to final settlement, and the option to enter a final closing that would lower the purchase price is considered a share-settled redemption feature. Therefore, the approximately $1.9 million of cash and non-cash issuance costs associated with such issuances were capitalized and subsequently recognized through the statement of operations as interest expense on the final closing date. As the VWAP of the final closing was lower than the VWAP on the initial closing, the share-settled redemption feature was triggered, and the Company recorded a $7.3 million non-cash loss on note extinguishment. The exercise price for the warrants included in the private placement was lowered from $0.35 per share to $0.21 per share. The exercise price modification resulted in the Company recognizing a $0.1 million non-cash discount on convertible notes.

In addition, approximately $1.0 million principal and interest of the Placement Agent Notes were converted into approximately 10.1 million units with the same terms as discussed above. See Note 5, *Convertible Instruments and Accrued Interest – Short-term Notes*, and *Liability-classified equity instruments* above for additional information.

Later in May 2024, the Company sold a total of approximately 1.5 million units for a total of approximately $0.2 million in proceeds, net of offering costs, as part of a follow-on offering with the same terms as the units sold in December 2023 through May 2024. As part of the offering, the Company issued approximately 1.5 million warrants to investors, with each such warrant having a five-year term and an exercise price of $0.21 per share. The warrants were immediately exercisable. In connection with the above, the Company paid the placement agent a total cash fee of approximately $26.0 thousand, equal to 13% of the gross proceeds of the offering.

Warrants

Warrant activity is presented in the table below:

(in thousands, except for share data and years)	Number of shares	Weighted average exercise price	Weighted average remaining contractual life in years	Aggregate intrinsic value
Warrants outstanding at May 31, 2022	73,248	$ 0.59	3.18	$ 352
Granted	201,771	$ 0.33		
Exercised	(6,207)	$ 0.63		758
Forfeited, expired, and cancelled	(8,902)	$ 0.75		
Warrants outstanding at May 31, 2023	259,910	$ 0.37	4.57	$ 7,276
Granted	115,582	$ 0.28		
Exercised	(3,000)	$ 0.10		480
Forfeited, expired, and cancelled	(11,047)	$ 0.63		
Warrants outstanding at May 31, 2024	361,445	$ 0.34	4.21	$ 2,697
Warrants outstanding and exercisable at May 31, 2024	361,445	$ 0.34	4.21	$ 2,697

Warrant exercises

During the fiscal year ended May 31, 2024, the Company issued approximately 3.0 million shares of common stock in connection with the exercise of an equal number of warrants. The stated exercise price was $0.10 per share, which resulted in aggregate gross proceeds of approximately $0.3 million.

Note 7. Equity Incentive Plan

Equity Incentive Plan

As of May 31, 2024, the Company had one active equity incentive plan, the *CytoDyn Inc. Amended and Restated 2012 Equity Incentive Plan* (the "2012 Plan"). The 2012 Plan contains an "evergreen provision" whereby the total number of shares available to be issued automatically increases annually on the first day of each fiscal year in an amount equal to 1.0% of the total outstanding shares on the last day of the prior fiscal year, unless the Board determines otherwise before the fiscal year end. As of May 31, 2024, the 2012 Plan covered a total of 56.3 million shares of common stock.

Stock options

Stock option activity is presented in the table below:

(in thousands, except per share data and years)	Number of shares	Weighted average exercise price	Weighted average remaining contractual life in years	Aggregate intrinsic value
Options outstanding at May 31, 2022	17,457	$ 1.53	7.79	$ —
Granted	12,417	$ 0.41		
Exercised	—	$ —		
Forfeited, expired, and cancelled	(10,051)	$ 1.16		
Options outstanding at May 31, 2023	19,823	$ 0.99	7.87	$ —
Granted	14,251	$ 0.21		
Exercised	—	$ —		
Forfeited, expired, and cancelled	(8,225)	$ 0.87		
Options outstanding at May 31, 2024	25,849	$ 0.60	7.77	$ —
Options outstanding and exercisable at May 31, 2024	19,679	$ 0.71	7.25	$ —

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,			
	2024		2023	
Expected Volatility	108.6% - 115.7	%	99.2% - 112.7	%
Weighted-Average Volatility	112.24	%	107.06	%
Expected Dividends	-	%	-	%
Expected Term (In years)	5.1 - 6.0		5.0 - 6.1	
Risk-Free Rate	3.96	%	3.83	%

In the fiscal years ended May 31, 2024, and 2023, stock-based compensation expense related to equity instruments totaled $2.4 million and $4.2 million, respectively; stock-based compensation expense is presented in general and administrative expense in the Company's consolidated statements of operations. The grant date fair value of options vested during the same periods was approximately $3.3 million and $4.9 million, respectively. As of May 31, 2024,

there was approximately $0.9 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 1.9 years.

