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, 2019

or

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

For the transition period from_____ to _____

Commission file number 000-49908

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

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

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

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

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

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

Title of class

Common Stock, par value $0.001 per share

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

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

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

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

Indicate by checkmark whether the registrant is a large accelerated filer, an accelerated filer, anon-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 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 asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter: $144,497,302 as of November 30, 2018.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date. As of June 30, 2019, the registrant had 364,748,563 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Document	Parts Into Which Incorporated
Portions of the Proxy Statement for the 2019 Annual Meeting of Stockholders	Part III

CYTODYN INC.

FORM 10-K FOR THE YEAR ENDED MAY 31, 2019

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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, including our clinical focus and our current and proposed trials. 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 differ 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. 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 sufficiency of our cash position and our ongoing ability to raise additional capital to fund our operations, (ii) our ability to complete the filing of a Biologics License Application ("BLA") with the U.S. Food and Drug Administration ("FDA") for leronlimab (PRO 140), as a combination therapy for the Human Immunodeficiency Virus ("HIV"), (iii) our ability to meet our debt obligations, if any, (iv) our ability to identify patients to enroll in our clinical trials in a timely fashion, (v) our ability to achieve approval of a marketable product, (vi) design, implementation and conduct of clinical trials, (vii) the results of our clinical trials, including the possibility of unfavorable clinical trial results for any clinical indication, (viii) the market for, and marketability of, any product that is approved, (ix) our ability to enter into partnership or licensing arrangements with third parties, (x) the existence or development of vaccines, drugs, or other treatments for infection with HIV that are viewed by medical professionals or patients as superior to our products, (xi) regulatory initiatives, compliance with governmental regulations and the regulatory approval process, (xii) general economic and business conditions, (xiii) changes in foreign, political, and social conditions, (xiv) the specific risk factors discussed under the heading "Risk Factors" below, and (xv) various other matters, many of which are beyond our 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 Form10-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 which may cause actual results to differ from those expressed or implied by these forward-looking statements.

PART I

Item 1. Business.

Overview/Corporate History

CytoDyn Inc. was originally incorporated under the laws of Colorado on May 2, 2002 under the name RexRay Corporation (our previous name). Effective August 27, 2015, we completed a reincorporation from Colorado to Delaware. Our principal business office is 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 contents from our website into this annual report. 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.

We are a late-stage biotechnology company focused on the clinical development and potential commercialization of leronlimab (PRO 140), a CCR5 antagonist to treat 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 annual report.

Our current business strategy is to prioritize the completion our BLA filing for leronlimab as a combination therapy for highly treatment experienced HIV patients, to advance our Phase 1b/2 clinical trial metastatic breast cancer, to continue our Phase 2 trial for graft-versus-host disease ("GvHD"), to finalize with the FDA our submitted protocol for a pivotal Phase 3 clinical trial with leronlimab as a monotherapy for HIV patients and concurrently to explore other cancer and immunologic indications for leronlimab.

Overview

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 a variety of indications. The target of leronlimab is the immunologic receptor CCR5. The CCR5 receptor is a protein located on the surface of a variety of 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 healthyT-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. 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.

Due to its selectivity and target-specific mechanism of action, leronlimab appears to allow chemokine binding (CCL3, CCL4) at therapeutic doses and appears not to be an agonist of the CCR5 receptor (i.e., it does not appear to activate the immune function of the receptor). This apparent target specificity differentiates leronlimab from other CCR5 antagonists. Other potential advantages of leronlimab include longer half-life and less frequent dosing requirements.

The CCR5 receptor has been identified as a target in HIV, GvHD, NASH, cancer metastasis, transplantation medicine, multiple sclerosis, traumatic brain injury, stroke recovery, and a variety of inflammatory conditions. As we progress in evaluating leronlimab via a pathways approach, we see an opportunity to build a broad pipeline of indications through label expansion following initial approval for multi-drug resistant HIV.

The preclinical and clinical development of PRO 140 was led by Progenics Pharmaceuticals, Inc. ("Progenics") through 2011. We acquired the asset from Progenics in October 2012, as described in "PRO 140 Acquisition and Licensing Arrangements" below, and filed the non-clinical portion of our BLA on March 18, 2019. The non-clinical portion constitutes the first of three sections of the BLA, and we are progressing forward with the preparation and submission of the clinical and Chemistry, Manufacturing, and Controls ("CMC") portions.

