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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, 2021

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. Yes ☒ No ☐

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and ask price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter: $1,534,001,633 as of November 30, 2020.

As of July 15, 2021, the registrant had 632,586,877 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Document	**Parts Into Which Incorporated**
Portions of the Proxy Statement for the 2021 Annual Meeting of Stockholders	**Part III**

CYTODYN INC.

FORM 10-K FOR THE YEAR ENDED MAY 31, 2021

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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," "hopes," "intends," "estimates," "expects," "projects," "plans," "anticipates" and variations thereof, or the use of future tense, identify forward-looking statements, but their absence does not mean that a statement is not forward-looking. Our forward-looking statements are not guarantees of performance, and actual results could vary materially from those contained in or expressed by such statements. In evaluating all such statements, we urge you to specifically consider various risk factors identified in this annual report, including the matters set forth under the heading "Risk Factors," any of which could cause actual results to differ materially from those indicated by our forward-looking statements.

Our forward-looking statements reflect our current views with respect to future events and are based on currently available financial, economic, scientific, and competitive data and information on current business plans. Forward-looking statements specifically include statements about leronlimab, its ability to provide health outcomes, the possible results of clinical trials, studies or other programs or ability to continue those programs, the ability to obtain regulatory approval for commercial sales, the market for actual commercial sales, and the impact of health epidemics, including the ongoing novel coronavirus disease ("COVID-19") pandemic, on our business and operations. You should not place undue reliance on our forward-looking statements, which are subject to risks and uncertainties relating to, among other things: (i) the regulatory determinations of leronlimab's efficacy to treat human immunodeficiency virus ("HIV") patients with multiple resistance to current standard of care, COVID-19 patients, and metastatic Triple Negative Breast Cancer ("mTNBC"), among other indications, by the U.S. Food and Drug Administration and various drug regulatory agencies in other countries; (ii) the Company's ability to raise additional capital to fund its operations; (iii) the Company's ability to meet its debt obligations; (iv) the Company's ability to enter into partnership or licensing arrangements with third-parties; (v) the Company's ability to identify patients to enroll in its clinical trials in a timely fashion; (vi) the Company's ability to achieve approval of a marketable product; (vii) the design, implementation and conduct of the Company's clinical trials; (viii) the results of the Company's clinical trials, including the possibility of unfavorable clinical trial results; (ix) the market for, and marketability of, any product that is approved; (x) 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; (xi) regulatory initiatives, compliance with governmental regulations and the regulatory approval process; (xii) legal proceedings, investigations or inquiries affecting the Company or its products; (xiii) general economic and business conditions; (xiv) changes in foreign, political, and social conditions; (xv) stockholder actions or proposals with regard to the Company, its management, or its board of directors; and (xvi) various other matters, many of which are beyond the Company's control. Should one or more of these risks or uncertainties develop, or should underlying assumptions prove to be incorrect, actual results may vary materially and adversely from those anticipated, believed, estimated, or otherwise indicated by our forward-looking statements.

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

PART I

Item 1. BUSINESS

Corporate History/Business Overview

CytoDyn Inc. was originally incorporated under the laws of Colorado on May 2, 2002, under the name RexRay Corporation and, effective August 27, 2015, was reincorporated under the laws of Delaware. 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 will make available on our website, free of charge, the proxy statements and reports on Forms 8-K, 10-K, and 10-Q that we file with the United States Securities and Exchange Commission ("SEC") as soon as reasonably practicable, after such material is electronically filed with or furnished to, the SEC. We do not intend to incorporate any content from our website into this Form 10-K. Unless the context otherwise requires, references in this annual report to "CytoDyn," the "Company," "we," "our," or "us" are to CytoDyn Inc. and its subsidiaries.

The Company is a late-stage biotechnology company focused on the clinical development and potential commercialization of leronlimab (PRO 140), a CCR5 antagonist to treat human immunodeficiency virus ("HIV") infection, with the potential for multiple therapeutic indications. In November 2018, the United States Adopted Names Council adopted "leronlimab" as the official nonproprietary name for PRO 140. The names leronlimab and PRO 140 will be used interchangeably throughout this Form 10-K. The Company has also received conditional acceptance by the U.S. Food and Drug Administration (the "FDA") of the proprietary name Vyrologix (pronounced—vie-ro-loj-iks) for leronlimab as a combination therapy for highly treatment experienced HIV patients in the United States. In addition, the Company has also received a notice of allowance from the U.S. Trademark Office for the trademark "Vyrologix".

The pre-clinical and clinical development of PRO 140 was led by Progenics Pharmaceuticals, Inc. ("Progenics") through 2011. The Company acquired the asset from Progenics in October 2012, as described in "PRO 140 Acquisition and Licensing Arrangements" below. In February 2018, we announced we had met the primary endpoint in our Phase 3 trial for leronlimab as a combination therapy with HAART for highly treatment-experienced HIV patients and submitted the non-clinical portion of our Biologics License Application ("BLA") to the FDA in March 2019. We submitted to the FDA the clinical, along with the Chemistry, Manufacturing, and Controls ("CMC"), portions of the BLA in April and May of 2020. In July 2020, the Company received a Refusal to File letter from the FDA regarding its BLA submission requesting additional information. In August and September 2020, the FDA provided written responses to the Company's questions and met telephonically with key Company personnel and its clinical research organization concerning its BLA submission in an effort to clarify and to expedite the resubmission of its BLA for this indication. The deficiencies cited by the FDA in its July 2020 Refusal to File letter consisted of administrative deficiencies, omissions, corrections to data presentation, and related analyses and clarifications of manufacturing processes. The Company is working with new consultants to cure the BLA deficiencies and resubmit the BLA in order to allow the FDA to perform their substantive review. The Company began to resubmit of the BLA in July 2021 and expected to be completed in October 2021.

To facilitate our clinical research plans and trials, we have engaged various contract research organizations ("CRO"), to provide comprehensive regulatory and clinical trial management services. We will require a significant amount of additional capital to complete our clinical trial programs for leronlimab, which are designed to accelerate and maximize the leverage of our multi-pathway approach to identifying and evaluating multiple opportunities for clinical indications. See "Liquidity and Capital Resources" under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" below.

Our current business strategy is to resubmit our BLA to the FDA as soon as possible, to finalize with the FDA our submitted protocol for a pivotal Phase 3 clinical trial with leronlimab as a monotherapy for HIV patients, to seek emergency use authorization and approval for leronlimab as a potential therapeutic benefit for COVID-19 patients with mild-to-moderate, severe-to-critical, and long-haulers indications in the U.S., Brazil, and other countries, to advance our clinical trials with leronlimab for various forms of cancer, including, among others, our Phase 2 clinical trial for metastatic triple-negative breast cancer and Phase 2 basket trial for 22 solid tumor cancers, to complete our Phase 2 trial

for liver fibrosis associated with nonalcoholic steatohepatitis ("NASH"), and to explore other cancer and immunologic indications for leronlimab. Each of these strategies is described in more detail below.

Leronlimab as a CCR5 Antagonist

We are focused on developing leronlimab, a monoclonal antibody C—C chemokine receptor type 5 ("CCR5") receptor antagonist, to be used as a platform drug for various indications. The target of leronlimab is the immunologic receptor CCR5. The CCR5 receptor is a protein located on the surface of various cells including white blood cells and cancer cells. On white blood cells, it serves as a receptor for chemical attractants called chemokines. The CCR5 receptor is also the co-receptor needed for certain strains of HIV to infect healthy T-cells. Recent research has identified the CCR5 receptor as an important target for many disease processes, including cancer metastasis and certain immunological conditions. Leronlimab is a unique humanized monoclonal antibody. We believe leronlimab prevents certain strains of HIV from using the CCR5 receptor as an entry gateway for 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. Calcium channel signaling of the CCR5 receptor is a crucial component to the spread of metastatic cancer.

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, leronlimab does not appear to activate the immune function of the CCR5 receptor through agonist activity. This apparent target specificity differentiates leronlimab from other CCR5 antagonists. Leronlimab is a competitive rather than allosteric inhibitor of the CCR5 receptor. Other potential advantages of leronlimab are believed to include longer half-life and less frequent dosing requirements.

The target of leronlimab is the immunologic receptor CCR5. We believe that the CCR5 receptor is more than the door for HIV to enter T-cells; it may also be a crucial component in inflammatory responses. This could present the potential for multiple pipeline opportunities for leronlimab, such as NASH, cancers, and COVID-19, among other indications.

The CCR5 receptor is a protein located on the surface of white blood cells that serves as a receptor for chemical attractants called chemokines. Chemokines are the key orchestrators of leukocyte trafficking by attracting immune cells to the sites of inflammation. At the site of an inflammatory reaction, chemokines are released. These chemokines are specific for CCR5 and cause the migration of T-cells to these sites promoting further inflammation. The mechanism of action of leronlimab has the potential to block the movement of T-cells to inflammatory sites, which could be instrumental in diminishing or eliminating inflammatory responses. Some disease processes that could benefit from CCR5 blockade include transplantation rejection, autoimmunity, and chronic inflammation such as rheumatoid arthritis and psoriasis.

Due to leronlimab's mechanism of action ("MOA"), we believe leronlimab may have significant advantages in reducing side effects over other CCR5 antagonists. Prior studies have demonstrated that leronlimab does not cause direct activation of T-cells. The CCR5 receptor has been identified as a target in HIV, GvHD (graft-versus-host disease), NASH, cancer metastasis, transplantation medicine, multiple sclerosis, traumatic brain injury, stroke recovery, and a variety of inflammatory conditions, including potentially COVID-19.

Leronlimab and Human Immunodeficiency Virus ("HIV")

We believe the leronlimab antibody shows promise as a powerful antiviral agent with the advantage of fewer side effects, lower toxicity and less frequent dosing requirements, as compared to daily drug therapies currently in use for the treatment of HIV. The leronlimab antibody belongs to a class of HIV therapies known as entry inhibitors that block HIV from entering and infecting specific cells. Leronlimab blocks HIV from entering a cell by binding to a molecule called CCR5, a normal cell surface receptor protein to which certain strains of HIV, referred to as "R5" strains, attach to as part of HIV's entry into a cell.

Our clinical trials suggest leronlimab does not appear to affect the normal function of the CCR5 co-receptor for HIV. Instead, 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 without appearing to affect the cell's normal function. The R5

strains of HIV currently represent approximately 67% of all HIV infections in the United States. 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 believe leronlimab is uniquely positioned to address a growing 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 nine clinical trials previously conducted, leronlimab was generally well tolerated, and limited drug-related serious adverse events ("SAEs"), or dose-proportional adverse events ("AEs"), were reported. In addition, there were no dose-limiting toxicities or patterns of drug-related toxicities observed during these trials. We believe the results of these trials establish that leronlimab's antiviral activity is potent, rapid, prolonged, dose-dependent, and statistically significant following a single dose. Because leronlimab's mechanism of action (for a monoclonal antibody use 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. We believe leronlimab, as a single agent therapy, has the potential to replace highly active antiretroviral therapy ("HAART") altogether for a subpopulation of R5 patients who have suppressed viral load with HAART, but who are seeking an alternative treatment that affords the patient an improved quality of life, with the advantages of fewer side effects, lower toxicity and less frequent dosing requirements.

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

- Patients desiring a break from existing treatment regimens, whether due to side effects or for any personal reasons;
- Patients with difficulty adhering to daily drug regimens;
- Patients who poorly tolerate existing therapies;
- Patients with compromised organ function, such as hepatitis C ("HCV") co-infection;
- Patients with complex concomitant medical requirements; and
- Patients who choose not to start their HAART regimen immediately after being infected with HIV.

Clinical trials for leronlimab have demonstrated potent antiretroviral activity and no drug-related SAEs or dose-proportional AEs. Consequently, we believe that leronlimab has the potential to be the first long-acting (weekly or every other week), self-administered HIV therapy. Leronlimab appears to inhibit CCR5-tropic HIV while preserving CCR5's natural function. As a result, we believe leronlimab represents a distinct class of CCR5 inhibitors with unique virological and immunological properties and may provide another distinct tool to treat HIV-infected patients.

Our HIV-related clinical trials and related activities during fiscal 2021, as summarized below, have been designed to demonstrate the proof of concept that leronlimab as a monotherapy can continue to suppress the viral load in certain HIV-infected, treatment-experienced patients who had suppressed viral load on HAART, but would like an alternative treatment that provides a higher quality of life with one dose a week through a self-injection. Once the viral load is undetectable, weekly administration of leronlimab could potentially help maintain the suppressed viral load in a subpopulation of R5 patients over an extended period, as currently shown in our Phase 2b extension study to be over approximately seven years.

In 2016, we initiated a pivotal Phase 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 have transitioned to an FDA-cleared rollover study, as requested by the treating physicians, to enable them to have continued access to leronlimab. An open label arm continued to enroll five more patients after the trial was concluded. The trial is the basis for our BLA submission with the FDA. We submitted the non-clinical portion of the BLA to the FDA in March 2019. We submitted to the FDA the clinical and CMC portions of the BLA in April and May of 2020. In July 2020, we received a Refusal to File letter from the FDA regarding the BLA submission requesting additional information. In August and September 2020, the FDA provided written responses to the Company's questions and met telephonically with key Company

personnel and its clinical research organization concerning the BLA. The Company began to resubmit the BLA in July 2021 and is expected to be completed in October 2021.

Importantly, and in parallel with the submission of our pivotal trial protocol for monotherapy, we recently announced the completion of the development of a receptor occupancy assay to measure the expression of CCR5 in HIV and tumor cells that are occupied by leronlimab. The development of this test could more precisely guide us in the identification of HIV patients at screening for monotherapy, thereby potentially improving therapeutic success, along with further identifying cancer-patient candidates who have a form of cancer that CCR5 is over expressed.

Rollover Study for HIV, as Combination Therapy

This study is designed for patients who successfully completed the pivotal Phase 3 combination therapy trial and for whom the treating physicians request a continuation of leronlimab therapy to maintain suppressed viral load. This extension study will be discontinued upon any FDA approval of leronlimab. Some of the patients are now reaching four years of treatment in this extension arm.

Phase 2b Extension Study for HIV, as Monotherapy

There are five patients in this ongoing extension study, and each has reached close to seven years of suppressed viral load with leronlimab as a single agent therapy. This extension study will be discontinued in the event of FDA approval, if any, of leronlimab for this indication.

Phase 2b/3 Investigative Trial for HIV, as Long-term Monotherapy

Enrollment for this trial closed after reaching over 560 patients. This trial assessed the subcutaneous use of leronlimab as long-acting single-agent maintenance therapy for 48 weeks in patients with suppressed viral load with CCR5 tropic HIV-1 infection. The primary endpoint is the proportion of participants with a suppressed viral load to those who experienced virologic failure (virologic failure defined as two consecutive viral load readings over 200 cp/mL). The secondary endpoint is the length of time to virologic failure. We completed the evaluation of two higher-dose arms, one with a 525 mg dose (a 50% increase from the original dosage of 350 mg), as well as a 700 mg dose (a 100% increase from the original dosage of 350 mg). We reported in August 2019 that interim data suggested both the 525 mg and the 700 mg dosages were achieving a responder rate of approximately 90% after the initial 10 weeks of monotherapy (defined as induction period). This trial has also been used to provide safety data for our BLA submission for leronlimab as a combination therapy. Given the high responder rate at the increased dosage levels, coupled with the newly developed CCR5 occupancy test, we filed a pivotal trial protocol with the FDA for leronlimab as monotherapy with 700 mg dose in May 2019. Many patients who completed the Phase 2b/3 trial and requested continued access to leronlimab are continuing in an extension study.

Phase 2b/3 Extension of the Investigative Trial for HIV, as Long-term Monotherapy

Many patients requested to continue on monotherapy with leronlimab upon successful completion of the Phase 2b/3, 48-week trial. Over 40 patients were given access to this trial and many have continued on this protocol for more than three years.

Leronlimab and Coronavirus Disease 2019

SARS-CoV-2 was identified as the cause of an outbreak of respiratory illness first detected in Wuhan, China. The origin of SARS-CoV-2 causing the COVID-19 disease is uncertain, and the virus is highly contagious. COVID-19 typically transmits person to person through respiratory droplets, commonly resulting from close personal contact. Coronaviruses are a large family of viruses, some causing illness in people and others that circulate among animals. For confirmed COVID-19 infections, symptoms have included fever, cough, and shortness of breath, amongst many others. The symptoms of COVID-19 may appear in as few as two days or as long as 14 days after exposure. Clinical manifestations in patients have ranged from non-symptomatic to severe and fatal. At this time, outside of current experimental vaccines there are minimal effective treatment options for COVID-19.

Based upon analyses of leronlimab's potential effect on the immune system and the results from over 60 Emergency Investigation New Drug ("EIND") authorizations provided by the FDA, the Company conducted three clinical trials for COVID-19 during fiscal 2021: a Phase 2 randomized clinical trial for mild-to-moderate COVID-19 population in the U.S., a Phase 3 randomized clinical trial for severe-to-critically ill COVID-19 population in several hospitals throughout the U.S. and, a Phase 2 investigative trial for long-haulers, as discussed in more detail below.

Phase 2 Trial to Evaluate the Efficacy and Safety of Leronlimab for Mild-to-Moderate COVID-19 (CD10)

This two-arm, randomized, double-blind, placebo-controlled multicenter study to evaluate the safety and efficacy of leronlimab in patients with mild-to-moderate symptoms of respiratory illness caused by COVID-19 infection was completed in July 2020. Patients were randomized to receive weekly doses of 700 mg leronlimab or placebo (two doses of 700 mg of leronlimab or placebo at day 0 and day 7). Leronlimab and placebo were administered via subcutaneous injection. The study had three phases: screening period, treatment period, and follow-up period. A total of 86 subjects were randomized 2:1 (active drug to placebo) in this study. The primary outcome measures were a clinical improvement as assessed by a change in total symptom score (for fever, myalgia, dyspnea, and cough). Secondary outcome measures included: (1) time to clinical resolution, (2) change from baseline in National Early Warning Score 2 (NEWS2), developed by the Royal College of Physicians in the U.S., (3) change from baseline in pulse oxygen saturation, (4) change from baseline in the patient's health status on a 7 category ordinal scale, (5) incidence of hospitalization, (6) duration (days) of hospitalization, (7) incidence of mechanical ventilation supply, (8) duration (days) of mechanical ventilation supply, (9) incidence of oxygen use, (10) duration (days) of oxygen use, (11) mortality rate, and (12) time to return to normal activity. Enrollment was completed in July 2020, and the Company reported positive tolerability results. The top-line report from the trial, including efficacy and complete safety data, showed that the trial did not achieve its designated primary or secondary endpoints, but we believe demonstrated clinical improvement at Day 3 compared to Day 0 for leronlimab versus placebo and statistically significant results for the secondary outcome for NEWS2 and was submitted to the FDA in August 2020.

Phase 3 Trial to Evaluate the Efficacy and Safety of Leronlimab for Patients with Severe-to-Critical COVID-19 (CD12)

This was a two-arm, randomized, double-blind, placebo-controlled, adaptive design multicenter study to evaluate the safety and efficacy of leronlimab in patients with severe-to-critical symptoms of respiratory illness caused by COVID-19. Patients were randomized to receive weekly doses of 700 mg leronlimab or placebo (two doses of 700 mg of leronlimab or placebo at day 0 and day 7). Leronlimab and placebo were administered via subcutaneous injection. The study had three phases: screening period, treatment period, and follow-up period. The primary outcome measured in this study was all-cause mortality at Day 28. Secondary outcomes measured were: (1) all-cause mortality at Day 14, (2) change in clinical status of subject at Day 14, (3) change in clinical status of subject at Day 28, and (4) change from baseline in Sequential Organ Failure Assessment (SOFA) score at Day 14. In August 2020, the Data Safety Monitoring Committee, or DSMC, reviewed compiled safety data from 149 of the 169 patients enrolled in the Phase 3 trial. The DSMC did not raise any safety concerns and recommended that the trial continue without modification. In October 2020, the DSMC for the ongoing Phase 3 trial completed its interim analysis of the data from the first 195 patients, recommended that the trial continue without modification, and requested another interim analysis when enrollment reached the 75% level to review patient mortality and other clinical outcome data between the two study arms. The Company completed enrollment in December 2020 with 394 patients and, accordingly, the last patient enrolled reached 28 days in mid-January 2021. We believe the results for a sub-population of 384 patients (mITT, modified intent to treat) may provide the basis for regulatory approval in one or more countries. This trial did not meet its designated primary or secondary endpoints, but the sub-population provided one statistically significant result for secondary endpoint. The FDA has requested an additional study of a larger population of mechanically ventilated critically ill COVID-19 patients. The Company has also supplied trial results to health authorities in Canada, the U.K., Philippines, Brazil and India. The Company is seeking an Emergency Use Authorization ("EUA") with Health Canada (via a request for Interim Order) and in the U.K., but both require additional trial data. In March 2021, the Philippines FDA granted a Compassionate Special Permit for leronlimab for the treatment of COVID-19 and the Company has since delivered leronlimab to a Philippines hospital to be administered to an additional 28 patients under a new CSP.

FDA Statement on Certain of Our COVID-19 Trials

On May 17, 2021, FDA issued a statement on its website responding to certain of our public communications related to our ongoing CD10 and CD12 clinical trials to investigate the safety and efficacy of leronlimab for the treatment of COVID-19. In that statement, FDA stated that the data currently available do not support the clinical benefit of leronlimab for the treatment of COVID-19.

With respect to the CD10 study, FDA stated that there was no observed effect of leronlimab on the trial's primary endpoint or on any of the secondary endpoints. The FDA found that the CD10 trial results showed no clinically meaningful differences in average change in "total clinical symptom score," the measure used to evaluate the primary endpoint of the CD10 study, from baseline to Day 14 between study arms (-3.5 in the leronlimab group versus -3.4 in the placebo group). Additionally, FDA stated that none of the secondary endpoints were met in this study, including mortality, time to symptom resolution, and time to return to normal activity.

The FDA reached the same conclusion for the CD12 study. The FDA stated that the CD12 trial failed to demonstrate any effect of leronlimab on the trial's primary endpoint, with no difference seen in mortality (20.5% in the leronlimab treatment group and 21.6% in the placebo treatment group); or on any of the trial's secondary endpoints, with no difference on the average length of hospitalization (21.4 days in both the leronlimab and the placebo treatment groups).

In response to our review and reports of analysis of data from subgroups from the CD12 trial, FDA stated that subgroup analyses have well-established limitations, especially in the context of a clinical trial that has failed to show a benefit in the overall study population. The agency indicated that data from CD12 illustrated imbalances in mortality among subgroups, some favoring leronlimab and some favoring placebo. The FDA concluded that none of these analyses met statistical significance when using established and reliable analytical methods that correct for multiple comparisons.

In closing, FDA stated that subgroup analyses may inform the design of future clinical trials investigating leronlimab for the treatment of COVID-19. And, that if we plan further trials of leronlimab to determine whether the product candidate can provide clinical benefit to individuals with COVID-19, FDA will continue to provide advice to us on our development program.

Phase 2 Investigational Trial to Evaluate the Efficacy and Safety of Leronlimab for Patients with Post-acute Sequelae of SARS COV-2 (PASC), also known as COVID-19 Long-Haulers (CD15)

In calendar 2021, the Company initiated a Phase 2 investigative trial for post-acute sequelae of SARS COV-2 (PASC), also known as COVID-19 Long-Haulers, which was completed in July 2021. This trial evaluated the effect of leronlimab on clinical symptoms and laboratory biomarkers to further understand the pathophysiology of PASC. This small investigative trial of 56 patients was not designed to show statistically significant differences due to the small sample size of the patients, but we believe potentially clinically meaningful improvements in leronlimab over placebo were observed for several symptoms. Preliminary results from the trial suggested leronlimab improved a majority of clinical symptoms with a Top-line Report expected to be issued after this filing. It is currently estimated that between 10-30% of those infected with COVID-19 develop long-term sequelae. Common symptoms include fatigue, cognitive impairment, sleep disorders, and shortness of breath. If this trial is successful, the Company plans to pursue additional clinical trials to evaluate leronlimab's effect on immunological dysregulation in other post-viral syndromes, including myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS).

Leronlimab and Cancer

Research indicates that the CCR5 receptor is the "GPS" system of a cancer cell that promotes metastatic disease. Pre-clinical studies have shown that leronlimab blocks the calcium channel signaling of the CCR5 receptor and has the potential to disable the GPS system. CCR5 inhibition may disrupt signaling and ultimately the spread of CCR5+ Circulating Tumor Cells ("CTCs"). Current therapies are directed to the primary tumor, rather than the movement or

spread of cancer in the bloodstream. Metastatic disease, not the primary tumor, is the cause of death in most of cancer patients.

Research has shown that most sampled patients in certain studies had increased CCR5 expression in their breast cancer. Increased CCR5 expression is an indicator of disease status in several cancers. Research has shown three key properties of the CCR5's mechanism of action ("MOA") in cancer. The first is that the CCR5 receptor on cancer cells was responsible for the migration and invasion of cells into the bloodstream, which leads to metastasis of breast, prostate, and colon cancer. The second is that blocking the CCR5 receptor also turns on anti-tumor fighting properties restoring immune function. The third key finding was that blockage of the CCR5/CCL5 interaction had a synergistic effect with chemotherapeutic therapy and controlled cancer progression. Chemotherapy traditionally increased expression of CCR5, so blocking it is expected to reduce the levels of invasion and metastasis.

In late November 2018, we received FDA approval of our Investigational New Drug application ("IND") submission and subsequently initiated a Phase 1b/2 clinical trial for metastatic Triple-Negative Breast Cancer ("mTNBC") patients. We have reported that our pre-clinical research with leronlimab reduced by more than 98% the incidence of human breast cancer metastasis in a mouse xenograft model for cancer through six weeks with leronlimab. The temporal equivalency of the murine 6 weeks study may be up to 6 years in humans. In May 2019, the FDA granted Fast Track designation for leronlimab for use in combination with carboplatin to treat patients with CCR5-positive mTNBC.

We conducted three clinical trials for cancer indications during fiscal 2021, as follows:

Phase 2 Trial for Triple-Negative Breast Cancer.

This trial evaluates the feasibility of leronlimab in combination with carboplatin in patients with CCR5+ mTNBC. This trial has advanced from a Phase 1b/2 to Phase 2. The Phase 2 trial is a single arm study with 30 patients to test the hypothesis that the combination of carboplatin intravenously and maximum tolerated dose of leronlimab subcutaneously will increase progression free survival. The change in circulating tumor cells ("CTCs") was evaluated every 21 days during treatment and will be used as an initial prognostic marker for efficacy. The first patient was treated in September 2019, and the Company reported encouraging initial results from the first patient in November 2019. In January 2020, the Company filed for Breakthrough Therapy designation ("BTD") with the FDA to use leronlimab as adjuvant therapy for the treatment of mTNBC. The FDA requested the Company to file for a pre-BTD meeting due to the small number of patients.

Compassionate Use Study of Leronlimab in Breast Cancer

This is a single-arm, compassionate use study with 30 patients for leronlimab combined with a treatment of Physician's Choice (TPC) in patients with CCR5+ mTNBC. Leronlimab will be 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 will be evaluated for tumor response approximately every three 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.

Basket Trial for 22 Solid Tumor Cancers

This is a Phase 2 trial to test the safety and efficacy of leronlimab on 22 different solid tumor cancers, including brain-glioblastoma, melanoma, lung, breast, ovarian, pancreas, bladder, throat, stomach, colon, testicular, uterine, among other indications. The first patient was treated in April 2020. Nine patients either reached one year or surpassed one year of treatment with leronlimab. The trial will conclude in 2021. A planned trial relating to colorectal cancer was combined into this trial.

Emergency IND Use Study of Leronlimab in Breast Cancer

One patient was administered leronlimab with stage 4 HER2 + breast cancer with metastasis to liver, lung, and brain. The patient received her first dose in November 2019 and still is still receiving 700 mg of leronlimab every week.

Leronlimab and Immunological Applications

The target of leronlimab is the immunologic receptor CCR5. We believe that the CCR5 receptor is more than the door for HIV to enter T-cells; it is also a crucial component in inflammatory responses, which could present a potential for multiple pipeline opportunities for leronlimab.

The CCR5 receptor is a protein located on the surface of white blood cells that serves as a receptor for chemical attractants called chemokines. Chemokines are the key orchestrators of leukocyte trafficking by attracting immune cells to the sites of inflammation. At the site of an inflammatory reaction, chemokines are released. These chemokines are specific for CCR5 and cause the migration of T-cells to these sites promoting further inflammation. The mechanism of action of leronlimab has the potential to block the movement of T-cells to inflammatory sites, which could be instrumental in diminishing or eliminating inflammatory responses. Some disease processes that could benefit from CCR5 blockade include transplantation rejection, autoimmunity, and chronic inflammation, such as rheumatoid arthritis and psoriasis.

Due to leronlimab's MOA, we believe leronlimab may have significant advantages in terms of reduced side effects over other CCR5 antagonists. Prior studies have demonstrated that leronlimab does not cause direct activation of T-cells.

We are also conducting a Phase 2 trial with leronlimab to prevent the progression of Non-Alcoholic Fatty Liver Disease ("NAFLD") into Non-Alcoholic Steatohepatitis ("NASH"). NAFLD is an inflammatory disease caused by the build-up of fat in hepatocytes (steatosis). In severe cases, NAFLD progresses into NASH. It is estimated that 30% to 40% of adults in the United States have NAFLD, while 3% to 12% of adults in the United States have NASH. If left untreated, NASH may progress to hepatocellular carcinoma and is expected to become the leading cause of liver transplantation.

In October 2019, the FDA granted clearance to CytoDyn to proceed with a Phase 2 study to test whether leronlimab may control the effects of liver fibrosis associated with NASH. This trial is designed to be a 60 patient, multi-center, randomized, double-blind, placebo-controlled Phase 2 clinical study of the safety and efficacy of leronlimab in adult patients with NASH. The first patient was enrolled in December 2020 and enrollment is ongoing.

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 remaining 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. remaining milestone payments and royalties as follows: (i) $500,000 upon filing a Biologic License Application with the FDA or non-U.S. equivalent regulatory body; (ii) $500,000 upon FDA approval or approval by

another non-U.S. equivalent regulatory body; and (iii) royalties of up to 3.5% of net sales for the longer of 10 years and the date of expiration of the last to expire licensed patent. Additionally, the PDL License provides for an annual maintenance fee of $150,000 until royalties paid exceed that amount. To the extent that such remaining milestone payments and royalties are not timely made, under the terms of the PDL License, AbbVie Inc. has certain termination rights relating to our license of leronlimab thereunder.

Effective July 29, 2015, we entered into a License Agreement (the "Lonza Agreement") with Lonza Sales AG ("Lonza") covering Lonza's "system know-how" technology with respect to our use of proprietary cell lines to manufacture new leronlimab material. The Lonza Agreement provides for an annual license fee and future royalty payments, both of which varies based on whether Lonza, or we or our strategic partner manufactures leronlimab. We currently use two independent parties as contract manufacturers for leronlimab. Therefore, if this arrangement continues, an annual license fee of £0.6 million (approximately $0.8 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.

Patents, Proprietary Technology and Data Exclusivity

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

Generally, patents issued in the U.S. are effective for either (i) 20 years from the earliest asserted filing date, if the application was filed on or after June 8, 1995, or (ii) the longer of 17 years from the date of issue or 20 years from the earliest asserted filing date, if the application was filed prior to that 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. We currently anticipate, absent patent term extension, patent protection relating to the leronlimab antibody itself will start to expire in 2023, certain methods of using leronlimab for treatment of HIV-1 will start to expire in 2026, certain methods of using small-molecule CCR5 antagonists for treatment of cancer metastasis will start to expire in 2032, and certain methods of using leronlimab (PRO 140) for treatment of COVID-19 will start to expire in 2040.

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. See related risk factors under the heading "Risk Factors" below. 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 in an effort to protect our intellectual property.

Separate from and in addition to the patent rights noted above, we expect that leronlimab will be subject to at least a 12-year market and data exclusivity period measured from the first date of FDA licensure, during which period no other applications referencing leronlimab will be approved by FDA. Further, no other applications referencing leronlimab will be accepted by FDA for a 4-year period measured from the first date of FDA licensure. Accordingly, this period of regulatory exclusivity is expected to provide at least a 12-year term of protection against competing products shown to be biosimilar or interchangeable with leronlimab. Similar data exclusivity or data protection periods of up to about five years or more are provided in at least Australia, Canada, Europe, Japan, and New Zealand.

We note that data exclusivity is not an extension of patent rights, and it does not prevent the introduction of generic versions of the innovative drug during the data exclusivity period, as long as the marketing approval of the generic version does not use or rely upon the innovator's test data. Patents and data exclusivity are different concepts, protect different subject matter, arise from different efforts, and have different legal effects over different time periods.

Information with respect to our current patent portfolio as of June 30, 2021, is set forth below.

	Number of Patents			Number of Patent Applications	
	U.S.	International	Expiration Dates[1]	U.S.	International
Leronlimab (PRO 140) product candidate[2]	4	37	2023-2032	1	3
Methods of treatment by indication (e.g., HIV-1; COVID-19; GvHD) [2]	6	12	2022-2041	11	21
Methods of treatment – Cancer involving leronlimab (PRO 140 and/or anti-CCR5 small molecules) [2]	2	13	2032-2033	4	9
Mouse Model[2]	-	-	-	1	1

(1) Patent term extensions and pending patent applications may extend periods of patent protection.

(2) Leronlimab (PRO 140) patents and applications relate to the antibody, formulations, and HIV-1, COVID-19, immunomodulation and GvHD treatments. Additional patents and applications relate to methods of treating cancer and include filings directed towards leronlimab (PRO 140) and/or anti-CCR5 small molecules.

Research, development and commercialization of a biopharmaceutical product often require choosing between alternative development and optimization routes at various stages in the development process. Preferred routes depend upon current—and may be affected by subsequent—discoveries and test results, availability of financial resources, and other factors, and cannot be identified with certainty. There are numerous third-party patents in fields in which we work, and we may need to obtain licenses under patents of others in order 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. See “Risk Factors” below.

Government Regulation

The research, development, testing, manufacture, quality control, packaging, labeling, storage, record-keeping, distribution, import, export, promotion, advertising, marketing, sale, pricing and reimbursement of pharmaceutical products are extensively regulated by governmental authorities in the United States and other countries. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with compliance with applicable statutes and regulations and other regulatory 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. We believe that our products will be regulated as biological products, or biologics. The failure to comply with the applicable U.S. requirements may result in FDA refusal to approve pending BLAs 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, 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 our product candidates for therapeutic indications before they may be marketed in the United States. For biologic products, the FDA must approve a BLA. An applicant seeking approval to market and distribute a new biologic in the United States generally must satisfactorily complete each of the following steps:

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

Pre-clinical Studies

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

The IND and IRB Processes

An IND is an exemption from the FDCA that allows an unapproved product candidate to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA authorization to administer such investigational product to humans. Such authorization must be secured prior to interstate shipment and administration of any product candidate that is not the subject of an approved NDA. In support of a request for an IND, applicants must submit a protocol for each 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, or thereafter, 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.

Following commencement of a clinical trial under an IND, the FDA may also place a clinical hold or partial clinical hold on that trial. 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.

A sponsor may choose, but is not required, to conduct a foreign clinical study 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 representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, 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. Other reasons for suspension or termination may be made by us based on evolving business objectives and/or competitive climate.

Information about clinical trials must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on its ClinicalTrials.gov website.

Emergency Use INDs

In some cases, the need for an investigational drug or biologic may arise in an emergency situation that does not allow time for submission of an IND. In such a case, FDA may authorize shipment of the test article in advance of the IND submission. Requests for such authorization may be made by telephone or other rapid communication means. Specifically, the FDA defines emergency use as the use of an investigational drug or biological product with a human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval. The emergency use provision in the FDA regulations is an exemption from prior review and approval by the IRB. The exemption, which may not be used unless all of the conditions described in FDA's regulations exist, allows for one emergency use of a test article without prospective IRB review. The FDA regulations generally require that any subsequent use of the investigational product at the institution have prospective IRB review and approval.

For the purposes of this exemption, FDA has defined life-threatening to include diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted and diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival. The criteria for life-threatening do not require the condition to be immediately life-threatening or to immediately result in death. Rather, the subjects must be in a life-threatening situation requiring intervention before review at a convened meeting of the IRB is feasible. Institutional procedures may require that the IRB be notified prior to such use, however, this notification should not be construed as an IRB approval.

Even for an emergency use, the investigator is required to obtain informed consent of the subject or the subject's legally authorized representative unless both the investigator and a physician who is not otherwise participating in the clinical investigation certify in writing all of the following: (a) the subject is confronted by a life-threatening situation necessitating the use of the test article; (b) informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from, the subject; (c) time is not sufficient to obtain consent from the subject's

legal representative; and (d) no alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject's life. If, in the investigator's opinion, immediate use of the test article is required to preserve the subject's life, and if time is not sufficient to obtain an independent physician's determination that the four conditions above apply, the clinical investigator should make the determination and, within 5 working days after the use of the article, have the determination reviewed and evaluated in writing by a physician who is not participating in the clinical investigation. The investigator must notify the IRB within 5 working days after the use of the test article.

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.

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, if a sponsor has a policy regarding how it responds to expanded access requests, it must make that policy publicly 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

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.

Phase 1 clinical trials are initially conducted in a limited population to test the product candidate for safety, including adverse effects, dose tolerance, absorption, metabolism, distribution, excretion and pharmacodynamics in healthy humans or in patients. During Phase 1 clinical trials, information about the product candidate's pharmacokinetics and pharmacological effects may be obtained to permit the design of well-controlled and scientifically valid Phase 2 clinical trials.

Phase 2 clinical trials are generally conducted in a limited patient population to identify possible adverse effects and safety risks, evaluate the efficacy of the product candidate for specific targeted indications and determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more costly Phase 3 clinical trials. Phase 2 clinical trials are well-controlled and closely monitored.

Phase 3 clinical trials proceed if the Phase 2 clinical trials demonstrate that a dose range of the product candidate is potentially effective and has an acceptable safety profile. Phase 3 clinical trials are undertaken within an expanded patient population to further evaluate dosage, provide substantial evidence of clinical efficacy and further test for safety in an expanded and diverse patient population at multiple geographically dispersed clinical trial sites. A well-controlled, statistically robust Phase 3 clinical trial may be designed to deliver the data that regulatory authorities will use to decide whether or not to approve, and, if approved, how to appropriately label a product. Such Phase 3 clinical trials are referred to as "pivotal" trials.

In some cases, the FDA may approve an NDA 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 document a clinical benefit in the case of products approved under 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 at least annually to the FDA and more frequently if serious adverse events occur. 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. 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.

Pediatric Studies

Under the Pediatric Research Equity Act of 2003, an application or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. Sponsors must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests and other information required by regulation. The applicant, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time.

For investigational products intended to treat a serious or life-threatening disease or condition, the FDA must, upon the request of an applicant, meet to discuss preparation of the initial pediatric study plan or to discuss deferral or waiver of pediatric assessments. In addition, the FDA will meet early in the development process to discuss pediatric study plans with sponsors, and the FDA must meet with sponsors by no later than the end-of-phase 1 meeting for serious or life-threatening diseases and by no later than ninety days after the FDA's receipt of the study plan.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data

requirements. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in the Food and Drug Administration Safety and Innovation Act, or FDASIA. The FDA maintains a list of diseases that are exempt from PREA requirements due to low prevalence of disease in the pediatric population. In 2017, with passage of the FDA Reauthorization Act of 2017, or FDARA, Congress further modified these provisions. Previously, investigational products that had been granted orphan drug designation were exempt from the requirements of the Pediatric Research Equity Act.

Expedited Review Programs

The FDA is authorized to expedite the review of BLAs in several ways. Under the Fast Track program, 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 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.

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.

- *Breakthrough therapy designation.* To qualify for the breakthrough therapy program, 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. The FDA will seek to ensure the sponsor of a breakthrough therapy product candidate receives 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. FDA aims to complete its review of priority review applications within six months as opposed to 10 months for standard review.
- *Accelerated approval*. Drug or biologic products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval. Accelerated approval means that a product candidate may be approved on the basis of adequate and well controlled clinical trials establishing that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or 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 biologic 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-approval of promotional materials.
- *Regenerative advanced therapy.* With passage of the 21st Century Cures Act, or the Cures Act, in December 2016, Congress authorized the FDA to accelerate review and approval of products designated as regenerative advanced therapies. A product is eligible for this designation if it is a regenerative medicine therapy that is intended to treat, modify, reverse or cure a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product candidate has the potential to address unmet medical needs for such disease or condition. The benefits of a regenerative advanced therapy designation include early interactions with the FDA to expedite development and review, benefits available to breakthrough therapies, potential eligibility for priority review and accelerated approval based on surrogate or intermediate endpoints.

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

In the event of a public health emergency declared by the Secretary of the HHS, the FDA has the authority to allow unapproved medical products or unapproved uses of cleared or approved medical products to be used in an emergency to diagnose, treat or prevent serious or life-threatening diseases or conditions caused by chemical, biological, radiological or nuclear warfare threat agents when there are no adequate, approved, and available alternatives.

The FDA may issue an Emergency Use Authorization, or EUA, for an unapproved product if the following four statutory criteria have been met: (1) a serious or life-threatening condition exists; (2) evidence that the product may be effective in diagnosing or treating such condition; (3) a risk-benefit analysis shows that the benefits of the product outweigh the risks; and (4) no adequate, approved and available alternatives exist for diagnosing, preventing or treating the disease or condition. Evidence of effectiveness includes products that "may be effective" to prevent, diagnose, or treat the disease or condition identified in a declaration of emergency issued by the Secretary of HHS. The "may be effective" standard for EUAs requires a lower level of evidence than the traditional standard of approval governing biologic products. The statute directs FDA to assess the potential effectiveness of a possible EUA product on a case-by-case basis using a risk-benefit analysis. In determining whether the known and potential benefits of the product outweigh the known and potential risks, the FDA examines the totality of the scientific evidence to make an overall risk-benefit determination. Such evidence, which could arise from a variety of sources, may include (but is not limited to) results of domestic and foreign clinical trials, in vivo efficacy data from animal models and in vitro data.

Once granted, an EUA will generally remain in effect until the earlier of (1) a determination by the Secretary of HHS that the public health emergency has ceased or (2) a change in the approval status of the product such that the authorized use(s) of the product are no longer unapproved. After the EUA is no longer valid, the product is no longer considered to be legally marketed, and FDA's non-emergency approval pathway would be necessary to resume or continue distribution of the product. The FDA also may revise or revoke an EUA if the circumstances justifying its issuance no longer exist, the criteria for its issuance are no longer met, or other circumstances make a revision or revocation appropriate to protect the public health or safety.

On January 31, 2020, the Secretary of HHS issued a declaration of a public health emergency related to COVID-19. On February 4, 2020, HHS determined that COVID-19 represents a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and, subsequently, declared on March 24, 2020, that circumstances exist to justify the authorization of emergency use of certain medical products, during the COVID-19 pandemic, subject to the terms of any authorization as issued by the FDA. The HHS Secretary's declaration has been further updated and the FDA has issued numerous guidance to sponsors seeking to obtain EUAs to diagnose and treat COVID-19.

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, 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 FY2021 this application fee is approximately $2.9 million), and the sponsor of an approved BLA is also subject to an annual program fee, currently more than $300,000 per program. These fees are typically adjusted annually, but exemptions and waivers may be available under certain circumstances.

The FDA conducts a preliminary review of all BLAs within 60 days of receipt and informs the sponsor by the 74th day after the FDA's receipt of the submission whether an application is sufficiently complete to permit substantive review. In pertinent part, FDA's regulations for BLAs state that an application "shall not be considered as filed until all pertinent information and data have been received" by the FDA. In the event that FDA determines that a BLA does not

satisfy this standard, it will issue a Refuse to File, or RTF, determination to the applicant. Typically, an RTF for a BLA will be based on administrative incompleteness, such as clear omission of information or sections of required information; scientific incompleteness, such as omission of critical data, information or analyses needed to evaluate safety, purity and potency or provide adequate directions for use; or inadequate content, presentation, or organization of information such that substantive and meaningful review is precluded. The FDA may request additional information rather than accept a BLA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing.

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

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

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

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

An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete and the application will not be approved in its present form. A CRL generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. The CRL may require additional clinical or other data, additional pivotal Phase 3 clinical trial(s) and/or other significant and time- consuming requirements related to clinical trials, pre-clinical studies or manufacturing. If a CRL is issued, the applicant may either resubmit the BLA addressing all of 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 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 regulatory 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

When a biological product is licensed for marketing by FDA with approval of a BLA, 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 reference biological product. To date, the FDA has approved a number of biosimilars. No interchangeable biosimilars, however, have been approved. The FDA has also issued several guidance documents outlining its approach to reviewing and approving biosimilars and interchangeable biosimilars.

Under the BPCIA, a manufacturer may submit an application that is "biosimilar to" or "interchangeable with" a previously approved biological product or "reference product." In order for the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and proposed biosimilar product in terms of safety, purity and potency. For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product and (for products administered multiple times) that the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Upon licensure by the FDA, an interchangeable biosimilar may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product, although to date no such products have been approved for marketing in the United States.

The biosimilar applicant 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. In addition, the applicant must show that the biosimilar and reference products have the same mechanism of action for the conditions of use on the label, route of administration, dosage and strength, and the production facility must meet standards designed to assure product safety, purity and potency.

A reference biological product is granted 12 years of exclusivity from the time of first licensure of the product, and the first approved interchangeable biologic 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 based on the reference biological product until four years after the date of first licensure of the reference product.

The BPCIA is complex and only beginning to be interpreted and implemented by the FDA. In addition, recent government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation and meaning of the BPCIA is 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 biologic for the disease or condition will be recovered from sales of the product in the United States.

Orphan drug designation qualifies a company for 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 becomes an orphan when it receives orphan drug designation from the Office of Orphan Products Development at the FDA based on acceptable confidential requests made under the regulatory provisions. The product must then 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 product 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 product 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 designation receives the first FDA approval for the disease or condition for which it has such designation or for a select indication or use within the rare disease or condition for which it was designated, 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 product for the same indication for seven years, except in certain limited circumstances. If a product designated as an orphan drug ultimately receives marketing approval for an indication broader than what was designated in its orphan drug application, it may not be entitled to exclusivity.