During the fiscal year ended May 31, 2024, the Company granted stock options covering a total of approximately 14.3 million shares of common stock to directors, employees, and consultants, with exercise prices ranging between $0.21 and $0.26 per share. Of the current year options, approximately 0.5 million options vest when performance conditions are completed, approximately 5.7 million vest over four years, and approximately 4.0 million vest over one year, with a ten-year term. Approximately 4.1 million were cancelled and new options were granted with the same vesting schedule and expiration dates as the original cancelled options. The grant date fair values of the stock options ranged between $0.15 and $0.17 per share. As of May 31, 2024, and May 31, 2023, there were approximately 19.7 million and 12.0 million vested stock options and approximately 6.1 million and 7.8 million unvested stock options outstanding, respectively.

RSUs and PSUs

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

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

(shares in thousands)	Number of RSUs and PSUs (1)	Weighted average grant date fair value	Weighted average remaining contractual life in years
Unvested RSUs and PSUs at May 31, 2022	300	$ 3.12	0.58
RSUs and PSUs granted	1,293	0.58	
RSUs and PSUs forfeited	(150)	3.12	
RSUs and PSUs vested	(150)	3.12	
Unvested RSUs and PSUs at May 31, 2023	1,293	0.58	0.81
RSUs and PSUs granted	—		
RSUs and PSUs forfeited	(1,293)	0.58	
RSUs and PSUs vested	—		
Unvested RSUs and PSUs at May 31, 2024	—	$ —	—

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

Issuance of shares to former and current executives and consultants

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

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

During the fiscal year ended May 31, 2024, the Board approved the issuance under the 2012 Plan of shares of common stock as severance payments to former employees. As a result, a total of 153,027 shares of common stock were issued as severance. The number of shares issued was based on the closing price of the common stock on the payment date.

In order to preserve cash resources, in April 2022, the Board approved the issuance under the 2012 Plan, through November 2022, to then executive officers of shares of common stock with a value equal to 25 percent of salary in lieu of cash, net of payroll deductions and withholding taxes. During the fiscal year ended May 31, 2023, a total of 522,382 shares of common stock were issued pursuant to this cash preservation program. No shares were issued pursuant to this cash preservation program in the fiscal year ended May 31, 2024. The number of shares issued was based on the closing price of the common stock on each payroll date.

In March 2022, the Board approved the issuance under the 2012 Plan of shares of common stock to consultants as payment for services provided. During the fiscal years ended May 31, 2024 and 2023, a total of 2,454,515 and 1,617,760 shares of common stock, respectively, were issued pursuant to the respective award agreements with the consultants.

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:

	Years ended May 31,	
(in thousands, except per share amounts)	**2024**	**2023**
Net loss	$ (49,841)	$ (79,824)
Less: Deemed dividends	—	(5,417)
Less: Accrued preferred stock dividends	(1,483)	(1,495)
Net loss applicable to common stockholders	$ (51,324)	$ (86,736)
Basic and diluted:		
Weighted average common shares outstanding	969,509	836,528
Loss per share	$ (0.05)	$ (0.10)

Refer to Note 13, *Subsequent Events* for additional information regarding the shares issued subsequent to May 31, 2024.