Leronlimab and Human Immunodeficiency Virus ("HIV")

We believe the leronlimab antibody shows promise as a powerful anti-viral 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 into and infecting certain 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 as part of HIV's entry into a cell.

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 patientnon-compliance issues, such as toxicity and side effects, coupled with the need for a strict regimen of daily dosing. In eight clinical trials previously conducted, leronlimab was generally well tolerated, and no 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. The results of these studies established that leronlimab's antiviral activity was 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 very useful method of suppressing the virus in treatment-experienced patients who have failed a prior HIV regimen and need new treatment options. Leronlimab, as a single agent therapy, has also demonstrated that it could potentially 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 (as compared to existing treatments) 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 ongoing HIV-related clinical trials, as summarized below, have been designed to demonstrate the proof of concept that leronlimab 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 can help maintain the suppressed viral load in a subpopulation of R5 patients over an extended period of time (currently shown to be in excess of four and a half years). Based on the preliminary results of such studies, we believe that a leronlimab treatment option could also address the unmet medical need for therapy options for certain HIV-infected patients with uncontrolled viral load, despite conventional HAART treatments. Accordingly, we recently submitted to the FDA a pivotal Phase 3 trial protocol for leronlimab as monotherapy.

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 test to measure the expression of CCR5 in HIV and tumor cells that are occupied by leronlimab. Development of this test could more precisely guide us in 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. Subsequently, we entered into an exclusive worldwide licensing agreement with IncellDX to sell non-commercial grade quantities of PA-14 or PRO 140 for use in the development and commercialization of immunoassays for quantitative measurement of CCR5 levels on human cells.

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 the vast majority of cancer patients.

Research has shown that a majority of 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 since announced that we will begin multiple pre-clinical studies on melanoma cancer, pancreatic, breast, prostate, colon, lung, liver, and stomach cancer. Pending the results of such studies, we could eventually advance multiple Phase 2 clinical trials with leronlimab in the cancer arena. We have reported that our pre-clinical research with leronlimab was able to reduce 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 (PRO 140) for use in combination with carboplatin for the treatment of patients with CCR5-positive mTNBC.

Leronlimab and Immunological Applications

We are continuing to explore opportunities for clinical applications for leronlimab involving the CCR5 receptor, other thanHIV-related treatments, such as inflammatory conditions, autoimmune diseases and cancer.

The target of leronlimab is the immunologic receptor CCR5. We believe that the CCR5 receptor is more than the door for HIV to enterT-cells: it is also a crucial component in inflammatory responses. This could open the 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 PRO 140 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 have already reported encouraging human safety data for our clinical trials with leronlimab in HIV-infected patients.

We have initiated our first clinical trial with leronlimab in an immunological indication – a Phase 2 clinical trial with leronlimab for GvHD in reduced intensity conditioning ("RIC") patients with acute myeloid leukemia ("AML") or myelodysplastic syndrome ("MDS") who are undergoing bone marrow stem cell transplantation. GvHD represents an unmet medical need, with patients who contract GvHD during stem cell transplant having a significantly decreased 1-year survival rate with relapsed GvHD as the leading cause of death. Ourpre-clinical study in GvHD has been published in the peer-reviewed journal *Biology of Blood and Marrow Transplantation*. The FDA has granted orphan drug designation to leronlimab for the prevention of acute GvHD.

GvHD is a risk when patients receive bone marrow stem cells donated from another person. GvHD is a serious complication that limits the use of Bone Marrow Stem Cell ("BMSC") transplantation in patients with blood cancers. GvHD occurs when the donor's immune cells attack the patient's normal tissues (skin, liver, gut). GvHD can be acute or chronic. Its severity depends on the differences in tissue type between patient and donor. Acute GvHD can occur soon after the transplanted cells begin to appear in the recipient and can range from mild to severe and can be life-threatening.

The CCR5 receptor, the target for leronlimab, appears to be an important mediator of GvHD, especially in the organ damage that is the usual cause of death. We believe that the CCR5 receptor on engrafted cells is critical for the development of acute GvHD and by blocking this receptor from recognizing certain immune signaling molecules could be a viable approach to mitigating acute GvHD. The potential of leronlimab to prevent this life-threatening condition could help extend the use of BMSC transplantation to effectively treat more patients.