The period of exclusivity begins on the date that the marketing application is approved by the FDA and applies only to the indication for which the product has been designated. 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 with the same drug for the same condition is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care. This is the case despite an earlier court opinion holding that the Orphan Drug Act unambiguously required the FDA to recognize orphan drug exclusivity regardless of a showing of clinical superiority. Under Omnibus legislation signed by President Trump on December 27, 2020, the requirement for a product to show clinical superiority applies to drugs and biologics that received orphan drug designation before enactment of FDARA in 2017, but have not yet been approved or licensed by FDA.

Pediatric Exclusivity

Pediatric exclusivity is a type of non patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non patent and orphan exclusivity. This six month exclusivity may be granted if a BLA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity that cover the product are extended by six months.

Patent Term Restoration and Extension

In the United States, a patent claiming a new biologic 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 manner in which 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 for the production of clinical and commercial quantities of our products 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. Future inspections by the FDA and other regulatory agencies may identify compliance issues at the facilities of our CMOs 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 the 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. Health Care 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 will apply only if and when we have an approved product, 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 Open Payments (or federal "sunshine" law), which requires pharmaceutical and medical device companies to monitor and report certain financial interactions with certain healthcare providers to the Center for Medicare & Medicaid Services within the U.S. Department of Health and Human Services for re-disclosure to the public, as well as ownership and investment interests held by physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- analogous state laws and regulations, including: state anti-kickback and false claims laws; state laws requiring pharmaceutical companies to comply with specific compliance standards, restrict financial interactions between pharmaceutical companies and healthcare providers or require pharmaceutical companies to report information related to payments to health care providers or marketing expenditures; and state laws governing privacy, security and breaches of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and
- laws and regulations prohibiting bribery and corruption such as the FCPA, which, among other things, prohibits U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations or foreign government-owned or affiliated entities, candidates for foreign public office, and foreign political parties or officials thereof.

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

Similar healthcare laws and regulations exist in the 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

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information, including laws requiring the safeguarding of personal information and laws requiring notification to governmental authorities and data subjects as well as remediation in the event of a data breach.

There have been several developments in recent years with respect to U.S. state data privacy laws. In 2018, California passed into law the California Consumer Privacy Act, or the CCPA, which took effect on January 1, 2020 and imposed many requirements on businesses that process the personal information of California residents. Many of the CCPA's requirements are similar to those found in the GDPR, including requiring businesses to provide notice to data subjects regarding the information collected about them and how such information is used and shared, and providing data subjects the right to request access to such personal information and, in certain cases, request the erasure of such personal information. The CCPA also affords California residents the right to opt-out of "sales" of their personal information. The CCPA contains significant penalties for companies that violate its requirements. It also provides California residents a private right of action, including the ability to seek statutory damages, in the event of a breach involving their personal information. Compliance with the CCPA is a rigorous and time-intensive process that may increase the cost of doing business or require companies to change their business practices to ensure full compliance. On November 3, 2020, California voters passed a ballot initiative for the California Privacy Rights Act, or the CPRA, which will significantly expand the CCPA to incorporate additional GDPR-like provisions including requiring that the use,

retention and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for sensitive personal information, and requiring greater disclosures related to notice to residents regarding retention of information. The CPRA will also expand personal information rights of California residents, including creating a right to opt out of sharing of personal information with third parties for advertising, expanding the lookback period for the right to know about personal information held by businesses, and expanding the right to erasure for information held by third parties. Most CPRA provisions will take effect on January 1, 2023, though the obligations will apply to any personal information collected after January 1, 2022. Similar laws have been proposed or passed at the U.S. federal and state level, including the Virginia Consumer Data Protection Act (CDPA), which will take effect on January 1, 2023.

Coverage, Pricing and Reimbursement

Sales of any biopharmaceutical products, if and when approved by the FDA or analogous authorities outside the United States, will depend in significant part on the availability of third-party coverage and adequate reimbursement for the products.

In the United States, third-party payors include government healthcare programs such as Medicare and Medicaid, private health insurers, managed care plans and other organizations. These third-party payors are increasingly challenging the price and examining the cost-effectiveness of medical products and services, including biopharmaceutical products. Significant uncertainty exists regarding coverage and reimbursement for newly approved healthcare products. Coverage does not ensure adequate reimbursement. It is time consuming and expensive to seek coverage and reimbursement from third-party payors. We may need to conduct expensive pharmacoeconomic studies to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA regulatory approvals. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication, or utilize other mechanisms to manage utilization (such as requiring prior authorization for coverage for a product for use in a particular patient). Limits on coverage may impact demand for our products. Even if coverage is obtained, third-party reimbursement may not be adequate to allow us to sell our products on a competitive and profitable basis. As result, we may not be sufficient to maintain price levels high enough to realize an appropriate return on investment in product development.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of our product candidate to currently available therapies (so called health technology assessment, or HTA) in order to obtain reimbursement or pricing approval. For example, subject to the requirements set out in Directive 89/105/EEC relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems, EU Member States have the legal competence to set national measures of an economic nature on the marketing of medicinal products in order to control public health expenditure on such products. Accordingly, EU Member States can restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. An EU Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Other EU Member States allow companies to fix their own prices for drug products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the EU do not follow price structures of the United States and generally tend to by significantly lower.

The downward pressure on health care costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by

various EU Member States and parallel import or distribution (arbitrage between low-priced and high-priced member states) can further reduce prices. Any country that has price controls or reimbursement limitations for products may not allow favorable reimbursement and pricing arrangements.

Health Care Reform

Health care reform has been a significant trend in the U.S. health care industry and elsewhere. In particular, government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products and services. Under the Trump administration, there were efforts to repeal or modify prior health care reform legislation and regulation and also to implement new health care reform measures, including measures related to payment for products under government health care programs. The nature and scope of health care reform in the wake of the transition from the Trump administration to the Biden administration remains uncertain but early actions include additional health care reform as well as challenges to actions taken under the Trump administration are likely.

There has been heightened governmental scrutiny in recent years over the manner in which manufacturers set prices for their marketed products, which has resulted in proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing and reform government program reimbursement methodologies for pharmaceutical and biologic products. At the state level, individual states are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. We expect that additional federal and state health care reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for health care products and services.

Approval and Regulation of Medical Products in the European Union

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products outside of the United States. Whether or not we obtain FDA approval for a product candidate, we must obtain approval by the comparable regulatory authorities of foreign countries or economic areas, such as the 27-member EU, before we may commence clinical trials or market products in those countries or areas. In the EU, our product candidates also may be subject to extensive regulatory requirements. As in the United States, medicinal products can be marketed only if a marketing authorization from the competent regulatory agencies has been obtained. Similar to the United States, the various phases of pre-clinical and clinical research in the EU are subject to significant regulatory controls.

With the exception of the EU/EEA applying the harmonized regulatory rules for medicinal products, the approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly between countries and jurisdictions and can involve additional testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Clinical Trials

The Clinical Trials Directive 2001/20/EC, the Directive 2005/28/EC on GCP and the related national implementing provisions of the individual EU Member States govern the system for the approval of clinical trials in the EU. Under this system, an applicant must obtain prior approval from the competent national authority of the EU Member

States in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial at a specific study site after the competent ethics committee has issued a favorable opinion. The clinical trial application must be accompanied by, among other documents, an IMPD (the Common Technical Document) with supporting information prescribed by Directive 2001/20/EC, Directive 2005/28/EC, and where relevant the implementing national provisions of the individual EU Member States and further detailed in applicable guidance documents. All suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the competent national authority and the Ethics Committee of the Member State where they occurred.

In April 2014, the new Clinical Trials Regulation, (EU) No 536/2014, or the Clinical Trials Regulation, was adopted and it is anticipated to come into application in late 2021 but could be delayed, subject to the full functionality of the Clinical Trials Information System (CTIS) through an independent audit. The Clinical Trials Regulation will come into application in all the EU Member States, repealing the current Clinical Trials Directive 2001/20/EC. Conduct of all clinical trials performed in the EU will continue to be bound by currently applicable provisions until the new Clinical Trials Regulation becomes applicable, which is scheduled for December 2021.

The extent to which ongoing clinical trials will be governed by the Clinical Trials Regulation will depend on when the Clinical Trials Regulation will come into application and on the duration of the individual clinical trial. According to the transitional provisions, if a clinical trial continues for more than three years from the day on which the Clinical Trials Regulation becomes applicable the Clinical Trials Regulation will at that time begin to apply to the clinical trial.

The Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the EU. The main characteristics of the regulation include: a streamlined application procedure via a single entry point, the "EU portal"; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed by the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted (Member States concerned). Part II is assessed separately by each Member State concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned EU Member State. However, overall related timelines will be defined by the Clinical Trials Regulation.

Marketing authorization applications, or MAA, can be filed either under the so-called centralized or national authorization procedures, albeit through the Mutual Recognition or Decentralized procedure for a product to be authorized in more than one EU member state.

Centralized Approval Procedure

The centralized procedure provides for the grant of a single marketing authorization following a favorable opinion by the European Medicines Agency, or EMA, that is valid in all EU Member States, as well as Iceland, Liechtenstein and Norway, which are part of the EEA. The centralized procedure is compulsory for medicines produced by specified biotechnological processes, products designated as orphan medicinal products, advanced-therapy medicines (such as gene-therapy, somatic cell-therapy or tissue-engineered medicines) and products with a new active substance indicated for the treatment of specified diseases, such as HIV/ AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions and viral diseases. The centralized procedure is optional for products that represent a significant therapeutic, scientific or technical innovation, or whose authorization would be in the interest of public health. Under the centralized procedure the maximum timeframe for the evaluation of an MAA by the EMA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the Committee for Medicinal Products for Human Use, or the CHMP. Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of an MAA under the accelerated assessment procedure is of 150 days, excluding stop-clocks.

National Authorization Procedures

There are also two other possible routes to authorize medicinal products in several EU countries, which are available for investigational medicinal products that fall outside the scope of the centralized procedure:

- Decentralized procedure. Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one EU country of medicinal products that have not yet been authorized in any EU country and that do not fall within the mandatory scope of the centralized procedure. The applicant may choose a member state as the reference member State to lead the scientific evaluation of the application.
- Mutual recognition procedure. In the mutual recognition procedure, a medicine is first authorized in one EU Member State (which acts as the reference member state), in accordance with the national procedures of that country. Following this, further marketing authorizations can be progressively sought from other EU countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization produced by the reference member state.

Under the above described procedures, before granting the marketing authorization, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

Conditional Approval

In specific circumstances, E.U. legislation (Article 14–a Regulation (EC) No 726/2004 (as amended by Regulation (EU) 2019/5 and Regulation (EC) No 507/2006 on Conditional Marketing Authorizations for Medicinal Products for Human Use) enables applicants to obtain a conditional marketing authorization prior to obtaining the comprehensive clinical data required for an application for a full marketing authorization. Such conditional approvals may be granted for product candidates (including medicines designated as orphan medicinal products) if (1) the product candidate is intended for the treatment, prevention or medical diagnosis of seriously debilitating or life-threatening diseases; (2) the drug candidate is intended to meet unmet medical needs of patients; (3) a marketing authorization may be granted prior to submission of comprehensive clinical data provided that the benefit of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required; (4) the risk-benefit balance of the product candidate is positive, and (5) it is likely that the applicant will be in a position to provide the required comprehensive clinical trial data. A conditional marketing authorization may contain specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new studies and with respect to the collection of pharmacovigilance data. Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions or specific obligations. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional marketing authorization.

Pediatric Studies

Prior to obtaining a marketing authorization in the EU, applicants have to demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan, or PIP, covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, a class waiver or a deferral for one or more of the measures included in the PIP. The respective requirements for all marketing authorization procedures are set forth in Regulation (EC) No 1901/2006, which is referred to as the Pediatric Regulation. This requirement also applies when a company wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorized. The Pediatric Committee of the EMA, or PDCO, may grant deferrals for some medicines, allowing a company to delay development of the medicine in children until there is enough information to demonstrate its effectiveness and safety in adults. The PDCO may also grant waivers when development of a medicine in children is not needed or is not appropriate because (a) the product is likely to be ineffective or unsafe in part or all of the pediatric population; (b) the disease or condition occurs only in adult population; or (c) the product does not represent a significant therapeutic benefit over existing treatments for pediatric population.

Before a marketing authorization application can be filed, or an existing marketing authorization can be amended, the EMA determines that companies actually comply with the agreed studies and measures listed in each relevant PIP.

PRIME Designation

The EMA grants access to the Priority Medicines, or PRIME, program to investigational medicines for which it determines there to be preliminary data available showing the potential to address an unmet medical need and bring a major therapeutic advantage to patients. As part of the program, EMA provides early and enhanced dialogue and support to optimize the development of eligible medicines and speed up their evaluation, aiming to bring promising treatments to patients sooner.

Regulatory Exclusivity

In the EU, new products authorized for marketing (i.e., reference products) qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic or biosimilar applicants from relying on the pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until ten years have elapsed from the initial authorization of the reference product in the EU. The ten-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

Orphan Drug Designation and Exclusivity

The criteria for designating an orphan medicinal product in the EU are similar in principle to those in the United States. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life- threatening or chronically debilitating condition, (2) either (a) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition. The term ‘significant benefit’ is defined in Regulation (EC) 847/2000 to mean a clinically relevant advantage or a major contribution to patient care.

Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity for the approved therapeutic indication. During this ten year market exclusivity period, the EMA or the competent authorities of the Member States of the EEA, cannot accept an application for a marketing authorization for a similar medicinal product for the same indication. A similar medicinal product is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The application for orphan designation must be submitted before the application for marketing authorization. The applicant will receive a fee reduction for the marketing authorization application if the orphan designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The ten-year market exclusivity in the EU may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently

profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar product for the same indication at any time if:

- the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior;
- the applicant consents to a second orphan medicinal product application; or
- the applicant cannot supply enough orphan medicinal product.

Pediatric Exclusivity

If an applicant obtains a marketing authorization in all EU Member States, or a marketing authorization granted in the centralized procedure by the European Commission, and the study results for the pediatric population are included in the product information, even when negative, the medicine is then eligible for an additional six-month period of qualifying patent protection through extension of the term of the Supplementary Protection Certificate, or SPC.

Periods of Authorization and Renewals

A marketing authorization is valid for five years in principle and the marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least nine months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Any authorization which is not followed by the actual placing of the drug on the EU market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid (the so-called sunset clause).

General data protection regulation

Many countries outside of the United States maintain rigorous laws governing the privacy and security of personal information. The collection, use, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals who are located in the EEA, and the processing of personal data that takes place in the EEA, is subject to the GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, and it imposes heightened requirements on companies that process health and other sensitive data, such as requiring in many situations that a company obtain the consent of the individuals to whom the sensitive personal data relate before processing such data. Examples of obligations imposed by the GDPR on companies processing personal data that fall within the scope of the GDPR include providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, appointing a data protection officer, providing notification of data breaches and taking certain measures when engaging third-party processors.

The GDPR also imposes strict rules on the transfer of personal data to countries outside the EEA, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR is a rigorous and time-intensive process that may increase the cost of doing business or require companies to change their business practices to ensure full compliance. In July 2020, the Court of Justice of the European Union, or the CJEU, invalidated the EU-U.S. Privacy Shield framework, one of the mechanisms used to legitimize the transfer of personal data from the EEA to the United States. The CJEU decision also drew into question the long-term viability of an alternative means of data transfer, the standard contractual clauses, for transfers of personal data from the EEA to the United States. Following the withdrawal of the U.K. from the EU, the U.K. Data Protection Act 2018 applies to the processing of personal data that takes place in the U.K. and includes parallel obligations to those set forth by GDPR.

Brexit and the Regulatory Framework in the United Kingdom

The United Kingdom's withdrawal from the EU took place on January 31, 2020. The EU and the U.K. reached an agreement on their new partnership in the Trade and Cooperation Agreement, or the Agreement, to be applied from January1, 2021. The Agreement focuses primarily on free trade by ensuring no tariffs or quotas on trade in goods, including healthcare products such as medicinal products. Thereafter, the EU and the U.K. will form two separate markets governed by two distinct regulatory and legal regimes. As such, the Agreement seeks to minimize barriers to trade in goods while accepting that border checks will become inevitable as a consequence that the U.K. is no longer part of the single market. As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or the MHRA, becomes responsible for supervising medicines and medical devices in Great Britain, comprising England, Scotland and Wales under domestic law whereas Northern Ireland will continue to be subject to EU rules under the Northern Ireland Protocol. The MHRA will rely on the Human Medicines Regulations 2012 (SI 2012/1916) (as amended), or the HMR, as the basis for regulating medicines. The HMR has incorporated into the domestic law the body of EU law instruments governing medicinal products that pre-existed prior to the U.K.'s withdrawal from the EU.

Furthermore, while the Data Protection Act of 2018 in the United Kingdom that "implements" and complements the European Union General Data Protection Regulation, or GDPR, has achieved Royal Assent on May 23, 2018 and is now effective in the United Kingdom, it is still unclear whether transfer of data from the EEA to the United Kingdom will remain lawful under GDPR. The Trade and Cooperation Agreement provides for a transitional period during which the United Kingdom will be treated like a European Union member state in relation to processing and transfers of personal data for four months from January 1, 2021. This may be extended by two further months. After such period, the United Kingdom will be a "third country" under the GDPR unless the European Commission adopts an adequacy decision in respect of transfers of personal data to the United Kingdom. The United Kingdom has already determined that it considers all EU 27 and EEA member states to be adequate for the purposes of data protection, ensuring that data flows from the United Kingdom to the EU/EEA remain unaffected. We may, however, incur liabilities, expenses, costs, and other operational losses under GDPR and applicable European Union Member States and the United Kingdom privacy laws in connection with any measures we take to comply with them.

Rest of the World Regulation

For other countries outside of the EU and the United States, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from jurisdiction to jurisdiction. Additionally, the clinical trials must be conducted in accordance with cGCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Registrational Clinical Trials Process

Described below is the traditional registrational drug development track.

Phase 1

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

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, often involving 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

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. See the discussion under the subheading "PRO 140 Acquisition and Licensing Arrangements" above.

Competition

The pharmaceutical, biotechnology and diagnostic industries are characterized by rapidly evolving technology and intense competition. Our development efforts may compete with more established biotechnology companies that have significantly greater financial and managerial resources than we do.

Advancing leronlimab to commercialization is our highest priority. Leronlimab blocks a cell receptor called CCR5, which is the entry point for most strains of HIV virus. Pfizer's Maraviroc (Selzentry®) is believed to be the only currently approved CCR5 blocking agent. Maraviroc, like all other HIV approved drugs, must be taken daily and is believed to have side effects and toxicity. For these reasons, we believe that our lead product candidate, leronlimab, a monoclonal antibody, may prove to be useful in patients that cannot tolerate existing HIV therapies or desire a respite from those therapies. Nonetheless, manufacturers of current therapies, such as Pfizer, Gilead Sciences, Merck, Bristol-Myers Squibb and ViiV Healthcare, are very large, multi-national corporations with significant resources. We expect that these companies will compete fiercely to defend and expand their market share.

To construct a HAART regimen, three drugs from two classes of drugs are typically needed. Currently there are only five different classes of drugs from which four are primarily used to construct a HAART regimen. Each of these four classes of drugs has many drugs available in its respective class, except the entry inhibitor ("EI") class, which has only two drugs available. We believe the only two drugs in the EI class approved by the FDA are Maraviroc, a small molecule drug (which is taken orally once or twice a day) and Ibalizumab (which is an IV infusion administered once every two weeks). If approved, we believe that leronlimab will be only the third approved drug outside of the main four classes of drugs approved for HIV since 2007.

Our potential competitors include entities that develop and produce therapeutic agents. These include numerous public and private academic and research organizations and pharmaceutical and biotechnology companies pursuing production of, among other things, biologics from cell cultures, genetically engineered drugs and natural and chemically synthesized drugs. Our competitors may succeed in developing potential drugs or processes that are more effective or less costly than any that may be developed by us or that gain regulatory approval prior to our potential drug candidates. Worldwide, there are many antiviral drugs for treating HIV. In seeking to manufacture, distribute and market the potential drugs we hope to have approved; we face competition from established global pharmaceutical companies.

Many of these potential competitors have substantially greater capital resources, management expertise, research and development capabilities, manufacturing and marketing resources and experience than we do.

We also expect that the number of our competitors and potential competitors will increase as more potential drugs receive commercial marketing approvals from the FDA or equivalent foreign regulatory agencies. Any of these competitors may be more successful than us in manufacturing, marketing and distributing HIV treatments, as well as for new therapies for cancer and immunological disorders.

We remain encouraged from the clinical outcomes from over 60 Emergency Investigation New Drug (EIND) authorizations granted by the FDA and the preliminary results from our recently completed COVID-19 trials, which, however, did not achieve their designated primary endpoints. We are continuing to advance the evaluation of leronlimab for COVID through re-designed protocols for two large Phase 3 trials in Brazil. In addition, we are continuing to evaluate the results of our COVID-19 long-haulers study. There are hundreds of companies concurrently exploring therapies for COVID-19 and conducting clinical trials. Many of these potential competitors have substantially greater capital resources, management expertise, research and development capabilities, manufacturing and marketing resources and experience than we do.

As we advance our evaluation of leronlimab for potential indications in cancer and immunology, we will face competition from formidable global research-based pharmaceutical companies. Potential competitors such as Roche, Celgene, Bristol-Myers Squibb, Merck, AbbVie and many others have vast financial, managerial, technical, commercialization and marketing resources than we do than we do.

Manufacturing

We do not own or operate manufacturing facilities for the production of leronlimab. As such, we must depend on third-party manufacturing organizations and suppliers for all of our clinical trial quantities of leronlimab, in addition to previously manufactured supplies of commercial grade leronlimab. We continue to explore alternative manufacturing sources, in order to ensure that we have access to sufficient manufacturing capacity in order to meet potential demand for leronlimab in a cost-efficient manner.

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

Research and Development Costs

The Company’s research and development expenses totaled approximately $58.4 million, $52.6 million and $42.5 million for the fiscal years ended May 31, 2021, May 31, 2020 and May 31, 2019, respectively. We expect our research and development expenses to continue to increase in future periods as the activity within the Company’s clinical trials expands and the Company’s biologics manufacturing processes and related regulatory compliance activities increase.

Employees and Human Capital Resources

We currently have 24 full-time employees, as well as several independent consultants assisting us with the Company’s BLA preparation, manufacturing activities, regulatory matters and management of our clinical trials. Approximately half of our employees work out of our corporate offices in Vancouver, WA and the rest of our employees work remotely in various locations throughout the United States and are members of our research and development

team. CytoDyn is committed to pay equity regardless of gender or race/ethnicity. There can be no assurances, however, that we will be able to identify or hire and retain additional employees or consultants on acceptable terms in the future.

We invest in our workforce by offering competitive salaries, wages, and benefits. We endeavor to foster a strong sense of ownership by offering all employees stock options under our stock incentive program. We also offer comprehensive and locally relevant benefits for all eligible employees. We recognize and support the growth and development of our employees.

We have implemented COVID-19 policies at our corporate office designed to ensure the safety and well-being of all employees and the people associated with them. As a result of the COVID-19 pandemic, to reduce risk, our corporate employees have been encouraged to be vaccinated, have been asked to avoid all non-essential travel, and engage in physical distancing.

None of our employees are subject to a collective bargaining agreement. We consider our relationship with our employees to be good.

Item 1A. RISK FACTORS

You should carefully consider the risks described below in addition to the other information set forth in this Annual Report on Form 10-K, including the Management's Discussion and Analysis of Financial Condition and Results of Operations section and the consolidated financial statements and related notes. These risks, some of which have occurred and any of which may occur in the future, can have a material adverse effect on our business, financial condition, results of operations or the price of our publicly traded securities. 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 and adversely affect our business, reputation, financial condition, results of operations or the price of our publicly traded securities. Therefore, historical operating results, financial and business performance, events and trends are often not a reliable indicator of future operating results, financial and business performance, events or trends. If any of the following risks occurs, our business, financial condition, and results of operations and future growth prospects could be materially and adversely affected.

Summary of Risk Factors

Our business is subject to numerous risks and uncertainties, including those highlighted in this section, that represent challenges we face in our efforts to successfully implement our strategy. The occurrence of one or more of the events or circumstances described in more detail below, alone or in combination with other events or circumstances, may have an adverse effect on our business, cash flows, financial condition and results of operations. Many of the risks facing us are summarized briefly below and, along with additional risk factors set forth in this Item 1A, are described in more detail in the discussion following this summary. For a more complete understanding of the risks and uncertainties we face, Item 1A should be read in its entirety, together with the other information presented in this Form 10-K.

Risks Related to Our Financial Position and Need for Additional Capital

- 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 are a clinical stage biotechnology company with a history of significant operating losses; we expect to continue to incur operating losses, and we may never achieve, let alone maintain, profitability.
- We will need substantial additional funding to continue to pursue our BLA submission for leronlimab as a combination therapy with HAART for HIV patients, to complete our current and planned clinical trials, to fund development of leronlimab for additional indications, and to operate our business, and such funding may not be available or, if it is available, such financing is likely to substantially dilute our existing stockholders.

- 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.
- We have capitalized pre-launch inventories prior to receiving FDA marketing approval. If either FDA approval or market acceptance post-approval does not occur on a timely basis prior to shelf-life expiration, we will be required to write off pre-launch inventories, which would materially and adversely affect our business, financial condition and stock price.

Risks Related to Development and Commercialization of Our Drug Candidates

- We are substantially dependent on the success of leronlimab. If we are unable to complete the clinical development of, obtain and maintain marketing approval for or successfully commercialize leronlimab, either alone or with collaborators, or if we experience significant delays in doing so, our business could be substantially harmed.
- Obtaining and maintaining regulatory approval of leronlimab or any future product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of those product candidates in other jurisdictions.
- 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.
- 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

- We are involved in a number of legal proceedings and, while we cannot predict the outcomes of such proceedings and other contingencies with certainty, some of these outcomes could adversely affect our business and financial condition.
- We are subject to the oversight of the SEC and other regulatory agencies. Investigations by those agencies could divert management's focus and have a material adverse effect on our reputation and financial condition.

Risks Related to Our Dependence on Third Parties

- We depend on the Vyera License Agreement for the commercialization of leronlimab for the treatment of HIV in humans in the U.S. Vyera's failure to successfully commercialize leronlimab for the treatment of HIV in the U.S., if approved by the FDA, could have a material adverse effect on our business, financial condition and results of operations.
- We will need to outsource and rely on third parties for the clinical development and manufacture, sales and marketing of product candidates, and our future success will be dependent on the timeliness and effectiveness of the efforts of these third parties.
- We rely on third parties, such as CROs, to conduct clinical trials for our product candidate, leronlimab, and if they do not properly and successfully perform their obligations to us, we may not be able to obtain regulatory approvals for our product candidate.

Risks Related to Our Intellectual Property Rights

- Our success depends substantially upon our ability to obtain and maintain intellectual property protection relating to our product candidate.
- 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 Obtaining Required Regulatory Approvals and Licensure

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

Risks Related to Healthcare Laws and Other Legal Compliance Matters

- We are subject to a complex regulatory scheme that requires significant resources to ensure compliance. Failure to comply with applicable laws could subject us to government scrutiny or government enforcement, potentially resulting in costly investigations and/or fines or sanctions, or impacting our relationships with key regulatory agencies such as the FDA, the U.S. Securities and Exchange Commission, or the SEC, or the EMA.

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.
- Our debt service obligations and our need for additional funding to finance operations may cause additional dilution to our existing stockholders.
- If we are unable to effectively maintain a system of internal control over financial reporting, we may not be able to accurately or timely report our financial results and our stock price could be adversely affected.

Risks Related to Our Financial Position and Need for Additional Capital

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 exception, in connection with the audit of our annual financial statements for the fiscal year ended May 31, 2021. A going concern exception to an audit opinion means that there is substantial doubt that we can continue as an ongoing business for the next 12 months. If we are unable to continue as a going concern, 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 are a clinical stage biotechnology company with a history of significant operating losses; we expect to continue to incur operating losses, and we may never achieve, let alone maintain, profitability.

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

Since our inception, we have been insolvent and have required debt and equity financing to maintain operations.

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 created a dilutive effect on our common stock, which has hampered our ability to attract reasonable financing terms. Issuances of additional equity or convertible debt securities will continue to reduce the percentage ownership of our then-existing stockholders. We may also be required to grant potential investors new securities rights, preferences or privileges senior to those possessed by our then-existing stockholders in order to induce them to invest in our company. The issuance of these senior securities may adversely affect the holders of our common stock by restricting our ability to declare dividends on the common stock, diluting the voting power of the common stock and subordinating the liquidation rights of the common stock. As a 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.

We will need substantial additional funding to continue to pursue our BLA submission for leronlimab as a combination therapy with HAART for HIV patients, to complete our current and planned clinical trials, to fund development of leronlimab for additional indications, and to operate our business, and such funding may not be available or, if it is available, such financing is likely to substantially dilute our existing stockholders.

The discovery, development, and commercialization of new treatments, such as our leronlimab product candidate, entail significant costs. In addition, to the extent we pursue further development and clinical trials of leronlimab for indications in addition to HIV, including COVID-19, cancer, and immunological disorders, we will need to raise substantial additional capital, or enter into strategic partnerships, to enable us to:

- fund clinical trials and seek regulatory approvals
- access manufacturing and commercialization capabilities;
- pay required license fees, milestone payments, and maintenance fees to Progenics, Lonza and AbbVie Inc.;
- develop, test, and, if approved, market leronlimab;
- acquire or license additional internal systems and other infrastructure;
- hire and support additional management and scientific personnel; and
- explore additional indications for leronlimab.

Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never achieve, we expect to finance our cash needs primarily through public or private equity offerings, debt financings, or strategic alliances. We cannot be certain that additional funding will be available on acceptable terms or at all. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of, or eliminate one or more of our clinical trials, collaborative development programs, or future commercialization initiatives. In addition, any additional funding that we do obtain will dilute the ownership held by our existing security holders.

The amount of this dilution may be substantially increased if we issue new securities at a lower sale price or conversion or exercise price per share than prior financings. For example, the terms of certain of our convertible notes provide for full-ratchet anti-dilution protection, pursuant to which the conversion price of the convertible note 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 or have been or become registered under the Securities Act of 1933, as amended the, or the 1933 Act. Regardless, the economic dilution to stockholders will be significant if our stock price does not increase significantly, or if the effective price of any sale is below the price paid by a particular stockholder. Any debt financing could involve substantial restrictions on our activities or ability to obtain additional financing, and creditors could seek additional pledges of some or all of our assets. We do not have commitments from any third parties to provide any future financing. If we fail to obtain additional funding as needed, we may be forced to cease or scale back operations, such that our financial condition and stock price would be adversely affected.

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

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

- the costs of our ongoing clinical trial programs and pre-clinical studies, as well as other development activities conducted by us directly, and our ability to successfully conclude the studies and achieve favorable results;
- our ability to attract strategic partners to pay for or share costs related to our product development efforts;
- the costs and timing of seeking and obtaining regulatory approvals and making related milestone payments due to Progenics, Lonza, and AbbVie;
- the costs of filing, prosecuting, maintaining, and enforcing patents and other intellectual property rights and defending against potential claims of infringement;
- decisions to hire additional scientific or administrative personnel or consultants;
- our ability to manage administrative and other costs of our operations; and
- the presence or absence of adverse developments in our clinical trial and commercialization readiness programs.

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

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

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

- the time and costs involved in obtaining regulatory approvals;
- the costs and results of our clinical trial programs and pre-clinical studies we are undertaking or may in the future pursue with leronlimab;
- the time and costs involved in our CMC activities;
- whether our outstanding convertible notes are converted into equity;
- whether we receive additional cash upon the exercise for common stock of our outstanding warrants and options;
- whether we are able to obtain funding under future licensing agreements, strategic partnerships, or other collaborative relationships, if any;
- 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 we underestimate our cash requirements, we may need to raise additional funds, which funding may not be available on acceptable terms or at all. If we fail to raise additional funds on a timely basis, we may need to scale back our business plans, which may require us to delay, reduce the scope of, or eliminate one or more of our clinical trials, collaborative development programs, or future commercialization initiatives, which would adversely affect our business, financial condition, and stock price. If we deplete our cash reserves, we may even be forced to discontinue our operations and liquidate our assets.

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

Under the Progenics Purchase Agreement, the PDL License and the Lonza Agreement, we must pay to Progenics, AbbVie and Lonza significant milestone payments, license fees for “system know-how” technology, and royalties. In

order to make the various milestone and license payments that are required, we will need to raise additional funds. In addition, our royalty obligations will reduce the economic benefits to us of any future sales if we do receive regulatory approval and seek to commercialize leronlimab. To the extent that such milestone payments and royalties are not timely made, under their respective agreements, Progenics has certain repurchase rights relating to the assets sold to us, and AbbVie has certain termination rights relating to our license of leronlimab under the PDL License. For more information, see "Business—PRO 140 Acquisition and Licenses," as well as the Progenics Purchase Agreement, the PDL License and the Lonza Agreement, each of which is incorporated by reference to Exhibits 2.1, 10.3, and 10.4, respectively, to this Form 10-K.

We have capitalized pre-launch inventories prior to receiving FDA marketing approval. If either FDA approval or market acceptance post-approval does not occur on a timely basis prior to shelf-life expiration, we will be required to write off pre-launch inventories, which would materially and adversely affect our business, financial condition and stock price.

Pre-launch inventories consist of costs of raw materials and work-in-progress related to our product candidate leronlimab. These costs have been capitalized prior to the date that we anticipate that such product will receive FDA final marketing approval. The BLA resubmission will require updating the previously provided analyses, which could result in significant delay in obtaining approval. If FDA approval is significantly delayed, the shelf-life of our pre-launch inventory may be limited, and the salability of our product may be affected. In addition, market acceptance of our product could fall short of our expectations, as a result of the introduction of a competing product, as a result of physicians being unwilling or unable to prescribe leronlimab to their patients, or if our target patient population is reluctant to try leronlimab as a new therapy. If any of these risks were to materialize with respect to our product, or if the launch of such product is significantly postponed, the salability of our pre-launch inventories would be adversely affected and may require write-off of the carrying value of our pre-launch inventories in amounts that could have a material adverse effect on our results of operations and financial condition.

We are a development stage company, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

Leronlimab in each indication is still in the development stage. We have not yet demonstrated our ability to obtain marketing approvals, manufacture a commercial scale medicine, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Typically, it takes about 10 to 15 years to develop one new medicine from the time it is discovered to when it is available for treating patients. Pre-clinical studies and clinical trials may involve highly uncertain results and a high risk of failure. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had more experience developing and commercializing our product candidate. In addition, as a development stage business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. To be profitable, we will need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

Risks Related to Development and Commercialization of Our Drug Candidate

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

We currently have no products approved for sale and are investing a significant portion of our efforts and financial 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 leronlimab will depend on a number of factors, including the following:

- our ability to secure the substantial additional capital required to complete clinical trials of leronlimab, and to fund the activities necessary to successfully commercially launch leronlimab if it receives regulatory approval for marketing in the United States;
- successful design, enrollment and completion of clinical trials;
- a safety, tolerability and efficacy profile that is satisfactory to the FDA, EMA, Health Canada or any other comparable foreign regulatory authority for marketing approval;
- timely receipt of marketing approvals from applicable regulatory authorities such as the FDA;
- the performance of the contract research organizations, or CROs, we have hired to manage our clinical studies, as well as that of our collaborators and other third-party contractors;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- maintenance of existing or establishment of new supply arrangements with third-party raw materials suppliers and manufacturers;
- obtaining and maintaining patent, trade secret protection and regulatory exclusivity, both in the United States and internationally, including our ability to maintain our license agreement with Abbvie, as successor to Progenics Pharmaceuticals, Inc.;
- protection of our rights in our intellectual property portfolio, including our ability to maintain our license agreement with AbbVie;
- successful launch of commercial sales of leronlimab for the treatment of HIV in humans by our collaborator Vyera following any marketing approval;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance by patients, the medical community and third-party payors; and
- our ability 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 commercialize leronlimab on our own or with our collaborators, or experience delays as a result of any of these factors or otherwise, our business could be substantially harmed.

The results of previous clinical trials may not be predictive of future results, and the results of our current and planned clinical trials may not satisfy the requirements of the FDA, EMA, Health Canada or other foreign regulatory authorities.

The process of obtaining approval of a drug product for use in humans is extremely lengthy and time-consuming, and numerous factors may prevent our successful development of leronlimab, including negative results in ongoing and future clinical trials, and inability to obtain sufficient additional funding to continue to pursue development. Our clinical trials may be unsuccessful, which would materially harm our business.

Further, the results from prior clinical trials of leronlimab may not be predictive of the results of future clinical trials or pre-clinical studies. Clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in prior clinical trials nonetheless have failed to obtain FDA approval. For example, in February 2018, we announced that we had met the primary endpoint in our Phase 3 trial for leronlimab as a combination therapy with HAART for highly treatment-experienced HIV patients and submitted the non-clinical portion of our biologics license application, or BLA to the FDA in March 2019. We submitted to the FDA the clinical, along with the chemistry, manufacturing, and controls, or CMC, portions of the BLA in April and May of 2020. In July 2020, we received a Refusal to File letter from the FDA regarding our BLA submission requesting additional information. The development timeline and regulatory approval and commercialization prospects for leronlimab, including our business and financial prospects, could be adversely affected by unforeseen risks and events.

In addition, a regulatory authority may change its requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a clinical trial that, if successful, would potentially form the basis for an application for approval by the FDA or another regulatory authority. The FDA may require us to procure the development of a companion diagnostic test to help identify patients who may be more likely to respond to leronlimab for certain uses. Furthermore, any of these regulatory authorities may also approve leronlimab for fewer or

more limited indications than we request or may grant approval contingent on the performance of costly post-marketing clinical trials.

The FDA, EMA, Health Canada, ANVISA and other foreign regulatory authorities retain broad discretion in evaluating the results of our clinical trials and in determining whether the results demonstrate that leronlimab is safe and effective. If prior to approval, we are required to conduct additional pre-clinical studies, clinical trials or other types of testing of leronlimab, including after the completion of our current and planned later phase clinical trials, we will need substantial additional funds, and there is no assurance that the results of any such additional clinical trials will be sufficient for approval.

Pre-clinical studies and clinical trials of leronlimab or any future product candidate may not be successful. If we are unable to commercialize leronlimab or any future product candidate or experience significant delays in doing so, our business will be materially harmed.

We and any collaborators, including our partners and sublicensees, are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining marketing approval from the FDA. Foreign regulatory authorities, such as the EMA, Health Canada, and ANVISA impose similar requirements. We and our collaborators must complete extensive pre-clinical development and clinical trials that demonstrate the safety and efficacy of our product candidate in humans before we can obtain these approvals.

Pre-clinical and clinical testing is expensive, is difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all, particularly given that many of our clinical trial sites are research hospitals that have imposed restrictions on entry and other activity as a result of the COVID-19 pandemic. The pre-clinical and clinical development of leronlimab or any future product candidate is susceptible to the risk of failure inherent at any stage of product development. Moreover, we, or any collaborators, may experience any of a number of possible unforeseen adverse events in connection with clinical trials, many of which are beyond our control, including:

- we, or our collaborators, may fail to demonstrate efficacy in a clinical trial or across a broad population of patients;
- it is possible that even if leronlimab or any future product candidate (x) has a beneficial effect, that effect will not be detected during pre-clinical or clinical evaluation or (y) may indicate an apparent positive effect of our product candidate that is greater than the actual positive effect as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials;
- we may fail to detect toxicity or intolerability of leronlimab or any future product candidate, or mistakenly believe that leronlimab or any future product candidate is toxic or not well tolerated when that is not in fact the case;
- adverse events or undesirable side effects caused by, or other unexpected properties of, leronlimab or any future drug candidates that we may develop could cause us, any collaborators, an institutional review board or regulatory authorities to interrupt, delay or halt clinical trials of leronlimab or such future product candidate and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or comparable foreign regulatory authorities;
- if leronlimab or any future product candidate is associated with adverse events or undesirable side effects or has properties that are unexpected, we, or any collaborators, may need to abandon development or limit development of leronlimab or such product candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective;
- regulators or institutional review boards may not authorize us, any collaborators or our or their investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we, or any collaborators, may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials of leronlimab or any future product candidate may produce unfavorable or inconclusive results, including with respect to the safety, tolerability or efficacy profile of leronlimab or such future product candidate;

- we, or any collaborators, may decide, or regulators may require us or them, to conduct additional clinical trials or abandon drug development programs;
- the number of patients required for clinical trials of leronlimab or any future product candidate in a particular indication may be larger than we, or any collaborators, anticipate, patient enrollment in these clinical trials may be slower than we, or any collaborators, anticipate or participants may drop out of these clinical trials at a higher rate than we, or any collaborators, anticipate;
- our estimates of the patient populations available for study may be higher than actual patient numbers and result in our inability to sufficiently enroll our trials;
- the cost of planned clinical trials of leronlimab or any future product candidate may be greater than we anticipate;
- our third-party contractors or those of any collaborators, including those manufacturing leronlimab or any future product candidate or components or ingredients thereof or conducting clinical trials on our behalf or on behalf of any collaborators, may fail to comply with regulatory requirements or meet their contractual obligations to us or any collaborators in a timely manner or at all;
- patients that enroll in a clinical trial may misrepresent their eligibility to do so or may otherwise not comply with the clinical trial protocol, resulting in the need to increase the needed enrollment size for the clinical trial, extend the clinical trial's duration, or drop the patients from the final efficacy analysis for the clinical trial, which can negatively affect the statistical power of the results;
- our decision, or a decision by regulators or institutional review boards, that may require us to suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or their standards of conduct, a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of the product candidate or findings of undesirable effects caused by a chemically or mechanistically similar product or product candidate;
- the FDA or comparable foreign regulatory authorities may disagree with our, or any collaborators', clinical trial designs or our or their interpretation of data from pre-clinical studies and clinical trials;
- the FDA or comparable foreign regulatory authorities may fail to approve or subsequently find fault with the manufacturing processes or facilities of third-party manufacturers with which we, or any collaborators, enter into agreements for clinical and commercial supplies;
- the supply or quality of raw materials or other materials necessary to conduct clinical trials of leronlimab or any future product candidate may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient to obtain marketing approval; and
- constraints on our, or any collaborators', ability to conduct or complete clinical trials for leronlimab or any future product candidate due to the COVID-19 pandemic, including slowdowns in patient enrollment, restrictions on patient monitoring at hospital clinical trial sites, closures of third party facilities, and other disruptions to clinical trial activities.

Product development costs for us and our collaborators will increase if we experience delays in testing or pursuing marketing approvals, and we may be required to obtain additional funds to complete clinical trials and prepare for possible commercialization. We do not know whether any trials will begin as planned, will need to be restructured, or will be completed on schedule or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidate or allow our competitors to bring products to market before we do could impair our ability to successfully commercialize our product candidate and may harm our business and results of operations. In addition, many of the factors that lead to clinical trial delays may ultimately lead to the denial of marketing approval of our product candidate.

Interim top-line and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publish interim top-line or preliminary data from our clinical trials.

Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or

topline results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our reputation and business prospects.

We may find it difficult to enroll patients in our clinical trials, which could delay or prevent clinical trials of our product candidates.

Identifying and qualifying patients to participate in clinical trials of leronlimab or any future product candidate is critical to our success. The timing of our clinical trials depends on the rate at which we can recruit patients to participate in testing our product candidate. If patients are unwilling to participate in our trials because of concerns about participating in clinical trials during the COVID-19 pandemic or other public health emergency, negative publicity from adverse events in the biotechnology industries, public perception of vaccine safety issues, or for other reasons, including competitive clinical trials for similar patient populations, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of potential products may be delayed. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology, or termination of the clinical trials altogether.

We may not be able to identify, recruit and enroll a sufficient number of patients, or those with the required enrollment criteria, to complete our clinical trials in a timely manner. Patient enrollment is affected by several factors, including:

- severity of the disease under investigation;
- design of the trial protocol;
- size of the patient population;
- eligibility criteria for the trial in question;
- perceived risks and benefits of the product candidate being tested;
- proximity and availability of clinical trial sites for prospective patients;
- availability of competing vaccines and/or therapies and related clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

We may not be able to initiate or continue clinical trials if we cannot enroll a sufficient number of eligible patients to participate in the clinical trials required by regulatory agencies.

Even if we enroll a sufficient number of eligible patients to initiate our clinical trials, we may be unable to maintain participation of these patients throughout the course of the clinical trial as required by the clinical trial protocol, in which event we may be unable to use the research results from those patients. If we have difficulty enrolling and maintaining the enrollment of a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which would have an adverse effect on our business.

We are conducting, and intend in the future to conduct, clinical trials for our product candidates at sites outside the United States. The FDA may not accept data from trials conducted in such locations and the conduct of trials outside the United States could subject us to additional delays and expense.

We are conducting, and intend in the future to conduct, one or more of our clinical trials with one or more trial sites that are located outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with good clinical practice. The FDA must be able to validate the data from the trial through an onsite inspection if necessary. The trial population must also have a similar profile to the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful, except to the extent the disease being studied does not typically occur in the United States. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials also complied with all applicable U.S. laws and regulations. There can be no assurance that the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from any trial that we conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and delay or permanently halt our development of our product candidate.

In addition, the conduct of clinical trials outside the United States could have a significant adverse impact on us. Risks inherent in conducting international clinical trials include:

- clinical practice patterns and standards of care that vary widely among countries;
- non-U.S. regulatory authority requirements that could restrict or limit our ability to conduct our clinical trials;
- administrative burdens of conducting clinical trials under multiple non-U.S. regulatory authority schema;
- foreign exchange rate fluctuations; and
- diminished protection of intellectual property in some countries.

We may not obtain marketing approvals for leronlimab.

We may not obtain marketing approval for leronlimab in the United States or other foreign jurisdictions. It is possible that the FDA or comparable foreign regulatory agencies may refuse to accept for substantive review any future application that we or a collaborator may submit to market and sell our product candidates, or that any such agency may conclude after review of our or our collaborator's data that such application is insufficient to obtain marketing approval of our product candidate.