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:

	Year ended May 31,	
(in thousands)	**2024**	**2023**
Stock options, warrants, and unvested restricted stock units	387,294	281,023
Convertible notes	12,000	12,000
Convertible preferred stock	37,046	34,071

Note 9. Income Taxes

Loss before provision for income taxes was $49.8 million and $79.8 million for the years ended May 31, 2024 and 2023, respectively, all of which was generated in the United States. The Company's provision for income taxes consists of the following:

	Years Ended May 31,	
	2024	2023
Current:		
Federal	$ —	$ —
State	—	—
Total Current	—	—
Deferred:		
Federal	57	—
State	—	—
Change in valuation allowance	(57)	—
Total deferred	—	—
Total income tax benefit (expense)	$ —	$ —

The Company's provision for income tax differs from the amount computed by applying the statutory federal income tax rate to income before taxes as follows:

	Years ended May 31,	
	2024	2023
Statutory federal income tax rate	21.0 %	21.0 %
Derivative loss	(0.1)	(2.3)
Non-deductible debt issuance costs	(7.1)	(2.6)
Non-deductible interest on convertible notes	(2.0)	(1.2)
Non-deductible loss on induced conversion	(2.8)	(1.4)
Non-deductible debt discount amortization	(0.5)	(0.6)
Stock Compensation	(7.2)	—
Other	(1.2)	0.8
Valuation allowance	(0.1)	(13.7)
Total provision for income taxes	0.0 %	0.0 %

As of May 31, 2024 and 2023, the net deferred tax assets consisted of the following:

	As of May 31,	
	2024	2023
Deferred tax assets:		
Net operating loss	$ 100,897	$ 96,338
Credits	2,063	2,063
ASC 718 expense on non-qualified stock options	2,665	6,400
Accrued expenses	411	73
Lease liability	59	89
Inventory charges	6,173	6,173
Inventory write-off	1,953	13,739
Contingent liability	9,202	—
Issued warrants	3,000	2,317
Section 174 R&D costs	2,056	858
Amortization	207	609
Fixed assets	5	4
Other	—	—
Total gross deferred tax asset	128,691	128,663
Less valuation allowance	(128,636)	(128,579)
Total deferred tax assets	55	84
Deferred tax liabilities:		
Right-of-use asset	(55)	(84)
Total deferred tax liabilities	(55)	(84)
Net deferred tax asset (liability)	$ —	$ —

Valuation allowances are established when necessary to reduce deferred tax assets, including temporary differences and net operating loss carryforwards, to the amount expected to be realized in the future. FASB guidance indicates that forming a conclusion that a valuation allowance is not needed is difficult when there is negative evidence such as cumulative losses in recent years. The Company had cumulative losses from continuing operations in the United States for the three-year period ended May 31, 2024. The Company considered this negative evidence along with all other available positive and negative evidence and concluded that, at May 31, 2024, it is more likely than not that the Company's U.S. deferred tax assets will not be realized. As of May 31, 2024, a valuation allowance has been recorded on the Company's deferred tax assets to recognize only the proportion of the deferred tax asset that is more likely than not to be recognized. The Company's total valuation allowance was $128.6 million at May 31, 2024 and $128.6 million at May 31, 2023. The Company's valuation allowance increased $0.1 million and $10.9 million during the fiscal years ended May 31, 2024 and 2023, respectively. A reconciliation of the beginning and ending amount of the valuation allowance is as follows:

	May 31,	
	2024	2023
Valuation allowance at beginning of year	$ 128,579	$ 117,638
Change in valuation allowance	57	10,941
Valuation allowance at end of year	$ 128,636	$ 128,579

As of May 31, 2024, the Company had cumulative federal net operating losses of approximately $480.5 million. Of these losses, $47.1 million were generated in 2004 through 2017, prior to the Tax Cuts and Jobs Act enactment, and will expire between 2025 to 2038 if not utilized. The remaining net operating losses have an indefinite carryforward period. As of May 31, 2023, the Company had cumulative federal net operating losses of approximately $458.8 million.

As of May 31, 2024, the Company had a $2.1 million deferred tax asset related to a federal research and development credit carryforward. If not utilized, the credits will expire between 2035 through 2038. As of May 31, 2023, the Company had a $2.1 million deferred tax asset related to a federal research and development credit carryforward.

As of May 31, 2024, the U.S. tax returns for fiscal year 2004 through fiscal year 2023 remain subject to examination. Annual tax provisions include amounts considered necessary to pay assessments that may result from examination of prior year tax returns; however, the amount ultimately paid upon resolution of issues may differ materially from the amount accrued. As of May 31, 2024, there are no income tax returns currently under audit.