We are also exploring the ability of leronlimab to prevent the progression ofNon-Alcoholic Fatty Liver Disease ("NAFLD") intoNon-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 by 2020.

We continue to expand the clinical focus with leronlimab to include the evaluation in certain cancer and immunological indications where CCR5 antagonism has shown initial promise.

Prostate Diagnostic Test—PCa Test

An important asset in development that we acquired from ProstaGene, LLC ("ProstaGene") is the Prostate Diagnostic Test (the "PCa Test"). This test, developed by a leading oncologist, is intended to determine outcomes of patients diagnosed with prostate cancer compared to the Gleason score, the current standard test for prostate cancer diagnosis. It leverages technology using an artificial intelligence approach based on gene signatures. The PCa Test employs 16 gene biomarker signatures for prognostication and therapeutic substratification of prostate cancer using sophisticated proprietary artificial intelligence algorithms.

Prostate cancer is the most commonly diagnosed cancer in men, except for non-melanoma skin cancer. About one in nine men in the United States will be diagnosed with prostate cancer during their lifetimes. It is believed to be the second leading cause of cancer death among men in the United States. Worldwide, it is estimated that there are well over 1 million new cases of prostate cancer and 366,000 prostate cancer deaths annually.

The current standard of care for treating prostate cancer is based upon the Gleason score. Patients with prostate cancer with a low Gleason score are observed, while those with higher Gleason scores typically undergo radical prostatectomy. The PCa Test potentially provides a "second opinion" and therefore could provide valuable guidance to assist physicians and patients to make more educated and informed decision regarding appropriate treatments. Our plan for the PCa Test is to successfully advance its development to obtain a Section 510(k) clearance from the FDA for commercial use or to out-license the proprietary technology to a third party.

Current Clinical Trials

We will require a significant amount of additional capital to complete the preparation and submission of the remaining two sections of our BLA filing and to complete our clinical trial programs for leronlimab. See "Liquidity and Capital Resources" under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" below.

To facilitate our clinical research plans and trials, we have previously engaged Amarex Clinical Research, LLC ("Amarex"), as our principal contract research organization ("CRO"), to provide comprehensive regulatory and clinical trial management services.

Leronlimab is currently being studied in the following clinical trials:

Phase 2b Extension Study for HIV, as Monotherapy. Currently, there are four patients in this ongoing extension study and each has surpassed four and one-half years of suppressed viral load with PRO 140 as a single agent therapy. This extension study will be discontinued upon any FDA approval of leronlimab.

Rollover Study for HIV as Combination Therapy. This study is designed for patients who successfully completed the pivotal Phase 2b/3 Combination Therapy trial (which met its primary endpoint and serves as the basis for our current BLA filing) and for whom the treating physicians request a continuation of leronlimab therapy in order to maintain suppressed viral load. This extension study will be discontinued upon any FDA approval of leronlimab.

Phase 2b/3 Investigative Trial for HIV, as Long-term Monotherapy Enrollment for this trial is now closed after reaching 500 patients. This trial assesses using leronlimab subcutaneously as a 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. The secondary endpoint is the length of time to virologic failure. We completed the evaluation two higher-dose arms, one with 525 mg dose (a 50% increase from the original dosage of 350 mg), as well as a 700 mg dose. We recently reported that interim data suggested that both the 525 mg and the 700 mg dosages are achieving a responder rate of approximately 90% after the initial 10 weeks. This trial has also been used to provide safety data for the BLA filing for leronlimab as a combination therapy. In view of the high responder rate at the increased dosage levels, coupled with the newly developed CCR5 occupancy test, we recently filed a pivotal trial protocol with the FDA for leronlimab as a monotherapy. Upon finalization with the FDA of the pivotal trial protocol for monotherapy, this Phase2b/3 investigative trial will likely be discontinued.

Phase 1b/2 Trial for Triple-Negative Breast Cancer. We recently received clearance from the FDA for our IND submission to initiate a Phase 1b/2 clinical trial for metastatic triple-negative breast cancer patients. In May 2019, the FDA granted leronlimab Fast Track designation for use in combination with carboplatin. We have identified five clinical trial sites and expect to dose the first patients during the third quarter of calendar 2019. The change in circulating tumor cells ("CTCs") number will be evaluated every 21 days during treatment and will be used as an initial prognostic marker for efficacy. Up to 48 patients are expected to be enrolled in this study. First patient dosing is expected in the third quarter of calendar 2019.