For example, in February 2018, we announced that we had met the primary endpoint in our Phase 3 trial for leronlimab as a combination therapy with HAART for highly treatment-experienced HIV patients and submitted the non-clinical portion of our BLA to the FDA in March 2019. We submitted to the FDA the clinical, along with the CMC portions of the BLA in April and May of 2020. In July 2020, we received a Refusal to File letter from the FDA regarding our BLA submission requesting additional information. In August and September 2020, the FDA provided written responses to our questions and met telephonically with certain of our key personnel and our CRO concerning our BLA submission in an effort to clarify and to expedite the resubmission of our BLA for this indication. The Company began to resubmit the BLA in July 2021 and is expected to be completed in October 2021.

If the FDA or other comparable foreign regulatory agency does not accept or approve our BLA for leronlimab or any application to market and sell leronlimab, such regulators may require that we conduct additional clinical trials, pre-clinical studies or manufacturing validation studies and submit that data before they will reconsider our application. Depending on the extent of these or any other required trials or studies, approval of any application that we submit may be delayed by several years, or may require us or our collaborator to expend more resources than we or they have available. It is also possible that additional trials or studies, if performed and completed, may not be considered sufficient by the FDA or other foreign regulatory agency to approve our applications for marketing and commercialization.

Any delay in obtaining, or an inability to obtain, marketing approvals would prevent us or our collaborators from commercializing our product candidate and generating revenues. If any of these outcomes occur, we would not be eligible for certain milestone and royalty revenue under our partnership agreements, our collaborators could terminate our partnership agreements, and we may be forced to abandon our development efforts for our product candidates, any of which could significantly harm our business.

Even if leronlimab or a future product candidate receives marketing approval, we or others may later discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, which could compromise our ability, or that of any collaborators, to market the product, and could cause regulatory authorities to take certain regulatory actions.

It is possible that our clinical trials may indicate an apparent positive effect of leronlimab or a future a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If, following approval of leronlimab or such future product candidate, we, or others, discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, any of the following adverse events could occur:

- regulatory authorities may withdraw their approval of the product or seize the product;
- we, or any of our collaborators, may be required to recall the product, change the way the product is administered or conduct additional clinical trials;
- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular product;
- we, or any of our collaborators, may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- we, or any of our collaborators, may be required to create a Medication Guide outlining the risks of the previously unidentified side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- physicians and patients may stop using our product; and
- our reputation may suffer.

Any of these events could harm our business and operations and could negatively impact our stock price.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates proceed through pre-clinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development activities, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Any of these changes could cause leronlimab or any future product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, including comparability testing to bridge earlier clinical data obtained from leronlimab produced under earlier manufacturing methods or formulations, and regulatory authorities may disagree on the interpretation of results from this testing. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of leronlimab or any future product candidate and jeopardize our ability to commence sales and generate revenue.

Obtaining and maintaining regulatory approval of leronlimab or any future product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of those product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of leronlimab and any future product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval

process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in Canada, the EU or the United States including additional pre-clinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States including Canada and certain jurisdictions in the EU, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We plan to submit marketing applications initially in Canada and the EU. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions and such regulatory requirements can vary widely from country to country. Obtaining other regulatory approvals and compliance with other regulatory requirements could result in significant delays, difficulties and costs for us and could require additional pre-clinical studies or clinical trials, which could be costly and time-consuming and could delay or prevent the introduction of our products in certain countries. The foreign regulatory approval process involves all of the risks associated with FDA approval. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in either domestic or international markets. If we fail to comply with the regulatory requirements in international markets and/or obtain and maintain applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of leronlimab or any future product candidates will be harmed.

Any of our current and future product candidates for which we, or any future collaborators, obtain regulatory approval in the future will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. If approved, leronlimab and any future product candidates could be subject to post-marketing restrictions or withdrawal from the market and we, or any future collaborators, may be subject to substantial penalties if we, or they, fail to comply with regulatory requirements or if we, or they, experience unanticipated problems with our products following approval.

Leronlimab or any future product candidates for which we, or any future collaborators, obtain regulatory approval, as well as the manufacturing processes, post-approval studies, labeling, advertising and promotional activities for such product, among other things, will be subject to ongoing requirements of and review by the FDA, EMA and other applicable regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. We and our contract manufacturers will also be subject to user fees and periodic inspection by regulatory authorities to monitor compliance with these requirements and the terms of any product approval we may obtain. Even if regulatory approval of a product candidate is granted, the approval may be subject to limitations on the indications or uses for which the product may be marketed or to the conditions of approval, including the requirement in the United States to implement a Risk Evaluation and Mitigation Strategy, or REMS.

The FDA, EMA and other regulatory authorities may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. For example, the FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. Regulatory authorities impose stringent restrictions on manufacturers' communications regarding off-label use. However, companies generally may share truthful and not misleading information that is otherwise consistent with a product's approved labeling. If we, or any future collaborators, do not market leronlimab or any of our future product candidates for which we, or they, receive regulatory approval for only their approved indications, we, or they, may be subject to warnings or enforcement action for off-label marketing if it is alleged that we are doing so. Violation of laws and regulations relating to the promotion and advertising of prescription drugs may lead to investigations or allegations of violations of federal and state health care fraud and abuse laws and state consumer protection laws, including the False Claims Act and any comparable foreign laws. In the EU, the direct-to-consumer advertising of prescription-only medicinal products is prohibited. Violations of the rules governing the promotion of medicinal products in the EU could be penalized by administrative measures, fines and imprisonment. These laws may further limit or restrict the advertising and promotion of our products to the general public, and may also impose limitations on our promotional activities with health care professionals.

In addition, later discovery of previously unknown adverse events or other problems with our products or their manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on the manufacturing of such products;
- restrictions on the labeling or marketing of such products;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- restrictions on coverage by third-party payors;
- fines, restitution or disgorgement of profits or revenues;
- exclusion from federal health care programs such as Medicare and Medicaid;
- suspension or withdrawal of regulatory approvals;
- refusal to permit the import or export of products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Even if leronlimab receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success and the market opportunity for the product candidate may be smaller than our estimates.

Regulatory approval of leronlimab, if any, is no guarantee of commercial success. The sale and marketing of drug products is a complicated and multifaceted process, and many approved drugs are not commercially successful. If approved for marketing, the commercial success of leronlimab will depend upon its acceptance by customers and other stakeholders, including physicians, patients and health care payors. The degree of market acceptance of leronlimab will depend on a number of factors, including:

- demonstration of clinical safety and efficacy;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse effects;
- the willingness of physicians to prescribe leronlimab and of the target patient population to try new therapies;
- safety, tolerability and efficacy of leronlimab compared to competing products;
- the introduction of any new products that may in the future become available to treat indications for which leronlimab may be approved;
- new procedures or methods of treatment that may reduce the incidences of the indications in which leronlimab may show utility;
- pricing and cost-effectiveness;
- the inclusion or omission of leronlimab in applicable treatment guidelines;
- the effectiveness of our or any future collaborators' sales and marketing strategies;
- limitations or warnings contained in FDA approved labeling;
- our ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage or reimbursement.

If leronlimab or any future drug candidates are approved, but do not achieve an adequate level of acceptance by physicians, health care payors and patients, we may not generate sufficient revenue and we may not be able to achieve or sustain profitability. Our efforts to educate the medical community and third-party payors on the benefits of our drug candidate may require significant resources and may never be successful.

In addition, even if we obtain regulatory approvals, the timing or scope of any approvals may prohibit or reduce our ability to commercialize our drug candidate successfully. For example, if the approval process takes too long, we

may miss market opportunities and give other companies the ability to develop competing products or establish market dominance.

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

The biopharmaceutical industry is intensely competitive, and our future success depends on our ability to demonstrate and maintain a competitive advantage with respect to the design, development and commercialization of product candidates. For example, there are current treatments that are quite effective at controlling the effects of HIV, and we expect that new developments by other companies and academic institutions in the areas of HIV treatment will continue. If approved for marketing by the FDA, depending on the approved clinical indication, leronlimab may be competing with existing and future antiviral treatments for HIV.

Our competitors may:

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

We expect to compete against large pharmaceutical and biotechnology companies and smaller companies that are collaborating with larger pharmaceutical companies, new companies, academic institutions, government agencies, and other public and private research organizations. See “Part I, Item 1. Business—Competition.” These competitors, in nearly all cases, operate research and development programs that have substantially greater financial resources than we do. Our competitors also have significantly greater experience in:

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

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

For a description of the key competitors for leronlimab in HIV, COVID-19, cancer, and immunological disorders and the products that are considered competitive with leronlimab, see “Part I, Item 1. Business – Competition”.

Third-party coverage and reimbursement and health care cost containment initiatives and treatment guidelines may constrain our future revenues.

Our ability to successfully market our product candidate will depend in part on the level of reimbursement that government health administration authorities, private health coverage insurers and other organizations provide for the cost of our product and related treatments. Countries in which our product candidate is expected to be sold through reimbursement schemes under national health insurance programs frequently require that manufacturers and sellers of pharmaceutical products obtain governmental approval of initial prices and any subsequent price increases. In certain countries, including the United States, government-funded and private medical care plans can exert significant indirect pressure on prices. We may not be able to sell our drug candidate profitably if adequate prices are not approved or coverage and reimbursement is unavailable or limited in scope. Increasingly, third-party payors attempt to contain health care costs in ways that are likely to impact our development of products including:

- failing to approve or challenging the prices charged for health care products;
- introducing reimportation schemes from lower priced jurisdictions;
- limiting both coverage and the amount of reimbursement for new therapeutic products;
- denying or limiting coverage for products that are approved by the regulatory agencies but are considered to be experimental or investigational by third-party payors; and
- refusing to provide coverage when an approved product is used in a way that has not received regulatory marketing approval.

If approved, leronlimab or any of our future product candidates that are regulated as biologics may face competition from biosimilars approved through an abbreviated regulatory pathway.

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, was enacted as part of the Patient Protection and Affordable Care Act, or the ACA, to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an approved biologic. Under the BPCIA, reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still develop and receive approval of a competing biologic, so long as their BLA does not reply on the reference product, sponsor's data or submit the application as a biosimilar application. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty, and any new policies or processes adopted by the FDA could have a material adverse effect on the future commercial prospects for our biological products.

We believe that leronlimab or any future product candidate we develop that is approved in the United States as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider the subject product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. The approval of a biosimilar of leronlimab or any future product candidates could have a material adverse impact on our business due to increased competition and pricing pressure.

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 the further development and approval of our product candidate, in one or more indications. Strategic alliances 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 do reach will achieve our goals or be on terms that prove to be economically beneficial to us. When we do enter into strategic or contractual relationships, we 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.

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, accounting, 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, our business and financial condition could be materially adversely affected. In addition, security breaches or system failures of this infrastructure may result in system disruptions, shutdowns, or unauthorized disclosure of confidential information. If we are unable to prevent such breaches or failures, our operations could be disrupted, and we may suffer financial damage or loss because of lost or misappropriated information.

The ongoing COVID-19 pandemic prevents a significant risk to our information technology systems to the extent that employees, contractors, and other corporate partners work remotely. As a result, we have been forced to 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 loss, and regulatory fines and intervention.

Risks Related to Legal Proceedings

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

The market price of our common stock has historically experienced and may continue to experience significant volatility. On March 17, 2021, following a period of volatility in the market price for our common stock, a putative class action was filed in the U.S. District Court for the Western District of Washington, Tacoma against us and certain officers. In the complaint, Plaintiff cites the volatility in our common stock and alleges the defendants made or are responsible for false and misleading statements regarding leronlimab's potential as a treatment for COVID-19. Plaintiff seeks a ruling that this case may proceed as a class action, and seeks unspecified damages, and attorneys' fees and costs. A similar class-action lawsuit was filed by a second stockholder on April 9, 2021. The Company and the individual defendants deny any allegations of wrongdoing and intend to vigorously defend the lawsuits. However, litigation, whether or not successful, may result in diversion of our management's attention and resources, and may require us to incur substantial costs, some of which may not be covered in full by insurance, which could harm our business and financial condition. During the course of litigation, there may be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a further negative effect on the market price of our common stock. See discussion of Legal Proceedings in Part I, Item 3 of this Form 10-K.

We are involved in a number of legal proceedings and, while we cannot predict the outcomes of such proceedings and other contingencies with certainty, some of these outcomes could adversely affect our business and financial condition.

We are, or may become, involved in legal proceedings, government and agency investigations, and derivative litigation (see discussion of Legal Proceedings in Part I, Item 3 of this Report). We have faced and continue to face allegations by securities litigation law firms claiming our disclosures are misleading, incomplete, or that we or our officers and directors have violated securities laws. We cannot predict with certainty the outcomes of these legal proceedings. The outcome of some of these legal proceedings could require us to take, or refrain from taking, actions which could negatively affect our operations or could require us to pay substantial amounts of money, adversely affecting our financial condition and results of operations. Additionally, defending against lawsuits and legal proceedings may involve significant expense and diversion of management's attention and resources. Negative publicity surrounding such legal proceedings may also harm our reputation and adversely impact our business and financial condition.

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

We are subject to the regulation and oversight of 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 are unable to predict the effect of any governmental investigations on our business, financial condition or reputation. In addition, publicity surrounding any investigation, even if ultimately resolved in our favor, could have a material adverse effect on our business. See discussion of Legal Proceedings in Part I, Item 3 of this Form 10-K.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidate.

We face a risk of product liability as a result of the clinical testing of leronlimab and will face an even greater risk if we commercialize leronlimab. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of leronlimab. Even successful defense could require significant financial and management resources. Regardless of the merits or eventual outcome, product liability claims may result in:

- decreased demand for leronlimab;
- withdrawal of clinical trial participants;
- delay or termination of our clinical trial;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- the inability to commercialize our product candidate;
- injury to our reputation and negative media attention; and
- a decline in our stock price.

Although we maintain general liability insurance and clinical trial liability insurance, this insurance may not fully cover potential liabilities that we may incur. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. We will need to increase our insurance coverage if we commercialize leronlimab, if approved. In addition, insurance coverage is becoming increasingly expensive. If we are unable to maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, it could prevent or inhibit the development and commercial production and sale of leronlimab, which could harm our business, financial condition, results of operations and prospects.

Risks Related to Our Dependence on Third Parties

We depend on the Vyera License Agreement for the commercialization of leronlimab for the treatment of HIV in humans in the U.S. Vyera's failure to successfully commercialize leronlimab for the treatment of HIV in the U.S., if approved by the FDA, could have a material adverse effect on our business, financial condition and results of operations.

On December 17, 2019, we entered into the Vyera License Agreement under which we granted Vyera an exclusive royalty-bearing license to commercialize pharmaceutical preparations containing leronlimab for treatment of HIV in humans in the U.S. following its approval, if any, by the FDA. Pursuant to the terms of the Vyera License Agreement, Vyera is obligated to use commercially reasonable efforts (as defined in the Vyera License Agreement) to commercialize leronlimab for the treatment of HIV in humans in the U.S.

Under the terms of the Vyera License Agreement, Vyera will make payments to us of up to $87.0 million based upon the achievement of certain sales and regulatory milestones. In addition, Vyera will pay a royalty to us equal to 50% of Vyera's gross profit margin from leronlimab sales (defined in the Vyera License Agreement as "Net Sales") in the

U.S. The right to potential future payments under the Vyera License Agreement represents a significant portion of the value of the Vyera License Agreement. We cannot be certain we will receive any future payments under the Vyera License Agreement, which may adversely affect the trading price of our common stock and have a material adverse effect on our business, financial condition and results of operations.

Vyera's ability to successfully commercialize and generate revenues from leronlimab depends on a number of factors, including Vyera's ability to:

- develop and execute its sales and marketing strategies for leronlimab;
- achieve, maintain and grow market acceptance of, and demand for, leronlimab;
- obtain and maintain adequate coverage, reimbursement and pricing from managed care, government and other third party payers;
- maintain and manage the necessary sales, marketing, manufacturing, managed markets, and other capabilities and infrastructure that are required to successfully integrate and commercialize leronlimab; and
- comply with applicable legal and regulatory requirements.

Additional factors that may affect the success of our commercialization arrangement with Vyera include the following:

- we may not succeed in obtaining regulatory approval for the sale of leronlimab or approval with commercially competitive labeling;
- Vyera may prioritize the commercialization of its other products over leronlimab;
- Vyera may pursue higher-priority programs, or change the focus of its marketing programs;
- Vyera may acquire or develop alternative products;
- changes in laws and regulations applicable to, and scrutiny of, the pharmaceutical industry may occur;
- market acceptance of leronlimab may fail to materialize;
- Vyera may experience financial difficulties; and
- Vyera may fail to comply with its obligations under our Vyera License Agreement and related agreements.

Any of the above factors could affect Vyera's commitment to, and ability to perform, its obligations under the Vyera License Agreement which, in turn, could adversely affect the commercial success of leronlimab for the treatment of HIV in humans in the U.S. Any such failure by Vyera to successfully commercialize leronlimab could have a material adverse effect on our business, financial condition and results of operations.

If Vyera is not successful in commercializing leronlimab for the treatment of HIV in humans in the U.S., our revenues and our business will suffer.

The commercial success of leronlimab for the treatment of HIV in humans in the U.S. will depend almost entirely on Vyera's commercialization efforts. Pursuant to the Vyera License Agreement, Vyera is responsible for marketing, pricing, promoting, selling and distributing leronlimab for the treatment of HIV in humans in the U.S. If the Vyera License Agreement is terminated in accordance with its terms, including due to a party's failure to perform its obligations or responsibilities under the Vyera License Agreement, we would need to commercialize leronlimab ourselves, for which we currently have no infrastructure, or enter into a new agreement with another commercialization partner, of which no assurance can be given. If we are unable to build the necessary infrastructure to commercialize leronlimab ourselves, which would substantially increase our expenses and capital requirements, which we are currently unable to fund, or are unable to find a suitable replacement commercialization partner, we would be unable to generate any revenue from leronlimab for the treatment of HIV in humans in the U.S. Even if we are successful at replacing the commercialization capabilities of Vyera, potential revenues and/or royalties from leronlimab could be adversely affected.

Vyera may market other products, causing leronlimab to vie for Vyera's promotional, marketing, and selling resources. If Vyera fails to commit sufficient promotional, marketing and selling resources to leronlimab, our potential royalties and receipt of milestone payments could be adversely impacted. Additionally, there can be no assurance that Vyera will commit the resources required for the successful commercialization of leronlimab.

If Vyera prices leronlimab inappropriately, fails to position and sell leronlimab properly, targets inappropriate physician specialties, or otherwise does not provide sufficient promotional support, potential product revenue and our potential royalties and milestone payments could be materially adversely affected.

We will depend on Vyera and any other future licensees and royalty-agreement counterparties for the determination of royalty and milestone payments. While we typically have primary or back-up rights to audit our licensees and royalty-agreement counterparties, the independent auditors may have difficulty determining the correct royalty calculation, we may not be able to detect errors, and payment calculations may entail retroactive adjustments. We may have to exercise legal remedies, if available, to resolve any disputes resulting from such audits.

The royalty and milestone payments we may receive pursuant to the Vyera License Agreement and any future license or commercialization agreements are dependent on reports by our licensees regarding their achievement of regulatory milestones and product sales. Each licensee's calculation of the royalty payments is subject to and dependent upon the adequacy and accuracy of its sales and accounting functions, and errors may occur from time to time in the calculations made by a licensee, or a licensee may fail to report the achievement of royalties or milestones in whole or in part. Our license and royalty agreements typically provide us the primary or back-up right to audit the calculations and sales data for the associated royalty payments; however, such audits may occur many months following our recognition of the royalty revenue, may require us to adjust our royalty revenues in later periods and may entail expense on the part of the Company. Further, our licensees and royalty-agreement counterparties may be uncooperative or have insufficient records, which may complicate and delay the audit process.

Although we intend to regularly exercise our royalty audit rights as necessary and to the extent available, we will be relying in the first instance on our licensees and royalty-agreement counterparties to accurately report the achievement of milestones and royalty sales and calculate and pay applicable milestones and royalties and, upon exercise of such royalty and other audit rights, we will rely on licensees' and royalty-agreement counterparties' cooperation in performing such audits. In the absence of such cooperation, we may be forced to exercise legal remedies, if available, to enforce our agreements.

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

We currently have five employees dedicated to CMC activities and quality control. We rely and intend to continue to rely on third parties to supplement many of these functions. We contract with Ama third party full service CROs, to manage our clinical trials. As a result, we are dependent on consultants and strategic partners in our development and commercialization activities, and it may be administratively challenging 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 will need to outsource and rely on third parties for the clinical development and manufacture, sales and marketing of product candidate, and our future success will be dependent on the timeliness and effectiveness of the efforts of these third parties.

We are dependent on third parties for important aspects of our product development strategy. We do not have the required financial and human resources to carry out independently the pre-clinical and clinical development for our product candidate, and do not have the capability or resources to manufacture, market or sell our current product candidate. As a result, we contract with and rely on third parties for important functions, including testing, storing, and manufacturing our products and managing and conducting clinical trials from which we may obtain a benefit. We have recently entered into several agreements with third parties for such services. If problems develop in our relationships with third parties, or if such parties fail to perform as expected, it could lead to delays or lack of progress, significant cost increases, changes in our strategies, and even failure of our product initiatives.

Any manufacturing problem or the loss of a contract manufacturer could be disruptive to our operations and result in lost sales. Any reliance on suppliers involves risks, including a potential inability to obtain critical materials and

reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to a future contract manufacturer caused by problems at suppliers could delay shipment of our products, increase our cost of goods sold, and result in lost sales.

We rely on third parties, such as CROs, to conduct clinical trials for our product candidate, leronlimab, and if they do not properly and successfully perform their obligations to us, we may not be able to obtain regulatory approvals for our product candidate.

We, in consultation with our collaborators, where applicable, design the clinical trials for our product candidate, leronlimab, but we rely on CROs and other third parties to perform many of the functions in managing, monitoring and otherwise carrying out many of these trials. We compete with larger companies for the resources of these third parties. In addition, these third parties may be adversely affected by the COVID-19 pandemic.

Although we plan to continue to rely on these third parties to conduct our ongoing and any future clinical trials, we are responsible for ensuring that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. Moreover, the FDA and foreign regulatory agencies require us to comply with regulations and standards, including good clinical practices, for designing, conducting, monitoring, recording, analyzing, and reporting the results of clinical trials to assure that the data and results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. The third parties on whom we rely generally may terminate their engagements with us at any time. If we are required to enter into alternative arrangements because of any such termination, the introduction of our product candidate to market could be delayed.

If these third parties do not successfully carry out their duties under their agreements with us, if the quality or accuracy of the data they obtain, process and analyze is compromised for any reason or if they otherwise fail to comply with clinical trial protocols or meet expected deadlines, our clinical trials may experience delays or may fail to meet regulatory requirements. If our clinical trials do not meet regulatory requirements or if these third parties need to be replaced, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated. If any of these events occur, we may not be able to obtain regulatory approval of our product candidate and our reputation could be harmed.

We rely on third-party manufacturers to produce our pre-clinical and clinical product candidate supplies, and we intend to rely on third parties to produce commercial supplies of our product candidate, if approved. Any failure by a third-party manufacturer to produce supplies for us may delay or impair our ability to complete our clinical trials or commercialize our product candidate.

We do not possess all of the capabilities to fully commercialize our product candidate, leronlimab, on our own. We have relied upon third-party manufacturers for the manufacture of our product candidate for pre-clinical and clinical testing purposes and intend to continue to do so in the future. If we are unable to arrange for third-party manufacturing sources, or to do so on commercially reasonable terms, we may not be able to complete development of such product candidate or to market them.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured our product candidate ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control, failure of the third party to accept orders for supply raw materials and the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities require that our product candidate be manufactured according to current good manufacturing practices, or current good manufacturing practices, or cGMPs, and similar foreign standards. Any failure by our third-party manufacturers to comply with cGMP or failure to scale-up manufacturing processes as needed, including any failure to deliver sufficient quantities of product candidate in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of our product candidate. In addition, such failure could be the basis for action by the FDA to withdraw approvals for any product candidate previously granted to us and for other regulatory action, including recall or seizure, fines, imposition of operating restrictions, total or partial suspension of production or injunctions.

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidate for our clinical studies and potential commercial manufacturing. There are a limited number of suppliers of raw and starting materials that we use to manufacture our product candidate. Such suppliers may not sell these materials to our manufacturers at the times we need them or on commercially reasonable terms. We do not have any control over the process or timing of the acquisition of these materials by our manufacturers.

Any significant delay in the supply of a product candidate or the raw material components thereof for an ongoing clinical trial or potential commercial launch due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidate. If our supply chain is disrupted due to any of these factors after regulatory approval has been obtained for our product candidate, there could be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidate. It may also cause us to breach our obligations under the Vyera Supply Agreement, pursuant to which we have agreed to supply leronlimab to Vyera for commercialization.

We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidate and we currently have no plans to build our own clinical or commercial scale manufacturing capabilities. To meet our projected needs for commercial manufacturing in the event that our product candidate gains marketing approval, third parties with whom we currently work may need to increase their scale of production or we may need to secure alternate suppliers.

Any failure of any of our upstream suppliers to deliver necessary quantities of leronlimab could result in delays in our commercialization schedule and adversely affect our ability to meet our supply obligations to Vyera. In addition, we may still be obligated to satisfy obligations to our upstream suppliers and/or licensors even if Vyera's commercialization achievements are insufficient to enable us to fully satisfy such obligations.

We will be dependent on our upstream supply agreements with various partners to satisfy our obligations under the Vyera Supply Agreement, also entered into in December 2019, to supply leronlimab to Vyera for commercialization. A failure in our upstream supply chain could adversely impact our ability to meet our supply obligations under the Vyera Supply Agreement and could impact Vyera's ability to successfully commercialize leronlimab. We have obligations to our upstream suppliers and licensors that are independent of Vyera's obligations to us. Therefore, if Vyera is not able to successfully commercialize leronlimab, we may still be obligated to meet certain of our obligations to our upstream suppliers. There can be no assurances that Vyera's commercialization of leronlimab will be sufficient to enable us to meet the obligations to our upstream suppliers and/or licensors.

We anticipate being able to provide to Vyera, in satisfaction of our supply obligations thereto, certain inventory of product that we have on hand in connection with the launch and initial commercialization period of leronlimab. If we are unable to do so due to dating restrictions at the time of regulatory approval of leronlimab, if any, the launch of leronlimab may be delayed and we will likely incur additional costs in order to provide Vyera with sufficient product for the launch and the initial commercialization period of leronlimab.

Risks Related to Our Intellectual Property Rights

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

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

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 FDA clearance of drugs that will be sold only after patent expiration, so our use of leronlimab in those FDA-related activities does 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 FDA clearance, the development and ultimate sale of a leronlimab product could be significantly delayed, and we could incur the expense of defending a patent infringement suit and potential liability for damages for 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.

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.

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

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

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

If any of these events occur, it could significantly harm our operations and financial condition and negatively affect our stock price.

Although no third party has 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. In addition, 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 undertake infringement or other legal proceedings against third parties, causing us to spend substantial resources on litigation and exposing our own intellectual property portfolio to challenge.

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

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

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

Risks Related to Obtaining Required Regulatory Approvals and Licensure

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

Clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in early phases of pre-clinical and clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. A failure of one or more of our clinical trials may occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent our ability to receive regulatory approval or commercialize leronlimab, or any future drug candidates. 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, which regulations differ from country to country. We are not permitted to market a drug candidate as prescription pharmaceutical products in the United States until we receive approval of BLA from the FDA, or in foreign markets until we receive the requisite approval from comparable regulatory authorities in such 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 BLA is approved. Regulatory authorities in other jurisdictions impose similar requirements. Of the large number of drugs in development, only a small percentage result in the submission of BLA to the FDA and even fewer are eventually approved for commercialization.

Receipt of necessary regulatory approval for the use of leronlimab for one or more indications is subject to a number of risks, including the following:

- the FDA or comparable foreign regulatory authorities or IRBs may disagree with the design or implementation of our clinical trials;
- we may not be able to provide acceptable evidence of the safety and efficacy of our drug candidate;
- the results of our clinical trials may not be satisfactory or may not meet the level of statistical or clinical significance required by the FDA, the European Medicines Agency (“EMA”), or other comparable foreign regulatory authorities for marketing approval;
- the dosing of our drug candidate in a particular clinical trial may not be at an optimal level;
- patients in our clinical trials may suffer adverse effects for reasons that may or may not be related to our drug candidate;
- the data collected from clinical trials may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Failure to obtain regulatory approval for leronlimab for the foregoing or any other reasons will prevent us from commercializing such product candidate as a prescription product, and our ability to generate revenue will be materially impaired. We cannot guarantee regulators will agree with our assessment of the results of our clinical trials or that such trials will be considered by regulators to have shown safety or efficacy of our product candidate. The FDA, EMA and other regulators have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional clinical trials, or pre-clinical or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate.

For example, in February 2018, we announced that we had met the primary endpoint in our Phase 3 trial for leronlimab as a combination therapy with HAART for highly treatment experienced HIV patients and submitted the non-clinical portion of our BLA with the FDA in March 2019. We completed our submission in May 2020. In July 2020, we received a Refusal to File letter from the FDA regarding the BLA submission. We have retained a leading global

healthcare diagnostics company, along with an expanded team of subject matter expert consultants, to assist us in the resubmission of our BLA, which commenced in July 2021 and is expected to be completed in October 2021. However, even upon resubmission, there can be no assurance as to if or when the FDA will declare the filing complete.

In addition, we have only limited experience in filing the applications necessary to gain regulatory approvals and expect to continue to rely on consultants and third-party contract research organizations, or CROs, with expertise in this area 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 to the FDA 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 our obtaining regulatory approval or prevent or limit commercial use with respect to one or all intended indications.

Finally, disruptions at the FDA and other agencies may prolong the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. If we experience any delays in obtaining approval or if we fail to obtain approval of our product candidate, the commercial prospects for our product candidate may be harmed, and our ability to generate revenues will be materially impaired.

We may not be able to receive Emergency Use Authorization (EUA) for leronlimab as a treatment for COVID-19, or such authorization may be delayed, which would materially affect our business, financial condition and stock price.

On February 4, 2020, the Secretary of Health and Human Services determined that COVID-19 represents a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and, subsequently, declared on March 24, 2020, that circumstances exist to justify the authorization of emergency use of certain medical products, during the COVID-19 pandemic, subject to the terms of any authorization as issued by the FDA.

With this declaration of a public health emergency, the FDA may issue an Emergency Use Authorization, or EUA, for an unapproved product if the following four statutory criteria have been met: (1) a serious or life-threatening condition exists; (2) evidence that the product may be effective in diagnosing or treating such condition; (3) a risk-benefit analysis shows that the benefits of the product outweigh the risks; and (4) no adequate, approved and available alternatives exist for diagnosing, preventing or treating the disease or condition. The statute directs FDA to assess the potential effectiveness of a possible EUA product on a case-by-case basis using a risk-benefit analysis. In determining whether the known and potential benefits of the product outweigh the known and potential risks, the FDA examines the totality of the scientific evidence to make an overall risk-benefit determination. Such evidence, which could arise from a variety of sources, may include (but is not limited to) results of domestic and foreign clinical trials, in vivo efficacy data from animal models and in vitro data.

Once granted, an EUA will generally remain in effect until the earlier of (1) a determination by the Secretary of HHS that the public health emergency has ceased or (2) a change in the approval status of the product such that the authorized use(s) of the product are no longer unapproved. After the EUA is no longer valid, the product is no longer considered to be legally marketed, and FDA's non-emergency approval pathway would be necessary to resume or continue distribution of the product. The FDA also may revise or revoke an EUA if the circumstances justifying its issuance no longer exist, the criteria for its issuance are no longer met, or other circumstances make a revision or revocation appropriate to protect the public health or safety.

We recently completed a Phase 3 clinical trial to evaluate the safety and efficacy of leronlimab as a treatment for patients with severe-to-critical COVID-19, which did not meet its primary endpoint. Since the COVID-19 pandemic began, we have expended significant time and financial resources to evaluate leronlimab as a therapeutic treatment for COVID-19. Obtaining and maintaining such an authorization is dependent upon a number of factors, which are not

under our control. If we are unable to receive an EUA from the FDA or other countries for treating COVID-19 patients, we will not be able to market leronlimab for COVID-19 in the U.S. or abroad for this condition and our ability to generate revenues will be adversely affected. Moreover, even if we are successful in receiving an EUA or approval from the FDA or elsewhere for the treatment of COVID-19 patients, the availability of vaccines against COVID-19 may significantly reduce the demand for leronlimab as a treatment for COVID-19 patients, which could materially affect our business.

We and our contract manufacturers are subject to significant regulation. The manufacturing facilities on which we rely may not continue to meet regulatory requirements, which could materially harm our business.

All entities involved in the preparation of product candidates for clinical trials or commercial sale, including any contract manufacturers, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants or to inadvertent changes in the properties or stability of our product candidate that may not be detectable in final product testing.

We or our contract manufacturers must supply all necessary documentation in support of a BLA on a timely basis and must adhere to the FDA's current Good Laboratory Practice and cGMP regulations enforced through its facilities inspection program. Our facilities and quality systems and the facilities and quality systems of some or all of our third-party manufacturers must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of any product candidate. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidate or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities do not pass a pre-approval plant inspection, FDA approval of the products will not be granted.

The regulatory authorities also may, at any time following approval of a product for sale, audit our manufacturing facilities or those of our third-party manufacturers. If any such inspection or audit identifies failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility, which may lead to temporary or permanent supply shortages. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

If we or our third-party manufacturers fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new product, or revocation of a pre-existing approval. Any such consequence would severely harm our business, financial condition and results of operations.

We may seek Fast Track designation, Breakthrough Therapy designation, or PRIME designation for our product candidate, but we might not receive any such designation, and even if we do, such designation may not actually lead to a faster development or regulatory review or approval process.

If a drug is intended for the treatment of a serious or life-threatening condition, and non-clinical or clinical data demonstrate the potential to address an unmet medical need for this condition, the product candidate may qualify for FDA Fast Track designation, for which sponsors must apply. Sponsors of fast track products may have more frequent interactions with the FDA, and, in some circumstances, the FDA may initiate review of sections of a fast track product's application before the application is complete. We have previously received Fast Track designation for HIV and mTNBC. We may submit an application for Fast Track designation for our product candidate for other indications. The FDA has broad discretion whether to grant this designation, and we may not receive it. Moreover, even if we receive Fast Track designation, Fast Track designation does not ensure that we will receive marketing approval or that approval will be granted within any particular time frame. We may not experience a faster development or regulatory review or

approval process with Fast Track designation compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.

When appropriate we may seek a Breakthrough Therapy designation for our product candidate for various indications if future results support such designation. A Breakthrough Therapy is defined as a drug (including biologic) that is intended, alone or in combination with one or more other drugs, to treat a serious condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Sponsors of products that have been designated as breakthrough therapies are eligible to receive more intensive FDA guidance on establishing an efficient drug development program, an organization commitment involving senior managers, and may be eligible for rolling review. Drugs designated as breakthrough therapies by the FDA may also be eligible for other expedited review programs, including accelerated approval and priority review, if supported by clinical data at the time the BLA or NDA is submitted to the FDA.

Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe that our product candidate meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. Even if we receive Breakthrough Therapy designation, the receipt of such designation may not result in a faster development or regulatory review or approval process compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if our product candidate qualifies as a Breakthrough Therapy, the FDA may later decide that it no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

In the EU, we may seek PRIME designation for our product candidate in the future. PRIME is a voluntary program aimed at enhancing the EMA's role to reinforce scientific and regulatory support in order to optimize development and enable accelerated assessment of new medicines that are of major public health interest with the potential to address unmet medical needs. The program focuses on medicines that target conditions for which there exists no satisfactory method of treatment in the EU or even if such a method exists, it may offer a major therapeutic advantage over existing treatments. PRIME is limited to medicines under development and not authorized in the EU and the applicant intends to apply for an initial marketing authorization application through the centralized procedure. To be accepted for PRIME, a product candidate must meet the eligibility criteria in respect of its major public health interest and therapeutic innovation based on information that is capable of substantiating the claims. The benefits of a PRIME designation include the appointment of a CHMP rapporteur to provide continued support and help to build knowledge ahead of a marketing authorization application, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review, meaning reduction in the review time for an opinion on approvability to be issued earlier in the application process. PRIME enables an applicant to request parallel EMA scientific advice and health technology assessment advice to facilitate timely market access. Even if we receive PRIME designation for our product candidate, the designation may not result in a materially faster development process, review or approval compared to conventional EMA procedures. Further, obtaining PRIME designation does not assure or increase the likelihood of EMA's grant of a marketing authorization.

Even if we obtain regulatory approval for our product candidate, we will still face extensive and ongoing regulatory requirements and obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with the product candidate.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval pre-clinical and clinical testing, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, and advertising and promotional activities for such product, among other things, will be subject to extensive and ongoing requirements of the FDA and other regulatory authorities. These requirements include submissions of safety and other post- marketing information and reports, establishment registration and drug listing requirements, continued compliance with current Good Manufacturing Practice, or cGMP, requirements regarding the

distribution of samples to physicians and recordkeeping and Good Laboratory Practice, or GLP, and GCP requirements for non-clinical studies and any clinical trials that we conduct post-approval.

The FDA may also require costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. Additionally, the FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in a manner that is consistent with the provisions of the approved labeling. If we market our products for uses beyond their approved indications or otherwise inconsistent with the FDA-approved labeling, we may be subject to enforcement action for off-label marketing by the FDA and other federal and state enforcement agencies, including the Department of Justice. Violation of the Federal Food, Drug, and Cosmetic Act, or FDCA, and other statutes, including the False Claims Act, and equivalent legislation in other countries relating to the promotion and advertising of prescription products may also lead to investigations or allegations of violations of federal and state and other countries' health care fraud and abuse laws and state consumer protection laws. Even if it is later determined we were not in violation of these laws, we may be faced with negative publicity, incur significant expenses defending our actions and have to divert significant management resources from other matters.

In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers, or manufacturing processes or failure to comply with regulatory requirements, may yield various results, including, but not limited to:

- restrictions on manufacturing such products;
- restrictions in the labeling or on the marketing of products;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- issuance of warning letters or untitled letters;
- refusal to approve pending applications or supplements to approved applications that we submit, or delays in such approvals;
- recalls or market withdrawals of products;
- fines, restitution, or disgorgement of profits or revenues;
- suspension or termination of ongoing clinical trials'
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure; and
- injunctions, consent decrees, or the imposition of civil or criminal penalties.

If we obtain FDA approval for our product candidate, safety risks not identified in our prior clinical trials may first appear after we obtain approval and commercialize the product candidate. Any new post-marketing adverse events may significantly impact our ability to market the drugs and may require that we recall and discontinue commercialization of the products. Furthermore, if any confirmatory post-marketing trial fails to confirm the clinical profile or clinical benefits of our product candidate, the FDA may withdraw its approval, which would materially harm our business.

We also cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. Further, the FDA's, EMA's and other comparable regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of a product candidate or increase the costs and regulatory burden of commercialization. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition, and results of operations. Furthermore, non-compliance by us or any collaborator with regulatory requirements, including safety monitoring or pharmacovigilance, may also result in significant financial penalties, which would adversely affect our business.

Failure to obtain marketing approval in foreign jurisdictions would prevent our product candidate from being marketed in other countries. Any marketing approval we are granted in the United States would not assure marketing approval in foreign jurisdictions.

In order to market and sell products in the European Union and other foreign jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The marketing approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, a product must be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may file for marketing approvals but not receive necessary approvals to commercialize any products in any market. Obtaining non-U.S. regulatory approvals and compliance with non-U.S. regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidate in any country. In addition, if we fail to obtain the non-U.S. approvals required to market products outside the United States or if we fail to comply with applicable non-U.S. regulatory requirements, our target markets will be reduced and our ability to realize the full market potential of our product candidate will be harmed and our business, financial condition, results of operations and prospects may be adversely affected.

Additionally, we could face heightened risks with respect to seeking marketing approval in the United Kingdom as a result of the recent withdrawal of the United Kingdom from the European Union, commonly referred to as Brexit. The United Kingdom and European Union entered into a Trade and Cooperation Agreement in connection with Brexit that sets out certain procedures for approval and recognition of medical products in each jurisdiction. Since the regulatory framework for pharmaceutical products in the United Kingdom covering the quality, safety, and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales, and distribution of pharmaceutical products is derived from European Union directives and regulations, Brexit could materially impact the future regulatory regime that applies to products and the approval of product candidate in the United Kingdom. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of the Trade and Cooperation Agreement would prevent us from commercializing our product candidate in the United Kingdom and/or the European Union and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or European Union for any product candidate, which could significantly and materially harm our business.

We expect that we will be subject to additional risks in commercializing our product candidate that receive marketing approval outside the United States, including tariffs, trade barriers and regulatory requirements; economic weakness, including inflation, or political instability in particular foreign economies and markets; compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; and workforce uncertainty in countries where labor unrest is more common than in the United States.

Risks Related to Healthcare Laws and Other Legal Compliance Matters

We are subject to a complex regulatory scheme that requires significant resources to ensure compliance. Failure to comply with applicable laws could subject us to government scrutiny or government enforcement, potentially resulting in costly investigations and/or fines or sanctions, or impacting our relationships with key regulatory agencies such as the FDA, the U.S. Securities and Exchange Commission, or the SEC, or the EMA.

A variety of laws apply to us or may otherwise restrict our activities, including the following:

- laws and regulations governing the conduct of pre-clinical and clinical studies in the United States and other countries in which we are conducting such studies;
- laws and regulations in the United States and in countries in which we are interacting with healthcare providers, patients, patient organizations and other constituencies that prohibit promoting a drug prior to approval and/or reimbursement;

- laws and regulations of countries outside the United States that prohibit pharmaceutical companies from promoting prescription drugs to the general public;
- laws, regulations and industry codes that vary from country to country and govern our relationships with healthcare providers, patients, patient organizations, and other constituencies, prohibit certain types of gifts and entertainment, establish codes of conduct and, in some instances, require disclosure to, or approval by, regulatory authorities for us to engage in arrangements with such constituencies;
- anti-corruption and anti-bribery laws, including the FCPA, the UK Bribery Act and various other anti-corruption laws in countries outside of the United States;
- data privacy laws existing in the United States, the EU and other countries in which we operate, including the U.S. Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, the GDPR, and state privacy and data protection laws, such as the California Consumer Privacy Act, or CCPA, as well as state consumer protection laws;
- federal and state laws requiring the submission of accurate product prices and notifications of price increases;
- federal and state securities laws; and
- international trade laws, which are laws that regulate the sale, purchase, import, export, re-export, transfer and shipment of goods, products, materials, services and technology.

Compliance with these and other applicable laws and regulations requires us to expend significant resources. Failure to comply with these laws and regulations may subject us to government investigations, enforcement actions by regulatory authorities, penalties, damages, fines, the restructuring of our operations, or the imposition of a clinical hold, any of which could materially adversely affect our business and would result in increased costs and diversion of management attention and could negatively impact the development, regulatory approval and commercialization of our product candidate, any of which could have a material adverse effect on our business.

We will incur significant liability if it is determined that we are promoting any "off-label" use of our product candidate or any other product we may develop, acquire or in-license.

Physicians are permitted to prescribe drug products for uses that differ from those approved by the FDA or other applicable regulatory agencies. Although the FDA and other regulatory agencies do not regulate a physician's choice of treatments, the FDA and other regulatory agencies do restrict manufacturer communications regarding unapproved uses of an approved drug. Companies are not permitted to promote drugs for unapproved uses or in a manner that is inconsistent with the FDA-approved labeling. There are also restrictions about making comparative or superiority claims based on safety or efficacy that are not supported by substantial evidence. Accordingly, we may not promote our product candidate in the United States for use in any indications other than the indication for which the product is approved.

Promoting a drug off-label is a violation of the Food, Drug and Cosmetic Act ("FDCA") and can give rise to liability under the federal False Claims Act, as well as under additional federal and state laws and insurance statutes. The FDA, the Department of Justice and other regulatory and enforcement authorities enforce laws and regulations prohibiting promotion of off-label uses and the promotion of products for which marketing approval has not been obtained, as well as the false advertising or misleading promotion of drugs. In addition, laws and regulations govern the distribution and tracing of prescription drugs and prescription drug samples, including the Prescription Drug Marketing Act of 1976 and the Drug Supply Chain Security Act, which regulate the distribution and tracing of prescription drugs and prescription drug samples at the United States federal level and set minimum standards for the regulation of drug distributors by the states. A company that is found to have improperly promoted off-label uses or to have otherwise engaged in false or misleading promotion or improper distribution of drugs will be subject to significant liability, potentially including civil and administrative remedies as well as criminal sanctions. It may also be subject to exclusion and debarment from federal healthcare reimbursement programs.

Risks Related to Employee Matters and Managing Potential Growth

We may not be able to attract or retain a majority of independent directors.

The Company's Board of Directors, or the Board, may not be composed of a majority of independent directors in the future. Currently, our Board consists of six members; four of whom are independent and two of whom are members of management. It is difficult to retain and recruit independent directors. If the Board is not composed of a majority of independent directors, there may be a lower level of oversight on executive management, and the Board may be influenced by the concerns, issues or objectives of management, including compensation and governance issues, to a greater extent than would occur with a majority of independent directors. As a result, the composition of the Board may afford less protection to our stockholders than if the Board were composed of a majority of independent directors.

A lack of independent directors may also make it difficult to create appropriately sized board committees meeting the requirements of the charters of the Board Committees and the listing standards of The Nasdaq Stock Market, pursuant to which we evaluate director independence. Historically, we have strived to have each of our Board Committees comprised solely of independent directors. Currently, our Audit Committee has only three members, tow of which are audit committee financial experts and our Nominating & Corporate Governance Committee also consists of two independent directors. Due to the fact that we currently have only four independent directors, it is difficult to establish appropriately sized and effective operating board committees composed of independent members to oversee committee functions without overburdening our existing directors.