On August 16, 2022, the Inflation Reduction Act ("IRA") was signed into law by President Biden. The IRA includes a corporate minimum tax of 15% on certain large corporations with greater than $1B in average adjusted financial statement income and an excise tax on certain stock repurchases executed after December 31, 2022. There are no impacts to the Company in 2024, and the Company does not expect a material impact on its consolidated financial statements in the future for the IRA.

On December 14, 2023, the FASB issued ASU 2023-09 (Improvements to Income Tax Disclosures). The object of the project is to improve the transparency and usefulness of income tax disclosures. For public business entities, the effective date is for fiscal years beginning after December 15, 2024. The Company does not expect a material impact on its consolidated financial statements related to ASU 2023-09.

Note 10. Commitments and Contingencies

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

In April 2019, the Company entered into several agreements with Samsung, pursuant to which Samsung agreed to perform technology transfer, process validation, manufacturing, pre-approval inspection, and supply services for the commercial supply of leronlimab bulk drug substance. In 2020, the Company entered into an additional agreement, pursuant to which Samsung agreed to perform technology transfer, process validation, vial filling, and storage services for clinical, pre-approval inspection, and commercial supply of leronlimab drug product.

On January 6, 2022, Samsung provided written notice to the Company alleging that the Company had materially breached the parties' Master Services and Project Specific Agreements (the "Samsung Agreements") for failure to pay an outstanding balance due on December 31, 2021.

On November 21, 2023, Samsung informed the Company of Samsung's intent to terminate the Samsung Agreements, effective January 5, 2024. Thereafter, the parties continued the negotiations that were already in progress in relation to the outstanding issues under the agreements and potential options moving forward.

On April 3, 2024, the Company and Samsung executed a side letter agreement (the "Letter Agreement"), wherein the parties reached an agreement for an orderly process for winding down services and a restructuring of the amount payable by the Company to Samsung (the "Total Balance"). The Total Balance due to Samsung, as restructured under the Letter Agreement, is now approximately $43.8 million. Except for a single $250,000 payment due on or before December 31, 2024, the entirety of the Total Balance is conditional, and will only be due and payable, upon the Company achieving a qualifying "Revenue" event, as defined in the Letter Agreement. Under the Letter Agreement, the Company has agreed to pay 20% of its qualifying Revenue generated in each calendar year, if any, with such payments to be applied to reduce the Total Balance until it is repaid in full. Interest will not accrue on the Total Balance throughout the prospective repayment period. Revenue is defined in the Letter Agreement as:

> "…the gross revenue generated by Client and its Affiliates, less the following items (if not previously deducted from the amount invoiced): (a) reasonable and customary trade, quantity, and cash discounts actually granted and legally permitted wholesaler chargebacks actually paid or credited by Client and its Affiliates to wholesalers of products; (b) reasonable, customary, and legally permitted rebates and retroactive price reductions actually granted; (c) freight charges for the delivery of products; (d) the portion of the administrative fees paid during the relevant time period to group purchasing organizations, pharmaceutical benefit managers and/or government-mandated Medicare or Medicaid Prescription Drug Plans relating specifically to the product; and (e) sales, use or excise taxes imposed and actually paid in connection with the sale of products (but excluding any value added taxes or taxes based on income or gross receipts)."

Since the carrying amount of the payable is equal to potential future cash flows, no gain was recognized. The $250,000 payment due on or before December 31, 2024, is included in accounts payable on the balance sheet, and the remaining balance of approximately $43.5 million is included in other liabilities.

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 vary based on whether Lonza, or we or our strategic partner manufactures leronlimab. We currently use two independent parties as contract manufacturers for leronlimab, and continually review this arrangement. Should the arrangement continue as-is, an annual license fee of £0.3 million (approximately $0.35 million given current exchange rate) would continue to apply, as well as a royalty, up to 2% of the net selling price upon commercialization of leronlimab, excluding value added taxes and similar amounts.

Operating Leases

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

fiscal years ended May 31, 2024 and 2023 were approximately $0.1 million and $0.2 million, respectively. Operating lease right-of-use assets are included in other non-current assets and the current portion of operating lease liabilities are included in accrued liabilities and compensation on the consolidated balance sheets. The long-term operating lease liabilities are presented separately as operating leases on the consolidated balance sheets. The following table summarizes the operating lease balances.