Phase 2 Trial for Graft-versus-Host Disease. This Phase 2 multi-center100-day study with 60 patients is designed to evaluate the feasibility of the use of leronlimab as an add-on therapy to standard GvHD prophylaxis treatment for prevention of acute GvHD in adult patients with AML or MDS undergoing allogeneic hematopoietic stem cell transplantation ("HST"). Enrollment of the first patient was announced in May of 2017. On October 5, 2017, we announced that the FDA had granted orphan drug designation to leronlimab (PRO 140) for the prevention of GvHD. In March 2018, we announced that the Independent Data Monitoring Committee ("IDMC") for leronlimab (PRO 140) Phase 2 trial in GvHD had completed a planned interim analysis of trial data on the first 10 patients enrolled. Following this review of data from the first 10 patients in the Phase 2 trial, we filed amendments to the protocol with the FDA. The amendments included switching the pretreatment conditioning regimen from aggressive myeloablative ("MA")

conditioning to a reduced intensity conditioning ("RIC"), and switching from a blinded one-for-one randomized placebo-controlled design to an open-label design under which all enrollees receive leronlimab. The amendments also provide for a 100% increase in the dose of leronlimab, to 700 mg, to more closely mimic pre-clinical dosing. The next review of data by the IDMC will occur following enrollment of 10 patients under the amended protocol after each patient has been dosed for 30 days. Due to the necessary prioritization of limited capital, enrollment under the amended protocol has been temporarily delayed.

Other Product Candidates

Except as otherwise disclosed above, until certain clinical trials for leronlimab have advanced further and the remaining two section of our BLA filing are submitted, we do not plan to devote material resources towards the development, research, testing, approval or commercialization of other product candidates.

PRO 140 Acquisition and Licensing Arrangements

We originally acquired PRO 140, 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 PRO 140; and (ii) royalty payments of up to 5% on net sales during the period beginning on the date of the first commercial sale of 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. 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 PRO 140 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 PRO 140 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 PRO 140 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 PRO 140. We currently use an independent party as a contract manufacturer for PRO 140. Therefore, if this arrangement continues, an annual license fee of £300,000 (approximately US$365,000 given current exchange rate) would continue to apply, as well as a royalty, up to 2% of the net selling price upon commercialization of PRO 140, excluding value added taxes and similar amounts.

Patents, Proprietary Technology and Data Exclusivity

Protection of our 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 that, absent patent term extension, patent protection relating to the PRO 140 antibody itself will start to expire in 2023, certain methods of using PRO 140 for treatment of HIV-1 will start to expire in 2026, certain formulations comprising PRO 140 will start to expire in 2031, and certain methods of using small-molecule CCR5 antagonists for treatment of cancer metastasis will start to expire in 2032.

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 generally 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 PRO 140 will be subject to at least al 2-year data exclusivity period measured from the first date of FDA licensure, during which period no other applications referencing PRO 140 will be approved by FDA. Further, no other applications referencing PRO 140 will be accepted by FDA for a 4-year period measured from the first date of FDA licensure. Accordingly, this period of data exclusivity is expected to provide at least a 12-year term of protection against competing products shown to be biosimilar or interchangeable with PRO 140. 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 28, 2019, is set forth below.

	Number of Patents		Expiration Dates(1)	Number of Patent Applications	
	U.S.	International		U.S.	International
PRO 140 product candidate(2)	8	35	2018-2032	12	26
Prostate cancer diagnostics				2	
Methods involving treatment of cancer metastasis and anti-CCR5 agents	1	3	2032-2033	3	12
Mouse model				1	1

(1) Patent term extensions and pending patent applications may extend periods of patent protection.
(2) PRO 140 patents and applications relate to HIV-1, GvHD, immunomodulation and cancer treatments.

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

Regulation of Health Care Industry

The health care industry is highly regulated, and state and federal health care laws and regulations are applicable to certain aspects of our business. For example, there are federal and state health care laws and regulations that apply to the business relationships between health care providers and suppliers, the privacy and security of health information and the conduct of clinical research.