As we attempt to identify new board members, we may find that highly-qualified individuals are not available or willing to serve as directors or on a committee. There can be no assurance that we will be able to identify, recruit and ultimately secure the services of such individuals in a timely manner or at all. If we are unable to attract and retain qualified individuals who possess the necessary technical, scientific and financial expertise and management and operational experience, our ability to successfully develop, test and commercialize our product candidate and generate revenues may be negatively affected.

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 directors, executive officers and key scientific and technical advisors. 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 may need to recruit additional directors, executive management employees, and advisors, particularly scientific and technical personnel, which will require additional financial resources. In addition, there is currently intense competition for skilled directors, executives and employees with relevant scientific and technical expertise, and this competition is likely to continue. We compete for these qualified personnel against companies with greater financial resources than ours. In order to successfully recruit and retain qualified employees, we will likely need to offer a combination of base salary, cash incentives, and equity compensation. Future issuances of our equity securities for compensatory purposes will dilute existing stockholders' ownership interests. If we are unable to attract and retain persons with sufficient 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 or transition of any member of our senior management team or any key employee could adversely affect our business.

Our success depends significantly on the continued individual and collective contributions of our senior management team and key employees. The individual and collective efforts of these employees will be important as we continue to develop our tests and services, and as we expand our commercial activities. The loss of the services of any

member of our senior management team or the inability to hire and retain experienced management personnel could harm our operating results.

We have experienced significant turnover among our senior executives over the past three years. The complexity inherent in integrating a new key member of the senior management team with existing senior management may limit the effectiveness of any such successor or otherwise adversely affect our business. Leadership transitions are inherently difficult to manage and may cause uncertainty or a disruption to our business or increase the likelihood of turnover of other key officers and employees. Further, we may incur significant expenses related to any executive transition costs that may impact our operating results. Finding suitable replacements for senior management and other key employees can be difficult, and there can be no assurance we will continue to be successful in attracting or retaining qualified personnel in the future.

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 Securities Exchange Act of 1934 (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 which provides information about penny stocks and the nature and level of risks in the penny stock market. The broker-dealer also must provide the customer 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 customer'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.

Although we have filed an application to list our securities on Nasdaq, there can be no assurance that our securities will be so listed or, if listed, that we will be able to comply with the continued listing standards.

On July 15, 2020, we announced that we had filed a comprehensive listing application package with The Nasdaq Stock Market, or Nasdaq, to request an uplisting of the Company's common stock. Although we believe we satisfy the initial listing requirements for The Nasdaq Capital Market, Nasdaq has not approved our application, and there can be no assurance that Nasdaq will agree, approve us for listing on The Nasdaq Capital Market and, even if our securities are listed, we cannot assure you that we will be able to maintain such listing. In addition, if after listing, Nasdaq delists our securities from trading on its exchange for failure to meet the continued listing standards, we and our shareholders could face significant material adverse consequences including a limited availability of market quotations for our common stock, confirmation that our stock is "penny stock" and subject to increased regulations, and a decreased ability to issue additional securities or obtain additional financing in the future.

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, 2020 through May 31, 2021, the market price of our common stock has fluctuated from a high of $10.01 per share to a low of $1.63 per share, and our stock price reached a 52-week high of $10.01 on June 30, 2020.

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.

We and our collaborators may not achieve development and commercialization goals in the estimated time frames that we publicly announce, which could have an adverse impact on our business and could cause our stock price to decline.

We set goals, and make public statements regarding our expected timing for certain accomplishments, such as statements we have made about the initiation and completion of clinical trials, filing and approval of regulatory applications and other developments and milestones under our research and development programs and those of our partners and collaborators for leronlimab. The actual timing of these events can vary significantly due to a number of factors, including those discussed "Part I, Item 1A. Risk Factors." As a result, there can be no assurance that our pre-clinical studies and clinical trials will advance or be completed in the time frames we expect or announce, that we will make regulatory submissions or receive regulatory approvals as planned or that we will be able to adhere to our currently anticipated schedule for the achievement of key milestones under any of our programs. If we fail to achieve one or more of the events described above as planned, our business could be materially adversely affected and the price of our common stock could decline.

We are subject to risks associated with proxy contests and other actions of activist shareholders.

In connection with the 2021 Annual Meeting of Shareholders, or the 2021 Meeting, a group of investors, The Rosenbaum Group, or the Activist Shareholders, has submitted notice of nominations of five candidates for election to our Board at the 2021 Meeting and pursuing a proxy contest. As of May 31, 2021, we had not incurred any costs in connection with the potential proxy contest. The Activist Shareholders filed preliminary proxy materials with the SEC in respect of the 2021 Meeting on July 20, 2021. As of the date of this Form 10-K the Company has not filed preliminary proxy materials for the 2021 Meeting. A proxy contest or related activities on the part of the Activist Shareholders or another shareholder could adversely affect our business for a number of reasons, including, without limitation, the following:

- responding to proxy contests and other actions by activist stockholders may be costly and time-consuming, and may disrupt our operations and divert the attention of management and our employees;
- perceived uncertainties as to the potential outcome of any proxy contest may result in our inability to consummate potential acquisitions, collaborations or in-licensing opportunities and may make it more difficult to attract and retain qualified personnel and business partners; and
- if individuals that have a specific agenda different from that of our management or other members of our Board are elected to our Board as a result of any proxy contest, such an election may adversely affect our ability to effectively and timely implement our strategic plan and create additional value for our stockholders.

Proxy contests may cause our stock price to experience periods of volatility. Further, if a proxy contest results in a change in control of our Board, such an event could subject us to risks relating to certain third parties' rights under our existing contractual obligations, which could adversely affect our business.

Our debt service obligations and our need for additional funding to finance operations may cause additional dilution to our existing stockholders.

Since our inception, we have not achieved cash flows from revenues to cover basic operating costs. As a result, we have relied heavily on debt and equity financing. The terms of our recent convertible note financings require us to make debt repayments of $7.5 million per month to retire earlier incurred debt. As a result, we will be required to use a significant portion of our available cash to make these debt repayments, which will reduce the amount of capital available to finance our operations and other business activities. We have to date, and may continue to, negotiate with our noteholders to exchange all or part of our outstanding debt for shares of common stock. If the Company enters into

any future exchange offers they will likely be negotiated at a discount to the market price of our common stock and will cause additional dilution to our existing stockholders. If the convertible noteholders sell the common stock they receive in exchange for outstanding debt, this could result in a decline in our stock price. In addition, the exercise of our existing outstanding warrants and stock options, which are exercisable for or convertible into shares of our common stock, and which we have encouraged through private warrant exchange offers, would dilute our existing common stockholders. As a result of these or other factors, the issuance of additional equity or convertible debt securities could have an adverse effect on the market price of our common stock. For the foreseeable future, we will need to continue to rely upon debt and equity financing to maintain our operations.

The significant number of shares of common stock issuable upon the exercise of outstanding common stock options and warrants could adversely affect the trading price of our common stock.

If our existing stockholders sell, or indicate an intent to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline significantly. In addition, as of July 15, 2021, we have 15.3 million shares subject to exercise of outstanding options, 5.1 million shares of unvested and performance based restricted stock units and 18.7 million shares reserved for grants future awards under our equity compensation plan; 40.2 million shares issuable upon the exercise of outstanding warrants. If our existing stockholders sell substantial amounts of our common stock in the public market, or if the public perceives that such sales could occur, the market price of our common stock could be adversely affected.

The significant number of shares of common stock issuable upon the exercise of outstanding common stock options and warrants could adversely affect the trading price of our common stock.

We have currently outstanding shares of Series B, Series C and Series D Preferred Stock, as well as convertible secured promissory notes, that are convertible into common stock at variable conversion prices and adjustments. As a result, future conversion of debt and convertible preferred shares or issuance of new convertible debt may result in significant dilution to our stockholders. As of July 15, 2021, we have reserved 51.6 million shares of common stock for further issuance upon conversion of our outstanding shares of preferred stock and convertible notes.

If we implement a reverse stock split, there can be no assurance that the price per share of our common stock will increase proportionately with the reverse stock split, or at all.

Reducing the number of outstanding shares of our common stock through a reverse stock split is intended, absent other factors, to increase the per share market price of our common stock, including in preparation for a potential uplisting to a national securities exchange. However, other factors, such as our financial results, market conditions and the market perception of our business, may adversely affect the market price of our common stock. As a result, there can be no assurance that a reverse stock split, if completed, will result in making our common stock more attractive to a broader range of institutional and other investors, that the per share market price of our common stock will increase following a reverse stock split or that the per share market price of our common stock will not decrease in the future. Additionally, we cannot assure shareholders that the per share market price per share of our common stock after a reverse stock split, if completed, will increase in proportion to the reduction in the number of shares of our common stock outstanding before the reverse stock split. Accordingly, the total market capitalization of our common stock after a reverse stock split may be lower than the total market capitalization before the reverse stock split.

If the beneficial ownership of our stock becomes highly concentrated, it may prevent our stockholders from influencing significant corporate decisions.

Our significant stockholders, if any, may exercise substantial influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets, or any other significant corporate transaction. These stockholders may also vote against a change of control, even if such a change of control would benefit our other stockholders.

Future sales of our securities could adversely affect the market price of our common stock and our future capital-raising activities could involve the issuance of equity securities, which would dilute your investment and could result in a decline in the trading price of our common stock.

We may sell securities in the public or private equity markets if and when conditions are favorable, or at prices per share below the current market price of our common stock, even if we do not have an immediate need for additional capital at that time. Sales of substantial amounts of our common stock, or the perception that such sales could occur, could adversely affect the prevailing market price of our shares and our ability to raise capital. We may issue additional shares of common stock in future financing transactions or as incentive compensation for our executive management and other key personnel, consultants and advisors. Issuing any equity securities would be dilutive to the equity interests represented by our then-outstanding shares of common stock. Moreover, sales of substantial amounts of shares in the public market, or the perception that such sales could occur, may adversely affect the prevailing market price of our common stock and make it more difficult for us to raise additional capital.

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

Our Board has the authority to fix and determine the relative rights and preferences of preferred stock. Currently, our Board has the authority to designate and issue up to 7.58 million additional shares of our preferred stock without further stockholder approval. As a result, our Board of Directors could authorize the issuance of another series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock. In addition, our Board could authorize the issuance of a series of preferred stock that has greater voting power than our common stock or that is convertible into our common stock, which could decrease the relative voting power of our common stock or result in dilution to our existing stockholders.

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

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

- allow us to designate and issue shares of preferred stock, without stockholder approval, that could adversely affect the rights, preferences and privileges of the holders of our common stock and could make it more difficult or less economically beneficial to acquire or seek to acquire us.
- provide that special meetings of stockholders may be called only by the Board acting pursuant to a resolution approved by the affirmative majority of the entire Board.

- provide that stockholders may, at a special stockholders meeting called for the purpose of removing directors, remove the entire Board or any lesser number, but only with cause, by a majority vote of the shares entitled to vote at an election of directors.
- do not include a provision for cumulative voting in the election of directors. Under cumulative voting, a minority stockholder holding a sufficient number of shares may be able to ensure the election of one or more directors. The absence of cumulative voting may have the effect of limiting the ability of minority stockholders to effect changes in the composition of our Board.

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

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

Section 404 of the Sarbanes-Oxley Act of 2002 and related regulations require us to evaluate the effectiveness of our internal control over financial reporting as of the end of each fiscal year, and to include a management report assessing the effectiveness of our internal control over financial reporting in our Annual Report on Form 10-K for that fiscal year. Management determined that as of the fiscal year ended May 31, 2021, our disclosure controls and procedures and internal control over financial reporting were effective. Prior to the fiscal year ended May 31, 2017, our disclosure controls and procedures and internal control over financial reporting were not effective, due to material weaknesses in our internal control over financial reporting related to inadequate segregation of duties over authorization, review and recording of transactions, as well as the financial reporting of such transactions. Any failure to maintain our controls or operation of these controls, could harm our operations, decrease the reliability of our financial reporting, and cause us to fail to meet our financial reporting obligations, which could adversely affect our business and reduce our stock price.

We do not expect any cash dividends to be paid on our common shares in 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.

Risks Related to the COVID-19 Pandemic

Our business and operations continue to be affected by the ongoing COVID-19 pandemic.

Our operational and financial performance continues to be affected by the COVID-19 pandemic. We expect our clinical trial activity to continue to face challenges and delays in patient enrollment as a result of concerns regarding infection spread and the Delta variant of COVID-19, governmental orders regarding travel and other measures to reduce disease spread, study site closures, and prioritization of hospital resources toward the pandemic. The COVID-19 pandemic has also affected the operations of governmental entities, such as the FDA, as well as contract research organizations, consultants, third-party manufacturers, third-party laboratories and manufacturers, and other third-parties upon whom we rely. The effects of work-from-home policies may negatively impact productivity, resulting in delays in our clinical programs and timelines. We have experienced, and expect to continue to experience, delays in our operations and in the operations of our third-party service providers as a result of disruptions COVID-19 has had on normal business operations. We may also be affected by a downturn in the U.S. economy, which could have an adverse effect on our ability to raise capital and obtain financing, which could in the future negatively affect our liquidity and ability to continue as a going concern. The extent to which COVID-19 continues to affect our business, financial condition, and results of operations will depend on future developments, which continue to evolve rapidly, and which are highly

uncertain and subject to change. These effects may continue to have a material adverse impact on our operations and financial condition.

The spread of COVID-19 has also led to disruption and volatility in the global capital markets, which increases the cost of, and adversely impacts access to, capital and increases economic uncertainty. To the extent the COVID-19 pandemic adversely affects our business, financial results and value of our common stock, it may also have an adverse effect on our ability to access capital and obtain financing, which could negatively affect our liquidity and ability to continue as a going concern.

We may be at increased risk of becoming the target of cyber-attacks due to our research involving leronlimab for treatment of COVID-19.

Cybersecurity authorities in the United States are currently investigating a number of incidents in which hackers are targeting pharmaceutical companies, medical research organizations, and universities in order to steal sensitive research data and intellectual property related to efforts to contain and treat coronavirus. In July 2020, the U.S. Department of Justice accused several groups of hackers of targeting companies conducting COVID-19 vaccine development research on behalf of foreign intelligence services. Because of leronlimab's potential effect on the immune system, it has been administered to COVID patients under single patient Emergency Investigation New Drug (EIND) authorizations, and the Company has initiated several clinical trials for COVID-19 in the U.S. and other countries. As a result of our ongoing clinical trials for leronlimab to treat COVID-19, our information technology systems, employees, contractors and corporate partners may be at greater risk for cyber-based attacks.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

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

Item 3. LEGAL PROCEEDINGS

For a description of any pending material legal proceedings, please see Note 10. Commitments and Contingencies of the Notes to Consolidated Financial Statements included in Part II, Item 8 of this Form 10-K.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Part II

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

Market Information

Our common stock is presently 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 very limited and the trades that have occurred cannot be characterized as amounting to an 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 actively traded.

Holders

The number of record holders of our common stock on July 15, 2021 was approximately 864.

Dividends

Holders of our common stock are entitled to receive dividends as may be declared from time to time 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, as described below, we have not paid any cash dividends since inception on our common stock and do not anticipate paying any in the foreseeable future. Our current policy is to 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, 2021, the Company had an accumulated deficit of approximately $511.3 million and has had a net loss in each of the last three fiscal years. As a result of the accumulated deficit, the Company is also currently prohibited from paying any dividends in the form of capital stock.

Brief summaries of the terms of our outstanding preferred stock are set forth below.

Holders of 8,452 shares of Series D Convertible Preferred Stock ("Series D Preferred Stock") outstanding at May 31, 2021, are entitled to receive, when and as declared by the Board and out of any assets at the time legally available therefor, cumulative dividends at the rate of ten percent (10%) per share per annum of the stated value of the Series D Preferred Stock, which is $1,000 per share. Any dividends paid by us will first be paid to the holders of Series D Preferred Stock prior and in preference to any payment or distribution to holders of our 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 DGCL Section 170, the holder may elect to be paid in cash or in restricted shares of common stock at the rate of $0.50 per share. If all holders were to elect to receive a dividend (if declared) in the form of common stock at December 31, 2020, approximately 3.2 million shares of common stock would be issued. If such dividends were to be paid in cash, such dividends would total approximately $1.6 million at December 31, 2020.

Holders of 8,203 shares of Series C Convertible Preferred Stock ("Series C Preferred Stock") outstanding at May 31, 2021, are entitled to receive, when and as declared by the Board and out of any assets 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. Any dividends paid by us will first be paid to the holders of Series C Preferred Stock prior and in preference to any payment or distribution to holders of our 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 DGCL Section 170, the holder may elect to be paid in cash or in restricted shares of common stock at the rate of $0.50 per share. If all holders were to elect to receive a dividend (if declared) in the form of common stock at December 31, 2020, approximately 4.0 million shares of common stock would be issued. If such dividends were to be paid in cash, such dividends would total approximately $2.0 million at December 31, 2020.

Holders of 79,000 shares of Series B Convertible Preferred Stock ("Series B Preferred Stock") outstanding at May 31, 2021, are entitled to receive, in preference to the common stock, annual cumulative dividends equal to $0.25 per share per annum from the date of issuance, which shall accrue, whether or not declared. At the time shares of Series B Preferred Stock are converted into common shares, accrued and unpaid dividends will be paid, at the election of the Company, in cash or with common shares. In the event we elect to pay dividends with common shares, the shares issued will be valued at $0.50 per share. On July 30, 2020, the Board declared a dividend and elected to pay such

dividend in the form of cash in the aggregate amount of approximately $243,000 to all Series B Preferred stockholders. At May 31, 2021, accrued dividends on the Series B Preferred stock totaled $17,800.

Unregistered Sales of Equity Securities

From June 11, 2021 to July 27, 2021, in satisfaction of the June and July 2021 Debt Redemption Amounts, the Company and the November 2020 Note holder entered into exchange agreements, pursuant to which the November 2020 Note was partitioned into new notes (the "Partitioned Notes") with an aggregate principal amount of $10.0 million. The outstanding balance of the November 2020 Note was reduced by the Partitioned Notes. The Company and the investor exchanged the Partitioned Notes for approximately 7.4 million shares. The Company and the holder of the November 2020 Note agreed to defer the remaining June 2021 Debt Redemption Amount of $1.5 million and the June 2021 Debt Redemption Amount of $3.5 million. Following these payments, the outstanding balance on the November 2020 Note, including accrued interest, was approximately $4.5 million. We relied on the exemption from registration afforded by Section 4(a)(2) of the Securities Act of 1933 in connection with the issuance and sale of the convertible promissory note and underlying shares of Common Stock.

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 Annual Report, including our Consolidated Financial Statements and related notes set forth in Item 8. This discussion and analysis contains forward-looking statements, including information about possible or assumed results of our financial condition, operations, plans, objectives and performance that involve risks, uncertainties and assumptions. The actual results may differ materially from those anticipated and set forth in such forward-looking statements. See "Forward-Looking Statements" preceding Part I and Item 1A. Risk Factors in Part I of this Form 10-K.

Overview of Our Business

The Company is a late-stage biotechnology company focused on the clinical development and potential commercialization of leronlimab (PRO 140), a CCR5 antagonist to treat HIV infection, as well as multiple other potential therapeutic indications. Our current business strategy is to resubmit our Biologics License Application ("BLA") for leronlimab as a combination therapy for highly treatment experienced HIV patients as soon as possible, as well as to seek approval for other HIV-related indications, to seek approval for leronlimab as a potential therapeutic benefit for COVID-19 patients with mild-to-moderate, severe-to-critical, and long-haulers indications in the U.S. and Brazil, to advance our clinical trials with leronlimab for various forms of cancer, and to concurrently explore other cancer and immunologic indications for leronlimab.

The target of leronlimab is the immunologic receptor CCR5. The CCR5 receptor is a protein located on the surface of white blood cells that serves as a receptor for chemical attractants called chemokines. Chemokines are the key orchestrators of leukocyte trafficking by attracting immune cells to the sites of inflammation. At the site of an inflammatory reaction, chemokines are released. These chemokines are specific for CCR5 and cause the migration of T-cells to these sites promoting further inflammation. The mechanism of action of leronlimab has the potential to block the movement of T-cells to inflammatory sites, which could be instrumental in diminishing or eliminating inflammatory responses. Some disease processes that could benefit from CCR5 blockade include transplantation rejection, autoimmunity, and chronic inflammation such as rheumatoid arthritis and psoriasis.

Due to leronlimab's mechanism of action ("MOA"), we believe leronlimab may have significant advantages in reducing side effects over other CCR5 antagonists. Prior studies have demonstrated that leronlimab does not cause direct activation of T-cells.

We continue to evaluate strategic licensing opportunities and supply and distribution partnerships, as well as conducting exploratory discussions with third parties with respect to other potential strategies to monetize our assets. As recently completed license and supply and distribution agreements demonstrate, such agreements are country or region specific and generally are limited to a specific clinical indication for leronlimab.

Business Highlights in Fiscal 2021

During the fiscal year ended May 31, 2021, we commenced several initiatives to advance our lead product candidate, leronlimab. The following is a brief summary of key accomplishments during the most recent fiscal year:

- We raised approximately $140 million in gross proceeds through offerings of convertible debt securities, combined with proceeds from the exercise of warrants and stock options;
- We entered into additional supply and distribution agreements for the distribution and sale of leronlimab in the Philippines, Brazil and India subject to regulatory approvals;
- We successfully manufactured 11 batches of commercial grade leronlimab pre-launch inventories;
- Our drug candidate, leronlimab, received over 60 Emergency Investigational New Drug (EIND) authorizations from the FDA to treat COVID-19 patients;
- We initiated and completed two double-blinded, placebo-controlled clinical trials for COVID-19, a Phase 2 trial for patients with mild-to-moderate symptoms and a Phase 3 trial for patients with severe-to-critical symptoms;
- We initiated a Phase 2 investigative trial for COVID-19 long-haulers, which was completed shortly after fiscal year end;
- We advanced our clinical trials to evaluate the safety and efficacy of leronlimab for several cancer indications by treating the first patients in metastatic triple-negative breast cancer and, metastatic breast cancer, as well as a basket trial for 22 solid tumor cancers:
- An animal study was published in Nature Communications regarding the use of leronlimab for HIV PrEP; and
- We initiated a Phase 2 clinical trial with leronlimab for the treatment of non-alcoholic steatohepatitis (NASH).

For additional information regarding our business, our clinical trials and our progress toward the resubmission of our BLA, see Item 1. Business in this Form 10-K. We will require a significant amount of additional capital to complete the resubmission of our BLA to the FDA, as well as completing or advancing additional clinical trials in the COVID-19, oncology and immunology spaces. See “Liquidity and Capital Resources” below.

Results of operations for the fiscal years ended May 31, 2021, 2020 and 2019

For the fiscal years ended May 31, 2021, 2020 and 2019, we had no activities that produced revenues from operations. The following schedule sets forth the results of operations for the fiscal years ended May 31, 2021, 2020 and 2019 (in thousands except per share amounts):

	Years ended May 31,			2021/2020 Change		2020/2019 Change	
	2021	2020	2019	$	%	$	%
Operating expenses:							
General and administrative	$ 34,320	$ 19,973	$ 12,117	$ 14,347	72 %	$ 7,856	65 %
Research and development	58,430	52,640	42,490	5,790	11	10,150	24
Amortization and depreciation	1,797	2,034	1,245	(237)	(12)	789	63
Intangible asset impairment charge	10,049	—	—	10,049	100	—	-
Total operating expenses	104,596	74,647	55,852	29,949	40	18,795	34
Operating loss	(104,596)	(74,647)	(55,852)	(29,949)	40	(18,795)	(34)
Other income (expense):							
Other income	—	500	—	(500)	(100)	500	100
Interest income	2	5	4	(3)	(60)	1	25
Change in fair value of derivative liabilities	—	(9,542)	1,666	9,542	(100)	(11,208)	(673)
Loss on extinguishment of convertible notes	(19,896)	—	(1,520)	(19,896)	100	1,520	(100)
Legal settlements	(10,628)	(22,500)	—	11,872	(53)	(22,500)	100
Interest expense:							
Finance charges	(147)	(936)	—	789	(84)	(936)	100
Amortization of discount on convertible notes	(3,591)	(1,645)	(1,707)	(1,946)	118	62	(4)
Amortization of debt issuance costs	(65)	(404)	(459)	339	(84)	55	(12)
Inducement interest expense	(11,366)	(7,904)	—	(3,462)	44	(7,904)	100
Inducement interest related to warrant tender offer	—	—	(196)	—	—	196	(100)
Interest on convertible notes payable	(4,387)	(7,330)	(950)	2,943	(40)	(6,380)	672
Total interest expense	(19,556)	(18,219)	(3,312)	(1,337)	7	(14,907)	450
Loss before income taxes	(154,674)	(124,403)	(59,014)	(30,271)	24	(65,389)	111
Income tax benefit	—	—	2,827	—	—	(2,827)	(100)
Net loss	$ (154,674)	$ (124,403)	$ (56,187)	$ (30,271)	24	$ (68,216)	121
Basic and diluted loss per share	$ (0.27)	$ (0.30)	$ (0.21)	$ 0.03	(9)	$ (0.09)	43
Basic and diluted weighted average common shares outstanding	587,590	421,078	272,041	166,512	40 %	149,037	55 %

Net loss

Net loss incurred during the fiscal years ended May 31, 2021 and 2020 was approximately $154.7 million and $124.4 million, respectively. The increase in net loss of approximately $30.3 million, or 24%, was primarily attributable to increased general and administrative ("G&A") expenses, an intangible asset impairment charge, increased research and development ("R&D") expenses, and increased loss from extinguishment of convertible notes, partially offset by decreased change in fair value of derivative liabilities and decreased legal settlement charges.

Loss per share

Net loss per share for the fiscal year ended May 31, 2021 was $0.27 compared to the net loss per share of $0.30 in the prior fiscal year. The decrease in loss per share of $0.03, or 9%, compared to the prior year was due to the significant increase in the number of weighted average common shares outstanding over the comparable period in 2020, partially offset by the increase in net loss. The increase in common stock was due to common stock issuances associated with the exercise of warrants and stock options, negotiated exchange settlements of certain convertible note obligations with common stock, and a private placement of equity.

Operating expenses

Operating expenses totaled approximately $104.6 million and $74.6 million during the fiscal years ended May 31, 2021 and May 31, 2020, respectively. The increase in operating expenses of approximately $29.9 million, or 40%, over the prior fiscal year was primarily attributable to an increased G&A expenses, increased R&D expenses, and an intangible asset impairment charge.

General and administrative expenses

General and administrative expenses for the fiscal years ended May 31, 2021, 2020 and 2019 consisted of the following (in thousands):

	Years ended May 31,			2021/2020 Change		2020/2019 Change	
	2021	2020	2019	$	%	$	%
General and administrative:							
Salaries and other compensation	$ 13,161	$ 5,488	$ 3,781	$ 7,673	140 %	$ 1,707	45 %
Stock-based compensation	10,429	6,548	3,388	3,881	59	3,160	93
Other	10,730	7,937	4,948	2,793	35	2,989	60
Total general and administrative	$ 34,320	$ 19,973	$ 12,117	$ 14,347	72 %	$ 7,856	65 %

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

Research and development expenses

R&D expenses were recorded where directly identifiable, consisting of the following during the fiscal years ended May 31, 2021, 2020, and 2019 (in thousands):

	Years ended May 31,			2021/2020 Change		2020/2019 Change	
	2021	2020	2019	$	%	$	%
Research and development:							
Clinical	$ 36,728	$ 29,553	$ 25,264	$ 7,175	24 %	$ 4,289	17 %
Non-Clinical	2,201	2,999	155	(798)	(27)	2,844	1,835
CMC	18,564	19,392	16,353	(828)	(4)	3,039	19
License and patent fees	937	696	718	241	35	(22)	(3)
Total research and development	$ 58,430	$ 52,640	$ 42,490	$ 5,790	11 %	$ 10,150	24 %

R&D expenses totaled approximately $58.4 million during the fiscal year ended May 31, 2021, an increase of approximately $5.8 million, or 11%, over the fiscal year ended May 31, 2020. R&D expenses consisted of clinical trials, non-clinical, Chemistry, Manufacturing and Controls (“CMC”), and license and patent fees. The 2021 increase over 2020 was primarily attributable to higher clinical trial expenses, partially offset by decreases in non-clinical and CMC expenses. The increase in clinical trial costs were attributable to COVID-19 clinical trial costs and clinical trial costs related to oncology and immunology indications. The future trend of R&D expenses will be dependent on the timing of resubmission of and FDA approval, if any, of our BLA, the timing of FDA clearance, if any, of our pivotal trial protocol for leronlimab as a monotherapy for HIV patients, the clinical progression of our COVID-19, metastatic triple-negative breast cancer and NASH trials, and the outcome of pre-clinical studies for several other cancer indications.

Amortization and depreciation expenses

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

Intangible asset impairment

For the fiscal year ended May 31, 2021, the Company recorded an intangible asset impairment charge of approximately $10.0 million, which represents an increase of 100% over the same period in 2020. This charge was

attributable to the full impairment of the net carrying value of the proprietary algorithm intangible asset the Company acquired in connection with the acquisition of the assets of ProstaGene, LLC in November 2018.

Other income

For the fiscal year ended May 31, 2021, other income decreased approximately $0.5 million, or 100%, compared to the prior year. Other income for the fiscal year ended May 31, 2020, of $0.5 million resulted from the execution of an agreement in which the Company granted an exclusive royalty-bearing license to a third-party to commercialize, use, and sell leronlimab for HIV in the U.S. upon BLA approval.

Change in fair value of derivative liabilities

For the fiscal year ended May 31, 2021, we did not realize a change in fair value of derivative liabilities as compared to the prior year change of approximately $9.5 million, as the originating instruments were all exercised and settled during the 2020 fiscal year. The originating underlying instruments were certain warrants that originated in September 2016 and two convertible note instruments originated in June 2018 and January 2019 containing contingent cash settlement provisions, which gave rise to a derivative liability. For each reporting period, the Company determined the fair value of the derivative liability and recorded a corresponding non-cash benefit or non-cash charge, due to a decrease or increase, respectively, in the calculated derivative liability.

Loss on extinguishment of convertible notes

For the fiscal year ended May 31, 2021, we recognized non-cash losses on the extinguishment of convertible notes of approximately $19.9 million. We did not recognize any losses on the extinguishment of debt during the prior year. The losses resulted from separately and independently negotiated exchange agreements to satisfy certain note payment obligations in which certain debt was agreed to be settled in exchange for shares issued at a price less than the closing price for the effective date of the respective transactions. The original underlying convertible notes were entered into on March 31, 2020, July 29, 2020, and November 10, 2020.

Legal settlements

Legal settlements for the fiscal year ended May 31, 2021 of $10.6 million were related to cash damages awarded to plaintiffs in legal proceedings against the Company. Legal settlements (non-cash) for the fiscal year ended May 31, 2020 of $22.5 million were related to the issuance of shares of common stock in settlement of a claim filed by the holder of the January 2019 Note alleging that the note holder was owed additional shares upon conversion of the note.

Interest expense

Interest expense totaled approximately $19.6 million for the fiscal year ended May 31, 2021, an increase of approximately $1.3 million, or 7%, from the fiscal year ended May 31, 2020. This increase was due primarily to increased amortization of discount on convertible notes resulting from increased repayment of our convertible notes payable, increase in inducement interest expense offset by decrease in interest on convertible notes payable.

The future trends of all expenses will be driven, in large part, by future outcomes of current and new clinical trials and the corresponding effect on research and development expenses, timing of the anticipated BLA approval, as well as G&A expenses and outcomes of any current or future legal proceedings, in addition to the manufacturing of new commercial leronlimab upon any regulatory approval, and other (income) expense, including interest expense, related to debt and equity transactions. We require a significant amount of additional capital, and our ability to continue to fund operations will continue to depend on our ability to raise such capital. See in particular, “Liquidity and Capital Resources” below and Item 1A “Risk Factors” above.

Please refer to Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K for the fiscal year ended May 31, 2020, filed on August 14, 2020, for additional information comparing our results of operations for the fiscal years ended May 31, 2020 and May 31, 2019.

Fluctuations in Operating Results

The Company's operating results may fluctuate due to a number of factors, such as the timing of product manufacturing activities, patient enrollment or completion rates in various trials, coupled with potential amendments to clinical trial protocols. As a non-revenue generating company, we are regularly conducting offerings to raise capital, which can create various forms of non-cash interest expense or amortization of issuance costs. Further, we regularly negotiate the settlement of debt payment obligations in exchange for equity securities of the Company, which can create a non-cash loss or gain on extinguishment of debt. In addition, in prior years a portion of the aforementioned derivative liabilities is tied to certain securities that included a contingent cash settlement provision, which can vary substantially from year to year, thereby creating a non-cash charge or benefit.

Liquidity and Capital Resources

As of May 31, 2021, we had a total of approximately $33.9 million in cash and approximately $152.5 million in short-term liabilities consisting primarily of approximately $62.7 million representing the current portion of long-term convertible notes payable and approximately $85.0 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 in anticipation of a fully commercialized leronlimab product. Despite the Company's negative working capital position, vendor relations remain accommodative and we do not currently anticipate delays in our business initiatives schedule due to liquidity constraints.

We cannot be certain, however, that future funding will be available to us when needed on terms that are acceptable to us, or at all. We sell securities and incur debt when the terms of such agreements are deemed favorable to both parties under then current circumstances and as necessary to fund our current and projected cash needs. In addition, as of May 31, 2021 we had approximately 40.9 million authorized shares of common stock available for future issuance in addition to those already issued or reserved for issuance.

Cash

The Company's cash position of approximately $33.9 million at May 31, 2021 increased approximately $19.6 million compared to the balance of approximately $14.3 million at May 31, 2020. During the fiscal year ended May 31, 2021, we provided funds for our operations by obtaining a total of approximately $139.3 million of net cash proceeds primarily through convertible debt issuances, private warrant exchange transactions, warrant and stock option exercises, and a private equity offering.

Inventories

Inventories as of May 31, 2021 and May 31, 2020 are presented below (in thousands):

	May 31,	
	2021	2020
Raw materials	$ 28,085	$ 19,147
Work-in-progress	65,394	—
Total	$ 93,479	$ 19,147

The Company's pre-launch inventories position of approximately $93.5 million at May 31, 2021 increased approximately $74.3 million as compared to a balance of approximately $19.1 million at May 31, 2020 as the Company increased inventory in preparation for commercialization. This inventory increase is related to raw materials purchased for commercial production and work-in-progress inventory related to the substantially completed commercial production of pre-launch inventories of leronlimab, in anticipation of regulatory approval of the product as a combination therapy for HIV patients by the FDA in the United States. During the quarter ended February 28, 2021, the Company was notified by a third-party contract manufacturing partner that due to an operational error committed by the contract manufacturer, one of the batches of a multiple-batch manufacturing campaign failed to meet quality standards, and thus would not be saleable upon regulatory approval. In accordance with the agreement, the contract manufacturer assumed liability for the failure, all costs to manufacture the batch, and committed to remanufacture the batch at a future date. As a result, the Company reduced work-in-progress inventory and the related amounts due to the contract manufacturer by $6.1 million. No other inventory was affected by this manufacturing issue, and all other inventory has successfully passed quality standards. As of May 31, 2021, the raw materials balance was $28.1 million and the total work-in-progress was $65.4 million. Work-in-progress consists of bulk drug substance, which is the manufactured drug stored in bulk storage, and drug product, which is the manufactured drug in unlabeled vials. Bulk drug substance and drug product comprised approximately $35.8 million and $29.6 million, respectively, of work-in-progress inventory. See "Capital Requirements—Contract Manufacturing" below for a further discussion of commitments with third-party contract manufacturing partners. See also "Critical Accounting Policies and Estimates" below.

Cash Flows

For the year ended May 31, 2021, the net change in cash was an increase of approximately $19.7 million, which was attributable to increased net cash provided by financing activities of approximately $57.7 million, offset in part by increased net cash used in operating activities of approximately $48.8 million, and increased cash used in investing activities of approximately $0.1 million.

	Years ended May 31,			2021/2020 Change	2020/2019 Change
(in thousands)	2021	2020	2019	$	$
Net cash (used in) provided by:					
Net cash used in operating activities	$ (117,573)	$ (68,804)	$ (50,466)	$ (48,769)	$ (18,338)
Net cash used in investing activities	$ (122)	$ (41)	$ (45)	$ (81)	$ 4
Net cash provided by financing activities	$ 137,346	$ 79,670	$ 52,747	$ 57,676	$ 26,923

Cash used in operating activities

Net cash used in operating activities totaled approximately $117.6 million during the fiscal year ended May 31, 2021, which reflects an increase of approximately $48.8 million over the approximately $68.8 million in fiscal 2020. The increase in net cash used in operating activities was due to increased pre-launch inventories, and net loss, offset in part by the intangible asset impairment charge, increased accounts payables and accrued liabilities, and increased non-cash loss on extinguishment of debt, when compared to the changes in the prior year.

Cash used in investing activities

Net cash used in investing activities was approximately $0.1 million during the fiscal year ended May 31, 2021, which reflects an insignificant increase over a year ago attributable to the purchase of office equipment and furniture.

Cash provided by financing activities

Net cash provided by financing activities totaled approximately $137.3 million during the fiscal year ended May 31, 2021 representing an approximate $57.7 million increase in net cash provided by financing activities when compared to the previous fiscal year. The increase in net cash provided from financing activities was primarily attributable to an increase in proceeds from convertible debt issuances and an increase in proceeds from private warrant

exchange transactions, offset by a decrease in ordinary warrant and stock option exercise proceeds, and the absence of proceeds from the sale of preferred stock, when compared to the same period in the prior year.

Convertible debt

The following schedule sets forth the outstanding balance of convertible notes as of May 31, 2021 and May 31, 2020. A detailed discussion of our various convertible debt arrangements is included in Note 5 to the Consolidated Financial Statements included in Item 8 of this Form 10-K (in thousands):

	March 2020 Note	July 2020 Note	November 2020 Note	April 2, 2021 Note	April 23, 2021 Note
Outstanding balance May 31, 2020	$ 15,467	$ -	$ -	$ -	$ -
Consideration received	-	25,000	25,000	25,000	25,000
Amortization of issuance discount and costs	1,369	1,097	740	268	182
Accrued interest	480	1,901	1,258	447	302
Cash repayments	(950)	-	-	-	-
Conversions	(9,538)	-	-	-	-
Fair market value of shares exchanged for repayment	(10,997)	(37,298)	(19,870)	-	-
Debt extinguishment loss	4,169	9,300	6,427	-	-
Outstanding balance May 31, 2021	$ -	$ -	$ 13,554	$ 25,715	$ 25,485

April 23, 2021 Note

On April 23, 2021, we issued a convertible note with a principal amount of $28.5 million resulting in net cash proceeds of $25.0 million, after $3.4 million of debt discount and $0.1 million of offering costs. The note accrues interest daily at a rate of 10% per annum, contains a stated conversion price of $10.00 per share, and matures in April 2023. After six months past the issuance date, the noteholder can request monthly redemptions of up to $7.0 million. The outstanding balance of the April 23, 2021 Note, including accrued interest, was approximately $25.5 million as of May 31, 2021.

April 2, 2021 Note

On April 2, 2021, we issued a convertible note with a principal amount of $28.5 million resulting in net cash proceeds of $25.0 million, after $3.4 million of debt discount and $0.1 million of offering costs. The note accrues interest daily at a rate of 10% per annum, contains a stated conversion price of $10.00 per share, and matures in April 2023. The April 2, 2021 Note requires monthly debt reduction payments of $7.5 million for the six months beginning in May 2021 which can also be satisfied by payments on the November 2020, and/or April 23, 2021 Note. After six months past the issuance date, the noteholder can request monthly redemptions of up to $3.5 million. The outstanding balance of the April 23, 2021 Note, including accrued interest, was approximately $25.7 million as of May 31, 2021.

November 2020 Note

During November 2020, 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 November 2022. The November 2020 Note requires monthly debt reduction payments of $7.5 million for the six months beginning in November 2020 which can also be satisfied by payments on the July 2020 Note and/or March 2020 Note, both of which have been paid in full, as discussed below. After six months past the issuance date, the noteholder can request monthly redemptions of up to $3.5 million. The outstanding balance of the November 2020 Note, including accrued interest, was approximately $13.6 million as of May 31, 2021.

July 2020 Note

During July 2020, 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 accrued interest daily at a rate of 10% per annum, contains a stated conversion price of $10.00 per share and matures in July 2022. Beginning six months after the issuance date, the noteholder could request monthly redemptions up to $3.5 million. During the quarter ended May 31, 2021, this note was fully retired as a result of the noteholder exercising the monthly redemption provision and the Company satisfying the monthly Debt Reduction Amount required under the November 2020 Note by making payments on the July 2020 Note. There was no balance outstanding under this note as of May 31, 2021.

March 2020 Note

During the quarter ended November 30, 2020, this note was fully retired as a result of the noteholder exercising the monthly redemption provision and the Company satisfying the monthly Debt Reduction Amount required under the November 2020 Note by making payments on the March 2020 Note. There was no balance outstanding under this note as of May 31, 2021.

Common stock

We have 800.0 million authorized shares of common stock. As of May 31, 2021, we had approximately 625.7 million shares of common stock outstanding, approximately 42.9 million shares of common stock issuable upon the exercise of warrants, approximately 33.0 million shares of common stock issuable upon conversion of convertible preferred stock and undeclared dividends, approximately 24.1 million shares of common stock issuable upon the exercise of outstanding stock options or the vesting of outstanding restricted stock, approximately 15.3 million shares of common stock reserved for future issuance under our equity compensation plans, and approximately 18.0 million shares of common stock reserved and issuable upon conversion of outstanding convertible notes. As a result, as of May 31, 2021, we had approximately 40.9 million authorized shares of common stock available for issuance.

Commitments and Contingencies

Contract Manufacturing with Samsung Biologics Co., Ltd ("Samsung")

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

Fiscal Year	Amount
2022	$ 46,961
2023	96,126
2024	58,528
2025	7,200
Total	$ 208,815

Management maintains relationships with two contract manufacturers that it believes best serve our strategic objectives for the anticipated resubmission of our BLA filing and, if approved, the long-term commercial manufacturing capabilities for leronlimab. Management will continue to assess manufacturing capacity requirements as new market information becomes available regarding anticipated demand, subject to FDA approval.

Commitments with Contract Research Organization ("CRO")

The Company has entered into project work orders for each of our clinical trials with our CRO and related laboratory vendors. Under the terms of these agreements, the Company has prepaid certain execution fees for direct services costs. In connection with our clinical trials, the Company has entered into separate project work orders for each trial with our CRO. In the event that the Company terminates any trial, certain financial penalties may be incurred which would become payable to the CRO. Based on the form of termination of any one trial, the financial penalties may range up to approximately $2.0 million. In the remote circumstance that all clinical trials are terminated, the collective financial penalties may range from a low of approximately $2.1 million to a high of approximately $3.3 million.

Operating Leases

We lease our principal office location in Vancouver, Washington and a office location in Fort Lauderdale, Florida. Under the terms of each lease, the Vancouver and Fort Lauderdale leases expire April 30, 2026 and March 31, 2022, respectively. The Fort Lauderdale office is currently being sublet to a tenant. Consistent with the guidance in ASC 842, we have recorded these leases in our consolidated balance sheet as operating leases. For the purpose of determining the right-of-use asset and associated lease liability, we determined that the renewal of the Vancouver lease was reasonably probable. The leases of both our Vancouver and Fort Lauderdale offices do not include any restrictions or covenants requiring special treatment under ASC 842. During the fiscal years ended May 31, 2021 and 2020, we recognized $0.3 million and $0.2 million of operating lease costs.

The following table summarizes the presentation of the operating leases in our consolidated balance sheet at May 31, 2021 and 2020 (in thousands):

	May 31,	
	2021	2020
Assets		
Right of use asset	$ 712	$ 176
Liabilities		
Current operating lease liability	$ 175	$ 115
Non-current operating lease liability	552	63
Total operating lease liability	$ 727	$ 178

The minimum (base rental) lease payments reconciled to the carrying value of the operating lease liabilities as of May 31, 2021 are expected to be as follows (in thousands):

Fiscal Year	Amount
2022	$ 202
2023	225
2024	175
2025	180
2026	183
Total operating lease payments	965
Less imputed interest	(238)
Present value of operating lease liabilities	$ 727

Legal Proceedings

The Company is a party to various legal proceedings. As of the year ended May 31, 2021, we were not party to any material pending legal proceedings, except those described in Note 10 to the Consolidated Financial Statements included in Item 8. of this Form 10-K. The Company recognizes accruals for such proceedings to the extent a loss is determined to be both probable and reasonably estimable. The best estimate of a loss within a possible range is accrued; however, if

no estimate in the range is more probable than another, then the minimum amount in the range is accrued. If it is determined that a material loss is not probable but reasonably possible and the loss or range of loss can be estimated, the possible loss is disclosed. It is not possible to determine the outcome of these proceedings, including the defense and other litigation-related costs and expenses that may be incurred by the Company, as the outcomes of legal proceedings are inherently uncertain, and the outcomes could differ significantly from recognized accruals. Therefore, it is possible that the ultimate outcome of any proceeding, if in excess of a recognized accrual, or if an accrual had not been made, could be material to the Company's consolidated financial statements. As of May 31, 2021 the Company recorded legal accruals of approximately $10.6 million related to the outcomes of the matters described in Note 10. "Legal Proceedings". The Company did not record any material accruals as of May 31, 2020. See Note 10 to the Consolidated Financial Statements for further discussion of legal proceedings.