(in thousands)	May 31, 2024	May 31, 2023
Assets		
Right-of-use asset	$ 264	$ 400
Liabilities		
Current operating lease liability	$ 142	$ 139
Non-current operating lease liability	141	283
Total operating lease liability	$ 283	$ 422

The minimum (base rental) lease payments reconciled to the carrying value of the operating lease liabilities as of May 31, 2024, are expected to be as follows (in thousands):

Fiscal Year	Amount
2025	$ 185
2026	169
Thereafter	—
Total operating lease payments	354
Less: imputed interest	(71)
Present value of operating lease liabilities	$ 283

Supplemental information related to the operating leases was as follows:

	May 31, 2024
Weighted average remaining lease term	1.9 years
Weighted average discount rate	10.0 %

Legal Proceedings

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

Securities Class Action Lawsuits

On March 17, 2021, a stockholder filed a putative class-action lawsuit (the "March 17, 2021 lawsuit") in the U.S. District Court for the Western District of Washington against the Company and certain former officers. The complaint generally alleges the defendants made false and misleading statements regarding the viability of leronlimab as a potential treatment for COVID-19. On April 9, 2021, a second stockholder filed a similar putative class action lawsuit in the same court, which the plaintiff voluntarily dismissed without prejudice on July 23, 2021. On August 9, 2021, the court appointed lead plaintiffs for the March 17, 2021 lawsuit. On December 21, 2021, lead plaintiffs filed an amended complaint, which is brought on behalf of an alleged class of those who purchased the Company's common stock between March 27, 2020 and May 17, 2021. The amended complaint generally alleges that the defendants violated Sections 10(b) and/or 20(a) of the Exchange Act 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 Biologic License Application ("BLA"). The amended complaint also alleges that the individual defendants violated Section 20A of the Exchange Act by selling shares of the Company's common stock purportedly while in possession of material nonpublic information. The amended complaint seeks, among other relief, a ruling that the case may proceed as a class action and unspecified damages and attorneys' fees and costs. On February 25, 2022, the defendants filed a motion to dismiss the amended complaint. On June 24, 2022, lead plaintiffs filed a second amended complaint. The second amended complaint is brought on behalf of an alleged class of those who purchased the Company's common stock between March 27, 2020 and March 30, 2022, makes similar allegations, names the same defendants, and asserts the same claims as the prior complaint, adds a claim for alleged violation of Section 10(b) of the Exchange Act and Rule 10b-5(a) and (c) promulgated thereunder, and seeks the same relief as the prior complaint. All defendants have filed motions to dismiss the second amended complaint in whole or in part. The Company and the individual defendants deny all allegations of wrongdoing in the complaint and intend to vigorously defend the matter. Since this case is in an early stage where the number of plaintiffs is not known, and the claims do not specify an amount of damages, the Company is unable to predict the ultimate outcome of the lawsuit and cannot reasonably estimate the potential loss or range of loss the Company may incur.

Shareholder Derivative Lawsuits

On June 4, 2021, a stockholder filed a purported derivative lawsuit against certain of the Company's former officers and directors, and the Company as a nominal defendant, in the U.S. District Court for the Western District of Washington. Two additional shareholder derivative lawsuits were filed against the same defendants in the same court on June 25, 2021 and August 18, 2021, respectively. The court has consolidated these three lawsuits for all purposes ("Consolidated Derivative Suit"). On January 20, 2022, the plaintiffs filed a consolidated complaint. The consolidated complaint generally alleges that the director defendants breached their fiduciary duties by allowing the Company to make false and misleading statements regarding, among other things, the safety and efficacy of leronlimab as a potential treatment for COVID-19, the Company's CD10 and CD12 clinical trials and its HIV BLA, and by failing to maintain an adequate system of oversight and controls. The consolidated complaint also asserts claims against one or more individual defendants for waste of corporate assets, unjust enrichment, contribution for alleged violations of the federal securities laws, and for breach of fiduciary duty arising from alleged insider trading. The consolidated complaint seeks declaratory and equitable relief, an unspecified amount of damages, and attorneys' fees and costs.