Regulation of Products

The design, testing, manufacture, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of our products is regulated by numerous third parties, including the FDA, foreign governments, independent standards auditors and our customers.

In the United States, biological products and medical devices, including diagnostic products, have long been subject to regulation by various federal and state agencies, primarily as to product safety, efficacy, manufacturing, advertising, labeling, import, export and safety reporting. The exercise of broad regulatory powers by the FDA through its and its Center for Biological Evaluation and Research and its Center for Devices and Radiological Health continues to result in increases in the amounts of testing and documentation for FDA clearance of current and new biologic products and medical devices. The FDA can ban certain products; detain or seize adulterated or misbranded products; order repair, replacement or refund of these products; and require notification of health professionals and others with regard to products that present unreasonable risks of substantial harm to the public health. The FDA may also enjoin and restrain certain violations of the Federal Food, Drug, and Cosmetic Act, as amended, or the Public Health Service Act pertaining to certain products or initiate action for criminal prosecution of such violations.

The lengthy process of seeking approvals, and the subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Failure to comply with applicable regulations can result in refusal by the FDA to approve product license applications. The FDA also has the authority to revoke previously granted product approvals.

Pharmaceutical products such as leronlimab (PRO 140) may not be commercially marketed without prior approval from the FDA and comparable agencies in foreign countries. In the United States, the process for obtaining FDA approval for products like leronlimab (PRO 140) typically includes pre-clinical studies, the filing of an IND, human clinical trials and filing and approval of either a New Drug Application (“NDA”), for chemical pharmaceutical products, or a BLA for biological pharmaceutical products, such as leronlimab (PRO 140). The results of pre-clinical testing, which include laboratory evaluation of product chemistry and formulation, animal studies to assess the potential safety and efficacy of the product and its formulations, details concerning the drug manufacturing process and its controls, and a proposed clinical trial protocol and other information must be submitted to the FDA as part of an IND that must be reviewed and become effective before clinical testing can begin. The study protocol and informed consent information for patients in clinical trials must also be submitted to an independent institutional review board (“IRB”), for approval. Once a sponsor submits an IND, the sponsor must wait 30 calendar days before initiating any clinical trials, during which time the FDA has an opportunity to review the IND and raise concerns or questions relating to the proposed clinical trials outlined in the IND. If the FDA has comments or questions, they must be resolved to the satisfaction of the FDA before clinical trials can begin. In addition, the FDA, an IRB or we may, at any time, impose a clinical hold on ongoing clinical trials. If the FDA imposes a clinical hold, clinical trials cannot commence or recommence without FDA authorization and then only under terms authorized by the FDA. Our non-clinical and clinical studies must conform to the FDA’s Good Laboratory Practice (“GLP”), and Good Clinical Practice (“GCP”), requirements, which are designed to ensure the quality and integrity of submitted data and protect the rights and well-being of study patients. Information for certain clinical trials also must be publicly disclosed within certain time limits on the clinical trial registry and results databank maintained by the National Institutes of Health (“NIH”).

The results of the pre-clinical and clinical testing, chemistry, manufacturing and control information and proposed labeling are then submitted to the FDA in the form of either an NDA or BLA for review and potential approval to commence commercial sales. In responding to an NDA or BLA, the FDA may grant marketing approval, request additional information in a complete response letter, or deny the approval if it determines that the NDA or BLA does not provide an adequate basis for approval. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of an NDA or BLA and may require additional testing. If and when those conditions have been met to the FDA’s satisfaction, the FDA will typically issue an approval letter, which authorizes commercial marketing of the product with specific prescribing information for specific indications, and sometimes with specified post-marketing commitments. Any approval required from the FDA might not be obtained on a timely basis, if at all.

Among the conditions for an NDA or BLA approval is the requirement that the manufacturing operations conform on an ongoing basis with current Good Manufacturing Practices (“cGMPs”). In complying with cGMPs, we must expend time, money and effort in the areas of training, production and quality control within our own organization and at our contract manufacturing laboratories. A successful inspection of the manufacturing facility by the FDA is a prerequisite for final approval of a biological product like leronlimab (PRO140). Following approval of the NDA or BLA, we and our third-party manufacturers remain subject to periodic inspections by the FDA. We also face similar inspections coordinated by the European Medicines Agency by inspectors from particular European Union (“EU”) member countries that conduct inspections on behalf of the EU and from other foreign regulatory authorities. Any determination by the FDA or other regulatory authorities of manufacturing or other deficiencies could materially adversely affect our business.