Distribution

In December 2019, the Company entered into a supply agreement with Vyera Pharmaceuticals, LLC ("Vyera") for the sale of leronlimab for HIV in the United States in conjunction with a commercialization and license agreement entered into with Vyera. See "Licensing" below for further discussion of the agreement. On July 2, 2020, the Company entered into an exclusive distribution and supply agreement with American Regent Inc. with respect to the distribution of leronlimab for the treatment of COVID-19 in the United States. The parties mutually agreed to terminate the agreement effective June 9, 2021. On April 6, 2021, the Company entered into an exclusive supply and distribution agreement with Biomm S.A., a Brazilian pharmaceutical company, granting the exclusive right to distribute and sell leronlimab in Brazil upon Brazilian regulatory approval. On April 15, 2021, the Company entered into an exclusive supply and distribution agreement with Chiral Pharma Corporation, a Philippine pharmaceutical company, granting the exclusive right to distribute and sell up to 200,000 vials of leronlimab during the 12 months ending April 15, 2022, to treat critically ill COVID-19 patients in the Philippines under Compassionate Special Permit ("CSP") or Emergency Use Authorization ("EUA") from the Food and Drug Administration of the Philippines. On May 11, 2021, the Company entered into an exclusive supply and distribution agreement with Macleods Pharmaceuticals Ltd., an Indian pharmaceutical company, granting the exclusive right to distribute and sell up to 200,000 vials of leronlimab in calendar year 2021 in India to treat COVID-19 patients under a CSP or EUA from the India Central Drugs Standard Control Organization.

Licensing

Under the Progenics Purchase Agreement, we are required to pay Progenics the following ongoing milestone payments and royalties: (i) $5.0 million 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 (PRO 140); and (ii) royalty payments of up to five percent (5%) on net sales during the period beginning on the date of the first commercial sale of leronlimab (PRO 140) 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. In addition, under a Development and License Agreement, dated April 30, 1999 (the "PDL License"), between Protein Design Labs (now AbbVie Inc.) and Progenics, which was previously assigned to us, we are required to pay AbbVie Inc. additional milestone payments and royalties as follows: (i) $0.5 million upon filing a BLA with the FDA or non-U.S. equivalent regulatory body; (ii) $0.5 million 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. As discussed elsewhere in this Form 10-K, the Company received a Refusal to File letter from the FDA in July 2020 with respect to its BLA as a combination therapy with HAART for highly treatment experienced HIV patients. In response to this letter, the Company commenced the resubmission of its BLA in July 2021 and is expected to be completed in October 2021. As such, until the BLA is accepted by the FDA, it is management's conclusion that the probability of achieving the subsequent future clinical development and regulatory milestones is not reasonably determinable, such that the future milestone payments payable to Progenics and its sub-licensors have been deemed contingent consideration and, therefore, not currently accruable.

In December 2019, the Company entered into a Commercialization and License Agreement and a Supply Agreement with Vyera Pharmaceuticals, LLC (the "License Agreement"). Pursuant to the License Agreement, the Company granted Vyera an exclusive royalty-bearing license to commercialize pharmaceutical preparations containing leronlimab for treatment of HIV in humans in the United States. Pursuant to the terms of the License Agreement, and

subject to the conditions set forth therein, Vyera will incur the cost of, and be responsible for, among other things, commercializing the product in the territory and will use commercially reasonable efforts to commercialize the product in the field in the territory. Under the terms of the License Agreement, CytoDyn is permitted to license the product outside of the territory for uses in the field or outside the field or for uses inside the territory outside of the field. In consideration of the license and other rights granted by the Company, Vyera agreed to pay the Company, within three business days of the effective date of the License Agreement, a $0.5 million license issue fee, with additional payments totaling up to approximately $87.0 million to be made upon the achievement of certain sales and regulatory milestones. Certain milestones are subject to reduction if not achieved within an agreed-upon timeframe. Vyera may also pay the Company additional potential milestone payments upon the regulatory approval of leronlimab for certain subsequent indications in the field. Whether a particular subsequent indication qualifies for an additional milestone payment will be determined in good faith by the parties. In addition, during the Royalty Term, as defined in the License Agreement, but, in any event, a period of not less than 10 years following the first commercial sale under the License Agreement, Vyera is obligated to pay the Company a royalty equal to 50% of Vyera's gross profit margin from product sales (defined in the License Agreement as "Net Sales") in the territory. The royalty is subject to reduction during the Royalty Term after patent expiry and expiry of regulatory exclusivity. Following expiration of the Royalty Term, Vyera will continue to maintain non-exclusive rights to commercialize the product.

Regulatory Matters

In July 2020, the Company received a Refusal to File letter from the FDA regarding its BLA submission for leronlimab as a combination therapy with HAART for highly treatment experienced HIV patients. The FDA informed the Company its BLA did not contain certain information needed to complete a substantive review and therefore, the FDA would not file the BLA. In particular, the FDA informed the Company that the receptor occupancy analysis performed by its third-party laboratory was not properly performed, and would be required to be resubmitted, and the Company would need to correct certain administrative submission deficiencies. The FDA's request does not require any additional clinical trials to be conducted. Subsequent to the Refusal to File letter, the Company received further clarification on the BLA's deficiencies. The Company has engaged a leading global healthcare diagnostic company, along with an expanded team of subject matter expert consultants, to conduct the receptor occupancy analysis necessary in order to resubmit the BLA. The Company began to resubmit the BLA in July 2021 and is expected to be completed in October 2021.

Going Concern

As reported in the accompanying financial statements, during the fiscal years ended May 31, 2021, May 31, 2020 and May 31, 2019, the Company incurred net losses of approximately $154.7 million, $124.4 million and $56.2 million, respectively. The Company has no activities that produced revenue in the periods presented and has sustained operating losses since inception.

We currently require and will continue to require a significant amount of additional capital to fund operations and pay our accounts payables, and our ability to continue as a going concern is dependent on our ability to raise such additional capital, commercialize our product and achieve profitability. If the Company is not able to raise such additional capital on a timely basis or on favorable terms, it may need to scale back operations or slow CMC-related activities, which could materially delay commercialization initiatives and its ability to achieve profitability. The Company's failure to raise additional capital could also affect its relationships with key vendors, disrupting its ability to timely execute its 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 sale of public and private equity securities and proceeds from convertible notes payable and related party notes payable. The Company intends to finance its future operating activities and its working capital needs largely from the sale of equity and debt securities, combined with additional potential funding from other traditional and non-traditional financing sources. As of the date of this filing, the Company has approximately 35.0 million shares of common stock authorized and available for issuance under its certificate of incorporation, as amended.

The sale of equity and convertible debt securities to raise additional capital may result in dilution to stockholders and those securities may have rights senior to those of common shares. If the Company raises funds through the issuance of additional preferred stock, convertible debt securities or other debt financing the related transaction documents could contain covenants restricting its operations. On November 10, 2020, April 2, 2021, and April 23, 2021, the Company entered into long-term convertible notes that are secured by all of our assets, except for our intellectual property, and also 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 and conditions. Any other third-party funding arrangements could require the Company to relinquish valuable rights. The Company expects to require additional capital beyond currently anticipated needs. Additional capital, if available, may not be available on reasonable or non-dilutive terms. See Part I, Item 1A. Risk Factors above for additional information.

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. The Company has incurred losses for all periods presented and has a substantial accumulated deficit. As of May 31, 2021, these factors, among several others, may 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's continuation as a going concern is dependent upon its ability to obtain a significant amount of additional operating capital, to continue 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.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

Critical Accounting Estimates

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

We believe the following critical policies reflect the more significant judgments and estimates used in preparation of the Consolidated Financial Statements.

Derivative Liabilities

We follow the provisions of the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 815 *Derivatives and Hedging*, ASC 480 *Distinguishing Liabilities from Equity*, and ASC 470 *Debt*. We have historically issued instruments that meet the criteria of derivative liabilities. Derivative financial instruments consist of financial instruments that contain a notional amount and one or more underlying variable (e.g., contingent cash settlement provision), require no initial net investment and permit net settlement. Derivative financial instruments may be free-standing or embedded in other financial instruments. We have induced conversion of certain instruments with bifurcated conversion options. To record certain conversion and the extinguishment of derivative liabilities, we have followed the general extinguishment model. As described in Notes 2 and 5, to the Consolidated Financial Statements included in Item 8 of this Form 10-K, we utilized a Binomial Lattice Model to value the conversion

options, which utilizes assumptions that market participants would likely consider in negotiating the transfer of the conversion options, including early conversions. These assumptions used in the model are based on unobservable market inputs and are subject to variability.

Inventories

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

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

For inventories capitalized prior to FDA marketing approval in preparation of product launch, anticipated future sales, shelf-lives, and expected approval date are considered when evaluating realizability of pre-launch inventories. The shelf-life of a product is determined as part of the regulatory approval process; however, in assessing whether to capitalize pre-launch inventory the Company considers the stability data of all inventories. As inventories approach their shelf-life expiration, the Company may perform additional stability testing to determine if the inventory is still viable, which can result in an extension of its shelf-life. Further, in addition to performing additional stability testing, certain raw materials inventory may be sold in its then current condition prior to reaching expiration. We also consider potential delays associated with regulatory approval in determining whether pre-approval inventory remains salable. See Note 4 – Inventories in the Notes to Consolidated Financial Statements in Item 8. of this Form 10-K for information regarding the remaining shelf-lives of our pre-launch inventory, by each category of inventory. Although we believe our product will receive market acceptance, the introduction of a competing product could negatively impact the demand for our product and affect the realizability of our inventories. In addition, if physicians are unwilling or unable to prescribe leronlimab to their patients, or the target patient population is reluctant to try leronlimab as a new therapy, the salability of our pre-launch inventory would be adversely affected.

Stock-based compensation

We use the Black-Scholes option pricing model to estimate the fair value of stock-based awards on the date of grant utilizing certain assumptions that require judgments and estimates. These assumptions include estimates for stock price volatility, expected term and risk-free interest rates in determining the fair value of the stock-based awards. The risk-free interest rate assumption is based on observed interest rates appropriate for the expected term of the stock-based award. The expected volatility is based on the historical volatility of the Company's common stock at monthly intervals. The computation of the expected option term is based on the "simplified method," as the options issued by the Company are considered "plain vanilla" options. We estimate forfeitures at the time of grant and revise, if necessary, in subsequent

periods, if actual forfeitures differ from those estimates. Based on limited historical experience of forfeitures, we estimated future unvested forfeitures at 0% for all periods presented. Quarterly expense is reduced during the period when grants are forfeited, such that the full expense is recorded at the time of grant and only reduced when the grant is truly forfeited.

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

Contingent liabilities

As discussed in Notes 8 and 9 to the Consolidated Financial Statements included in Item 8. of this Form 10-K, we have significant license and contingent milestone and royalty liabilities. We must estimate the likelihood of paying these contingent liabilities periodically based on the progress of our clinical trials, BLA approval status, and status of commercialization.

We are party to various legal proceedings as described in Note 10 to the Consolidated Financial Statements included in Item 8. 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 it is disclosed and if the loss or range of loss can be estimated, the possible loss is also disclosed. It is not possible to determine the ultimate outcome of these proceedings, including the defense and other litigation-related costs and expenses that may be incurred by the Company, as the outcomes of legal proceedings are inherently uncertain, and the outcomes could differ significantly from recognized accruals. Therefore, it is possible that the ultimate outcome of any proceeding, if in excess of a recognized accrual, or if an accrual had not been made, could be material to the Company's consolidated financial statements. We periodically reassess these matters when additional information becomes available and adjust our estimates and assumptions when facts and circumstances indicate the need for any changes.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a smaller reporting company we are not required to provide the information required by this Item.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

CYTODYN INC.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
CytoDyn Inc.

Opinion on the Consolidated Financial Statements
We have audited the accompanying consolidated balance sheets of CytoDyn Inc. (the Company) as of May 31, 2021 and 2020 and the related consolidated statements of operations, changes in stockholders' (deficit) equity, and cash flows for each of the years in the three-year period ended May 31, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the years in the three-year period ended May 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of May 31, 2021, based on criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated July 30, 2021 expressed an unqualified opinion.

Substantial Doubt as to the Company's Ability to Continue as a Going Concern
The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company incurred a net loss of approximately $154,674,000 for the year ended May 31, 2021 and has an accumulated deficit of approximately $511,294,000 through May 31, 2021, which raises substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters
The critical audit matters communicated below 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. 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.

I. Evaluation of the Carrying Value of Identifiable Intangible Assets

Description of Matter and Relevant Accounts and Disclosures - As explained in Note 2 to the consolidated financial statements, the Company has various intangibles which include patents, proprietary algorithms and non-compete

agreements with the acquisition of ProstaGene, Inc. The Company evaluates on a quarterly basis whether any conditions exist, or events have occurred or are likely to occur that would impair the carrying value of the intangible assets.

Auditing the Company's impairment assessment was challenging because the accrual involved a higher degree of management judgment with regards to the analysis of the undiscounted expected cash flows to the carrying value for the identifiable intangible assets.

How We Addressed the Matter in Our Audit - To evaluate the carrying value of identifiable intangible assets, our audit procedures included, among others:

- Obtained an understanding, evaluated the design and tested the operating effectiveness of certain internal controls related to the valuation and potential impairment charge. This included a control related to the comparison of the undiscounted expected future cash flows to the carrying value.
- Evaluation of triggering events that may indicate the carrying amount of the assets may not be recoverable.
- Evaluation of the assumptions used by management in the calculation of the undiscounted expected future cash flows, including inquiries of management and specialists involved in the drug development process.

II. Evaluation of the Capitalization and Carrying Value of Pre-Launch Inventory

Description of Matter and Relevant Accounts and Disclosures - As explained in Note 2 to the consolidated financial statements, the Company capitalizes pre-launch inventories procured or produced for product launches sufficient to support estimated initial demand. Typically, capitalization of such pre-launch inventory begins when the results of the clinical trial have reached a status sufficient for regulatory approval and the Company has determined that the capitalized costs will provide future economic benefits. Anticipated future sales, shelf lives, and expected approval dates are all factors when evaluating the realizability of capitalized inventory.

Auditing the Company's pre-launch inventory was challenging because it involved a higher degree of management judgment to evaluate the probable future benefit to determine if the pre-launch inventory should be capitalized before regulatory approval.

How We Addressed the Matter in Our Audit - To evaluate the carrying value of pre-launch inventory our audit procedures included, among others:

- Obtained an understanding, evaluated the design and tested the operating effectiveness of certain internal controls related to the existence and valuation of inventory. This included controls related to the approval for the purchase of inventory, physical inventory count observations, shelf life and review of valuation of inventory.
- External confirmation of inventories held by others.
- Review of manufacturing contracts and inquiries of management who oversee research and development efforts.
- Testing the accuracy and completeness of the underlying data used in the estimate.
- Evaluating the factors used by management to determine if the pre-launch inventory should be capitalized before regulatory approval.

/s/ Warren Averett, LLC

We have served as the Company's auditor since 2007.
Birmingham, Alabama
July 30, 2021

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
CytoDyn Inc.

Opinion on Internal Control over Financial Reporting
We have audited CytoDyn Inc.'s (the Company's) internal control over financial reporting as of May 31, 2021, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of May 31, 2021, based on criteria established in Internal Control – Integrated Framework (2013) issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the balance sheets and the related consolidated statements of operations, changes in stockholders' (deficit) equity, and cash flows of the Company, and our report dated July 30, 2021, expressed an unqualified opinion.

Basis for Opinion
The Company's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with 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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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

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

/s/ Warren Averett, LLC

Birmingham, Alabama
July 30, 2021

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

	May 31, 2021	May 31, 2020
Assets		
Current assets:		
Cash	$ 33,943	$ 14,282
Restricted cash	—	10
Inventories, net	93,479	19,147
Prepaid expenses	616	498
Prepaid service fees	1,543	2,890
Total current assets	129,581	36,827
Operating leases right-of-use asset	712	176
Property and equipment, net	134	55
Intangibles, net	1,653	13,456
Total assets	$ 132,080	$ 50,514
Liabilities and Stockholders' (Deficit) Equity		
Current liabilities:		
Accounts payable	$ 65,897	$ 29,479
Accrued liabilities and compensation	19,073	6,879
Accrued interest on convertible notes	2,007	292
Accrued dividends on convertible preferred stock	2,647	981
Operating leases liabilities	175	115
Convertible notes payable, net	62,747	6,745
Warrant exercise proceeds held in trust	—	10
Total current liabilities	152,546	44,501
Long-term liabilities:		
Convertible notes payable, net	—	8,431
Operating leases liabilities	552	63
Total long-term liabilities	552	8,494
Total liabilities	153,098	52,995
Commitments and Contingencies (Note 10)		
Stockholders' (deficit) equity:		
Preferred Stock, $0.001 par value; 5,000 shares authorized		
Series D convertible preferred stock, $0.001 par value; 12 authorized; 9 issued and outstanding at May 31, 2021 and May 31, 2020, respectively	—	—
Series C convertible preferred stock, $0.001 par value; 8 authorized; 8 issued and outstanding at May 31, 2021 and May 31, 2020, respectively	—	—
Series B convertible preferred stock, $0.001 par value; 400 shares authorized, 79 and 92 shares issued and outstanding at May 31, 2021 and May 31, 2020, respectively	—	—
Common stock, $0.001 par value; 800,000 shares authorized, 626,123 and 519,262 issued and 625,680 and 518,976 outstanding at May 31, 2021 and May 31, 2020, respectively	626	519
Additional paid-in capital	489,650	351,711
Accumulated (deficit)	(511,294)	(354,711)
Treasury stock, $0.001 par value; 443 and 286 shares at May 31, 2021 and May 31, 2020, respectively	—	—
Total stockholders' (deficit) equity	(21,018)	(2,481)
Total liabilities and stockholders' (deficit) equity	$ 132,080	$ 50,514

See accompanying notes to Consolidated Financial Statements.

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

	Years ended May 31,		
	2021	2020	2019
Operating expenses:			
General and administrative	$ 34,320	$ 19,973	$ 12,117
Research and development	58,430	52,640	42,490
Amortization and depreciation	1,797	2,034	1,245
Intangible asset impairment charge	10,049	—	—
Total operating expenses	104,596	74,647	55,852
Operating loss	(104,596)	(74,647)	(55,852)
Other income (expense):			
Other income	—	500	—
Interest income	2	5	4
Change in fair value of derivative liabilities	—	(9,542)	1,666
Loss on extinguishment of convertible notes	(19,896)	—	(1,520)
Legal settlements	(10,628)	(22,500)	—
Interest expense:			
Finance charges	(147)	(936)	—
Amortization of discount on convertible notes	(3,591)	(1,645)	(1,707)
Amortization of debt issuance costs	(65)	(404)	(459)
Inducement interest expense	(11,366)	(7,904)	(196)
Interest on convertible notes payable	(4,387)	(7,330)	(950)
Total interest expense	(19,556)	(18,219)	(3,312)
Loss before income taxes	(154,674)	(124,403)	(59,014)
Income tax benefit	—	—	2,827
Net loss	$ (154,674)	$ (124,403)	$ (56,187)
Basic and diluted loss per share	$ (0.27)	$ (0.30)	$ (0.21)
Basic and diluted weighted average common shares outstanding	587,590	421,078	272,041

See accompanying notes to Consolidated Financial Statements.

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

	Preferred stock		Common stock		Treasury stock		Additional	Accumulated	Total stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	paid-in capital	deficit	(deficit) equity
Balance May 31, 2018	92	$ —	216,882	$ 217	159	$ —	$ 159,765	$ (173,139)	$ (13,158)
Acquisition of ProstaGene LLC	—	—	18,658	19	—	—	11,539	—	11,558
Issuance of stock payment shares	—	—	8,342	8	—	—	(8)	—	—
Issuance of stock for note payable redemption	—	—	3,756	4	—	—	1,451	—	1,455
Registered direct offerings ($0.50/share)	—	—	23,630	24	—	—	11,791	—	11,815
Offering costs related to registered direct offering	—	—	—	—	—	—	(1,130)	—	(1,130)
Private equity offerings ($0.50/share)	—	—	46,975	47	—	—	23,441	—	23,488
Offering costs related to private equity offering	—	—	—	—	—	—	(2,697)	—	(2,697)
Issuance costs related to debt offering	—	—	—	—	—	—	261	—	261
Debt discount costs related to debt offering	—	—	—	—	—	—	3,059	—	3,059
Beneficial conversion feature on note payable and relative fair value associated with warrants	—	—	—	—	—	—	3,535	—	3,535
Private warrant exchanges	—	—	11,312	11	—	—	2,955	—	2,966
Offering costs related to private warrant exchange	—	—	—	—	—	—	(267)	—	(267)
Inducement interest expense on private warrant exchange	—	—	—	—	—	—	196	—	196
Proceeds from preferred stock offering	3	—	—	—	—	—	3,084	—	3,084
Dividends accrued on preferred stock	—	—	—	—	—	—	—	(37)	(37)
Legal fees in connection with equity offerings	—	—	—	—	—	—	(243)	—	(243)
Stock-based compensation	—	—	—	—	—	—	3,388	—	3,388
Net loss for May 31, 2019							—	(56,187)	(56,187)
Balance May 31, 2019	95	—	329,555	330	159	—	220,120	(229,363)	(8,913)
Issuance of stock for note payable repayment	—	—	22,967	23	—	—	10,799	—	10,822
Note conversion and extension fees	—	—	8,232	8	—	—	3,891	—	3,899
Registered direct offering	—	—	38,856	39	—	—	12,627	—	12,666
Offering costs related to registered direct offering	—	—	—	—	—	—	(378)	—	(378)
Warrant exercises	—	—	42,024	42	—	—	20,458	—	20,500
Relative fair market value associated with warrants exercised	—	—	—	—	—	—	11,949	—	11,949
Public warrant tender offers	—	—	45,376	45	—	—	11,855	—	11,900
Offering costs related to public warrant tender offers	—	—	—	—	—	—	(1,059)	—	(1,059)
Inducement interest expense—tender offers and debt conversions	—	—	—	—	—	—	2,713	—	2,713
Private warrant exchanges	—	—	20,529	20	—	—	6,001	—	6,021
Offering costs related to private warrant exchanges	—	—	—	—	—	—	(197)	—	(197)
Inducement interest expense—private warrant exchanges	—	—	—	—	—	—	5,191	—	5,191
Preferred stock offerings	14	—	—	—	—	—	13,409	—	13,409
Offering costs related to preferred stock offering	—	—	—	—	—	—	(437)	—	(437)
Exercise of option to repurchase common stock	—	—	—	—	—	—	(8)	—	(8)
Dividends accrued on preferred stock	—	—	—	—	—	—	—	(945)	(945)
Legal fees in connection with equity offerings	—	—	—	—	—	—	(16)	—	(16)
Stock issued for services	—	—	2,620	3	—	—	(3)	—	—
Stock issued for bonuses and tendered for income tax	—	—	380	—	127	—	154	—	154
Stock option exercises	—	—	8,723	9	—	—	5,594	—	5,603
Stock-based compensation	—	—	—	—	—	—	6,548	—	6,548

See accompanying notes to Consolidated Financial Statements.

	Preferred stock		Common stock		Treasury stock		Additional paid-in capital	Accumulated deficit	Total stockholders' (deficit) equity
	Shares	Amount	Shares	Amount	Shares	Amount			
Legal settlement	—	—	—	—	—	—	22,500	—	22,500
Net Loss for May 31, 2020	—	—	—	—	—	—	—	(124,403)	(124,403)
Balance May 31, 2020	109	—	519,262	519	286	—	351,711	(354,711)	(2,481)
Issuance of stock for convertible note repayment	—	—	24,154	24	—	—	77,679	—	77,703
Issuance of legal settlement shares	—	—	4,000	4	—	—	(4)	—	—
Stock option exercises	—	—	2,591	3	—	—	1,835	—	1,838
Stock issued for incentive compensation and tendered for income tax	—	—	323	—	157	—	828	—	828
Stock issued for private offering ($1.50 per share)	—	—	667	1	—	—	999	—	1,000
Conversion of Series B convertible preferred stock to common stock	(13)	—	131	—	—	—	—	—	—
Private warrant exchanges	—	—	37,054	37	—	—	17,519	—	17,556
Offering costs related to private warrant exchanges	—	—	—	—	—	—	(495)	—	(495)
Warrant exercises	—	—	37,941	38	—	—	19,390	—	19,428
Inducement interest expense related to private warrant exchanges	—	—	—	—	—	—	11,366	—	11,366
Dividends accrued and paid on preferred stock	—	—	—	—	—	—	—	(1,909)	(1,909)
Stock-based compensation	—	—	—	—	—	—	8,822	—	8,822
Net Loss for May 31, 2021	—	—	—	—	—	—	—	(154,674)	(154,674)
Balance May 31, 2021	96	$ —	626,123	$ 626	443	$ —	$ 489,650	$ (511,294)	$ (21,018)

See accompanying notes to Consolidated Financial Statements.

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

	Years ended May 31,		
	2021	2020	2019
Cash flows from operating activities:			
Net loss	$ (154,674)	$ (124,403)	$ (56,187)
Adjustments to reconcile net loss to net cash used in operating activities:			
Amortization and depreciation	1,797	2,034	1,245
Amortization of debt issuance costs	65	404	459
Amortization of discount on convertible notes	3,591	1,645	1,707
Legal settlement	—	22,500	—
Inducement interest expense	11,366	7,904	196
Interest expense associated with accretion of convertible notes payable	—	6,615	513
Change in fair value of derivative liabilities	—	9,542	(1,666)
Stock-based compensation	10,429	6,548	3,388
Loss on extinguishment of convertible notes	19,896	—	1,520
Intangible asset impairment charge	10,049	—	—
Deferred income tax benefit	—	—	(2,827)
Changes in operating assets and liabilities:			
(Increase) in inventories, net	(74,332)	(19,147)	—
Decrease (increase) in miscellaneous receivables	—	91	(91)
Decrease (increase) in prepaid expenses	1,228	(1,577)	(464)
Increase in accounts payable and accrued expenses	53,012	19,040	1,741
Net cash used in operating activities	(117,573)	(68,804)	(50,466)
Cash flows from investing activities:			
Intangibles	—	—	(19)
Furniture and equipment purchases	(122)	(41)	(26)
Net cash used in investing activities	(122)	(41)	(45)
Cash flows from financing activities:			
Proceeds from warrant transactions, net of offering costs	17,060	—	—
Proceeds from sale of common stock and warrants	1,000	12,666	38,269
Proceeds from warrant exercises	19,428	38,422	—
Proceeds from sale of preferred stock, net of offering costs	—	13,409	3,084
Payment on convertible notes	(950)	(2,185)	—
Exercise of option to repurchase shares held in escrow	—	(8)	—
Release of funds held in trust for warrant tender offer	(10)	(844)	854
Proceeds from stock option exercises	1,839	5,602	—
Payment of payroll withholdings related to tender of common stock for income tax withholding	(778)	(89)	—
Proceeds from convertible notes payable, net	100,000	15,000	14,877
Payment of conversion offering costs	—	(2,303)	(4,337)
Dividend declared and paid on Series B preferred stock	(243)	—	—
Net cash provided by financing activities	137,346	79,670	52,747
Net change in cash	19,651	10,825	2,236
Cash and restricted cash, beginning of period	14,292	3,467	1,231
Cash and restricted cash, end of period	$ 33,943	$ 14,292	$ 3,467
Cash and restricted cash consisted of the following:			
Cash	$ 33,943	$ 14,282	$ 2,613
Restricted cash	—	10	854
Total cash and restricted cash	$ 33,943	$ 14,292	$ 3,467
Supplemental disclosure of cash flow information:			
Cash paid during the period for interest	$ 147	$ 243	$ —
Non-cash investing and financing transactions:			
Issuance of common stock for principal and interest of convertible notes	$ 77,703	$ 15,092	$ 1,680
Accrued dividends on convertible preferred stock	$ 1,666	$ 944	$ 37
Cashless exercise of warrants	$ 11	$ —	$ —
Issuance of stock for legal settlement	$ 4	$ —	$ —
Derivative liability associated with warrants	$ —	$ 11,949	$ —
Common stock issued for accrued bonus compensation	$ —	$ 155	$ —
Common stock issued for services	$ —	$ 3	$ 8
Common stock issued for acquisition of ProstaGene, LLC	$ —	$ —	$ 11,558
Beneficial conversion feature and fair value of warrant issued with note payable	$ —	$ —	$ 3,535
Debt discount and issuance costs associated with convertible note payable	$ —	$ —	$ 3,059
Derivative liability associated with a convertible note payable	$ —	$ —	$ 2,750
Issuance costs associated with placement agent warrants	$ —	$ —	$ 261

See accompanying notes to Consolidated Financial Statements.

CYTODYN INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
AS OF MAY 31, 2021

Note 1. Organization

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 late-stage biotechnology company developing innovative treatments for multiple therapeutic indications based on leronlimab, a novel humanized monoclonal antibody targeting the CCR5 receptor. Leronlimab is in a class of therapeutic monoclonal antibodies designed to address unmet medical needs for which the Company is focused on developing treatments in the areas of human immunodeficiency virus ("HIV"), cancer, immunology, and novel coronavirus disease ("COVID-19").

Leronlimab belongs to a class of HIV therapies known as entry inhibitors which block HIV from entering and infecting specific cells. For cancer and immunology, the CCR5 receptor also appears to be implicated in human metastasis and in immune-mediated illnesses such as triple-negative breast cancer, other metastatic solid tumor cancers, and non-alcoholic steatohepatitis ("NASH"). For COVID-19 the Company believes leronlimab may be shown to provide therapeutic benefit by enhancing the immune response and also mitigating the "cytokine storm" that leads to morbidity and mortality in patients experiencing this syndrome.

Note 2. Summary of Significant Accounting Policies

Principles of Consolidation

The Consolidated Financial Statements include the accounts of the Company and its wholly owned subsidiary, CytoDyn Operations Inc. All intercompany transactions and balances are eliminated in consolidation.

Reclassifications

Certain prior year amounts shown in the accompanying Consolidated Financial Statements have been reclassified to conform to the current period presentation. These reclassifications did not have any effect on the Company's financial position, results of operations, stockholders' (deficit) equity, or net cash provided by financing activities as previously reported.

Going Concern

The consolidated accompanying 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 shown in the accompanying Consolidated Financial Statements, the Company had losses for all periods presented. The Company incurred a net loss of $154.7 million, $124.4 million, and $56.2 million for the years ended May 31, 2021, May 31, 2020, and May 31, 2019, respectively, and has an accumulated deficit of $511.3 million as of May 31, 2021. These factors, among others, raise substantial doubt about the Company's ability to continue as a going concern.

The Consolidated Financial Statements do not include any adjustments relating to the recoverability of assets and classification of liabilities that might be necessary should the Company be unable to continue as a going concern. The Company's continuation as a going concern is dependent upon its ability to obtain additional operating capital, complete development of its product candidate, leronlimab, obtain approval to commercialize leronlimab from regulatory agencies, continue to outsource manufacturing of leronlimab, and ultimately achieve initial revenues and attain profitability. The Company continues to engage in significant research and development activities related to leronlimab for multiple indications and expects to incur significant research and development expenses in the future primarily related to its clinical trials. These research and development activities are subject to significant risks and uncertainties. The Company intends to finance its future development activities and its working capital needs largely from the sale of

equity and debt securities, combined with additional funding from other traditional sources. There can be no assurance, however, that the Company will be successful in these endeavors.

Use of Estimates

The preparation of the Consolidated Financial Statements in accordance with U.S. GAAP requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, and the disclosure of contingent assets and liabilities at the date of Consolidated Financial Statements and the reported amounts of expenses during the reporting period. Estimates are assessed each period and updated to reflect current information, such as the economic considerations related to the impact that the recent coronavirus disease could have on our significant accounting estimates and assumptions. The Company's estimates are based on historical experience and on various market and other relevant, appropriate assumptions. Actual results could differ from these estimates.

Cash

Cash is maintained at federally insured financial institutions and, at times, balances may exceed federally insured limits. The Company has never experienced any losses related to these balances. Balances in excess of federally insured limits at May 31, 2021 and May 31, 2020 approximated $33.7 million and $14.0 million, respectively.

Identified Intangible Assets

The Company follows the provisions of ASC 350, *Intangibles-Goodwill and Other*, which establishes accounting standards for the impairment of long-lived assets such as intangible assets subject to amortization. The Company reviews long-lived assets to be held and used for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. If the sum of the undiscounted expected future cash flows over the remaining useful life of a long-lived asset group is less than its carrying value, the asset is considered impaired. Impairment losses are measured as the amount by which the carrying amount of the asset group exceeds the fair value of the asset. The Company recognized an impairment charge of approximately $10.0 million for the year ended May 31, 2021, and none for the years ended May 31, 2020, and May 31, 2019. The value of the Company's patents would be significantly impaired by any adverse developments as they relate to the clinical trials pursuant to the patents acquired as discussed in Note 8.

Research and Development

Research and development costs are expensed as incurred. Clinical trial costs incurred through third-parties are expensed as the contracted work is performed. Contingent milestone payments that are due to third parties under research and development collaboration arrangements or other contractual agreements are expensed when the milestone conditions are probable and the amount of payment is reasonably estimable. See Notes 9 and 10.

Inventories

The Company values inventory at the lower of cost or net realizable value using the average cost method. Inventories consist of raw materials, bulk drug substance, and drug product in unlabeled vials to be used for commercialization of the Company's biologic, leronlimab, which is in the regulatory approval process. 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. Inventory is evaluated for recoverability by considering the likelihood that revenue will be obtained from the future sale of the related inventory, in light of the status of the product within the regulatory approval process.

The Company evaluates its inventory levels on a quarterly basis and writes down inventory that has become obsolete, or has a cost in excess of its expected net realizable value, and inventory quantities in excess of expected requirements. In assessing the lower of cost or net realizable value for pre-launch inventory, the Company relies on independent analyses provided by third-parties knowledgeable of the range of likely commercial prices comparable to current comparable commercial product.

The Company capitalizes inventories procured or produced in preparation for product launches sufficient to support estimated initial market demand. Typically, capitalization of such inventory begins when the results of clinical trials have reached a status sufficient to support regulatory approval, uncertainties regarding ultimate regulatory approval have been significantly reduced and 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 is aware of any specific material risks or contingencies other than the normal regulatory review and approval process or if there are any specific issues identified relating to safety, efficacy, manufacturing, marketing or labeling, the related inventory may no longer qualify for capitalization.

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 inventory, the Company considers the product stability data of all of the pre-approval inventory procured or produced to date to determine whether there is adequate shelf life. As inventories approach their shelf-life expiration, the Company may perform additional stability testing to determine if the inventory is still viable, which can result in an extension of its shelf-life. Further, in addition to performing additional stability testing, certain raw materials inventory may be sold in its then current condition prior to reaching expiration.

Fair Value of Financial Instruments

The Company's financial instruments consist primarily of cash, accounts receivable, right-of-use assets, accounts payable, accrued liabilities, short-term and long-term lease liabilities, and short-term and long-term debt. As of May 31, 2021, the carrying value of the Company's cash, accounts payable, and accrued liabilities approximate their fair value due to the short-term maturity of the instruments. Short-term and long-term debt are 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.

During the fiscal year ended May 31, 2021 the Company carried derivative financial instruments at fair value as required by U.S. GAAP. Derivative financial instruments consist of financial instruments that contain a notional amount and one or more underlying variables (e.g., interest rate, security price, variable conversion rate or other variables), require no initial net investment and permit net settlement. Derivative financial instruments may be free-standing or embedded in other financial instruments. The Company follows the provisions of ASC 815, *Derivatives and Hedging*, as their instruments are recorded as a derivative liability, at fair value, and ASC 480, *Distinguishing Liabilities from Equity,* as it relates to warrant liability, with changes in fair value reflected in the Consolidated Statement of Operations.

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

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

The Company did not have any assets or liabilities measured at fair value using Level 1 or 2 of the fair value hierarchy as of May 31, 2021 and May 31, 2020. As of May 31, 2020, there were no assets or liabilities measured at fair value

using Level 3 inputs; previous outstanding derivative warrants and related convertible debt valued at fair value using level 3 inputs were converted prior to May 31, 2020 according to the terms of the agreements.

A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurements. These instruments are not quoted on an active market. During the 2020 fiscal year, the Company used a Binomial Lattice Model to estimate the value of the warrant derivative liability and a Monte Carlo Simulation to value the derivative liability of the redemption provision within a convertible promissory note. These valuation models were used because management believes they reflect all the assumptions that market participants would likely consider in negotiating the transfer of the instruments. The Company's derivative liabilities were classified within Level 3 of the fair value hierarchy because certain unobservable inputs were used in the valuation models.

The following is a reconciliation of the beginning and ending balances for liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) from inception to the year ended May 31, 2020 (in thousands):

Investor warrants issued with registered direct equity offering	$ 4,360
Placement agent warrants issued with registered direct equity offering	819
Fair value adjustments	(3,855)
Balance at May 31, 2018	1,324
Inception date value of redemption provisions	2,750
Fair value adjustments—convertible notes	(745)
Fair value adjustments—warrants	(922)
Balance at May 31, 2019	2,407
Fair value adjustments—convertible notes	(2,005)
Fair value adjustments—warrants	11,547
Exercise of derivative warrants	(11,949)
Balance at May 31, 2020	$ —

Operating Leases

Operating leases are included in operating lease right-of-use ("ROU") assets, current portion of operating leases payable and operating leases liabilities in the Consolidated Balance Sheets.

Operating lease ROU assets and operating lease 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. The Company has lease agreements with lease and non-lease components, which are generally accounted for separately.

Stock-Based Compensation

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

The Company accounts for stock-based awards established by the fair market value of the instrument using the Black-Scholes option pricing model utilizing certain weighted average assumptions including stock price volatility, expected term and risk-free interest rates, as of the grant date. For stock-based awards with defined vesting, the Company recognizes compensation expense over the requisite service period, when designated milestones have been achieved or when pre-defined performance conditions are met. The Company estimates forfeitures at the time of grant and revised, if

necessary, in subsequent periods, if actual forfeitures differ from those estimates. Based on limited historical experience of forfeitures, the Company estimated future unvested forfeitures at 0% for all periods presented. Periodically, the Company will issue restricted common stock to executives or third parties as compensation for services rendered. Such stock awards are valued at fair market value on the effective date of the Company's obligation.

The Company periodically issues stock options or warrants to consultants and advisors for various services. The Black-Scholes option pricing model, as described more fully above, is used to measure the fair value of the equity instruments on the date of issuance. The Company recognizes the compensation expense associated with the equity instruments over the requisite service or vesting period.

Debt

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

Offering Costs

The Company periodically incurs direct incremental costs associated with the sale of equity securities as fully described in Note 12. The costs are recorded as a component of equity upon receipt of the proceeds.

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 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 years ended May 31, 2021, May 31, 2020 and May 31, 2019 (in thousands):

	Years ended May 31,		
	2021	2020	2019
Stock options, warrants & unvested restricted stock	82,386	131,361	178,592
Convertible notes payable	18,000	3,864	11,346
Convertible preferred stock	33,008	30,130	7,974

Income Taxes

Deferred taxes are provided on the asset and liability method, whereby deferred tax assets are recognized for deductible temporary differences and operating loss and tax credit carry forwards and 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, in the opinion of management, 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 2021 and 2020 tax years. The net tax expense for the years ended May 31, 2021 and May 31, 2020 was zero. The Company recorded a tax benefit of $2.8 million for the year ended May 31, 2019. The Company has a full valuation allowance as of May 31, 2021 and May 31, 2020, as management does not consider it more than likely than not that the benefits from the net deferred taxes will be realized.

Recent Accounting Pronouncements

Recent accounting pronouncements, other than below, issued by the FASB (including its EITF), the AICPA and the SEC did not or are not believed by management to have a material effect on the Company's present or future Consolidated Financial Statements.

In December 2019, the FASB issued ASU No. 2019-12, *Simplifying the Accounting for Income Taxes (Topic 740)*. The objective of the standard is to improve areas of U.S. GAAP by removing certain exceptions permitted by ASC 740 and clarifying existing guidance to facilitate consistent application. The standard is effective for the Company beginning on June 1, 2021. The Company does not expect the new standard to have a material impact on its financial condition, results of operations, cash flows, and financial statement disclosures.

In August 2020, the FASB issued ASU No. 2020-06, *Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40)* which simplifies the accounting for convertible instruments. The guidance removes certain accounting models which separate the embedded conversion features from the host contract for convertible instruments. Either a modified retrospective method of transition or a fully retrospective method of transition is permissible for the adoption of this standard. Update No. 2020-06 is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted no earlier than the fiscal year beginning after December 15, 2020. The Company is currently evaluating the potential impact, if any, of adoption on its Consolidated Financial Statements.

Note 3. Inventories

The Company's pre-launch inventories consist of raw materials purchased for commercial production and work-in-progress inventory related to the substantially completed commercial production of pre-launch inventories of leronlimab to support the Company's expected approval of the product as a combination therapy for HIV patients in the United States. Work-in-progress consists of bulk drug substance, which is the manufactured drug stored in bulk storage, and drug product, which is the manufactured drug in unlabeled vials.

Inventories as of May 31, 2021 and May 31, 2020 are presented below (in thousands):

	May 31,	
	2021	2020
Raw materials	$ 28,085	$ 19,147
Work-in-progress	65,394	—
Total	$ 93,479	$ 19,147

During the quarter ended February 28, 2021, the Company was notified by a third-party contract manufacturing partner that, due to an operational error committed by the contract manufacturer, one of the batches of a multiple-batch manufacturing campaign failed to meet quality standards, and thus would not be saleable upon regulatory approval. In accordance with the agreement, the contract manufacturer assumed liability for the failure and all costs to manufacture the batch, and committed to remanufacture the batch at a future date. As a result, the Company reduced work-in-progress inventory and the related amounts due to the contract manufacturer by $6.1 million. No other inventory was affected by this failure, and all other inventory has successfully passed quality standards.

The Company believes that material uncertainties related to the ultimate regulatory approval of leronlimab for commercial sale have been significantly reduced based on positive data from its Phase 3 clinical trial for leronlimab as a combination therapy with HAART for highly treatment-experienced HIV patients, as well as information gathered from meetings with the FDA related to its Biologics License Application ("BLA") for this indication. The Company submitted the last two portions of the BLA (clinical and manufacturing) with the FDA in April 2020 and May 2020. In July 2020, the Company received a Refusal to File letter from the FDA regarding its BLA submittal requesting additional information. In August and September 2020, the FDA provided written responses to the Company's questions and met telephonically with key Company personnel and its clinical research organization concerning its BLA to expedite the resubmission of its BLA.

The deficiencies cited by the FDA in its July 2020 Refusal to File letter consisted of administrative deficiencies, omissions, corrections to data presentation, and related analyses and clarifications of manufacturing processes. The Company commenced its resubmission of the BLA in July 2021 and expected to be completed in October 2021.

The Company is working with new consultants to cure the BLA deficiencies and resubmit the BLA in order to allow the FDA to perform their substantive review. The Company anticipates that when the FDA completes their review, leronlimab will be approved, and we will achieve market acceptance of leronlimab as a treatment for HIV, realizing the amount of pre-launch inventory on-hand prior to shelf-life expiration. Accordingly, management believes the Company will realize future economic benefit in excess of the carrying value of its pre-launch inventory.

The expiration of remaining shelf-life of the Company's inventories consists of the following as of May 31, 2021 (in thousands):

Expiration period ending May 31,	Remaining shelf-life	Raw materials	Work-in-progress bulk drug product	Work-in-progress finished drug product in vials	Total inventories
2022	0 to 12 months	$ 2,684	$ -	$ -	$ 2,684
2023	12 or 24 months	19,750	-	-	19,750
2024	24 to 36 months	682	-	-	682
2025	36 to 48 months	1,792	-	29,633	31,425
2026	48 to 60 months	732	-	-	732
Thereafter	60 or more months	3,140	35,761	-	38,901
Total inventories		28,780	35,761	29,633	94,174
Inventories reserved		(695)	-	-	(695)
Total inventories, net		$ 28,085	$ 35,761	$ 29,633	$ 93,479

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. Further, in addition to performing additional stability testing, certain raw materials inventory may be sold in its then current condition prior to reaching expiration; however, at May 31, 2021 and 2020 there was no drug product inventory that may be sold. If the Company determines it is not likely shelf-life will be able to be extended or the inventory cannot be sold prior to expiration, the Company will write-down the inventory to its net realizable value. For the fiscal year ended May 31, 2021 the Company recognized expense related to the write-down of obsolete inventory of $0.7 million and recognized zero expense during the years ended May 31, 2020, and May 31, 2019.

Note 4. Accounts Payable and Accrued Liabilities

As of May 31, 2021 and May 31, 2020, the accounts payable balance was approximately $65.9 million and $29.5 million, respectively. The Company had two vendors that accounted for approximately 72% and 14%, and 49% and 20%, of the total balance of accounts payable as of May 31, 2021 and May 31, 2020, respectively.

The components of accrued liabilities were as follows as of May 31, 2021 and 2020 (in thousands):

	May 31,	
	2021	2020
Accrued compensation and related expense	$ 4,005	$ 1,723
Accrued legal settlement and fees	11,008	400
Accrued other liabilities	4,060	4,756
Total accrued liabilities	$ 19,073	$ 6,879

Note 5. Convertible Instruments

Convertible Preferred Stock

Series D Convertible Preferred Stock

As of May 31, 2021, the Company had authorized 11,737 shares of Series D Convertible Preferred Stock, $0.001 par value per share ("Series D Preferred Stock"), of which 8,452 shares were outstanding. 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 (the "Board") and out of any assets at the time legally available therefor, cumulative dividends at the rate of ten percent (10%) per share per annum of the stated value of the Series D Preferred Stock, which is $1,000 per share (the "Series D Stated Value"). Any dividends paid by the Company will first be paid to the holders of Series D Preferred Stock prior and in preference to any payment or distribution to holders of common stock. Dividends on the Series D Preferred Stock are cumulative, and will accrue and be compounded annually, whether or not declared and whether or not there are any profits, surplus or other funds or assets of the Company legally available therefor. There are no sinking fund provisions applicable to the Series D Preferred Stock. The Series D Preferred Stock does not have redemption rights. Dividends, if declared by the Board, are payable to holders in arrears on December 31 of each year. Subject to the provisions of applicable Delaware law, the holder may elect to be paid in cash or in restricted shares of common stock at the rate of $0.50 per share. As of May 31, 2021, and May 31, 2020, the accrued dividends were approximately $1.1 million, or approximately 2.2 million shares of common stock, and approximately $0.3 million, or approximately 0.5 million shares of common stock, respectively.