On January 29, 2024, two purported stockholders filed a purported derivative lawsuit against certain of the Company's former officers, certain current and former directors, and the Company as a nominal defendant, in the Delaware Court of Chancery. The complaint generally makes allegations similar to those set forth in the Consolidated Derivative Suit and asserts that the individual defendants breached their fiduciary duties by allowing the Company to make false and misleading statements and by failing to maintain an adequate system of oversight and controls. The complaint also asserts claims against certain individual defendants for breach of fiduciary duty arising from alleged insider trading.

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 suit(s) is/are in an early stage and the claims do not specify an amount of damages, the Company cannot predict the ultimate outcome of the matter(s) 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 SEC and the United States Department of Justice ("DOJ") requesting documents and information concerning, among other matters, leronlimab, the Company's public statements regarding the use of leronlimab as a potential treatment for COVID-19, HIV, and triple-negative breast cancer, related communications with the FDA, investors, and others, litigation involving former employees, the Company's retention of investor relations consultants, and trading in the Company's securities. Certain former Company executives and directors have received subpoenas concerning similar issues and have been interviewed by the DOJ and SEC, including the Company's former CEO, Nader Z. Pourhassan.

On January 24, 2022, Mr. Pourhassan was terminated and removed from the Board of Directors and has had no role at the Company since. On December 20, 2022, the DOJ announced the unsealing of a criminal indictment charging both Mr. Pourhassan, and Kazem Kazempour, CEO of Amarex, a subsidiary of NSF International, Inc., and which had

formerly served as the Company's contract research organization ("CRO"). Mr. Pourhassan was charged with one count of conspiracy, four counts of securities fraud, three counts of wire fraud, and three counts of insider trading. Mr. Kazempour was charged with one count of conspiracy, three counts of securities fraud, two counts of wire fraud, and one count of making a false statement. That same day, the SEC announced charges against both Mr. Pourhassan and Mr. Kazempour for alleged violations of federal securities laws.

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

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

Settlement of Amarex Dispute

On July 2, 2024, the Company and Amarex Clinical Research, LLC ("Amarex"), the Company's former clinical research organization ("CRO"), entered into an agreement settling a lawsuit filed by the Company in October 2021 (the "Settlement Agreement").

The terms of the Settlement Agreement include: (i) the payment by Amarex of $12,000,000 to the Company, of which $10,000,000 was paid on execution of the Settlement Agreement and the balance will be paid on or before July 2, 2025; (ii) the release of the Company's surety bond posted in the lawsuit and the return of the Company's cash collateral in the amount of $6,500,000 provided as security to the surety; (iii) the crediting of all amounts claimed by Amarex as due and payable for its CRO services, totaling approximately $14,000,000, reducing the Company's outstanding balance to zero, with no funds required to be paid by the Company; and (iv) a mutual release of claims, resolving all legal claims between the parties.

Note 11. Related Party Transactions

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

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

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 fiscal years ended May 31, 2024 and 2023, the Company incurred an expense of approximately $0.1 million for qualified non-elective contributions.

Note 13. Subsequent Events

Tender offer

On July 19, 2024, the Company closed a tender offer where warrants to purchase approximately 127.1 million shares of common stock were exercised at a $0.09387 exercise price, resulting in gross proceeds of approximately $11.9 million and net proceeds of approximately $10.5 million. The Company also issued approximately 25.4 million shares of common stock as bonus shares in the tender offer.

Induced note conversions

On July 8, 2024, in satisfaction of a redemption, the Company and the April 23, 2021 Noteholder entered into an exchange agreement, pursuant to which a portion of the April 23, 2021 Note was partitioned into a new note with an aggregate principal amount of $0.5 million, which was exchanged concurrently for approximately 3.9 million shares.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

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

Our management, with the participation of our Chief Executive Officer and Interim Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a15(e) and 15d15(e) under the Exchange Act) as of May 31, 2024. 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 has concluded, based upon the evaluation described above, that as of May 31, 2024, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting. Internal control over financial reporting is defined in Rules 13a15(f) and 15d15(f) under the Exchange Act as the process designed by, or under the supervision of, our Principal Executive Officer and effected by the Company's board of directors, management, and other personnel, to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of our financial statements for external purposes in accordance with generally accepted accounting principles ("GAAP"), and includes those policies and procedures that:

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

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

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

Under the supervision and with the participation of our management, including our Principal Executive Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework provided in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of May 31, 2024.