Regulatory requirements and approval processes in EU countries are similar in principle to those in the United States and can be at least as costly and uncertain. The EU has established a unified centralized filing and approval system administered by the Committee for Medicinal Products for Human Use designed to reduce the administrative burden of processing applications for pharmaceutical products derived from new technologies. In addition to obtaining regulatory approval of products, it is generally necessary to obtain regulatory approval of the facility in which the product will be manufactured.

We use and plan to continue to use third-party manufacturers to produce our products in clinical and commercial quantities. Future FDA inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of problems with a product, including new safety risks, or the failure to comply with requirements may result in restrictions on a product, manufacturer or holder of an approved NDA or BLA, including withdrawal or recall of the product from the market or other voluntary or FDA-initiated action that could delay further marketing. Newly discovered or developed safety or efficacy data may require changes to an approved product's approved labeling, including the addition of new warnings and contraindications, the imposition of additional mandatory post-market studies or clinical trials, or the imposition of or revisions to a risk evaluation mitigation strategies ("REMS ") program, including distribution and/or use restrictions.

Once a BLA is approved, a product will be subject to certain post-approval requirements, including requirements for adverse event reporting and submission of periodic reports to the FDA, recordkeeping, product sampling and distribution, and, as discussed above, may be subject to mandatory post-market study and REMS requirements. In addition, the FDA strictly regulates the promotional claims that may be made about prescription drug products and biologics. In particular, a drug or biologic may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. 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. The FDA also requires substantiation of any claims of superiority of one product over another, including the requirement that such claims be proven by adequate and well-controlled head-to-head clinical trials. The FDA also requires all promotional materials that discuss the use or effectiveness of a prescription drug or biologic to disclose in a balanced manner the risks and safety profile of the product.

Regulation of Laboratory Operations

Clinical laboratories that perform laboratory testing (except for research purposes only) on human patients are subject to regulation under Clinical Laboratory Improvement Amendments ("CLIA"). CLIA regulates clinical laboratories by requiring that the laboratory be certified by the federal government, licensed by the state and comply with various operational, personnel and quality requirements intended to ensure that clinical laboratory test results are accurate, reliable and timely. State law and regulations also apply to the operation of clinical laboratories.

State Governments

Most states in which we operate have regulations that parallel federal regulations. Most states conduct periodic unannounced inspections and require licensing under such state's procedures. Our research and development activities and the manufacture and marketing of our products are and will be subject to rigorous regulations relating to product safety and efficacy by numerous governmental authorities in the United States and other countries.

Other Laws and Regulations

We are subject to various laws and regulations relating to safe working conditions, clinical, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research. The extent of government regulation applying to our business that might result from any legislative or administrative action cannot be accurately predicted.

Environmental

We are subject to a variety of federal, state and local environmental protection measures. We believe that our operations comply in all material respects with applicable environmental laws and regulations. Our compliance with these regulations did not have during the past year and is not expected to have a material effect upon our capital expenditures, cash flows, earnings or competitive position.

Registrational Clinical Trials Process

Described below is the traditional registrational drug development track. Our current business strategy is to focus on completing our BLA filing for leronlimab as a combination therapy for highly treatment experienced HIV patients, advance our Phase 1b/2 clinical trial metastatic breast cancer, continue our Phase 2 trial for GvHD, finalize with the FDA our submitted protocol for a pivotal Phase 3 clinical trial with leronlimab as a monotherapy for HIV patients and to concurrently explore other cancer and immunologic indications for leronlimab.

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 have been 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 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, 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. 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 second approved drug outside of the main four classes of drugs approved for HIV since 2007.

The only other monoclonal antibody that recently received FDA approval isTMB-335, also referred to as Ibalizumab, which was developed by TaiMed Biologics. Ibalizumab targets the CD4 receptor on T-cells which is one of the two co-receptors required for HIV entry into T-cells.

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 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 analogous 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.

As we evaluate 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.

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 two global contract manufacturing organizations (“CMOs”) to initiate thescale-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 a suitable CMO to fill, 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 CMO’s for all of our developmental and commercial needs.