In the event of any liquidation, dissolution or winding up of the Company, the holders of Series D Preferred Stock will be entitled to receive, on a pari passu basis with the holders of the Series C Convertible Preferred Stock, $0.001 par value per share ("Series C Preferred Stock"), and in preference to any payment or distribution to any holders of the Series B Convertible Preferred Stock, $0.001 par value per share ("Series B Preferred Stock"), or common stock, an amount per share equal to the Series D Stated Value plus the amount of any accrued and unpaid dividends. If, at any time while the Series D Preferred Stock is outstanding, the Company effects any reorganization, merger or consolidation of the Company, sale of substantially all of its assets, or other specified transaction (each, as defined in the Series D Certificate of Designation, a "Fundamental Transaction"), a holder of the Series D Preferred Stock will have the right to receive any shares of the acquiring corporation or other consideration it would have been entitled to receive if it had been a holder of the number of shares of common stock then issuable upon conversion in full of the Series D Preferred Stock immediately prior to the Fundamental Transaction. Each share of Series D Preferred Stock is convertible at any time at the holder's option into that number of fully paid and nonassessable shares of common stock determined by dividing the Series D Stated Value by the conversion price of $0.50 (subject to adjustment as set forth in the Series D Certificate of Designation). No fractional shares will be issued upon the conversion of the Series D Preferred Stock. Except as otherwise provided in the Series D Certificate of Designation or as otherwise required by law, the Series D Preferred Stock has no voting rights.

Series C Convertible Preferred Stock

As of May 31, 2021, the Company had authorized 8,203 shares of Series C Convertible Preferred Stock, $0.001 par value per share ("Series C Preferred Stock"), of which 8,203 shares were outstanding. The Series C Certificate of Designation provides, among other things, that holders of Series C Preferred Stock shall be entitled to receive, when and

as declared by the Board and out of any assets at the time legally available therefor, cumulative dividends at the rate of ten percent (10%) per share per annum of the stated value of the Series C Preferred Stock, which is $1,000 per share (the "Series C Stated Value"). Any dividends paid by the Company will be paid to the holders of Series C Preferred Stock prior and in preference to any payment or distribution to holders of common stock. Dividends on the Series C Preferred Stock are cumulative, and will accrue and be compounded annually, whether or not declared and whether or not there are any profits, surplus or other funds or assets of the Company legally available therefor. There are no sinking fund provisions applicable to the Series C Preferred Stock. The Series C Preferred Stock does not have redemption rights. Dividends, if declared by the Board, are payable to holders in arrears on December 31 of each year. Subject to the provisions of applicable Delaware law, the holder may elect to be paid in cash or in restricted shares of common stock at the rate of $0.50 per share. As of May 31, 2021 and May 31, 2020, the accrued dividends were approximately $1.5 million or, approximately 3.0 million shares of common stock, and approximately $0.7 million or approximately 1.4 million shares of common stock, respectively.

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

Series B Convertible Preferred Stock

As of May 31, 2021, the Company had authorized 400,000 shares of Series B Preferred Stock, of which 79,000 shares remain outstanding. Each share of the Series B Preferred Stock is convertible into ten (10) shares of the Company's common stock. Dividends are payable to the Series B Preferred stockholders when and as declared by the Board at the rate of $0.25 per share per annum. Such dividends are cumulative and accrue whether or not declared and whether or not there are any profits, surplus or other funds or assets of the Company legally available therefor. At the option of the Company, dividends on the Series B Preferred Stock may be paid in cash or shares of the Company's common stock, valued at $0.50 per share. The holders of the Series B Preferred Stock can only convert their shares to shares of common stock if the Company has sufficient 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. On July 30, 2020, the Board declared a dividend and elected to pay such dividend in the form of cash in the aggregate amount of approximately $0.2 million to all Series B Preferred stockholders. As of May 31, 2021, and May 31, 2020, the undeclared dividends were approximately $17,800 or 35,500 shares of common stock, and approximately $0.2 million, or 0.5 million shares of common stock, respectively.

Convertible Notes

The following schedule sets forth the outstanding balance of convertible notes as of May 31, 2021 and May 31, 2020 (in thousands).

	March 2020 Note	July 2020 Note	November 2020 Note	April 2, 2021 Note	April 23, 2021 Note
Outstanding balance May 31, 2020	$ 15,467	$ -	$ -	$ -	$ -
Consideration received	-	25,000	25,000	25,000	25,000
Amortization of issuance discount and costs	1,369	1,097	740	268	182
Accrued interest	480	1,901	1,258	447	302
Cash repayments	(950)	-	-	-	-
Conversions	(9,538)	-	-	-	-
Fair market value of shares exchanged for repayment	(10,997)	(37,298)	(19,870)	-	-
Debt extinguishment loss	4,169	9,300	6,427	-	-
Outstanding balance May 31, 2021	$ -	$ -	$ 13,554	$ 25,715	$ 25,485

2019 Short-term Convertible Notes

During the year ended May 31, 2019, the Company issued approximately $5.5 million of nine-month unsecured Convertible Notes (the "2019 Short-term Convertible Notes") and related warrants to investors for cash. The principal amount of the 2019 Short-term Convertible Notes, including any accrued but unpaid interest thereon, was convertible at the election of the holder at any time into shares of common stock at any time prior to maturity at a conversion price of $0.50 per share. The 2019 Short-term Convertible Notes accrued simple interest at the annual rate of 10%. Principal and accrued interest, to the extent not previously paid or converted, was due and payable on the maturity date. At the commitment dates, the Company determined that the conversion feature related to these 2019 Short-term Convertible Notes was beneficial to the investors. As a result, the Company determined the intrinsic value of the beneficial conversion feature utilizing the fair value of the underlying common stock on the commitment dates and the effective conversion price after discounting the 2019 Short-term Convertible Notes for the fair value of the related warrants. In connection with the sale of the 2019 Short-term Convertible Notes, detachable common stock warrants to purchase a total of 5.46 million common shares, with an exercise price of $0.30 per share and a five-year term, were issued to the investors. The Company determined the fair value of the warrants at issuance using the Black-Scholes option pricing model utilizing certain weighted average assumptions, such as expected stock price volatility, expected term of the warrants, risk-free interest rates, and expected dividend yield at the grant date.

	2018 - 2019
Expected dividend yield	0 %
Stock price volatility	55.8 - 55.88 %
Expected term	5 year
Risk-free interest rate	2.48 - 2.56 %
Grant-date fair value	$ 0.30 - $0.38

The fair value of the warrants, coupled with the beneficial conversion features, was recorded as a debt discount to the 2019 Short-term Convertible Notes and a corresponding increase to additional paid-in capital and will be amortized over the life of the 2019 Short-term Convertible Notes. In connection with the 2019 Short-term Convertible Notes, the placement agent earned a "tail fee" comprising warrants covering approximately 0.97 million shares of common stock and a cash fee of approximately $0.6 million. The placement agent warrants were exercisable at a price of $0.50 per share, expire five years from the date of issuance and include a cashless exercise provision. During the year ended May 31, 2019, in connection with the 2019 Short-term Convertible Notes, the Company incurred debt discount of approximately $3.1 million, related to the beneficial conversion feature and detachable warrants issued with the 2019 Short-term Convertible Notes and approximately $0.8 million in issuance costs. The debt discount and issuance costs will be amortized over the term of the 2019 Short-term Convertible Notes. Accordingly, the Company recognized

approximately $1.7 million and $0.5 million of debt discount and issuance costs, respectively, during the year ended May 31, 2019. See Note 17.

Beginning on September 30, 2019 and through November 14, 2019, principal and interest totaling approximately $5.9 million became due. Holders of notes totaling approximately $1.1 million in principal and accrued interest agreed to extend their notes for another three months, and holders of notes totaling approximately $4.1 million in principal and accrued interest agreed to extend their notes for another six months. One noteholder with principal and accrued interest totaling approximately $0.2 million converted to shares of common stock. During the quarter ended November 30, 2019, a total of approximately $0.7 million of principal and accrued interest was repaid in cash. In addition, detachable stock warrants to purchase a total of 4.75 million warrants with a five-year term and an exercise price of $0.30 per share were issued to investors who extended their notes. One investor received 0.2 million warrants with a five-year term and an exercise price of $0.45 per share for converting the entire principal and accrued interest on its note. In connection with the 2019 Short-term Convertible Note extensions and conversion, the Company recorded a non-cash inducement interest expense of approximately $0.3 million during the quarter ended November 30, 2019. The new principal amount of the 2019 Short-term Convertible Notes, including any accrued but unpaid interest thereon, was convertible at the election of the holders at any time into shares of common stock at any time prior to maturity at a conversion price of $0.50 per share. At the new commitment dates, the Company determined that there was a decrease in the fair value of the embedded conversion option resulting from the modification, the value of which is not required to be recognized under U.S. GAAP.

During the fiscal year ended May 31, 2020, holders of the 2019 Short-term Convertible Notes in the aggregate principal amount of $5.2 million, including accrued but unpaid interest, tendered notices of conversion at the stated conversion rate of $0.50 per share. The Company issued approximately 10.4 million shares of common stock in satisfaction of the conversion notices. Following the redemptions, the 2019 Short-term Convertible Notes have been fully satisfied and there is no outstanding balance at May 31, 2021.

Activity related to the 2019 Short-term Convertible Notes was as follows (in thousands):

	Years ended May 31,	
	2020	2019
Face value of Short-term Convertible Notes	$ 5,460	$ 5,460
Unamortized discount	—	(1,470)
Unamortized issuance costs	—	(404)
Accrued interest converted into principal	154	—
Note repayment	(460)	—
Note conversions into common stock	(5,154)	—
Carrying value of Short-term Convertible Notes	$ —	$ 3,586

The Company recognized approximately $0.4 million and $0.2 million of interest expense for the fiscal years ended May 31, 2020 and May 31, 2019, respectively.

Long-term Convertible Note - June 2018 Note

On June 26, 2018, the Company entered into a securities purchase agreement, pursuant to which the Company issued a convertible promissory note (the “June 2018 Note”) with a two-year term to an institutional accredited investor in the initial principal amount of $5.7 million. The investor paid consideration of $5.0 million to the Company. The June 2018 Note accrued interest at an annual rate of 10% and was convertible into common stock, at a conversion rate of $0.55 per share. The June 2018 Note provided for conversion in whole, or in part, of the outstanding balance, into common stock at any time beginning six months following the issue date upon five trading days’ notice, subject to certain adjustments and ownership limitations specified in the June 2018 Note, and allowed for redemption, at any time beginning six months following the issue date upon five trading days’ notice, subject to a maximum monthly redemption amount of $0.35 million. The securities purchase agreement required the Company to reserve shares for future conversions or redemptions by dividing the outstanding principal balance plus accrued interest by the conversion price of $0.55 per

share times 1.5. As a result of the entry into the January 2019 Note (as defined below), the Company's obligations under the June 2018 Note were secured by all of the assets of the Company, excluding the Company's intellectual property.

Effective November 15, 2018, the June 2018 Note was amended to allow the investor to redeem the monthly redemption amount of $0.35 million in cash or stock, at the lesser of (i) $0.55, or (ii) the lowest closing bid price of the Company's common stock during the 20 days prior to the conversion, multiplied by a conversion factor of 85%. The variable rate redemption provision meets the definition of a derivative instrument and subsequent to the amendment, it no longer meets the criteria to be considered indexed to the Company's common stock. As of November 15, 2018, the redemption provision required bifurcation as a derivative liability at fair value under the guidance in ASC 815, *Derivatives and Hedging*.

The amendment of the June 2018 Note was also evaluated under ASC 470-50-40, *Debt Modifications and Extinguishments*. Based on the guidance, the instruments were determined to be substantially different, and debt extinguishment accounting was applied. The Company recorded approximately $1.5 million as an extinguishment loss, which was the difference in the net carrying value of the June 2018 Note prior to the amendment of approximately $5.4 million, and the fair value of the June 2018 Note and embedded derivatives after the amendment of approximately $6.9 million. The extinguishment loss included a write-off of unamortized debt issuance costs and the debt discount associated with the original June 2018 Note.

The Company recognized approximately $0.4 million of interest expense related to the June 2018 Note during each of the fiscal years ended May 31, 2020 and May 31, 2019. During the year ended May 31, 2019, the Company received redemption notices from the holder of the Company's June 2018 Note, requesting an aggregate redemption of approximately $1.5 million of the outstanding balance thereof. In satisfaction of the redemption notices, the Company issued a total of approximately 3.8 million shares of common stock to the June 2018 Note holder in accordance with the terms of the June 2018 Note. During the year ended May 31, 2020, the Company received redemption notices requesting an aggregate redemption of approximately $4.5 million settling the remaining outstanding balance in full, including accrued but unpaid interest. In satisfaction of the redemption notice, the Company issued approximately 8.5 million shares of common stock and paid cash totaling approximately $0.5 million to the June 2018 Note holder in accordance with the terms of the June 2018 Note. Following the redemptions, the June 2018 Note was fully satisfied and there was no outstanding balance at May 31, 2020.

Long-term Convertible Note - January 2019 Note

On January 30, 2019, the Company entered into a securities purchase agreement, pursuant to which the Company issued a convertible promissory note with a two-year term to the holder of the June 2018 Note in the initial principal amount of $5.7 million (the "January 2019 Note"). In connection with the issuance of the January 2019 Note, the Company granted a lien against all the assets of the Company, excluding the Company's intellectual property, to secure all obligations owed to the investor by the Company (including those under both the January 2019 Note and the June 2018 Note). The investor paid consideration of $5.0 million to the Company, reflecting original issue discount of $0.6 million and issuance costs of $0.1 million. The January 2019 Note accrued interest at an annual rate of 10% and was convertible into common stock, at a conversion rate of $0.50 per share. The January 2019 Note provided for conversion in whole, or in part, of the outstanding balance, at any time beginning six months following the issue date upon five trading days' notice, subject to certain adjustments and ownership limitations specified in the January 2019 Note. The Company analyzed the conversion option for derivative accounting treatment under ASC 815, *Derivatives and Hedging,* and determined that the embedded conversion option did not qualify for derivative accounting.

The January 2019 Note provided the investor with the right to redeem any portion of the January 2019 Note, at any time beginning six months following the issue date upon five trading days' notice, subject to a maximum monthly redemption amount of $0.35 million. The monthly redemption amount may be paid in cash or common stock, at the Company's election, at the lesser of (i) $0.50, or (ii) the lowest closing bid price of the Company's common stock during the 20 days prior to the conversion, multiplied by a conversion factor of 85%. The redemption provision met the definition of a derivative instrument and did not meet the criteria to be considered indexed to the Company's common stock. Therefore, the redemption provision required bifurcation as a derivative liability at fair value under the guidance in ASC 815,

Derivatives and Hedging. The securities purchase agreement required the Company to reserve 20 million shares of common stock for future conversions or redemptions.

In conjunction with the January 2019 Note, the investor received a warrant to purchase 5.0 million shares of common stock with an exercise price of $0.30 which is exercisable until the 5-year anniversary of the date of issuance. All the warrants were exercised during the fiscal year ended May 31, 2020. The warrant achieved equity classification at inception. The net proceeds of $5.0 million were allocated first to the redemption provision at its fair value, then to the warrants at their relative fair value and the beneficial conversion feature at its intrinsic value as follows (in thousands):

	January 30, 2019
Fair value of redemption provision	$ 1,465
Relative fair value of equity classified warrants	858
Beneficial conversion feature	2,677
Net proceeds of January 2019 Note	$ 5,000

Under the guidance of ASC 815, *Derivatives and Hedging*, after allocation of proceeds to the redemption provision, relative fair value of equity classified warrants and the beneficial conversion feature, there were no proceeds remaining to allocate to the convertible note payable. Therefore, principal, accrued interest, debt discount and offering costs will be recognized as interest expense, which represents the accretion of the convertible note payable and related debt discount and issuance costs. During the fiscal years ended May 31, 2020 and May 31, 2019, the Company recognized approximately $6.1 million and approximately $0.1 million, respectively, of interest expense related to the January 2019 Note. Interest expense recorded during the year ended May 31, 2020 included approximately $5.8 million representing accretion of the remaining unamortized discount on the January 2019 Note that was recognized immediately upon conversion of the debt in accordance with ASC 470-20-40-1. During the year ended May 31, 2020, the Company received a redemption notice from the holder of the January 2019 Note, requesting an aggregate redemption of approximately $6.3 million settling the remaining outstanding balance in full, including accrued interest. In satisfaction of the redemption notice, the Company issued approximately 10.8 million shares of common stock and paid cash totaling $0.85 million to the January 2019 Note holder in accordance with the terms of the January 2019 Note. Following the redemption, the January 2019 Note has been fully satisfied and there is no outstanding balance at May 31, 2020.

Activity related to the June 2018 Note and the January 2019 Note is as follows (in thousands):

	Current	Non-current	Total
June 2018 Note	$ 2,100	$ 3,600	$ 5,700
Monthly redemption provision	2,100	(2,100)	—
Note amendment, net	—	112	112
Redemptions	—	(1,455)	(1,455)
Interest accretion - June 2018 and January 2019 Notes	—	298	298
Carrying value of Notes at May 31, 2019	4,200	455	4,655
Redemptions	(10,689)	(57)	(10,746)
Interest accretion - June 2018	6,489	39	6,528
Extinguishment of note	—	(437)	(437)
Carrying value of Notes at May 31, 2020	$ —	$ —	$ —

Long-term Convertible Note - March 2020 Note

On March 31, 2020, the Company entered into a securities purchase agreement pursuant to which the Company issued a secured convertible promissory note with a two-year term to an institutional accredited investor in the initial principal amount of $17.1 million (the "March 2020 Note"). The Company received consideration of $15.0 million, reflecting an original issue discount of $2.1 million. The March 2020 Note is secured by all the assets of the Company, excluding the Company's intellectual property. The March 2020 Note accrued interest at an annual rate of 10% and was convertible into common stock at $4.50 per share. The March 2020 Note provided for conversion in total, or in part, of the outstanding balance, at any time beginning six months following the issue date upon five trading days' notice, subject to certain adjustments and volume and ownership limitations specified in the note. The Company analyzed the conversion

option for derivative accounting treatment under ASC 815, *Derivatives and Hedging*, and determined that the embedded conversion option did not qualify for derivative accounting. 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 March 2020 Note provided the investor with the right to redeem any portion of the March 2020 Note, at any time beginning six months following the issue date, upon three trading days' notice, subject to a Maximum Monthly Redemption Amount of $0.95 million. During the quarter ended November 30, 2020, the Company issued an additional secured convertible promissory note to an affiliate of the holder of the March 2020 Note (the "November 2020 Note," as described below), which obligates the Company to reduce the aggregate outstanding note balances held by the investor by $7.5 million per month (the "Debt Reduction Amount," as described under *Long-term Convertible Note – November 2020 Note* below), beginning in the month of November 2020.

The original issue discount of $2.1 million related to the March 2020 Note was recorded as a discount on the March 2020 Note and the discount has been amortized over the term of the March 2020 Note. Amortization of the March 2020 debt discount during the fiscal years ended May 31, 2021 and May 31, 2020 amounted to $1.9 million and $0.2 million, respectively, and is recorded as interest expense in the accompanying consolidated statements of operations. Interest expense for the year ended May 31, 2021 amounted to approximately $0.5 million. From June 26, 2020 to July 27, 2020, the investor converted an aggregate of approximately $9.5 million of combined principal and accrued interest into approximately 2.1 million shares of common stock at the $4.50 per share conversion price. During the quarter ended November 30, 2020, the Company received a redemption notice from the holder of the March 2020 Note, requesting a redemption of $0.95 million. In satisfaction of the redemption notice, the Company paid cash of $0.95 million to the March 2020 Note holder. Additionally, the Company elected to satisfy the Debt Reduction Amount for November 2020 by making repayments on the March 2020 Note, resulting in the note being fully satisfied during the quarter ended November 30, 2020. To settle this Debt Reduction Amount, the Company and the investor entered into three separately negotiated exchange agreements, pursuant to which the remaining balance of the March 2020 Note was partitioned into three new notes (the "Partitioned Notes"). The Company and the investor exchanged the Partitioned Notes for approximately 4.3 million shares of common stock. As a result of these exchanges, there was no outstanding balance on the March 2020 Note at May 31, 2021.

In connection with extinguishment of the March 2020 Note, the Company analyzed the restructured note for potential requirement of debt extinguishment accounting under ASC 470, *Debt Modifications and Extinguishments*. The Company concluded debt extinguishment accounting treatment to be necessary and accordingly recorded aggregate debt extinguishment loss of approximately $4.2 million during the fiscal year ended May 31, 2021, as the difference between the fair market value of the shares issued and the carrying value of the debt retired, which included the amortization of the relative debt discount and issuance costs.

Long-term Convertible Note—July 2020 Note

On July 29, 2020, the Company entered into a securities purchase agreement pursuant to which the Company issued a secured convertible promissory note with a two-year term to an institutional accredited investor in the initial principal amount of $28.5 million (the "July 2020 Note"). The Company received consideration of $25.0 million, reflecting an original issue discount of $3.4 million and issuance costs of $0.1 million. The July 2020 Note was secured by all the assets of the Company, excluding the Company's intellectual property. The July 2020 Note accrued interest at an annual rate of 10% and was convertible into shares of common stock at a conversion rate of $10.00 per share. The July 2020 Note provided for conversion in whole, or in part, of the outstanding balance, at any time beginning six months following the issue date upon five trading days' notice, subject to certain adjustments and volume and ownership limitations specified in the note. The Company analyzed the conversion option for derivative accounting treatment under ASC 815, *Derivatives and Hedging*, and determined that the embedded conversion option did not qualify for derivative accounting. 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 investor had the right to redeem any portion of the July 2020 Note, at any time beginning six months following the issue date, upon three trading days' notice, subject to a Maximum Monthly Redemption Amount of $1.6 million. As

noted above, during the quarter ended November 30, 2020, the Company issued the November 2020 Note to an affiliate of the holder of the March 2020 and July 2020 Notes, which obligates the Company to reduce the aggregate outstanding note balances held by the investor by the Debt Reduction Amount beginning in the month of November 2020.

The Company agreed to use commercially reasonable efforts to file a Registration Statement on Form S-3 with the SEC by September 15, 2020, to register approximately 2.9 million shares of common stock, the number of shares estimated to be required to convert the entire principal and interest balance of the July 2020 Note. The Form S-3 (Registration No. 333-248823) was declared effective on September 25, 2020.

The original issue discount of $3.4 million related to the July 2020 Note was recorded as a discount on the July 2020 Note and the discount has been amortized over the term of the July 2020 Note. Amortization of debt discounts and issuance costs during the fiscal year ended May 31, 2021 amounted to approximately $3.5 million, recorded as interest expense and loss on extinguishment in the accompanying consolidated statement of operations. Interest expense for the year ended May 31, 2021 approximately $1.9 million. From January 29, 2021 to April 30, 2021 the Company applied the monthly Debt Reduction Amounts of $7.5 million for each month and approximately $7.9 million for the April Debt Reduction Amount toward the July 2020 Note for an aggregate redemption amount of $30.4 million of principal and accrued interest. In satisfaction of the monthly Debt Reduction Amounts, the Company and the investor entered into separately negotiated exchange agreements, pursuant to which the July 2020 Note was partitioned into new notes (the "July 2020 Note Partitioned Notes"). The outstanding balance of the July 2020 Note was reduced by the July 2020 Partitioned Notes, and the Company and the investor exchanged the Partitioned Note for approximately 11.3 million shares of common stock. Following these exchanges, there is no outstanding balance on the July 2020 Note at May 31, 2021.

The embedded conversion feature in the July 2020 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 common 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 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 reconsidered the value of the default put provisions each reporting period to determine if the value was material to the financial statements.

In connection with the extinguishment of the July 2020 Note, the Company analyzed the restructured note for potential requirement of debt extinguishment accounting under ASC 470, *Debt Modifications and Extinguishments*. The Company concluded debt extinguishment accounting treatment to be necessary and accordingly recorded aggregate debt extinguishment loss of approximately $9.3 million during the fiscal year ended May 31, 2021 as the difference between the fair market value of the shares issued and the carrying value of the debt retired, which included the amortization of the relative debt discount and issuance costs.

Long-term Convertible Note—November 2020 Note

On November 10, 2020, the Company entered into a securities purchase agreement pursuant to which the Company issued a secured convertible promissory note with a two-year term to an institutional accredited investor affiliated with the holder of the March 2020 and July 2020 Notes in the initial principal amount of $28.5 million (the "November 2020 Note"). The Company received consideration of $25.0 million, reflecting an original issue discount of $3.4 million and issuance costs of $0.1 million. The November 2020 Note is secured by all the assets of the Company, excluding the Company's intellectual property.

Interest accrues on the outstanding balance of the November 2020 Note at an annual rate of 10%. Upon the occurrence of an event of default, interest will accrue at the lesser of 22% per annum or the maximum rate permitted by applicable law. In addition, upon any event of default, the investor may accelerate the outstanding balance payable under the November 2020 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 November 2020 Note, which can be accessed through the Exhibit Index in this Form 10-K.

The investor may convert all or any part the outstanding balance of the November 2020 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 specified in the November 2020 Note. In addition to standard anti-dilution adjustments, the conversion price of the November 2020 Note is subject to full-ratchet anti-dilution protection, pursuant to which the conversion price will be automatically reduced to equal the effective price per share in any new offering by the Company of equity securities that have registration rights, are registered or become registered under the Securities Act of 1933, as amended. The November 2020 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 November 2020 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 November 2020 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 November 2020 Note, in part or in full, plus a 15% premium, at any time upon 15 trading days' notice. In addition, beginning in the month of November 2020 and for each of the following five months, the Company was obligated to reduce the outstanding balance of the November 2020 Note by $7.5 million per month (the "Debt Reduction Amount"). Payments the Company made under the March 2020 and July 2020 Notes were applied toward the payment of each monthly Debt Reduction Amount. These payments were not subject to the 15% prepayment premium, which would otherwise be triggered if the Company were to make payments against such notes exceeding the allowed maximum monthly redemption amount. Consistent with ASC 470-50-40-10, *Debt Modifications and Extinguishments*, the Company assessed the restructuring of the outstanding agreements with the investor as either a debt modification or debt extinguishment through performance of the 10% cash flow test. The Company noted the change in present value of future cash flows to be less than 10% for all modifications, and therefore, accounted for the restructuring as a debt modification.

Pursuant to the terms of the securities purchase agreement and the November 2020 Note, the Company must obtain the investor's consent before assuming additional debt with aggregate net proceeds to the Company of less than $25.0 million. In the event of any such approval, the outstanding principal balance of the November 2020 Note will increase automatically by 5% upon the issuance of such additional debt.

The Company filed a Registration Statement on Form S-3 (Registration No. 333-252154) with the SEC on January 15, 2021, which was declared effective on January 22, 2021, registering a number of shares of common stock sufficient to convert the entire principal balance of the November 2020 Note.

The embedded conversion feature in the November 2020 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 reconsiders 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, 2021, in satisfaction of the December 2020 Debt Reduction Amount, the Company and the investor entered into a separately negotiated exchange agreement, pursuant to which the November 2020 Note was partitioned into a new note (the "December 2020 Partitioned Note") with a principal balance equal to $7.5 million. The outstanding balance of the November 2020 Note was reduced by the December 2020 Partitioned Note, and the Company and the investor exchanged the December 2020 Partitioned Note for approximately 2.2 million shares of the Company's common stock. In satisfaction of the May 2021 Debt Reduction Amount, the Company and the investor entered into two separately negotiated exchange agreements, pursuant to which the November 2020 Note was partitioned

into two new notes (the "May 2021 Partitioned Notes") with a principal balance equal to an aggregate of $7.5 million. The outstanding balance of the November 2020 Note was reduced by the May 2021 Partitioned Notes, and the Company and the investor exchanged the May 2021 Partitioned Notes for approximately 4.2 million shares of the Company's common stock.

In connection with the December 2020 Partitioned Note and the May 2021 Partitioned Notes, the Company analyzed the restructured note for potential requirement of debt extinguishment accounting under ASC 470, *Debt Modifications and Extinguishments*. The Company concluded debt extinguishment accounting treatment to be necessary and accordingly recorded aggregate debt extinguishment loss of approximately $6.4 million during the fiscal year ended May 31, 2021 as the difference between the fair market value of the shares issued and the carrying value of the debt retired, which included the amortization of the relative debt discount and issuance costs.

Amortization of debt discounts and issuance costs associated with the November 2020 Note during the fiscal year ended May 31, 2021 amounted to approximately $2.3 million recorded as interest expense and loss on extinguishment in the consolidated statement of operations. The unamortized discount and issuance costs balance for the November 2020 Note is approximately $1.2 million as of May 31, 2021. The accrued interest balance for the November 2020 Note is approximately $1.3 million as of May 31, 2021 resulting from approximately $1.3 million of interest expense for the fiscal year ended May 31, 2021. The outstanding balance on the November 2020 Note, including accrued interest, was approximately $13.6 million as of May 31, 2021.

On June 11, 2021, June 21, 2021 and June 30, 2021, in satisfaction of the June 2021 Debt Redemption Amount, the Company and the investor entered into separately negotiated exchange agreements, pursuant to which the November 2020 Note was partitioned into new notes (the "June 2021 Partitioned Notes") with a principal balance equal to $6.0 million. The Company and the holder of the November 2020 Note agreed to defer the remaining $1.5 million June 2021 Debt Redemption Amount. The outstanding balance of the November 2020 Note was reduced by the June 2021 Partitioned Notes, and the Company and the investor exchanged the June 2021 Partitioned Notes for approximately 4.2 million shares of the Company's common stock. Following these payments, the outstanding balance on the November 2020 Note, including accrued interest, was approximately $7.9 million.

On July 14, 2021 and July 27, 2021, in satisfaction of the July 2021 Debt Reduction Amount, the Company and the November 2020 Note holder entered into exchange agreements, pursuant to which the November 2020 Note was partitioned into new notes (the "July 2021 Partitioned Notes") with a principal amount equal to $4.0 million. The Company and the holder of the November 2020 Note agreed to defer the remaining $3.5 million July 2021 Debt Redemption Amount. The outstanding balance of the November 2020 Note was reduced by the July 2021 Partitioned Notes. The Company and the investor exchanged the July 2021 Partitioned Notes for approximately 3.3 million shares of common stock. Following the June and July 2021 payments, the outstanding balance of the November 2020 Note, including accrued interest, was approximately $4.5 million.

Long-term Convertible Note—April 2, 2021 Note

On April 2, 2021, the Company entered into a securities purchase agreement pursuant to which the Company issued a secured convertible promissory note with a two-year term to an institutional accredited investor affiliated with the holder of the November 2020 Note in the initial principal amount of $28.5 million (the "April 2, 2021 Note"). The Company received consideration of $25.0 million, reflecting an original issue discount of $3.4 million and issuance costs of $0.1 million. The April 2, 2021 Note is secured by all the assets of the Company, excluding the Company's intellectual property.

Interest accrues on the outstanding balance of the April 2, 2021 Note at an annual rate of 10%. Upon the occurrence of an event of default, interest will accrue at the lesser of 22% per annum or the maximum rate permitted by applicable law. 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, which can be accessed through the Exhibit Index in this Form 10-K.

The investor may convert all or any part the outstanding balance of the April 2, 2021 Note into shares of common stock at an initial conversion price of $10.00 per share upon five trading days' notice, subject to certain adjustments and volume and ownership limitations specified in the April 2, 2021 Note. In addition to standard anti-dilution adjustments, the conversion price of the April 2, 2021 Note is subject to full-ratchet anti-dilution protection, pursuant to which the conversion price will be automatically reduced to equal the effective price per share in any new offering by the Company of equity securities that have registration rights, are registered or become registered under the Securities Act of 1933, as amended. The 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 April 2, 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 $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 April 2, 2021 Note, in part or in full, plus a 15% premium, at any time upon 15 trading days' notice. In addition, beginning in the month of May 2021 and for each of the following five months, the Company is obligated to reduce the outstanding balance of the April 2, 2021 Note by $7.5 million per month (the "Debt Reduction Amount"). Payments the Company makes under the November 2020 and April 23, 2021 Notes may be applied toward the payment of each Debt Reduction Amount. These payments were not subject to the 15% prepayment premium, which would otherwise be triggered if the Company were to make payments against such notes exceeding the allowed maximum monthly redemption amount. Consistent with ASC 470-50-40-10, *Debt Modifications and Extinguishments*, the Company will assess the restructuring of the outstanding agreements with the investor as either a debt modification or debt extinguishment through performance of the 10% cash flow test. The Company will assess if the change in present value of future cash flows is less than 10% for all modifications, and therefore, accounted for the restructuring as a debt modification.

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 Company is required to file a Registration Statement on Form S-3 with the SEC within 120 days of the April 2, 2021 Note's issuance, registering a number of shares of common stock sufficient to convert the entire principal balance of the April 2, 2021 Note. Subsequent to May 31, 2021, the Company obtained a 30 day extension.

The embedded conversion feature in 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 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 reconsiders the value of the default put provisions each reporting period to determine if the value becomes material to the financial statements.

Amortization of debt discounts and issuance costs associated with the April 2, 2021 Note during the fiscal year ended May 31, 2021 amounted to approximately $0.3 million. The unamortized discount and issuance costs balance for the April 2, 2021 Note is approximately $3.2 million as of May 31, 2021. The accrued interest balance for the April 2, 2021 Note is approximately $0.4 million as of May 31, 2021 resulting from approximately $0.4 million of interest expense for the fiscal year ended May 31, 2021. The outstanding balance on the April 2, 2021 Note, including accrued interest, was approximately $25.7 million as of May 31, 2021.

Long-term Convertible Note—April 23, 2021 Note

On April 23, 2021, the Company entered into a securities purchase agreement pursuant to which the Company issued a secured convertible promissory note with a two-year term to an institutional accredited investor affiliated with the holder

of the April 2, 2021 Note in the initial principal amount of $28.5 million (the "April 23, 2021 Note"). The Company received consideration of $25.0 million, reflecting an original issue discount of $3.4 million and issuance costs of $0.1 million. The April 23, 2021 Note is secured by all the assets of the Company, excluding the Company's intellectual property.

Interest accrues on the outstanding balance of the April 23, 2021 Note at an annual rate of 10%. Upon the occurrence of an event of default, interest will accrue at the lesser of 22% per annum or the maximum rate permitted by applicable law. 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, which can be accessed through the Exhibit Index in this Form 10-K.

The investor may convert all or any part the outstanding balance of the April 23, 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 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 of 1933, as amended. 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 Company is required to file a Registration Statement on Form S-3 with the SEC withing 120 days of the Notes' issuance, registering a number of shares of common stock sufficient to convert the entire principal balance of the April 23, 2021 Note.

The embedded 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 reconsiders the value of the default put provisions each reporting period to determine if the value becomes material to the financial statements.

Amortization of debt discounts and issuance costs associated with the April 23, 2021 Note during the fiscal year ended May 31, 2021 amounted to approximately $0.2 million. The unamortized discount and issuance costs balance for the April 23, 2021 Note is approximately $3.3 million as of May 31, 2021. The accrued interest balance for the April 23, 2021 Note is approximately $0.3 million as of May 31, 2021 resulting from approximately $0.3 million of interest expense for the fiscal year ended May 31, 2021. The outstanding balance on the April 23, 2021 Note, including accrued interest, was approximately $25.5 million as of May 31, 2021.

Note 6. Derivative Liabilities

The investor and placement agent warrants issued in connection with a registered direct offering in September 2016 contained a provision for net cash settlement if there is a fundamental transaction (contractually defined as a merger, sale of substantially all assets, tender offer or share exchange, whereby a person or group acquires more than 50% of the outstanding common stock). If a fundamental transaction occurs in which the consideration issued consists principally of cash or stock in a successor entity, then the warrant holder has the option to receive cash equal to the fair value of the remaining unexercised portion of the warrant. Due to this contingent cash settlement provision, the investor and placement agent warrants require liability classification as derivatives in accordance with ASC 480, *Distinguishing Liabilities from Equity,* and ASC 815, *Derivatives and Hedging,* and are recorded at fair value. All of the investors and placement agent warrants were exercised during the fiscal year ended May 31, 2020.

The following table summarizes the fair value of the warrant derivative liability and related common shares as of inception date (September 15, 2016), May 31, 2019 and May 31, 2020 (in thousands):

	Shares indexed	Derivative liability
Inception date September 15, 2016	7,733	$ 5,179
Change in fair value of derivative liability	—	(4,777)
Balance May 31, 2019	7,733	402
Change in fair value of derivative liability	—	11,547
Fair value of warrants exercised	7,733	(11,949)
Balance May 31, 2020	—	$ —

Changes in the fair value of the derivative liability are reported as “Change in fair value of derivative liabilities” in the Consolidated Statements of Operations. During the fiscal years ended May 31, 2020 and May 31, 2019 the Company recognized a non-cash (loss) gain of approximately ($11.5) million and $0.9 million, respectively, due to the changes in the fair value of the liability associated with such classified warrants.

ASC 820, *Fair Value Measurement,* provides requirements for disclosure of liabilities that are measured at fair value on a recurring basis in periods after the initial recognition. Fair values for the warrants were determined using a Binomial Lattice valuation model.

The Company estimated the fair value of the warrant derivative liability as of inception date (September 15, 2016), and May 31, 2019 using the following assumptions:

	September 15, 2016	May 31, 2019
Fair value of underlying stock	$ 0.78	$ 0.39
Risk free rate	1.20 %	1.94 %
Expected term (in years)	5	2.29
Stock price volatility	106 %	61 %
Expected dividend yield	—	—
Probability of fundamental transaction	50 %	50 %
Probability of holder requesting cash payment	50 %	50 %

Due to the fundamental transaction provision contained in the warrants, which could provide for early redemption of the warrants, the model also considered subjective assumptions related to the fundamental transaction provision. The fair value of the warrants will be significantly influenced by the fair value of the Company’s stock price, stock price volatility, changes in interest rates and management’s assumptions related to the fundamental transaction provisions.

As described in Note 5 above, the redemption provision embedded in the June 2018 and January 2019 Notes required bifurcation and measurement at fair value as a derivative. The fair value of the note redemption provision derivative liabilities was calculated using a Monte Carlo Simulation which uses randomly generated stock-price paths obtained

through a Geometric Brownian Motion stock price simulation. The fair value of the redemption provision will be significantly influenced by the fair value of the Company's stock price, stock price volatility, changes in interest rates, and management's assumptions related to the redemption factor. The Company estimated the fair value of the redemptive provision using the following assumptions on the closing dates of November 15, 2018, and January 30, 2019, and on May 31, 2019:

	November 15, 2018	January 30, 2019	May 31, 2019	
			June 2018 Note	January 2019 Note
Fair value of underlying stock	$ 0.57	$ 0.49	$ 0.39	$ 0.39
Risk free rate	2.78 %	2.52 %	2.21 %	1.95 %
Expected term (in years)	1.61	2	1.07	1.67
Stock price volatility	58.8 %	61 %	62.2 %	62.2 %
Expected dividend yield	—	—	—	—
Discount factor	85 %	85 %	85 %	85 %

As discussed above, the June 2018 and January 2019 Notes were fully satisfied and there is no outstanding balance as of May 31, 2021 or May 31, 2020.

The following table summarizes the fair value of the convertible note redemption provision derivative liability as of inception dates November 15, 2018 and January 30, 2019, and May 31, 2019 (in thousands):

	Net proceeds	Derivative liability	
		Inception date	May 31, 2019
Inception date June 2018 Note, November 15, 2018	$ 5,000	$ 1,285	$ 847
Inception date January 2019 Note, January 30, 2019	5,000	1,465	1,158
Total			$ 2,005

The Company recognized approximately $2.0 million and $0.4 million of non-cash gain, due to the changes in the fair value of the liability associated with such classified redemption provision for the fiscal year ended May 31, 2020 and May 31, 2019, respectively. There was no gain or loss for the fiscal year ended May 31, 2021, as the notes were fully satisfied during the fiscal year ended May 31, 2020.

Note 7. Equity Awards and Warrants

The Company has one active stock-based equity plan at May 31, 2021, the CytoDyn Inc. Amended and Restated 2012 Equity Incentive Plan (the "2012 Plan") and one stock-based equity plan that is no longer active, but under which certain prior awards remain outstanding, the CytoDyn Inc. 2004 Stock Incentive Plan (the "2004 Plan" and, together with the 2012 Plan, the "Incentive Plans"). In September 2020, the stockholders approved the CytoDyn Inc. Amended and Restated 2012 Equity Incentive Plan to increase the number of shares available for issuance from 25 million to 50 million shares, among other amendments. The total number of shares available to be issued will increase on the first day of each fiscal year in an amount equal to 1% of the total outstanding shares on the last day of the prior fiscal year, and the term of the Plan was extended for an additional 10 years to September 30, 2030. As of May 31, 2021, the Company had 15.3 million shares available for future stock-based grants under the 2012 Plan.

Stock Options and Other Equity Awards

During the fiscal year ended May 31, 2021, the Company granted stock options, covering a total of approximately 2.3 million shares of common stock to non-executive employees and consultants, with exercise prices ranging between $2.02 and $6.15 per share. These stock option awards vest annually over three years, with a ten-year term and grant date fair values ranging between $1.53 and $4.46 per share.

During the fiscal year ended May 31, 2021, the Company issued approximately 2.6 million shares of common stock in connection with the exercise of stock options. The stated exercise prices ranged from $0.30 to $1.40 per share which

resulted in aggregate gross proceeds of approximately $1.8 million to the Company. As of May 31, 2021 and May 31, 2020 approximately 12.8 million and 12.9 million vested stock options and approximately 5.8 million and 2.7 million unvested stock options were outstanding, respectively.

Upon stockholder approval of the amended 2012 Plan in September 2020, the Company issued to executives of the Company non-qualified stock options covering 3.35 million shares of common stock, time-vested restricted stock units ("RSUs") covering 1.12 million shares of common stock, and performance-based RSUs ("PSUs") covering 4.35 million shares of common stock (the "September 2020 Performance Shares"). The stock options have a per share exercise price of $3.12, grant date fair value of $2.12 per share, and vest in three equal installments beginning on the first anniversary of the grant date. The RSUs similarly vest over three years and have a grant date fair value of $3.12 per share. The issuance of common stock underlying the PSUs granted for performance in fiscal year ending May 31, 2021 are subject to the Compensation Committee's determination if, and to what extent, certain performance conditions set forth in the awards are met. On June 25, 2020, the Board approved the grant of stock options to three non-employee directors covering a total of 675,000 shares of common stock as the equity portion of the annual director compensation program, of which 506,250 options were subject to stockholder approval of the amended 2012 Plan. The options were issued with a per share exercise price of $6.15 and grant date fair value of $4.20 per share, and vested in four equal quarterly installments beginning on August 31, 2020.

Warrants

During the fiscal year ended May 31, 2021, the Company issued compensatory warrants covering a total of approximately 0.1 million shares of common stock to consultants. The warrants have a five-year term and an exercise price of $3.07. The grant date fair value of these warrants was $2.11 per share.

During the fiscal year ended May 31, 2021, the Company issued approximately 27.3 million shares of common stock in connection with the exercise of an equal number of warrants. The stated exercise prices ranged from $0.30 to $1.35 per share, which resulted in aggregate gross proceeds of approximately $19.4 million. Additionally, during the fiscal year ended May 31, 2021, the Company issued approximately 10.6 million shares of common stock in connection with the cashless exercise of approximately 11.7 million warrants with stated exercise prices ranging from $0.40 to $1.35. In connection with various private warrant exchange agreements during the fiscal year ended May 31, 2021, the Company issued approximately 37.1 million shares of common stock in connection with the exercise of approximately 34.1 million warrants. See Note 11.

Compensation expense related to stock options and warrants for the fiscal years ended May 31, 2021, May 31, 2020 and May 31, 2019 was approximately $8.8 million, $6.5 million and $3.4 million, respectively. The grant date fair value of options and warrants vested during the fiscal years ended May 31, 2021, May 31, 2020, and May 31, 2019 was approximately $4.7 million, $3.3 million, and $2.1 million, respectively. As of May 31, 2021, there was approximately $8.2 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 1.46 years.

The following table represents stock option and warrant activity for the years ended May 31, 2020 and May 31, 2021:

	Number of shares	Weighted average exercise price	Weighted average remaining contractual life in years	Aggregate intrinsic value
Options and warrants outstanding May 31, 2019	178,592	$ 0.71	3.66	$ 896
Granted	57,720	$ 0.47	—	—
Exercised	(101,853)	$ 0.56	—	—
Forfeited, expired, and cancelled	(3,099)	$ 0.74	—	—
Options and warrants outstanding May 31, 2020	131,360	$ 0.65	5.79	$ 302,961
Granted	7,036	$ 3.82	—	—
Exercised	(75,735)	$ 0.59	—	—
Forfeited, expired, and cancelled	(1,088)	$ 1.66	—	—
Options and warrants outstanding May 31, 2021	61,573	$ 0.95	4.40	$ 68,756
Outstanding exercisable May 31, 2021	55,713	$ 0.78	3.98	$ 67,151

Note 8. Acquisition of Patents and Intangibles

The following presents intangible assets activity, inclusive of patents (in thousands):

	May 31, 2021	May 31, 2020
Leronlimab (PRO 140) patent	$ 3,500	$ 3,500
ProstaGene, LLC intangible asset acquisition, net of impairment	2,926	15,126
Website development costs	20	20
Gross carrying value	6,446	18,646
Accumulated amortization, net of impairment	(4,793)	(5,190)
Total amortizable intangible assets, net	$ 1,653	$ 13,456

Amortization expense related to all intangible assets for the fiscal year ended May 31, 2021, May 31, 2020, and May 31, 2019 was approximately $1.8 million, $2.0 million and $1.2 million, respectively. The following table summarizes the estimated aggregate future amortization expense related to the Company's intangible assets with finite lives as of May 31, 2021 (in thousands):

Fiscal Year	Amount
2022	$ 669
2023	384
2024	85
2025	85
Thereafter	430
Total	$ 1,653

The Company consummated an asset purchase on October 16, 2012, and paid $3.5 million for certain assets, including intellectual property, certain related licenses and sublicenses, FDA filings and various forms of the leronlimab (PRO 140) drug substance. The Company followed the guidance in ASC 805, *Business Combinations,* to determine if the Company acquired a business. Based on the prescribed accounting, the Company acquired assets and not a business. As of May 31, 2021 and May 31, 2020, the Company has recorded and is amortizing $3.5 million of intangible assets related to the patent rights acquired. The Company estimates the acquired patent has an estimated life of ten years. Subsequent to the acquisition date, the Company has continued to expand, amend and file new patents central to its current clinical trial strategies, which, in turn, have extended the protection period for certain methods of using leronlimab and formulations comprising leronlimab through at least 2031 and 2038, respectively, in various countries.