Changes in Internal Control Over Financial Reporting

Other than as described above, during the quarter ended May 31, 2024, there were no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Exchange Act, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Attestation Report of the Registered Public Accounting Firm

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

Item 9B. Other Information

None.

Part III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by Item 10 will be contained in, and is incorporated herein by reference to, our definitive proxy statement for our 2024 Annual Meeting of Stockholders under the captions *Proposal 1: Election of Directors, Information about our Executive Officers,* and *Delinquent Section 16(a) Reports*, to be filed with the SEC within 120 days of the end of the Company's fiscal year ended May 31, 2024 (the 2024 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, principal financial officer, and principal accounting officer (our interim Chief Financial Officer), and senior financial officers, or persons performing similar functions. We make our code of ethics and business conduct available free of charge on our website at www.cytodyn.com.

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

Item 11. Executive Compensation.

The information required by Item 11 relating to executive compensation will be contained in, and is incorporated herein by reference to, our 2024 Proxy Statement under the captions *Executive Compensation* (excluding *Pay versus Performance*) and *Director Compensation*.

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

The information required by Item 12 relating to security ownership of certain beneficial owners and management and related stockholders' matters will be contained in, and is incorporated herein by reference to, our 2024 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 2024 Proxy Statement under the captions *Related Person Transactions* and *Director Independence*.

Item 14. Principal Accountant Fees and Services.

The information required by Item 14 relating to principal accountant fees and services will be contained in, and is incorporated herein by reference to, our 2024 Proxy Statement under the caption *Matters Relating to the Company's Independent Registered Public Accounting Firm*.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

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

(1) Consolidated Financial Statements

The consolidated financial statements for the fiscal years ended May 31, 2024, and 2023 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 November 9, 2023		S-1	3.1	2/7/2024
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		S-1	4.1	2/7/2024
4.2	Form of Common Stock Certificate		8-K12G3	4.1	9/1/2015
4.3	Form of Warrant Agreement (Private Offerings)		8-K	4.1	9/4/2018
4.4	Form of Warrant Agreement (Registered Offerings)		8-K	4.1	4/5/2019
4.5	Form of Warrant Agreement (Series C Convertible Preferred Stock Offering)		8-K	4.1	3/20/2019
4.6	Form of Warrant Agreement (Series C Convertible Preferred Stock Offering)		8-K	4.1	10/22/2019
4.7	Form of Warrant Agreement (Series D Convertible Preferred Stock Offering)		8-K	4.1	2/3/2020
4.8	Form of Warrant to Purchase Common Stock (December 2018 Convertible Note Offering)		8-K	4.2	1/3/2019
4.9	Form of Warrant to Purchase Common Stock		8-K	4.1	1/31/2019
4.10	Form of Common Stock Purchase Warrant		8-K	4.1	8/29/2019
4.11	Form of Common Stock Purchase Warrant		8-K	4.1	12/27/2019
4.12	Warrant to Purchase Common Stock by and between CytoDyn Inc. and Iliad Research and Trading, L.P.		8-K	4.2	1/31/2019
4.13	Secured Convertible Promissory Note between CytoDyn Inc. and Streeterville Capital, LLC, dated April 2, 2021		8-K	4.1	4/8/2021

4.14	Secured Convertible Promissory Note between CytoDyn Inc. and Uptown Capital, LLC, dated April 23, 2021	8-K	4.1	4/29/2021
4.15	Form of Warrant	8-K	4.1	9/7/2021
4.16	Initial Warrant Issued under Surety Bond Backstop Agreement	8-K	4.1	2/17/2022
4.17	Make-Whole Warrant Issued under Surety Bond Backstop Agreement	8-K	4.2	2/17/2022
4.18	Warrant Issued to Richard G. Pestell	10-K	4.22	8/15/2022
4.19	Initial Warrant Issued under Surety Bond Backstop Extension	10-K	4.19	9/14/2023
4.20	Subsequent Warrant Issued under Surety Bond Backstop Extension	10-K	4.20	9/14/2023
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	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
10.4	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
10.5	Form of Indemnification Agreement	10-Q	10.2	10/9/2018
10.6	Security Agreement between CytoDyn Inc. and Streeterville Capital, LLC, dated April 2, 2021	8-K	10.2	4/8/2021
10.7	Security Agreement between CytoDyn Inc. and Uptown Capital, LLC, dated April 23, 2021	8-K	10.2	4/29/2021
10.8*	CytoDyn Inc. Amended and Restated 2012 Equity Incentive Plan (the “2012 Plan”)	10-Q	10.4	1/9/2023