Regulation of Medical Devices, Including Diagnostics such as the PCa Test

Medical Device Classification

The FDA classifies medical devices into one of the following three classes on the basis of the amount of risk associated with the medical device and the controls deemed necessary to reasonably ensure their safety and effectiveness:

- Class I, requiring general controls, including labeling, device listing, reporting and, for some products, adherence to good manufacturing practices through the FDA’s quality system regulations and pre-market notification;
- Class II, requiring general controls and special controls, which may include performance standards and post-market surveillance; or
- Class III, requiring general controls and approval of a premarket approval application (“PMA”), which may include post-market approval conditions and post-market surveillance.

As a result of the intended use of the PCa Test and the technology upon which it is based, we anticipate that the PCa test could be regulated by FDA as either a Class III or a Class II medical device.

US Regulatory Approval Process

Products that are regulated as medical devices and that require review by the FDA are subject to either a premarket notification, also known as a 510(k), which must be submitted to the FDA for clearance, or a PMA application, which the FDA must approve prior to marketing in the U.S. We believe that the PCa Test will be subject to the 510(k) premarket notification procedure, but the FDA will ultimately determine the appropriate regulatory path.

To obtain 510(k) marketing clearance for a medical device, an applicant must submit a premarket notification application to the FDA demonstrating that the device is "substantially equivalent" to a predicate device, which is typically a legally marketed Class II device in the United States. A device is substantially equivalent to a predicate device if it has the same intended use and (i) the same technological characteristics, or (ii) has different technological characteristics and the information submitted demonstrates that the device is as safe and effective as a legally marketed device and does not raise different questions of safety or effectiveness. In some cases, the submission must include data from human clinical studies. Marketing may commence when the FDA issues a clearance letter finding substantial equivalence. While less onerous than the PMA process, the 510(k) process can be lengthy and expensive. The current average time between submission of a 510(k) application and FDA clearance is approximately six months. In addition, significant modifications to a cleared 510(k) device may require the submission of a new 510(k).

A PMA must be submitted to the FDA if a device cannot be cleared through another approval process or is not otherwise exempt from the FDA's premarket clearance and approval requirements. A PMA is required for most Class III medical devices. A PMA must generally be supported by extensive data, including without limitation technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA's satisfaction the safety and efficacy of the device for its intended use. During the review period, the FDA will typically request additional information or clarification of the information previously provided. Also, an advisory panel of experts from outside the FDA may be convened to review and evaluate the PMA and provide recommendations to the FDA as to the approvability of the device, although the FDA may or may not accept any such panel's recommendation. In addition, the FDA will generally conduct a pre-approval inspection of the manufacturing facility or facilities involved with producing the device to ensure compliance with the cGMP regulations. Upon approval of a PMA, the FDA may require that certain conditions of approval, such as conducting a post-market approval clinical trial, be met.

The PMA approval process can be lengthy and expensive and requires an applicant to demonstrate the safety and efficacy of the device based, in part, on data obtained from clinical trials. The PMA process is estimated to take from one to three years or longer, from the time the PMA application is submitted to the FDA until an approval is obtained.

Further, if post-approval modifications are made that affect the safety or efficacy of the device, including, for example, certain types of modifications to the device's indication for use, manufacturing process, labeling or design, then new PMAs or PMA supplements would be required. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is typically limited to information needed to support the changes from the device covered by the original PMA and accordingly may not require as extensive clinical and other data.

We have not submitted to the FDA for either 510(k) or a PMA or commenced clinical trials. Even if we conduct successful preclinical and clinical studies and submit a 510(k) or PMA, the FDA may not permit commercialization of PCa Test for the desired indications, on a timely basis, or at all. Our inability to achieve regulatory approval for PCa Test in the U.S. for the desired indication could materially adversely affect our ability to grow our business.

Post-Approval Regulation

After a medical device obtains approval from the applicable regulatory agency and is launched in the market, numerous post-approval regulatory requirements apply, including:

- product listing and establishment registration;
- requirements that manufacturers, including third-party manufacturers, follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling and other advertising regulations, including prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication;
- approval of product modifications that affect the safety or effectiveness of any of our devices that may achieve approval;

- post-approval restrictions or conditions, including post-approval study commitments;
- post-market surveillance regulations, which apply, when necessary, to protect the public health or to provide additional safety and effectiveness data for the device;
- the recall authority of the applicable government agency and regulations pertaining to voluntary recalls; and
- reporting requirements, including reports of incidents in which a product may have caused or contributed to a death or serious injury or in which a product malfunctioned, and notices of corrections or removals.