On November 16, 2018, the Company completed the acquisition of substantially all the assets of ProstaGene, LLC ("ProstaGene"), a biotechnology start-up company, which included patents related to clinical research, a proprietary CCR5 algorithm technology for early cancer diagnosis, and a noncompetition agreement with ProstaGene's founder and Chief Executive Officer, Richard G. Pestell. The Company accounted for the ProstaGene acquisition as an asset acquisition under ASC 805-10-55, *Business Combinations,* because the assets acquired from ProstaGene did not include an assembled workforce, and the gross value of the assets acquired met the screen test in ASC 805-10-55-5A related to substantially all of the fair value being concentrated in a single asset or group of assets (i.e., the proprietary technology and patents) and, thus, is not considered a business. Thus, management concluded that the acquisition did not include both an input and substantive processes that together significantly contribute to the ability to create outputs. The acquisition of ProstaGene's assets expanded the Company's clinical development of leronlimab into cancer indications and potential commercialization of certain cancer diagnostic tests. The aggregate purchase price of the ProstaGene acquisition was approximately $11.6 million based on the issuance of approximately 20.3 million shares of the Company's common stock at $0.57 per share, including approximately 1.6 million shares issued to an investment bank for advisory services.

A summary of the net purchase price and allocation to the acquired assets is as follows (in thousands):

	ProstaGene, LLC
CytoDyn Inc. equity	$ 11,558
Acquisition expenses	741
Release of deferred tax asset	2,827
Total cost of acquisition	$ 15,126
Intangible assets	$ 15,126
Other	—
Allocation of acquisition costs	$ 15,126

Assets acquired from ProstaGene included (1) patents issued in the United States and Australia related to "Prostate Cancer Cell Lines, Gene Signatures and Uses Thereof" and "Use of Modulators of CCR5 in the Treatment of Cancer and Cancer Metastasis," (2) an algorithm used to identify a 14-gene signature to predict the likelihood and severity of cancer diagnoses, and (3) a noncompetition agreement in connection with an employment agreement with Dr. Pestell as Chief Medical Officer of the Company. The fair value of the assets acquired approximated the consideration paid. The Company did not assume any liabilities.

The fair value of the technology acquired was identified using the Income Approach. The fair value of the patents acquired is identified using the Cost to Reproduce Method. The fair value of the noncompetition agreement acquired was identified using the Residual Value Method. Goodwill was not recorded as the transaction represented an asset acquisition in accordance with ASU 2017-01. Acquisition costs for asset acquisitions are capitalized and included in the total cost of the transaction. In addition, pursuant to ASC 805, the net tax effect of the deferred tax liability arising from the book to tax basis differences was recorded as a cost of the acquisition.

The Company concluded a five-day arbitration hearing on March 19, 2021 concerning a claim by ProstaGene for approximately 3.1 million shares of common stock that the Company withheld for damages incurred by the Company in connection with the acquisition of the proprietary algorithm intangible asset from ProstaGene in November 2018. Expert testimony and report during the arbitration hearing revealed the stage of development was low, among other issues, and projected the technology would require a sizable amount of incremental capital and development time to advance towards a possible monetization. Based on this expert testimony and report, it was management's conclusion the net carrying value of the proprietary algorithm is fully impaired. As such, the Company recorded an intangible asset impairment charge of approximately $10.0 million during the quarter ended February 28, 2021 resulting from the write-off of the allocated purchase price of $12.2 million and $2.2 million of associated accumulated amortization.

In connection with the ProstaGene purchase transaction, the Company entered into a Stock Restriction Agreement with Dr. Pestell, (the "Stock Restriction Agreement"), restricting the transfer of approximately 8.3 million shares of common stock (the "Restricted Shares") issued to Dr. Pestell. The Stock Restriction Agreement provided that, in the event Dr. Pestell's employment with the Company were terminated by Dr. Pestell other than for Good Reason or by the

Company for Cause, as defined in Dr. Pestell's employment agreement with the Company, the Company would have an option to repurchase the Restricted Shares from Dr. Pestell at a purchase price of $0.001 per share. The Restricted Shares were to vest and be released from the Stock Restriction Agreement in three equal annual installments commencing on November 16, 2019. On July 25, 2019, the Board terminated the employment of Dr. Pestell prior to the vesting of any of the Restricted Shares. The Restricted Shares are subject to litigation between the Company and Dr. Pestell. See Note 10.

As of May 31, 2021 and May 31, 2020, the Company has recorded and is amortizing $4.6 million of intangible assets in the form of patents attributable to the leronlimab acquisition and the ProstaGene transaction. The Company estimates the acquired patents have an estimated life of ten years. Subsequent to the acquisition dates, the Company has continued to expand, amend and file new patents central to its current clinical trial strategies, which, in turn, have extended the protection period for certain methods of using leronlimab and formulations comprising PRO 140 through at least 2031 and 2038, respectively, in various countries.

Note 9. License Agreements

The Company has two license agreements with a third-party licensor covering the licensor's "system know-how" technology with respect to the Company's use of proprietary cell lines to manufacture new leronlimab material. The Company accrues annual license fees of £0.6 million (approximately $0.8 million based on current exchange rates), which fees are payable annually in December. Future annual license fees and royalty rate will vary depending on whether the Company manufactures leronlimab, utilizes the third-party licensor as a contract manufacturer, or utilizes an independent party as a contract manufacturer. The licensor does not charge an annual license fee when it serves as the manufacturer. In addition, the Company will incur royalties of up to 0.75% to 2.0% of net sales, depending on who serves as the manufacturer, when the Company commences its first commercial sale, which will continue as long as the license agreement is maintained. For the fiscal years ended May 31, 2021 and May 31, 2020 the Company recorded a prepaid asset of approximately $0.1 million related to this arrangement.

Note 10. Commitments and Contingencies

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

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

Fiscal Year	Amount
2022	$ 46,961
2023	96,126
2024	58,528
2025	7,200
Total	$ 208,815

Commitments with Contract Research Organization ("CRO")

The Company has entered into project work orders, as amended, for each of our clinical trials with our CRO and related laboratory vendors. Under the terms of these agreements, the Company incurs execution fees for direct services costs, which are recorded as a current asset. In the event the Company were to terminate any trial, it may incur certain financial penalties that would become payable to the CRO. Conditioned upon the form of termination of any one trial, the financial penalties may range up to approximately $3.4 million. In the remote circumstance that the Company would

terminate all clinical trials, the collective financial penalties may range from a low of approximately $2.0 million to an approximate high of approximately $3.7 million.

Operating Leases

We lease our principal office location in Vancouver, Washington and office in Fort Lauderdale, Florida. The Vancouver and Fort Lauderdale leases expire on April 30, 2026 and on March 31, 2022, respectively. The Fort Lauderdale office is currently being sublet to a tenant. Consistent with the guidance in ASC 842, we have recorded the leases in our consolidated balance sheet as operating leases. For the purpose of determining the ROU asset and associated lease liability, we determined that the renewal of the Vancouver lease was reasonably probable. The leases of our Vancouver and Fort Lauderdale offices do not include any restrictions or covenants requiring special treatment under ASC 842. During the fiscal years ended May 31, 2021 and 2020, we recognized $0.3 million and $0.2 million of operating lease costs.

The following table summarizes the presentation of the operating leases in our consolidated balance sheet at May 31, 2021 and 2020 (in thousands):

	May 31,	
	2021	2020
Assets		
Right of use asset	$ 712	$ 176
Liabilities		
Current operating lease liability	$ 175	$ 115
Non-current operating lease liability	552	63
Total operating lease liability	$ 727	$ 178

The minimum (base rental) lease payments reconciled to the carrying value of the operating lease liabilities as of May 31, 2021 are expected to be as follows (in thousands):

Fiscal Year	Amount
2022	$ 202
2023	225
2024	175
2025	180
2026	183
Total operating lease payments	965
Less imputed interest	(238)
Present value of operating lease liabilities	$ 727

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.

As of May 31, 2021, the Company recorded legal accruals of approximately $10.6 million related to the outcomes of the matters described below. The Company did not record any accruals as of May 31, 2020.

Delaware Shareholder Derivative Lawsuit

On April 24, 2020, certain stockholders of the Company (the "Plaintiffs") filed a derivative action in the Delaware Court of Chancery (the "Delaware Court"), alleging claims for breach of fiduciary duty and unjust enrichment against the Company's CEO, former CFOs, CMO, and certain current and former members of the Board (the "Defendants"), in connection with certain equity awards to these individuals granted in December 2019 and January 2020 (the "December 2019 Awards"). The Company was named a nominal defendant in the lawsuit. The Plaintiffs demanded the rescission of the December 19 Awards, a finding that the named directors breached their fiduciary duty to the Company, and an unspecified amount of damages. The Company appointed a Special Litigation Committee (the "SLC"), consisting solely of independent directors not named in the complaint, to investigate the allegations in the complaint.

On December 15, 2020, the Defendants reached an agreement in principle with the SLC (collectively, "Parties") to resolve the lawsuit. On December 18, 2020, the Parties executed a memorandum of understanding outlining the key terms of their agreement. On January 27, 2021, the Parties entered into a proposed Stipulation and Agreement of Compromise, Settlement, and Release (the "Stipulation") to settle the derivative action. Pursuant to the Stipulation, the current directors agreed to implement a series of corporate governance reforms related to director and executive officer compensation and certain Defendants agreed to forfeit a substantial portion of the December 2019 Awards following approval of the settlement by the Delaware Court, in exchange for a release of claims and the dismissal of the derivative action with prejudice.

The corporate governance reforms to be implemented pursuant to the Stipulation comprised:

- exploring the addition of a new director who meets NASDAQ standards for independence;
- reconstitution of the Compensation Committee to consist of at least three independent directors; and
- adoption of a five-year executive officer and director compensation policy requiring the Compensation Committee to:
    - develop and approve compensation,
    - retain and receive written recommendations of an independent compensation advisor to assist the Compensation Committee with the determination of the types and levels of compensation;
    - perform at a minimum an annual assessment of compensation levels and structure of its peer group based on discussions with its independent compensation advisor with regard to relevance, in particular, companies in the same industry and of similar market capitalization;
    - only determine compensation on an annual basis with the exception of new additions, promotions, or exceptional circumstances as determined by the Compensation Committee; and
    - adopt a prohibition on bonuses for nonemployee directors based on Company performance.

The Board appointed a new director, expanded the membership of the Compensation Committee, and approved the executive officer and director compensation policy as described above effective prior to the deadline set forth in the Stipulation.

The December 2019 Awards were forfeited effective June 4, 2021 as follows: 100% of the December 19 Awards to Michael A. Klump, Jordan G. Naydenov, and David F. Welch, Ph.D., covering 2.25 million shares, 60% of the December 2019 Award to Scott A. Kelly, M.D., covering 0.75 million shares; and 100% of the warrant to acquire 2.0 million shares issued to Nader Z. Pourhassan, Ph.D. In addition, Dr. Pourhassan forfeited vested options to purchase approximately 0.4 million shares from the December 2019 Awards. The Delaware Court held hearings on April 19 and June 4, 2021, and approved the Stipulation at the hearing on June 4, 2021.

On March 19, 2021, the Plaintiffs filed a brief agreeing to the proposed settlement and seeking an award of approximately $4.1 million for bringing the lawsuit. Plaintiff's demand was based on the claimed value or benefit to the Company and its stockholders from the value of the forfeited equity awards, in addition to the time incurred by the Plaintiffs' attorneys with regard to this action. On April 8, 2021, the SLC filed a brief opposing the Plaintiffs' motion

contending that the amount of the award demanded was not legally supported. Following a hearing on June 4, 2021, the Delaware Court issued a ruling granting the Plaintiffs' fee application in the amount of $3.0 million, inclusive of expenses, for which the Company fully accrued as of May 31, 2021.

September 2020 Washington Shareholder Derivative Lawsuit

On September 10, 2020, the same Plaintiffs as in the Delaware Shareholder Derivative Lawsuit filed another derivative action against CEO Nader Z. Pourhassan, Ph.D. claiming that he had violated Section 16(b) of the Securities Exchange Act of 1934 with respect to certain personal stock transactions in the Company's stock. The parties filed cross-motions to dismiss. On March 12, 2021, the U.S. District Court for the Western District of Washington (the "U.S. District Court") granted Dr. Pourhassan's motion to dismiss with prejudice. On April 9, 2021, the Plaintiffs filed a Notice of Appeal to the Ninth Circuit Court of Appeals appealing the decision of the U.S. District Court. The Plaintiffs filed their opening brief with the Ninth Circuit on July 8, 2021.

Placement Agent Arbitration Claim

On April 29, 2020, Torreya Capital LLC ("Torreya") filed an arbitration claim against the Company demanding payment of a transaction fee in the amount of $0.6 million plus attorney fees, for the Company's alleged failure to pay a transaction fee to Torreya under the terms of its engagement letter with the Company, and amended its claim on September 17, 2020 to add an additional transaction fee claim, increasing its demand to approximately $1.8 million. The Company denied Torreya's contractual right to any fee under the terms of the engagement letter. The parties filed dispositive motions in August 2020 and September 2020, which the arbitrator denied on October 5, 2020. On February 18, 2021, a one-day arbitration hearing was held to determine Torreya's right to approximately $1.8 million in transaction fees plus attorney fees. Closing briefs were filed on April 1, 2021. On April 22, 2021, the arbitrator ruled in favor of the Company, denied Torreya's claim for any fees or legal costs and awarded the Company legal fees and costs of approximately $0.1 million.

Pestell Employment Dispute

On July 25, 2019, the Company's Board terminated the employment of Dr. Pestell, the Company's former Chief Medical Officer, for cause pursuant to the terms of Dr. Pestell's employment agreement. On August 22, 2019, Dr. Pestell filed a lawsuit in the U.S. District Court for the District of Delaware (Pestell v. CytoDyn Inc., et al.), against the Company, its Chief Executive Officer and the Chairman of the Board, alleging breach of the employment agreement, a failure to pay wages and defamation, among other claims, and seeking damages related to severance entitlements for a non-cause termination under the employment agreement and a stock restriction agreement, among other relief. The treatment of those entitlements, including severance and approximately 0.4 million unvested stock options and 8.3 shares of unvested restricted common stock, in each case granted or issued on November 16, 2018 and which vest ratably over three years or upon a non-cause termination, are expected to be determined by the outcome of this litigation. It is possible that if a court ruled in favor of Dr. Pestell on the equity entitlements, it would award damages based on a decline in the value of the shares. On November 2, 2020, the Court dismissed Dr. Pestell's wage claims with prejudice and the Company's Chief Executive Officer and the Chairman of the Board were dismissed from the proceeding. The Company filed its answer and counterclaims thereafter. A bench trial is currently set for April 2022. The Company disputes all of Dr. Pestell's claims and intends to vigorously defend the action. The Company cannot predict the ultimate outcome and cannot reasonably estimate the potential loss or range of loss that the Company may incur.

ProstaGene Arbitration

On March 19, 2021, the Company concluded a five-day arbitration hearing concerning a claim by ProstaGene and counterclaims by the Company for approximately 3.1 million shares of the Company's common stock held in escrow as holdback stock pursuant to the transaction agreement for the acquisition of certain intangible assets from ProstaGene in November 2018. The Company recognized a full impairment charge against the net carrying value of a certain acquired intangible asset in the quarter ended February 28, 2021. See Note 8 of the Notes to Consolidated Financial Statements included herein above. Notwithstanding the foregoing, ProstaGene also sought monetary damages, in an amount to be determined by the arbitration panel, including any lost value in stock price and its attorney fees and costs. Post-hearing

briefing concluded mid-May 2021. The Company disputed ProstaGene's claim and has vigorously defended against that claim, and the Company believes its counterclaims are meritorious and had vigorously prosecuted its counterclaims. Nonetheless, on July 2, 2021, an arbitration panel determined that ProstaGene is entitled to release of the Shares, as well as a cash monetary award in the amount of approximately $6.2 million, plus interest, fees and costs estimated to total approximately $1.4 million. The Company satisfied the arbitration award obligations in July 2021.

Securities Class Action Lawsuits

On March 17, 2021, a stockholder filed a putative class-action lawsuit in the U.S. District Court against the Company and certain current and former officers. The complaint generally alleges that the defendants made false and misleading statements regarding the viability of leronlimab as a potential treatment for COVID-19. The plaintiff seeks a ruling that this case may proceed as a class action, and seeks unspecified damages and attorneys' fees and costs. 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. Motions to appoint a lead plaintiff for the lawsuit are pending. The Company and the individual defendants deny any allegations of wrongdoing in the complaint and intend to vigorously defend the matter. In light of the fact that this case is in its early stage, the number of plaintiffs are not known, and the claims do not specify an amount of damages, the Company cannot predict the ultimate outcome of the lawsuit and cannot reasonably estimate the potential loss or range of loss that the Company may incur.

June 2021 Washington Shareholder Derivative Lawsuits

On June 4, 2021, a purported shareholder derivative lawsuit was filed against certain of the Company's current and former officers, certain board members, and the Company as a nominal defendant, in the U.S. District Court ("First Derivative Suit"). The complaint generally alleges that the director defendants breached fiduciary duties owed to the Company by allowing the Company to make false and misleading statements regarding the viability of leronlimab as a potential treatment for COVID-19 and by failing to maintain an adequate system of oversight and internal controls. The complaint asserts claims against one or more individual defendants for breach of fiduciary duty, waste of corporate assets, and unjust enrichment, and seeks to recover on behalf of the Company for any liability the Company incurs as a result of the individual defendants' alleged misconduct. The complaint also seeks contribution on behalf of the Company from certain individual defendants for their alleged violations of federal securities laws. The complaint seeks declaratory and equitable relief, an unspecified amount of damages, and attorneys' fees and costs. On June 25, 2021, a second shareholder derivative lawsuit was filed against the same defendants in the same court ("Second Derivative Suit", and together with the First Derivative Suit, "Derivative Suits"), which includes allegations and claims similar to those made in the First Derivative Suit, adds claims against certain individual defendants based on allegedly false and misleading proxy statement disclosures and for breach of fiduciary duty arising from alleged insider trading, and seeks similar relief as the First Derivative Suit. The Company and the individual defendants deny any allegations of wrongdoing in the complaints and intend to vigorously defend the litigation. In light of the fact that these cases are in their early stages and the claims do not specify an amount of damages, the Company cannot predict the ultimate outcome of the Derivative Suits and cannot reasonably estimate the potential loss or range of loss that the Company may incur.

Securities and Exchange Commission and Department of Justice Investigations

The Company has received subpoenas from the United States Securities and Exchange Commission 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 and related communications with the FDA, investors, and others, and trading in the securities of CytoDyn. The SEC has informed the Company that this inquiry should not be construed as an indication that any violations of law have occurred or that the SEC has any negative opinion of any person, entity or securities trading activity.

In addition, the Company and certain of its executives have received subpoenas in connection with an investigation being conducted by the United States Department of Justice. The subpoenas seek testimony and/or records concerning, among other matters, leronlimab, the Company's public statements regarding the use of leronlimab as a potential treatment for COVID-19 and related communications with the FDA, investors, and others, and trading in the securities of CytoDyn.

The Company is cooperating fully with these non-public, fact-finding investigations, and as of the date of this filing, the Company is unable to predict the ultimate outcome and cannot reasonably estimate the potential possible loss or range of loss, if any.

Note 11. Public Warrant Tender Offers

During June 1, 2019 to July 31, 2019, the Company conducted two public warrant tender offers, in which accredited investors purchased common stock at either $0.30 or $0.40 per share. Pursuant to the offers, the Company sold a total of approximately 45.4 million shares of common stock, $0.001 par value, for aggregate gross proceeds of approximately $11.9 million. The Company paid placement agent fees of approximately $1.1 million for services in connection with the tender offers. The Company also recorded a non-cash inducement interest expense of approximately $2.4 million in connection with the tender offers.

Note 12. Private Equity Securities Offerings

On March 20, 2019, the Company issued in private placements to accredited investors an aggregate of 3,246 shares of its Series C Preferred Stock, together with warrants to purchase an aggregate of up to approximately 3.9 million shares of its common stock, with an initial exercise price of $0.50 per share, for aggregate gross proceeds to the Company of approximately $3.2 million. In connection with the private placement, the Company issued and sold to certain lead investors additional warrants to purchase an aggregate of up to 1.0 million shares of Common Stock, on identical terms to the other warrants issued to investors.

On August 29, 2019 the Company issued the remaining 1,754 shares of Series C Preferred Stock at $1,000.00 per share for cash proceeds totaling approximately $1.5 million, net of placement agent fees and legal fees totaling approximately $0.2 million.

During the three months ended August 31, 2019, in connection with a Series C convertible preferred offering, as fully described in Note 4, the Company issued common stock warrants covering a total of approximately 2.6 million shares of common stock to investors. The investor warrants have a five-year term and an exercise price of $0.50 per share.

On October 11, 2019, the Company amended its certificate of designation to authorized an increase in authorized Series C Preferred Stock from 5,000 shares to 20,000 shares. Between October 21, 2019 and November 8, 2019, the Company issued an additional 2,788 shares of Series C Convertible Preferred Stock, and on December 6, 2020 the Company issued 415 shares of Series C Convertible Preferred Stock. On January 28, 2020, the Company further amended its Series C Certificate of Designation to reduce the number of authorized shares of Series C Preferred Stock from 20,000 shares to 8,203 shares, all of which remain outstanding as of May 31, 2020.

During the year ended May 31, 2019, the Company conducted private equity offerings (the “2019 Equity Offerings”), in which accredited investors purchased unregistered shares of common stock at $0.50 per share with warrant coverage of 50% based on the number of shares purchased. Pursuant to the 2019 Equity Offerings, the Company sold a total of approximately 47.0 million shares for aggregate gross proceeds of approximately $23.5 million and issued five-year warrants covering approximately 23.5 million shares, with an exercise price of $0.75 per share. In conjunction with the 2019 Equity Offerings, the Company paid an aggregate cash fee of approximately $2.7 million to the placement agent and issued warrants covering an aggregate of approximately 4.4 million shares to the placement agent as additional compensation.

On July 31, 2019, the Company concluded a private warrant exchange in which accredited investors purchased unregistered shares of common stock at the lower of the stated exercise price on their warrant or $0.40 per share. The Company sold a total of approximately 7.5 million shares, as well as approximately 3.8 million additional shares as an inducement to exercise their warrants, for a total of approximately 11.3 million shares. Aggregate gross proceeds from the private warrant exchange were approximately $3.0 million. In conjunction with the private warrant exchange, the Company incurred a non-cash inducement interest expense of approximately $0.2 million and paid an aggregate cash fee of approximately $0.3 million to the placement agent. See Note 17.

On December 20, 2019, the Company entered into a private warrant exchange in which certain accredited investors purchased unregistered shares of common stock at a range of $0.22 to $0.25 per share as compared to the stated exercise prices ranging from $0.45 to $0.75 per share. The Company sold approximately 3.4 million shares, as well as approximately 1.3 million additional shares as an inducement to exercise their warrants, for a total of approximately 4.7 million shares. Aggregate gross proceeds from the private warrant exchange were approximately $0.8 million.

On December 30, 2019, the Company entered into a private warrant exchange in which certain accredited investors purchased unregistered shares of common stock at a reduced exercise price per share of $0.50 for any warrant with a stated exercise price greater than $0.50 per share and no discount for warrants with a stated exercise price equal to or less than $0.50 per share. The Company sold 2.2 million shares, as well as 0.5 million additional shares as an inducement to exercise their warrants, for a total of approximately 2.7 million shares. Aggregate gross proceeds from the private warrant exchange were approximately $1.1 million.

On January 31, 2020, the Company issued 7,570 shares of Series D Convertible Preferred Stock, $0.001 par value per share ("Series D Preferred Stock"), at $1,000.00 per share for cash proceeds totaling approximately $7.6 million, net of offering costs of $4,645.

On March 13, 2020, the Company entered into subscription agreements with certain investors for the sale of 882 shares of Series D convertible preferred stock at a purchase price of $1,000.00 per share ("March 13, 2020 offering"). The investors in the March 13, 2020 offering also received warrants to purchase approximately 0.3 million shares of common stock with an exercise price of $1.00 per share and a five-year term. The Company received net proceeds from the March 13, 2020 offering of approximately $0.9 million.

During January 2020, the Company entered into a private warrant exchange in which certain accredited investors purchased unregistered shares of common stock at a reduced exercise price per share of $0.50 for any warrant with a stated exercise price greater than $0.50 per share and no discount for warrants with a stated exercise price equal to or less than $0.50 per share. The Company issued approximately 4.0 million shares, as well as approximately 0.4 million additional shares as an inducement to exercise their warrants, for a total of approximately 4.4 million shares. Aggregate gross proceeds from the private warrant exchange were approximately $1.9 million.

On February 28, 2020, the Company entered into a private warrant exchange in which certain accredited investors purchased unregistered shares of common stock at a range of $0.18 to $0.45 per share as compared to the stated exercise prices on their warrants, which ranged from $0.30 to $0.75 per share. The Company issued approximately 7.8 million shares, as well as approximately 0.8 million additional shares as an inducement to exercise their warrants, for a total of approximately 8.6 million shares. Aggregate gross proceeds from the private warrant exchange were approximately $2.2 million.

On March 4, 2020, the Completed a private warrant exchange in which an accredited investor purchased shares of common stock at a price of $0.45 per share as compared to the stated exercise price of $0.75. The Company issued 80,000 shares, as well as 8,000 additional shares as an inducement to the investor to exercise the warrants, for a total of 88,000 shares, resulting in gross proceeds of approximately $36,000.

For the fiscal year-ended May 31, 2020 the Company recorded non-cash inducement interest expense totaling approximately $5.5 million in connection with the private warrant exchange offerings.

On June 17, 2020, the Company entered into privately negotiated warrant exchange agreements with certain accredited investors, pursuant to which the investors purchased shares of common stock at a range of $0.21 to $0.70 per share in exchange for warrants with exercise prices ranging from $0.35 to $1.35 per share. The Company issued approximately 16.5 million shares in exchange for approximately 16.5 million warrants to purchase common stock, which resulted in net aggregate proceeds of approximately $7.4 million after offering costs of approximately $0.4 million. In connection with this transaction, the Company recognized approximately $3.3 million in non-cash inducement interest expense.

On October 14, 2020, the Company entered into privately negotiated warrant exchange agreements with certain accredited investors, pursuant to which the investors purchased common stock at a range of $0.24 to $0.80 per share in

exchange for warrants with exercise prices ranging from $0.30 to $1.00 per share. The Company issued approximately 7.0 million shares of common stock, $0.001 par value, in exchange for approximately 6.4 million warrants to purchase common stock, which resulted in net aggregate proceeds of approximately $2.7 million. In connection with this transaction, the Company recognized approximately $2.2 million of non-cash inducement interest expense.

On October 26, 2020, the Company entered into privately negotiated warrant exchange agreements with certain accredited investors, pursuant to which the investors purchased shares of common stock at a range of $0.24 to $0.60 per share in exchange for warrants with an exercise prices ranging from $0.30 to $0.75 per share. The Company issued approximately 5.0 million shares in exchange for approximately 4.5 million warrants to purchase common stock, which resulted in net aggregate proceeds of approximately $1.6 million. In connection with this transaction, the Company recognized approximately $1.4 million of non-cash inducement interest expense.

On November 30, 2020, the Company entered into privately negotiated warrant exchange agreements with certain accredited investors, pursuant to which the investors purchased shares of common stock at $0.60 per share in exchange for warrants with an exercise price of $0.75 per share. The Company issued approximately 0.5 million shares in exchange for 0.5 million warrants to purchase common stock, which resulted in net aggregate proceeds of approximately $0.3 million. In connection with this transaction, the Company recognized approximately $0.2 million of non-cash inducement interest expense.

On November 17, 2020, the Company sold approximately 0.67 million unregistered shares of common stock at a purchase price of $1.50 per share to Christopher P. Recknor, M.D., Chief Operating Officer, who was a non-executive at the time of the transaction, for aggregate proceeds to the Company of $1.0 million. The transaction was approved by the Board. See Note 17.

On December 4, 2020, the Company entered into a privately negotiated warrant exchange agreement with an accredited investor, pursuant to which the investor purchased shares of common stock at $0.36 per share in exchange for warrants with an exercise price of $0.45 per share of common stock. The Company issued approximately 0.3 million shares of common stock, $0.001 par value, in exchange for approximately 0.3 million warrants to purchase common stock, which resulted in net aggregate proceeds of approximately $0.1 million. In connection with this transaction, the Company recognized approximately $0.1 million of non-cash inducement interest expense.

On December 8, 2020, the Company entered into a privately negotiated warrant exchange agreement with an accredited investor, pursuant to which the investor purchased shares of common stock at $0.24 per share in exchange for warrants with an exercise price of $0.30 per share. The Company issued approximately 2.0 million shares in exchange for approximately 1.9 million warrants to purchase common stock, which resulted in net aggregate proceeds of approximately $0.4 million. In connection with this transaction, the Company recognized approximately $0.7 million of non-cash inducement interest expense.

On January 28, 2021, the Company entered into privately negotiated warrant exchange agreements with certain accredited investors, pursuant to which the investors purchased unregistered shares of common stock at a range of $0.45 to $0.75 per share in exchange for warrants with exercise prices ranging from $0.90 to $1.50 per share. The Company issued approximately 3.6 million shares in exchange for approximately 2.5 million warrants to purchase common stock, which resulted in net aggregate proceeds of approximately $2.9 million. In connection with this transaction, the Company recognized approximately $3.4 million of non-cash inducement interest expense and approximately $0.1 million in offering costs.

On March 18, 2021, the Company entered into a private warrant exchange in which an accredited investor purchased unregistered shares of common stock at a range of $0.60 to $0.90 per share in exchange for warrants with exercise prices ranging from $0.30 to $0.45 per share. The Company issued approximately 0.1 million shares of common stock, as well as approximately 0.1 million additional shares as an inducement to the investor to exercise the warrants, for a total of approximately 0.2 million shares. Aggregate gross proceeds from the private warrant exchange were approximately $0.1 million. In connection with this transaction, the Company recognized approximately $32,000 of non-cash inducement interest expense.

On April 2, 2021, the Company entered into a private warrant exchange in which an accredited investor purchased unregistered shares of common stock at $0.90 per share in exchange for warrants with an exercise price of $0.45 per share. The Company issued approximately 0.8 million shares of common stock, as well as approximately 0.3 million additional shares as an inducement to the investor to exercise the warrants, for a total of approximately 1.1 million shares. Aggregate gross proceeds from the private warrant exchange were approximately $0.7 million. In connection with this transaction, the Company recognized approximately $0.1 million of non-cash inducement interest expense.

As described in Note 5, a total of approximately 19.9 million shares of common stock were issued in exchange for the retirement of the March 2020 Note, the July 2020 Note, and partial repayment of a portion of the November 2020 Note during the fiscal year ended May 31, 2021.

For the year-ended May 31, 2021 the Company recorded non-cash inducement interest expense of approximately $11.4 million in connection with the private warrant exchange offerings.

Note 13. Registered Direct Equity Offerings

From June 1, 2019 to November 30, 2019, the Company entered into subscription agreements with certain investors for the sale of approximately 19.1 million shares of common stock at purchase prices ranging between $0.30 and $0.40 per share in registered direct offerings, pursuant to a registration statement on Form S-3. The investors in these offerings also received warrants to purchase approximately 12.0 million shares of common stock with an exercise price of $0.45 per share and a five-year term. The Company received net proceeds from the offerings of approximately $6.3 million. In addition, the placement agent received warrants covering approximately 0.7 million shares of common stock (or 1.3% of total shares sold to investors) with per share exercise prices ranging between $0.40 and $0.44, a five-year term and a cashless exercise provision.

On December 9, 2019, the Company entered into subscription agreements with certain investors for the sale of approximately 2.6 million shares of common stock at a purchase price of $0.30 per share in a registered direct offering, pursuant to a registration statement on Form S-3. The investors in this offering also received warrants to purchase 1.9 million shares of common stock with an exercise price of $0.45 per share and a five-year term. The Company received net proceeds from the offering of approximately $0.75 million.

On December 13, 2019, the Company entered into subscription agreements with certain investors for the sale of approximately 2.4 million shares of common stock at a purchase price of $0.30 per share in a registered direct offering, pursuant to a registration statement on Form S-3. The investors in this offering also received warrants to purchase approximately 1.8 million shares of common stock with an exercise price of $0.45 per share and a five-year term. The Company received net proceeds from the offering of approximately $0.73 million.

On December 23, 2019, the Company entered into subscription agreements for the sale of approximately 14.8 million shares of common stock and warrants to purchase up to an aggregate of approximately 7.4 million shares of common stock for a combined purchase price of $0.305 per share in a registered direct offering, pursuant to a registration statement on Form S-3. Each share of common stock was sold together with one-half of one warrant to purchase one share of common stock for a combined purchase price of $0.305 per share. As partial consideration for execution of a License Agreement and Supply Agreement, Vyera's parent company, Phoenixus AG ("Phoenixus"), made a $4.0 million equity investment pursuant to the registered direct offering. The offering also included $0.5 million of shares and related warrants sold to an entity associated with David F. Welch Ph.D., a then member of the Board, on terms identical to those applicable to Phoenixus. The Company received net proceeds from this offering of approximately $4.5 million.

Note 14. Stock Grants to Employees

On December 24, 2019, the Company issued a total of approximately 0.4 million shares of registered common stock to two executives in connection with the stock portion of their incentive compensation earned for the fiscal year ended May 31, 2018. The two executives simultaneously tendered back to the Company a total of approximately 0.1 million shares of the registered common stock to cover the income tax withholding requirements.

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

On July 31, 2020, the Company awarded approximately 0.3 million shares of common stock to Nader Z. Pourhassan, Ph.D., Chief Executive Officer, of which approximately 0.2 million were tendered back to the Company to cover income tax withholding requirements. As a result, the Company incurred approximately $1.6 million in stock compensation expense.

As described in Note 7 of these Notes to Consolidated Financial Statements, upon the September 30, 2020 stockholder approval of the Amended and Restated 2012 Stock Incentive Plan, the Company issued to executives of the Company non-qualified stock options covering 3.35 million shares of common stock, time-vesting restricted stock units ("RSUs") covering 1.12 million shares of common stock and performance based RSUs ("PSUs") covering 4.35 million shares of common stock. The RSUs vest equally over three years, and the PSUs will vest over the fiscal year ending May 31, 2021 only if certain performance conditions set forth in the awards are met. The options vest equally over three years. The issuance of common stock underlying the PSUs granted for performance in fiscal year ending May 31, 2021 are subject to the Compensation Committee's determination if certain performance conditions set forth in the awards are met.

On October 16, 2020, in connection with the hiring of it's previous Chief Science Officer, the Company granted 0.2 million RSUs vesting equally over three years. The RSUs were forfeited prior to vesting upon termination of his employment.

Note 15. Employee Benefit Plan

The Company has an employee savings plan (the "401(k) Plan") pursuant to 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 year ended May 31, 2021, May 31, 2020 and May 31, 2019, the Company incurred an expense of approximately $0.7 million, $0.1 million, and $0.1, million respectively, for qualified non-elective contributions.

Note 16. Income Taxes

Deferred taxes are recorded for all existing temporary differences in the Company's assets and liabilities for income tax and financial reporting purposes. Other than approximately a $2.8 million benefit from a basis difference in the acquired assets of ProstaGene, due to the valuation allowance for deferred tax assets, as noted below, there was no other net deferred tax benefit or expense for the periods ended May 31, 2021, May 31, 2020 and May 31, 2019.

Reconciliation of the federal statutory income tax rate of 21% for the years ended May 31, 2021, May 31, 2020 and May 31, 2019, to the effective income tax rate is as follows for all periods presented:

	Years ended May 31,		
	2021	2020	2019
Income tax provision at statutory rate:	21.0 %	21.0 %	21.0 %
State income taxes net	—	—	—
Rate change	—	—	—
Loss on debt extinguishment	—	—	(0.5)
Derivative gain (loss)	—	(1.6)	0.6
Valuation allowance release from asset acquisition	—	—	4.8
Non-deductible debt issuance costs	—	(0.1)	—
Non-deductible interest on convertible notes	(0.6)	(1.2)	(0.3)
Inducement interest expense	(1.5)	(1.3)	(0.1)
Other	—	(0.3)	—
Credit carry forward generated (released)	(0.1)	(0.1)	(3.8)
Non-deductible loss on extinguishment of debt	(2.6)	—	—
Non-deductible debt discount amortization	(0.6)	(0.3)	—
IRC section 162(m) limitation	(1.1)	(2.4)	—
Stock compensation in excess of ASC 718	1.7	3.2	—
Non-deductible legal settlement expense	(1.2)	(3.8)	—
Valuation allowance	(15.0)	(13.1)	(16.9)
Effective income tax rate	0.0 %	0.0 %	4.8 %

Net deferred tax assets and liabilities are comprised of the following as of May 31, 2021 and 2020:

	May 31,	
	2021	2020
Deferred tax asset (liability) non-current:		
Net operating loss	$ 74,258	$ 55,624
Credits	2,063	2,063
ASC 718 expense on NQO's	5,510	4,069
Charitable contribution—carry forward	14	—
Accrued vacation & payroll	87	112
ASC 842 lease accounting	(3)	—
Inventory reserve	146	
Accrued expenses	874	349
Fixed assets	(0)	(1)
Amortization	396	373
Debt discount	—	—
Basis difference in acquired assets	(91)	(2,483)
Valuation allowance	(83,254)	(60,106)
Deferred tax asset (liability) non-current	$ —	$ —
Noncurrent asset (liabilities)	83,254	60,106
Valuation allowance	(83,254)	(60,106)
Deferred tax asset (liability) non-current	$ —	$ —

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

As of May 31, 2021, May 31, 2020 and May 31, 2019 the Company had available net operating loss carry forwards of approximately $353.6 million, $264.9 million and $190.5 million, respectively, which expire beginning in 2023.

The Company's income tax returns remain subject to examination by all tax jurisdictions for tax years ended May 31, 2018 through 2020.

Note 17. Related Party Transactions

The Board's Audit Committee, composed of independent directors, or the full Board, reviews and approves all related party transactions. The terms and amounts described below are not necessarily indicative of the terms and amounts described below that would have been incurred had comparable transactions been entered into with independent parties.

On July 12, 2018, the Company announced certain leadership changes in connection with the strategic expansion and entry into certain cancer and immunologic indications. In connection with such leadership changes and effective July 11, 2018, Denis R. Burger, Ph.D. and A. Bruce Montgomery, M.D., resigned as members the Board. Dr. Burger also resigned as Chief Science Officer of the Company, which was not an executive officer position. On July 10, 2018, in connection with the resignations of Dr. Burger and Dr. Montgomery, the Board determined to accelerate the vesting of all outstanding and unvested stock options held by Dr. Burger and Dr. Montgomery. Upon the effectiveness of their resignations, stock options covering 0.5 million shares and 0.1 million shares, held by Dr. Burger and Dr. Montgomery, respectively, became fully vested. The stock options retained their exercise period through their respective expiration dates and the terms of the stock options remained otherwise unchanged.

On November 16, 2018, the Company closed its acquisition of ProstaGene assets. In connection with the closing of the acquisition, the Company hired Richard Pestell, M.D., as its Chief Medical Officer. Prior to the acquisition Dr. Pestell was the holder of approximately 77.2% of the outstanding equity interests in ProstaGene and consequently held an indirect interest in (i) approximately 8.6 million of approximately 13.3 million shares of the Company's common stock and (ii) approximately 4.2 million of 5.4 million shares of common stock, in each case held in escrow for the benefit of ProstaGene and its members, which were subject to being released ratably every six months over the eighteen-month period following the closing date and forfeiture to satisfy certain indemnity obligations of ProstaGene. In addition, as specified in a Stock Restriction Agreement between Dr. Pestell and the Company, approximately 8.3 million restricted shares of common stock previously distributed to Dr. Pestell in the ProstaGene acquisition are currently the subject of litigation. See Note 8 and 10.

As specified in a Confidential Information, Inventions and Noncompetition Agreement between the Company and Dr. Pestell, which was entered into on the closing date of the ProstaGene acquisition, the Company obtained the right to participate in the development and license of certain intellectual property created by Dr. Pestell, in connection with Dr. Pestell's then ongoing research obligations to outside academic institutions. The Company also obtained the right to work with Dr. Pestell to manage any potential conflict between the Company's clinical development activities and such ongoing research obligations.

On December 10, 2018, Anthony D. Caracciolo resigned as the Chairman of the Board of Directors, but remained a director and Scott A. Kelly, M.D., was appointed Chairman of the Board. On December 19, 2018, the Compensation Committee of the Board approved an amendment to certain compensation arrangements for Mr. Caracciolo, pursuant to which his employment with the Company was extended through April 16, 2019, at a salary reduced from $16,667 to $5,000 per month, with continuing benefits. In addition, the Compensation Committee approved an extension to a total of 10 years of the term of certain previously awarded stock options covering an aggregate of 0.15 million shares of the Company's common stock, provided that such stock options were out-of-the-money on the date of such extension. These arrangements were conditioned upon Mr. Caracciolo's agreement to resign from the Board upon identification by the Company of an appropriately qualified candidate to fill the vacancy. Mr. Caracciolo's resignation was effective January 10, 2019. These arrangements were not the result of any disagreement with the Company on any matter relating to the Company's operations, policies or practices.

On January 8, 2019, Argonne Trading LLC ("Argonne"), participated in the private placement of convertible promissory notes. See Note 5. Michael A. Klump, the manager of Argonne, was a director of the Company at the time of investment.

Argonne purchased a convertible promissory note, in the aggregate principal amount of $0.5 million bearing interest at an annual rate of 10% and received a warrant covering 0.5 million shares of common stock at an exercise price of $0.30 per share. The terms and conditions of the Argonne investment were identical to those offered to all other investors in the offering and the investment was approved by the Board's Audit Committee.

On May 8, 2019, Dr. David F. Welch entered into exercise agreements for warrants beneficially owned by him, covering an aggregate of approximately 1.7 million shares of common stock and approximately 0.8 million additional shares. Additionally, Michael A. Klump entered into exercise agreements for warrants beneficially owned by him, covering an aggregate of approximately 3.6 million shares of common stock and approximately 1.8 million additional shares. Dr. Welch and Mr. Klump were members of the Board at the time of exercise and participated on terms identical to those applicable to other investors. See Note 12.

On July 15, 2019, the Company entered into consulting agreements with two of its directors, Scott A. Kelly, M.D. in the capacity of non-executive Chief Science Officer, and David F. Welch, Ph.D., in the capacity of non-executive interim Strategy Advisor. Dr. Kelly's agreement terminated on April 9, 2020 when he became the Company's Chief Medical Officer as a full-time employee. On September 12, 2019, the Company and Dr. Welch agreed to amend his consulting agreement to eliminate any cash compensation (including previously earned entitlements) thereunder and in October 2019, the consulting agreement between Dr. Welch and the Company was terminated. The Company has issued stock options as compensation pursuant to the agreements, as follows: to Dr. Kelly for 0.75 million shares at an exercise price of $0.385 per share on September 12, 2019, and 0.2 million shares at an exercise price of $0.39 per share on October 7, 2019; and options to Dr. Welch for 0.25 million shares at an exercise price of $0.385 per share on September 12, 2019, and 0.2 million shares at an exercise price of $0.39 per share on October 7, 2019. The options granted on September 12, 2019 vested immediately upon issuance and have a 10-year term. The options issued on October 7, 2019 vested in four equal quarterly installments beginning on the grant date and have a 10-year term.

On June 12, 2019, the Company concluded a warrant tender offer (the "June 2019 Warrant Tender Offer") for certain outstanding series of eligible warrants, offering the holders of such warrants the opportunity to amend and exercise their warrants at a reduced exercise price equal to the lower of (i) their respective existing exercise price or (ii) $0.40 per share. As an inducement to holders to participate in the June 2019 Warrant Tender Offer, the Company offered to issue to participating holders shares of common stock equal to an additional 50% of the number of shares issuable upon exercise of the eligible warrants (collectively, the "Additional Shares"). Dr. Kelly validly tendered warrants beneficially owned by him, covering an aggregate of 50,000 shares, and received 25,000 Additional Shares. Dr. Kelly participated on terms identical to those applicable to other holders in the June 2019 Warrant Tender Offer.

On July 31, 2019, the Company concluded an additional warrant tender offer on terms identical to the June 2019 Warrant Tender Offer (the "July 2019 Warrant Tender Offer"). See Note 12. Dr. Welch tendered warrants beneficially owned by him, covering an aggregate of 1.0 million shares, and received 0.5 million Additional Shares. Dr. Welch participated on terms identical to those applicable to other holders in the July 2019 Warrant Tender Offer. See Note 12.

On September 30, 2019, an entity controlled by Dr. Welch exchanged a 2019 Short-term Convertible Note in the principal amount of $1.0 million and accrued but unpaid interest of $75,343, for an exchange note in the principal amount of $1.1 million and a warrant to purchase 1.0 million shares of common stock. The entity controlled by Dr. Welch participated on similar terms to the other holders in the exchange. See Note 5.

On October 8, 2019, an entity controlled by then director, Michael Klump, exchanged a 2019 Short-term Convertible Note in the principal amount of $0.5 million and accrued but unpaid interest of $37,397, for an exchange note in the principal amount of approximately $0.5 million and a warrant to purchase 0.5 million shares of common stock. The entity controlled by Mr. Klump participated on similar terms to the other holders in the exchange. See Note 5.

On December 13, 2019, Jordan Naydenov, a director of the Company, participated in a registered direct equity offering. Mr. Naydenov purchased approximately 0.8 million shares of common stock and received warrants covering approximately 0.6 million shares. The terms and conditions of Mr. Naydenov's $0.25 million investment were identical to those offered to other investors in this offering. See Note 12.

On December 23, 2019, an entity controlled by Dr. Welch participated in a registered direct equity offering. The entity controlled by Dr. Welch purchased approximately 1.6 million shares of common stock and received warrants covering approximately 0.8 million shares. The terms and conditions of the $0.5 million investment made by the entity controlled by Dr. Welch were identical to those offered to other investors in the offering. See Note 12.