10.9*	Form of Stock Option Award Agreement for Executive Employees under the 2012 Plan		10-K	10.43	8/14/2020
10.10*	Form of Stock Option Award Agreement for Non-Employee Directors under the 2012 Plan		10-K	10.9	8/29/2013
10.11*	Form Stock Option Award Agreement (For Non-Employee Directors)		10-Q	10.2	1/9/2023
10.12*	Form Stock Option Award Agreement (For Executives)		10-Q	10.3	1/9/2023
10.13*	Employment Agreement between CytoDyn Inc. and Tyler Blok, effective August 15, 2023		10-Q	10.1	10/23/2023
10.14*	Consulting Agreement between the Company and Rapid Deployment LLC		10-Q	10.1	4/15/2024
10.15*	Employment Agreement between the Company and Jacob P. Lalezari, M.D., dated January 26, 2024		8-K	10.1	1/29/2024
21	Subsidiaries of the Registrant	X			
23.1	Consent of Macias Gini & O'Connell LLP	X			
23.2	Consent of Marcum LLP	X			
31.1	Certification of Principal Executive Officer under Rule 13a-14(a)	X			
31.2	Certification of Interim Chief Financial Officer under Rule 13a-14(a)	X			
32	Certification of Principal Executive Officer and Interim 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

* 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, 2024

CYTODYN INC.
(Registrant)

By: /s/ Jacob Lalezari
Jacob Lalezari
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated on August 15, 2024.

Principal Executive Officer:

/s/ Jacob Lalezari
Jacob Lalezari
Chief Executive Officer

Principal Financial and Accounting Officer:

/s/ Mitchell Cohen
Mitchell Cohen
Interim Chief Financial Officer

Directors

/s/ Tanya Durkee Urbach
Tanya Durkee Urbach, Chair

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

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

/s/ Ryan M. Dunlap
Ryan M. Dunlap

/s/ Stephen M. Simes
Stephen M. Simes

Exhibit 21

SUBSIDIARIES

Name	Jurisdiction of Incorporation or Organization
CytoDyn Operations Inc.	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

/s/ Macias Gini & O'Connell LLP

San Jose, California
August 15, 2024

Exhibit 23.2

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statement of CytoDyn, Inc. on Form S-1 (FILE NO. 333-272815 and 333-276912) and Form S-8 (FILE NO. 333-249179) of our report dated August 15, 2024, which includes an explanatory paragraph as to the Company's ability to continue as a going concern with respect to our audit of the consolidated financial statements of CytoDyn, Inc. as of May 31, 2024 and for the year ended May 31, 2024, which report is included in this Annual Report on Form 10-K of CytoDyn Inc. for the year ended May 31, 2024.

/s/ Marcum LLP

Hartford, CT
August 15, 2024

Exhibit 31.1

Certification of Principal Executive Officer

I, Jacob Lalezari, 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, 2024

/s/ Jacob Lalezari
Jacob Lalezari
Chief Executive Officer

Exhibit 31.2

Certification of Chief Financial Officer

I, Mitchell Cohen, 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, 2024

/s/ Mitchell Cohen
Mitchell Cohen
Interim Chief Financial Officer

Exhibit 32

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350

In connection with the Annual Report of CytoDyn Inc. (the "Company") on Form 10-K for the fiscal year ended May 31, 2024, 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/ Jacob Lalezari	/s/ Mitchell Cohen
Jacob Lalezari	Mitchell Cohen
Chief Executive Officer	Interim Chief Financial Officer
Date: August 15, 2024	Date: August 15, 2024

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.