On January 31, 2020, an entity controlled by Dr. Welch participated in the January 31, 2020 offering of Series D Preferred Stock. The entity controlled by Dr. Welch purchased 1,000 shares and received warrants covering 0.5 million shares of common stock. The terms and conditions of the $1.0 million investment made by the entity controlled by Dr. Welch were identical to those offered to other investors in this offering. See Note 12.

On February 26, 2020, an entity controlled by Dr. Welch entered into a private warrant exchange in which the entity purchased shares of common stock for $0.18 per share as compared to the stated exercise price of the warrants of $0.30 per share. The entity purchased approximately 1.8 million shares of common stock, and received 0.2 million additional shares as an inducement to exercise its warrants, for a total of approximately 2.0 million shares. The terms and conditions of the approximate $0.33 million investment made by the entity were identical to those offered to other investors in this offering. See Note 12.

On November 17, 2020, the Company conducted a private equity offering, in which Christopher Recknor, M.D., who was a non-executive at the time of the offering, purchased unregistered shares of common stock for $1.50 per share. Pursuant to the offering, the Company sold approximately 0.7 million shares to Dr. Recknor for aggregate proceeds of $1.0 million. The transaction was approved by the Board. See Note 12.

On March 11, 2021, the Company appointed Christopher Recknor, its former Vice President, Clinical Operations, as its Chief Operating Officer (“COO”). The Center for Advanced Research & Education, LLC (“CARE”), owned by Dr. Christopher Recknor’s spouse, Julie Recknor, Ph.D., (and owned by Dr. Christopher Recknor until March 11, 2021) is one of several clinical locations for the Company’s ongoing NASH and COVID-19 long-hauler clinical trials, and was a clinical location for the Company’s completed Phase 2b/3 mild-to-moderate and severe-to-critical COVID-19 clinical trials. Dr. Julie Recknor serves as the Site Director of CARE and manages its day-to-day operations. The Company entered into a Clinical Trial Agreement (“CTA”) with CARE for each of the foregoing clinical trials. Each CTA was negotiated in the ordinary course of business by Amarex, the Company’s clinical research organization, prior to Dr. Christopher Recknor’s appointment as COO, and the operational and financial terms of the CTAs with CARE are comparable to the terms available to unrelated clinical locations. Dr. Christopher Recknor was not involved in the Company’s decision to choose CARE as a clinical location for its ongoing trials, and he is not involved in patient treatment at the CARE site. During the fiscal year ended May 31, 2020, the Company made no payments to CARE, as it had not yet received any services under the CTA in effect prior to that date. As of May 31, 2021, the Company had approximately $0.9 million in accounts payable due to CARE and made payments of approximately $0.9 million to CARE during the fiscal year ended May 31, 2021. In July 2021, the Company entered into an amendment to the previously approved CTA with CARE, wherein such amendment provided for the additional recording of patient information giving rise to an approximate increase of less than $0.1 million.

Note 18. Subsequent Events

On June 15, 2021, The Company issued 0.4 million shares of common stock to executives in connection with the vesting of RSUs granted on June 15, 2020 and subsequently issued following stockholder approval of the Amended and Restated 2012 Equity Incentive Plan on September 30, 2020.

From June 1, 2021 to July 23, 2021, the Company issued approximately 0.6 million shares of common stock in connection with the exercise of outstanding warrants and stock options covering approximately 0.6 million shares. The stated exercise prices ranged from $0.45 to $1.35 per share, which resulted in aggregate gross proceeds to the Company of approximately $0.5 million.

On June 11, 2021, June 21, 2021, and June 30, 2021, in satisfaction of the June 2021 Debt Redemption Amount, the Company and the November 2020 Note holder entered into exchange agreements, pursuant to which the November 2020 Note was partitioned into new notes (the “June 2021 Partitioned Notes”) with a principal amount equal to the June 2021

Debt Reduction Amount of $6.0 million. The outstanding balance of the November 2020 Note was reduced by the June 2021 Partitioned Notes. The Company and the investor exchanged the June 2021 Partitioned Notes for approximately 4.2 million shares. The Company and the holder of the November 2020 Note agreed to defer the remaining June 2021 Debt Redemption Amount of $1.5 million. Following these payments, the outstanding balance on the November 2020 Note, including accrued interest, was approximately $7.9 million.

On July 14, 2021 and July 27, 2021, in satisfaction of the July 2021 Debt Reduction Amount, the Company and the November 2020 Note holder entered into exchange agreements, pursuant to which the November 2020 Note was partitioned into new notes (the "July 2021 Partitioned Notes") with a principal amount equal to the July 2021 Debt Reduction Amount of $4.0 million. The outstanding balance of the November 2020 Note was reduced by the July 2021 Partitioned Notes. The Company and the investor exchanged the July 2021 Partitioned Notes for approximately 3.3 million shares of common stock. The Company and the holder of the November 2020 Note agreed to defer the remaining July 2021 Debt Redemption Amount of $3.5 million. Following the June and July 2021 payments, the outstanding balance of the November 2020 Note, including accrued interest, was approximately $4.5 million.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

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

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of May 31, 2021 (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded, based upon the evaluation described above that, as of May 31, 2021, our disclosure controls and procedures were effective at the reasonable-assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

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

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

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

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

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework provided in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of May 31, 2021.

Changes in Internal Control Over Financial Reporting

During the quarter ended May 31, 2021, there have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Exchange Act, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None

Part III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by Item 10 will be contained in, and is incorporated herein by reference to, our definitive proxy statement for our 2021 Annual Meeting of Stockholders under the captions "Proposal 1: Election of Directors," "Information about our Executive Officers," "Delinquent Section 16(a) Reports" and "Corporate Governance," to be filed with the SEC within 120 days of the end of the Company's fiscal year May 31, 2021 (the 2021 Proxy Statement").

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

Item 11. Executive Compensation.

The information required by Item 11 relating to executive compensation will be contained in, and is incorporated herein by reference to, our 2021 Proxy Statement under the captions "Executive Compensation" and "Director Compensation".

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

The information required by Item 12 relating to security ownership of certain beneficial owners and management and related stockholders' matters will be contained in, and is incorporated herein by reference to, our 2021 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 2021 Proxy Statement under the

captions "Related Person Transactions," and "Meetings and Committees of the Board of Directors—Director Independence."

Item 14. Principal Accountant Fees and Services.

The information required by Item 14 relating to principal accountant fees and services will be contained in, and is incorporated herein by reference to, our 2021 Proxy Statement under the caption "Matters Relating to the Company's Independent Registered Public Accounting Firm."

PART IV

Item 15. Exhibits and Financial Statement Schedules.

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

(1) Consolidated Financial Statements

The Consolidated Financial Statements for the years ended May 31, 2021 and 2020 are included under 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

			Incorporated by Reference		
Exhibit No	**Description**	**Filed Herewith**	**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
2.2	Transaction Agreement by and among CytoDyn Inc., Point NewCo, Inc., Point Merger Sub, Inc., ProstaGene, LLC, and Dr. Richard Pestell, dated August 27, 2018		8-K	2.1	8/28/2018
3.1	Amended and Restated Certificate of Incorporation		10-Q	3.1	10/9/2020
3.2	Amended and Restated Bylaws of CytoDyn Inc.		8-K12G3	3.2	11/19/2018
4.1	Description of the Registrant's Capital Stock	X			
4.2	Form of Common Stock Certificate		8-K12G3	4.1	9/1/2015
4.3	Form of Consultant Warrant		8-K	4.4	6/22/2017
4.4	Form of Placement Agent Warrant		8-K	4.3	6/22/2017
4.5	Form of Placement Agent Warrant (Private Offerings, as Amended)		10-K	4.11	7/27/2018

4.6	Form of Placement Agent Warrant (Registered Offerings, as Amended)	10-K	4.12	7/27/2018
4.7	Form of Warrant Agreement (Private Offerings)	8-K	4.1	9/4/2018
4.8	Form of Warrant Agreement (Registered Offerings)	8-K	4.1	4/5/2019
4.9	Form of Warrant Agreement (Series C Convertible Preferred Stock Offering)	8-K	4.1	4/20/2019
4.10	Form of Warrant Agreement (Series C Convertible Preferred Stock Offering)	8-K	4.1	10/22/2019
4.11	Form of Warrant Agreement (Series D Convertible Preferred Stock Offering)	8-K	4.1	2/3/2020
4.12	Form of Warrant to Purchase Common Stock (December 2018 Convertible Note Offering)	8-K	4.2	1/3/2019
4.13	Form of Warrant to Purchase Common Stock	8-K	4.1	1/31/2019
4.14	Form of Common Stock Purchase Warrant	8-K	4.1	8/29/2019
4.15	Form of Common Stock Purchase Warrant	8-K	4.1	12/27/2019
4.16	Warrant to Purchase Common Stock by and between CytoDyn Inc. and Iliad Research and Trading, L.P.	8-K	4.2	1/31/2019
4.17	Form of Convertible Promissory Note	8-K	4.1	6/27/2018
4.18	Form of Convertible Promissory Note (December 2018 Convertible Note Offering)	8-K	4.1	1/3/2019
4.19	Secured Convertible Promissory Note by and between CytoDyn Inc. and Iliad Research and Trading, L.P.	8-K	4.1	1/30/2019
4.20	Secured Convertible Promissory Note, as amended, by and between CytoDyn Inc. and Iliad Research and Trading, L.P.	8-K	4.1	4/6/2020
4.21	Secured Convertible Promissory Note between CytoDyn Inc. and Streeterville Capital, LLC, dated November 10, 2020	8-K	4.1	11/16/2020
4.22	Secured Convertible Promissory Note between CytoDyn Inc. and Streeterville Capital, LLC, dated April 2, 2021	8-K	4.1	4/8/2021
4.23	Secured Convertible Promissory Note between CytoDyn Inc. and Uptown Capital, LLC, dated April 23, 2021	8-K	4.1	4/29/2021
10.1	Development and License Agreement between Protein Design Labs, Inc. (to which AbbVie Biotherapeutics Inc. is successor in interest) and Progenics Pharmaceuticals, Inc. (to which CytoDyn Inc. is successor in interest) effective as of April 30, 1999, as amended by letter agreement dated November 24, 2003	10-K	10.21	8/29/2013

10.2	License Agreement between CytoDyn Inc. and Lonza Sales AG dated July 29, 2015		8-K/A	10.1	8/19/2015
10.3#	Commercialization and License Agreement between CytoDyn Inc. and Vyera Pharmaceuticals, LLC, dated December 17, 2019		10-Q	10.5	1/9/2020
10.4#	Product Specific Agreement between CytoDyn Inc. and Samsung BioLogics Co., Ltd, dated April 1, 2019		10-K	10.12	8/14/2019
10.5#	Supply Agreement between CytoDyn Inc. and Vyera Pharmaceuticals, LLC, dated December 17, 2019		10-Q	10.6	1/9/2020
10.6#	Distribution and Supply Agreement between CytoDyn Inc. and American Regent, Inc.		10-K	10.16	8/14/2020
10.7#	Exclusive Supply and Distribution Agreement between CytoDyn Inc. and Biomm S.A., dated April 6, 2021	X			
10.8#	Exclusive Supply and Distribution Agreement between CytoDyn Inc. and Chiral Pharma Corporation	X			
10.9#	Exclusive Supply and Distribution Agreement between CytoDyn Inc. and Chiral Pharma Corporation, as amended by Amendment No. 1, dated April 19, 2021	X			
10.10#	Exclusive Supply and Distribution Agreement between CytoDyn Inc. and Macleods Pharmaceuticals Ltd., dated May 11, 2021	X			
10.11	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
10.12	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
10.13#	Master Services Agreement between CytoDyn Inc. and Samsung BioLogics Co., Ltd, dated April 1, 2019		10-K	10.11	8/14/2019
10.14	Placement Agent Agreement (August 2019 Offering)		8-K	10.3	8/29/2019
10.15	Escrow Agreement, dated as of November 16, 2018, by and among ProstaGene, LLC, CytoDyn Inc., and Computershare Trust Company, N.A.		8-K12G3	10.2	11/19/2018
10.16	Confidential Information, Inventions and Noncompetition Agreement, dated as of November 16, 2018, by and among CytoDyn Inc., CytoDyn Operations Inc. and Dr. Richard G. Pestell		8-K12G3	10.4	11/19/2018
10.17	Form of Indemnification Agreement		10-Q	10.2	10/9/2018

10.18	Stock Restriction Agreement, dated as of November 16, 2018, by and among CytoDyn Inc., ProstaGene, LLC and Dr. Richard G. Pestell	8-K12G3	10.3	11/19/2018
10.19	Form of Securities Purchase Agreement (December 2016 Offering)	8-K	10.1	12/12/2016
10.20	Form of Securities Purchase Agreement (September 2017 Offering)	8-K	10.2	9/8/2017
10.21	Securities Purchase Agreement between CytoDyn Inc. and Streeterville Capital, LLC, dated November 10, 2020	8-K	10.1	11/16/2020
10.22	Security Agreement between CytoDyn Inc. and Streeterville Capital, LLC, dated November 10, 2020	8-K	10.2	11/16/2020
10.23	Securities Purchase Agreement between CytoDyn Inc. and Streeterville Capital, LLC, dated April 2, 2021	8-K	10.1	4/8/2021
10.24	Security Agreement between CytoDyn Inc. and Streeterville Capital, LLC, dated April 2, 2021	8-K	10.2	4/8/2021
10.25	Securities Purchase Agreement between CytoDyn Inc. and Uptown Capital, LLC, dated April 23, 2021	8-K	10.1	4/29/2021
10.26	Security Agreement between CytoDyn Inc. and Uptown Capital, LLC, dated April 23, 2021	8-K	10.2	4/29/2021
10.27	Exchange Agreement between CytoDyn Inc. and Streeterville Capital, LLC, dated December 18, 2020	S-3	10.3	12/18/2020
10.28	Form of Waiver and Subscription Agreement (Make-Whole Offering)	8-K	10.2	12/6/2017
10.29	Form of Subscription Agreement (Registered Direct Offering)	8-K	10.1	1/31/2019
10.30	Form of Subscription Agreement (Series C Convertible Preferred Stock Offering)	8-K	10.1	3/20/2019
10.31	Form of Subscription Agreement (August 2019 Offering)	8-K	10.1	8/29/2019
10.32	Form of Subscription Agreement (August 2019 Series C Convertible Preferred Stock Offering)	8-K	10.2	8/29/2019
10.33	Form of Subscription Agreement (September 2019 Registered Direct Offering)	8-K	10.1	9/19/2019
10.34	Form of Subscription Agreement (October 2019 Registered Direct Offering)	8-K	10.1	10/3/2019
10.35	Form of Series C Subscription Agreement	8-K	10.1	10/22/2019

10.36	Form of Subscription Agreement (November 2019 Registered Direct Offering)	8-K	10.1	11/7/2019
10.37	Form of Subscription Agreement (December 2019 Registered Direct Offering)	8-K	10.1	12/27/2019
10.38	Form of Subscription Agreement (January 2020 Series D Convertible Preferred Stock Offering)	8-K	10.1	2/3/2020
10.39	Form of Exercise Agreement	8-K	10.1	5/9/2019
10.40	Form of Warrant Exercise Agreement	8-K	10.2	12/27/2019
10.41*	Form of Warrant Exercise Inducement Agreement	8-K	10.1	1/29/2021
10.42*	CytoDyn Inc. 401(k) Profit Sharing Plan	10-K	10.11	8/5/2011
10.43*	CytoDyn Inc. 2004 Stock Incentive Plan (the "2004 Plan")	10-K	10.10	8/5/2011
10.44*	CytoDyn Inc. Amended and Restated 2012 Equity Incentive Plan (the "2012 Plan")			
10.45*	Form of Stock Option Award for Employees under the 2004 Plan	10-K	10.5	8/29/2013
10.46*	Form of Stock Option Award for Non-Employee Directors under the 2004 Plan	10-K	10.6	8/29/2013
10.47*	Form of Stock Option Award Agreement for Executive Employees under the 2012 Plan	10-K	10.43	8/14/2020
10.48*	Form of Stock Option Award Agreement for Non-Employee Directors under the 2012 Plan	10-K	10.9	8/29/2013
10.49*	Form of Stock Option Award Agreement for Employees under the 2012 Plan	8-K	10.3	6/19/2020
10.50*	Form of Restricted Stock Unit Agreement under the 2012 Plan	8-K	10.1	6/19/2020
10.51*	Form of Performance-Based Restricted Stock Unit Agreement under the 2012 Plan	8-K	10.2	6/19/2020
10.52*	Form of Stock Option Award Agreement for Employees granted under an arrangement not approved by the Registrant's shareholders	10-K	10.10	8/29/2013
10.53*	Form of Stock Option Award Agreement for Non-Employee Directors granted under an arrangement not approved by the Registrant's shareholders	10-K	10.11	8/29/2013
10.54*	Form of Performance Share Award Agreement	10-Q	10.9	4/9/2020

10.55*	Second Amended and Restated Employment Agreement by and between CytoDyn Inc. and Nader Pourhassan dated June 15, 2020		8-K	10.5	6/19/2020
10.56*	Amended and Restated Employment Agreement by and between CytoDyn Inc. and Michael D. Mulholland dated June 15, 2020		8-K	10.6	6/19/2020
10.57*	Amended and Restated Employment Agreement by and between CytoDyn Inc. and Nitya G. Ray, Ph.D., dated June 15, 2020		10-K	10.58	8/14/2020
10.58*	Employment Agreement, dated as of November 16, 2018, by and among CytoDyn, Inc., CytoDyn Operations Inc. and Dr. Richard G. Pestell		8-K12G3	10.5	11/19/2018
10.59*	Employment Agreement by and between CytoDyn Inc. and Craig S. Eastwood, dated December 6, 2019		10-Q	10.7	1/9/2020
10.60*	Employment Agreement by and between CytoDyn Inc. and Arian Colachis, dated March 16, 2020		10-K	10.63	8/14/2020
10.61*	Employment Agreement by and between CytoDyn Inc. and Scott A. Kelly, M.D., dated April 10, 2020		10-K	10.64	8/14/2020
10.62*	Employment Agreement by and between CytoDyn Inc. and Christopher P. Recknor, M.D., dated March 11, 2021		10-K	10.4	4/14/2021
10.63*	Consulting Agreement, dated July 15, 2019, between CytoDyn Inc. and Scott A. Kelly, M.D.		8-K	10.1	7/19/2019
10.64*	Consulting Agreement, dated July 15, 2019, between CytoDyn Inc. and David F. Welch, Ph.D.		8-K	10.2	7/19/2019
10.65*	Separation Agreement and Release of Claims between CytoDyn Inc. and Craig S. Eastwood, dated April 24, 2020		10-K	10.62	8/14/2020
10.66*	Separation Agreement and Release of Claims between CytoDyn Inc. and Mahboob U. Rahman, M.D., Ph.D., dated June 1, 2021	X			
21	Subsidiaries of the Registrant	X			
23	Consent of Warren Averett, LLC	X			
24	Power of Attorney of executive officers and directors	X			
31.1	Certification of Chief Executive Officer under Rule 13a-14(a)	X			
31.2	Certification of Chief Financial Officer under Rule 13a-14(a)	X			
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350	X			

101.INS	Inline XBRL Instance Document	X
101.SCH	Inline XBRL Taxonomy Extension Schema Document	X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	X

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

* Management contract, compensatory plan or arrangement.

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: July 30, 2021

CYTODYN INC.
(Registrant)

By: /s/ Nader Z. Pourhassan
Nader Z. Pourhassan, Ph.D.
President and 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 July 30, 2021.

Principal Executive Officer and Director:

/s/ Nader Z. Pourhassan
Nader Z. Pourhassan, Ph.D.
President and Chief Executive Officer, Director

Principal Financial and Accounting Officer:

/s/ Antonio Migliarese
Antonio Migliarese
Chief Financial Officer

Remaining Directors:

*
Scott A. Kelly, M.D., Chairman

*
Gordon A. Gardiner

*
Jordan G. Naydenov

*
Samir R. Patel, M.D.

*
Alan P. Timmins

*By: /s/ Antonio Migliarese Date: July 30, 2021
Antonio Migliarese
Attorney-In-Fact

Exhibit 4.1

DESCRIPTION OF THE REGISTRANT'S CAPITAL STOCK

General

CytoDyn, Inc. (the "Company" or "we") is authorized to issue up to 805 million shares of capital stock, including 800 million shares of common stock, par value $0.001 per share, and 5 million shares of preferred stock, par value $0.001 per share. As of May 31, 2021, we had 625.7 million shares of common stock, 79,000 shares of Series B Preferred Stock (as defined below), 8,203 shares of Series C Preferred Stock (as defined below) and 8,452 shares of Series D Preferred Stock (as defined below) issued and outstanding.

The additional shares of our authorized stock available for issuance may be issued at times and under circumstances so as to have a dilutive effect on earnings per share and on the equity ownership of the holders of our common stock. The ability of our Board of Directors to issue additional shares of stock could enhance the Board's ability to negotiate on behalf of the stockholders in a takeover situation but could also be used by the Board to make a change-in-control more difficult, thereby denying stockholders the potential to sell their shares at a premium and entrenching current management. The following description is a summary of the material provisions of our capital stock, and is qualified by reference to our certificate of incorporation, as amended, and bylaws, both of which are on file with the SEC as exhibits to previous Securities and Exchange Commission ("SEC") filings, for additional information. The summary below is qualified by provisions of applicable law.

Common Stock

Each outstanding share of common stock entitles the holder to one vote, either in person or by proxy, on all matters submitted to a vote of stockholders, including the election of directors. There is no cumulative voting in the election of directors. All actions required or permitted to be taken by stockholders at an annual or special meeting of the stockholders must be effected at a duly called meeting, with a quorum present of a majority in voting power of the shares entitled to vote thereon. Special meetings of the stockholders may only be called by our Board of Directors acting pursuant to a resolution approved by the affirmative majority of the entire Board of Directors. Stockholders may not take action by written consent. As more fully described in our Certificate of Incorporation, holders of our common stock are not entitled to vote on certain amendments to the Certificate of Incorporation related solely to our preferred stock.

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

The rights, preferences and privileges of holders of common stock are subject to the rights of the holders of any outstanding shares of preferred stock.

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

Preferred Stock

Our Board of Directors is authorized to issue up to 5 million shares of preferred stock, par value $0.001 per share, in one or more series, approximately 4.6 million of which shares are undesignated. Our Board of Directors has the authority, within the limitations and restrictions prescribed by law and without stockholder approval, to provide by

resolution for the issuance of shares of preferred stock, and to fix the rights, preferences, privileges and restrictions thereof, including dividend rights, conversion rights, voting rights, terms of redemption, liquidation preference and the number of shares constituting any series of the designation of such series, by delivering an appropriate certificate of amendment to our certificate of incorporation to the Delaware Secretary of State pursuant to the Delaware General Corporation Law (the "DGCL"). The issuance of preferred stock could have the effect of decreasing the market price of the common stock, impeding or delaying a possible takeover and adversely affecting the voting and other rights of the holders of our common stock.

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

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

Series B Convertible Preferred Stock

As of May 31, 2021, the Company has authorized Series B Convertible Preferred Stock ("Series B Preferred Stock"), of which 79,000 shares were outstanding. Each share of the Series B Preferred Stock is convertible to ten (10) shares of the Company's common stock. Dividends are payable to the Series B Preferred stockholders when and as declared by the Board of Directors at the rate of $0.25 per share per annum. Such dividends are cumulative and accrue whether or not declared and whether or not there are any profits, surplus or other funds or assets of the Company legally available therefor. At the option of the Company, dividends on the Series B Preferred Stock may be paid in cash or shares of common stock valued at $0.50 per share. The holders of the Series B Preferred Stock can only convert their shares to shares of common stock if the Company has sufficient shares of common stock authorized and available for issuance at the time of conversion. The Series B Preferred Stock has liquidation

preferences over the common shares at $5.00 per share, plus any accrued and unpaid dividends. Except as otherwise provided by law, the Series B holders have no voting rights.

Series C Convertible Preferred Stock

As of May 31, 2021, the Company has authorized 8,203 shares of Series C Convertible Preferred Stock, $0.001 par value per share ("Series C Preferred Stock"), of which 8,203 shares were outstanding. The Series C Certificate of Designation provides, among other things, that holders of Series C Preferred Stock shall be entitled to receive, when and as declared by the Board of Directors and out of any assets at the time legally available therefor, cumulative dividends at the rate of ten percent (10%) per share per annum of the stated value of the Series C Preferred Stock, which is $1,000 per share (the "Series C Stated Value"). Any dividends paid by the Company will be paid to the holders of Series C Preferred Stock, prior and in preference to any payment or distribution to holders of common stock. Dividends on the Series C Preferred Stock are cumulative, and will accrue and be compounded annually, whether or not declared and whether or not there are any profits, surplus or other funds or assets of the Company legally available therefor. There are no sinking fund provisions applicable to the Series C Preferred Stock. The Series C Preferred Stock does not have redemption rights. Dividends, if declared by the Board of Directors, are payable to holders in arrears on December 31 of each year. Subject to the provisions of applicable Delaware law, the holder may elect to be paid in cash or in restricted shares of common stock at the rate of $0.50 per share.

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

Series D Convertible Preferred Stock

As of May 31, 2021, the Company had authorized 11,737 shares of Series D Convertible Preferred Stock, $0.001 par value per share ("Series D Preferred Stock"), of which 8,452 shares remain outstanding. The Series D Certificate of Designation provides, among other things, that holders of Series D Preferred Stock shall be entitled to receive, when and as declared by the Board of Directors and out of any assets at the time legally available therefor, cumulative dividends at the rate of ten percent (10%) per share per annum of the stated value of the Series D Preferred Stock, which is $1,000 per share (the "Series D Stated Value"). Any dividends paid by the Company will be paid to the holders of Series D Preferred Stock, prior and in preference to any payment or distribution to holders of common stock. Dividends on the Series D Preferred Stock are cumulative, and will accrue and be compounded annually, whether or not declared and whether or not there are any profits, surplus or other funds or assets of the Company legally available therefor. There are no sinking fund provisions applicable to the Series D Preferred Stock. The Series D Preferred Stock does not have redemption rights. Dividends, if declared by the Board, are payable to holders in arrears on December 31 of each year. Subject to the provisions of applicable Delaware law, the holder may elect to be paid in cash or in restricted shares of common stock at the rate of $0.50 per share.

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

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

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

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

Special meetings of the stockholders may only be called by our Board of Directors acting pursuant to a resolution approved by the affirmative majority of the entire Board of Directors. Stockholders may not take action by written consent.

The stockholders may, at a special stockholders meeting called for the purpose of removing directors, remove the entire Board of Directors or any lesser number, but only with cause, by a majority vote of the shares entitled to vote at an election of directors.

Additional Warrants

As of May 31, 2021, we had issued and outstanding warrants to purchase up to approximately 42.9 million shares of common stock, exercisable at prices ranging from $0.30 per share to $3.73 per share.

Stock Options

As of May 31, 2021, we had issued and outstanding options to purchase up to approximately 14.9 million shares of common stock, exercisable at prices ranging from $0.39 per share to $6.15 per share.

Exhibit 10.7

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

EXCLUSIVE SUPPLY AND DISTRIBUTION AGREEMENT

Entered into by and between

BIOMM S.A.

And

CYTODYN INC.

April 6, 2021

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

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

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

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

RECITALS

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

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

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

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

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

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

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

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

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

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

AGREEMENT

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

1. CERTAIN DEFINITIONS.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1.22 "Territory" means the country of Brazil.

2. PERFORMANCE OBLIGATIONS

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

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

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

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

2.4 Distribution

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

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

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

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

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

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

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

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

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

2.9 Inspection.

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

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

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

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

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

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

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

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

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

3. PURCHASE ORDERS

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

3.2 [*]

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

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

3.5 Production and Delivery Capacity.

(a) [*]

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

4. DELIVERY AND ACCEPTANCE; RECALL

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

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

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

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

4.3 Inspection and Rejection.

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

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

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

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

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

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

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

5. Invoices: Method of Payment

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

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

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

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

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

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

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

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

6. Representations And Warranties; Covenants

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

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

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

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

6.5 Covenants.

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

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

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

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

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

7. Indemnification And Liability

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

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

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

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

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

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

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

10. Term; Termination

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

10.2 Termination Events

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

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

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

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

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

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

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

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

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

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

(c) transfer all Approvals to CytoDyn;

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

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

11. CONFIDENTIALITY

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

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

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

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

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

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

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

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

12. MISCELLANEOUS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[Signature page follows]

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

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

Witnesses:

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

SCHEDULE B
PHARMACOVIGILANCE AGREEMENT
[TO BE INSERTED UPON EXECUTION]

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

Exhibit 10.8

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

EXCLUSIVE SUPPLY AND DISTRIBUTION AGREEMENT

KNOW ALL PERSONS BY THESE PRESENTS:

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

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

("**CPC**");

&

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

Collectively known as the "**Parties**"

WITNESSETH;

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

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

NOW THEREFORE, the Parties hereto have agreed as follows:

1. APPOINTMENT

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

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

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

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

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

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

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

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

2. SUPPLY OF PRODUCT

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

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

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

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

2.4 Acceptance; Rejection.

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

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

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

2.5 Rejection Procedures.

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

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

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

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

3. PAYMENT

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

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

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

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

4. INTELLECTUAL PROPERTY

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

5. REPRESENTATION & WARRANTY

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

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

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

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

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

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

6. LIABILITY AND CROSS-INDEMNIFICATIONS

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

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

7. ADVERSE REACTIONS, COMPLAINTS AND RECALLS

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

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

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

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

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

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

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

8. CONFIDENTIALITY

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

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

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

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

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

9. TERMINATION

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

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

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

9.4 Effects of Termination. Upon termination:

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

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

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

10. INDEPENDENT PARTY

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

11. ASSIGNMENT

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

12. FORCE MAJEURE

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

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

13. SEVERABILITY

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

14. ENTIRE AGREEMENT

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

15. WAIVER

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

16. GOVERNING LAW

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

17. NOTICE

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

If to CPC:

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

If to CytoDyn:

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

Product complaints and quality issues: jflisak@cytodyn.com

18. COUNTERPARTS

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

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

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

Exhibit 10.9

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

Amendment No.1 to Exclusive Supply and Distribution Agreement

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

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

1. Amendments.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Exhibit 10.10

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

EXCLUSIVE SUPPLY AND DISTRIBUTION AGREEMENT

KNOW ALL PERSONS BY THESE PRESENTS:

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

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

("**MACLEODS**");

&

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

Collectively known as the "**Parties**"

WITNESSETH;

WHEREAS, CYTODYN is the owner of product Leronlimab.

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

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

NOW THEREFORE, the Parties hereto have agreed as follows:

1. APPOINTMENT

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

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

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

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

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

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

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

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

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

2. SUPPLY OF PRODUCT

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

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

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

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

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

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

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

2.4 Acceptance; Rejection.

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

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

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

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

2.5 Rejection Procedures.

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

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

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

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

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

3. PAYMENT

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

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

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

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

4. INSPECTIONS AND COMMUNICATIONS

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

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

5. INTELLECTUAL PROPERTY

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

6. REPRESENTATION & WARRANTY

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

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

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

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

7. LIABILITY AND CROSS-INDEMNIFICATIONS

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

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

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

8. ADVERSE REACTIONS, COMPLAINTS AND RECALLS

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

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

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

9. CONFIDENTIALITY

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

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

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

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

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

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

10. TERMINATION

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

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

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

10.4 Effects of Termination. Upon termination:

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

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

11. INDEPENDENT PARTY

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

12. ASSIGNMENT

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

13. FORCE MAJEURE

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

14. SEVERABILITY

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

15. ENTIRE AGREEMENT

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

16. WAIVER

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

17. GOVERNING LAW

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

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

18. NOTICE

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

If to MACLEODS:

Macleods Phrmaceuticals Ltd

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

Attention: Vijay Agarwal

Email: vijay@macleodspharma.com

If to CYTODYN:

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

Attention: Chief Executive Officer

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

Product complaints and quality issues: jflisak@CYTODYN.com

19. COUNTERPARTS

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

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

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

SIDE LETTER TO EXCLUSIVE SUPPLY AND DISTRIBUTION AGREEMENT

[Dated and Effective as of May 11, 2021]

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

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

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

1.4 Intentionally Omitted.

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

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

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

Exhibit 10.66

SEPARATION AGREEMENT AND RELEASE OF CLAIMS

This Separation Agreement and Release of Claims (the "Agreement") is made and entered into by and between Mahboob U. Rahman, M.D. Ph.D. ("Employee") and CytoDyn Inc. ("Employer"). It is intended to clearly set forth the terms and conditions of Employee's separation from employment with Employer, and to facilitate a smooth and amicable transition from employment.

NOW, THEREFORE, in consideration of the mutual terms, conditions, promises, and covenants set forth below, it is agreed as follows:

1. Separation of Employment. Employee's last day of employment was April 5, 2021 (the "Separation Date"). Employee has received his final paycheck for wages earned through the Separation Date and any accrued, but unused PTO, less applicable taxes and withholdings, on the next regular payroll date occurring after the Separation Date.

2. Consideration. In consideration of Employee's acceptance of this Agreement without revocation as provided in Section 11 below, Employer will provide Employee with the following:

a. Severance. Employer agrees to pay Employee a severance equal to nine (9) months of Employee's regular salary as of the Separation Date, less taxes and withholdings ("Severance Payment"). The Severance Payment will be paid in equal bi-weekly installments over a nine (9) month period through the Employer's normal payroll processing commencing on the next regular payroll date after this Agreement has become effective as set forth in Section 11.

b. *Extended Health Insurance Benefits.* Employee's group health coverage (if any) will continue until July 31, 2021 at Employer's expense, provided Employee elects continuation coverage and completes the required continuation documentation. Additional coverage is not available under the Employer's plan beyond this time period.

3. Return of Employer's Property. Employee warrants and represents that he has not removed and will not remove any Employer property from its premises, servers, databases, or equipment, except and to the extent authorized by Employer in writing. Employee further warrants that he has returned all property in any form whatsoever, unaltered and undamaged, to Employer.

4. Release of Claims.

a. By Employee. With the exception of the obligations arising under this Agreement, Employee knowingly and voluntarily, unconditionally and forever, waives and releases any and all claims, damages, causes of action and rights, whether known or unknown, contingent or noncontingent, contractual or otherwise against Employer or any of its directors, officers, agents, representatives and employees, past and present, and each of their successors and assigns (collectively "Releasees"). Employee makes this commitment even though he understands that he may not, as of this date, know all of the claims he may lawfully have against the Releasees and that he is relinquishing the right to pursue any claims which he could have pursued before courts without having the opportunity to pursue those claims to a trial and have the damages, if any, set by a judge and/or jury, including without limitation any claims under the Civil Rights Acts of 1964 and 1991 as amended ("Title VII"), the Washington State Law Against Discrimination ("WLAD"), the Americans with Disabilities Act ("ADA"), the Rehabilitation Act of 1973, the Fair Labor Standards Act ("FLSA"), the Employee Retirement Income Security Act ("ERISA"), the National Labor Relations Act ("NLRA") and its Washington equivalent, the

Occupational Safety and Health Act, as amended ("OSHA") and its Washington counterpart ("WISHA"), as amended, state and federal medical leave acts, Executive Order 11246, as amended, any and all federal civil rights statutes or ordinances, including Sections 1983 and 1981, as well as under any other federal, state, or local statute, regulation otherwise governing the employment relationship, as well as any claims arising under common law, including contract and tort claims.

This release includes a release of claims of discrimination or retaliation on the basis of workers' compensation status under Washington law, but does not include workers' compensation claims for injuries sustained during employment, rights to unemployment, or any other claims which by law cannot be waived in a private agreement between the parties. Employee is also not releasing any claim for indemnity he may have under any contract of insurance, corporate by-law or policy of indemnity with Employer.

b. By Employer. Employer likewise waives and releases any and all claims, damages, causes of action and rights, whether known or unknown, contingent or noncontingent, contractual or otherwise that it may have or be entitled to assert against Employee that arises out of or relates to Employee's employment with Employer as of the Separation Date. This release does not include (a) claims asserted against Employer by third parties to the extent they are covered by available insurance, (b) any breach by Employee of the obligations set forth in this Agreement, including the continuing obligation of confidentiality, (c) claims arising out of the NDA, or (d) any claims for fraud, embezzlement or theft.

5. No Additional Compensation or Benefits. By signing below, Employee expressly affirms that he has been paid and/or has received all leave or required paid time off (paid or unpaid), compensation, wages (including overtime), bonuses, commissions, and/or benefits to which he may be entitled and that no other compensation, wages, bonuses, commissions, and/or benefits are due to him as a result of his employment with Employer, except as expressly provided in this Agreement.

6. Promise Not to Sue. Employee represents that he has not filed any claim that was released in this Agreement against any of the Releasees with any court or government agency, and that in the future, Employee will not, unless allowed by applicable law, bring a lawsuit against any Releasee based on a claim that was released in this Agreement. However, this section shall not limit Employee from filing a claim to enforce the terms of the Agreement, shall not apply to claims alleging discrimination if doing so would violate applicable law, and shall not apply to any other claim that cannot be waived by law. If any government agency brings any claim or conducts any investigation against Employer, nothing in this Agreement forbids Employee from cooperating in such proceedings, but by this Agreement, Employee waives and agrees to relinquish any damages or other individual relief that may be awarded as a result of any such proceedings.

7. Continuing Confidentiality. Employee acknowledges and reaffirms his post-employment commitments to confidentiality as reflected in the Inventions Assignment and Non-Disclosure Agreement signed by him during employment (the "NDA"), the Nondisclosure Agreement signed by him before employment commenced and effective August 18, 2020 (the "Pre-Employment NDA"), Employer's confidentiality policies and directives communicated to him during employment, and applicable law.

8. Mutual Non-Disparagement. Employee agrees not to make to any other party any statement (whether oral, written, electronic, anonymous, on the Internet, or otherwise) that directly or indirectly impugns the quality or integrity of Employer's or any other Releasee's business practices, products, or operations, or any other disparaging or derogatory remarks about Employer or any Releasee. Likewise, Employer agrees not to authorize any communication that directly or indirectly impugns Employee's professional reputation, and to direct its officers, directors, and executives of this obligation. Notwithstanding the foregoing, this section does not prohibit either party from testifying truthfully in any proceeding, if subject to court order or subpoena.

9. Employee's Protected Rights. Nothing in this Agreement, including Section 8 above, is intended to or shall interfere with Employee's rights under applicable federal or state laws to: (a) file a good faith charge or complaint with the Equal Employment Opportunity Commission, the Occupational Safety and Health Administration, or any other federal, state, or local governmental agency or commission ("Government Agencies"); (b) communicate with any Government Agencies or otherwise participate in any investigation or proceeding that may be conducted by any Government Agency in good faith, including providing documents or other information, without notice to Employer; or (c) receive an award for information provided to any Government Agencies. On the other hand, by signing this Agreement, Employee waives and releases any right to any claims for money damages and equitable relief pursuant to the filing or prosecution of any administrative charge against Employer or any resulting civil proceeding or lawsuit that may be commenced on his behalf for the recovery of such relief, and which arises out of the matters that are and may be released in this Agreement.

10. Non-admission of Liability. This Agreement is to be entered into on a non-precedential basis and shall not be construed in any way as an admission by Employer of any liability whatsoever against Employee or any other persons. Employer specifically disclaims any liability to, or any acts of wrongdoing against Employee or any other persons.

11. Review and Revocation Period. This Agreement was previously presented to Employee, and revised following negotiations through the parties' respective counsel. By signing below Employee acknowledges that he is knowingly and voluntarily waiving and releasing any rights that he may have under the Age Discrimination in Employment Act ("ADEA"). Employee further acknowledges that he has been advised by this writing, as required by the ADEA and the Older Workers Benefit Protection Act ("OWBPA"), that (a) this Agreement does not apply to any rights or claims that may arise after the execution date of this Agreement; (b) Employee has been advise to consult counsel and has in fact been represented by counsel and been advised by an attorney of his choosing in the negotiations and execution of this Agreement; (c) Employee has twenty-one (21) days to consider this Agreement following his receipt of this agreement on June 1, 2021, so until 11:59 pm on June 21, 2021, or the offer of severance and other benefits contained herein is automatically revoked (although Employee may choose to voluntarily execute this Agreement at any time before June 21, 2021 and by doing so thereby waives such period of consideration); (d) Employee has seven (7) days following the execution of this Agreement to revoke the Agreement by written notice to Employer by email delivery to its General Counsel Arian Colachis by email at acolachis@cytodyn.com; and (e) this Agreement will not be effective until the date upon which the revocation period has expired, which will be the eighth (8^{th}) day after this Agreement is executed by Employee, provided that he does not revoke the Agreement by delivering notice of his intent to revoke acceptance by the same message specified in (d) above prior to the expiration of the revocation period ("Effective Date"). Nothing in this Agreement prevents or

precludes Employee from challenging or seeking a determination in good faith of the validity of this waiver under the ADEA, nor does it impose any condition precedent, penalties or costs for doing so, unless specifically authorized by federal law.

12. No Representations. Employee acknowledges that, except as expressly set forth herein, no representations of any kind or character have been made to him by Employer or by any of Employer's agents, representatives, or attorneys to induce the execution of this Agreement.

13. Ownership of Claims. Employee represents that he has not assigned or transferred, or purported to assign or transfer, to any person or entity, any claim or any portion thereof or interest therein related in any way to Employer, its officers, employees, or agents. Employee further agrees to indemnify, defend, and hold harmless each and all of the Releasees against any and all claims based on, arising out of, or in connection with any such transfer or assignment, or purported transfer or assignment, of any claims or any portion thereof or interest therein.

14. Enforceability and Applicable Law. Employee and Employer agree this, and the NDA, represent the entire agreement between them and supersedes any and all prior agreements or understandings with regard to the matters covered herein and can only be modified in writing, signed by both parties. Its separate provisions are binding and enforceable. This Agreement shall be governed by and construed in accordance with the laws of the State of Washington.

15. Knowing and Voluntary Waiver. Employee acknowledges that any questions he may have about this Agreement have been answered to Employee's satisfaction, that he has been represented by counsel in connection with the negotiation and acceptance of this Agreement, that his waiver and release of any rights or claims he may have against Employer is knowing and voluntary, and that he has signed this Agreement freely, without coercion or duress.

16. Counterparts and Electronic Signatures. This Agreement may be executed in counterparts and each shall be deemed an original, but all of which together shall constitute a single instrument. The parties agree further that the exchange of copies of this Agreement and of signature pages by facsimile or electronic mail in "portable document format" (".pdf") form, or by any other electronic means intended to preserve the original graphic and pictorial appearance of a document, shall constitute effective execution and delivery of this Agreement as to the parties and may be used in lieu of the original Agreement for all purposes. Signatures of the parties transmitted by electronic means as described herein shall be deemed to be their original signatures for all purposes.

PLEASE READ CAREFULLY. THIS AGREEMENT INCLUDES A RELEASE OF CERTAIN KNOWN OR UNKNOWN CLAIMS.

EMPLOYEE:	EMPLOYER:
	CytoDyn Inc.
/s/ Mahboob U. Rahman	/s/ Nader Pourhassan
Mahboob U. Rahman, M.D., Ph.D.	By: Nader Pourhassan, Ph.D.
Date: 6/1/2021	Date: 6/1/2021

Exhibit 21

SUBSIDIARIES

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

Exhibit 23

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-206813, 333-223884, 333-237490 and 333-206813) and Registration Statements on Form S-3 (Nos. 333-228991, 333-233526, 333-236198, 333-248823, 333-251522, 333-252154 and 333-253843) of our report dated July 30, 2021, with respect to the consolidated financial statements of CytoDyn Inc. and the effectiveness of internal control over financial reporting of CytoDyn Inc., included in this Annual Report on Form 10-K for the year ended May 31, 2021. Our report on the consolidated financial statements contains an explanatory paragraph regarding substantial doubt as to CytoDyn Inc.'s ability to continue as a going concern.

/s/ Warren Averett, LLC

Birmingham, Alabama
July 30, 2021

Exhibit 24

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Nader Z. Pourhassan and Antonio Migliarese, and each of them, his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, to sign the registrant's Annual Report on Form 10 K for the fiscal year ended May 31, 2021, including any and all amendments and supplements thereto, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully and to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Signatures	Title	Date
/s/ Nader Z. Pourhassan	Director, President and Chief Executive Officer	July 29, 2021
Nader Z. Pourhassan, Ph.D.	(Principal Executive Officer)	
/s/ Antonio Migliarese	Chief Financial Officer and Treasurer	July 30, 2021
Antonio Migliarese	(Principal Financial Officer and Principal Accounting Officer)	
/s/ Scott A. Kelly	Director, Chairman	July 29, 2021
Scott A. Kelly, M.D.		
/s/ Gordon A. Gardiner	Director	July 29, 2021
Gordon A. Gardiner		
/s/ Jordan G. Naydenov	Director	July 29, 2021
Jordan G. Naydenov		
/s/ Samir R. Patel	Director	July 29, 2021
Samir R. Patel, M.D.		
/s/ Alan P. Timmins	Director	July 29, 2021
Alan P. Timmins		

Exhibit 31.1

Certification of Chief Executive Officer

I, Nader Z. Pourhassan, 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 quarterly 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 quarterly 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: July 30, 2021

/s/ Nader Z. Pourhassan
Nader Z. Pourhassan, Ph.D.
President and Chief Executive Officer

Exhibit 31.2

Certification of Chief Financial Officer

I, Antonio Migliarese, certify that:

1. I have reviewed this Annual Report on Form 10-K of CytoDyn Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:
    a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly 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 quarterly 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: July 30, 2021

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

Exhibit 32

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350

In connection with the Annual Report of CytoDyn Inc. (the "Company") on Form 10-K for the fiscal year ended May 31, 2021, 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/ Nader Z. Pourhassan
Nader Z. Pourhassan, Ph.D.
President and Chief Executive Officer
Date: July 30, 2021

/s/ Antonio Migliarese
Antonio Migliarese
Chief Financial Officer
Date: July 30, 2021

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.