Failure by us or by our third-party manufacturers and other suppliers to comply with applicable regulatory requirements could result in enforcement action by various regulatory authorities, which may result in monetary fines, the imposition of operating restrictions, product recalls, criminal prosecution or other sanctions.

Research and Development Costs

Our research and development expenses totaled approximately $42.5 million, $38.2 million and $20.2 million for the fiscal years ended May 31, 2019, May 31, 2018 and May 31, 2017, respectively. We expect our research and development expenses to continue to increase in future periods as the activity within our clinical trials expands and our biologics manufacturing processes and related regulatory compliance activities increase.

Employees and Consultants

We currently have 10 full-time employees, as well as several independent consultants assisting us with our BLA preparation, manufacturing activities, regulatory matters and management of our clinical trials. 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.

Item 1A. Risk Factors.

The risks enumerated below are not the only risks we face, and the listed risk factors are not intended to be anall-inclusive discussion of all of the potential risks relating to our business. Any of the risk factors described below could significantly and adversely affect our business, prospects, financial condition and results of operations. Additional risks and uncertainties not currently known or that are currently considered to be immaterial may also materially and adversely affect our business.

Risks Related to Our Business

We are a biotechnology company and have a history of significant operating losses; we expect to continue to incur operating losses, and we may never achieve or maintain profitability.

We have not generated any 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 in connection with research and development activities and general and administrative expenses associated with our operations. Our current drug candidate, leronlimab, is in the later stages of clinical trials and the filing of a BLA is underway. During the fiscal years ended May 31, 2019 and 2018, we incurred net losses of approximately $56.2 million and $50.1 million, respectively, and at May 31, 2019, we had an accumulated deficit of approximately $229.4 million and a stockholders' deficit of $8.9 million. We expect to incur losses for the foreseeable future as we continue development of, and seek regulatory approvals for, our drug candidate and commercialize any approved product usages. If our current drug candidate fails to gain regulatory approval, or if it or other candidates we own do not achieve approval and market acceptance, we will not be able to generate any 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 losses, our shareholders could lose all or part of their investments.

Any failure to attract and retain skilled directors, executives, employees and consultants could impair 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, which may affect their ability to provide services to us in a timely manner. We may need to recruit additional directors, executive management employees, and advisers, 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. 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.

In July 2019, Dr. Richard G. Pestell was terminated as our Chief Medical Officer. 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 can be inherently difficult to manage and may cause uncertainty or a disruption to our business or may increase the likelihood of turnover of other key officers and employees. Specifically, a leadership transition in the commercial team may cause uncertainty about or a disruption to our commercial organization, which may impact our ability to achieve sales and revenue targets.

We expect to rely on third party manufacturers and will be dependent on their quality and effectiveness.

Our primary product candidate and potential drug candidates require precise, high-quality manufacturing. The failure to achieve and maintain high manufacturing standards, including failure to detect or control unexpected events or unanticipated manufacturing errors or the frequent occurrence of such errors, could result in patient injury or death, discontinuance or delay of ongoing or planned clinical trials, delays or failures in product testing or delivery, cost overruns, product recalls or withdrawals and other problems that could seriously hurt our business. Contract manufacturers of biopharmaceutical drugs can encounter difficulties involving manufacturing processes, facilities, operations, production yields, quality control, compliance and shortages of qualified personnel. These manufacturers are subject to stringent regulatory requirements, including the FDA's current good-manufacturing-practices (cGMP) regulations and similar foreign laws and standards. If our contract manufacturers fail to maintain ongoing compliance at any time, we may be

unable to obtain regulatory approval for our products. In addition, the production of our product candidate could be interrupted, resulting in delays or discontinuance of our clinical trials, disruption in our release of commercial supplies, or other factors that could cause increases in costs and loss of potential revenues.

If for any reason, these third parties are unable or unwilling to perform, we may not be able to terminate our agreements with them, and we may not be able to locate alternative manufacturers or formulators or enter into favorable agreements with them and we cannot be certain that any such third parties will have the manufacturing capacity to meet future requirements. If these manufacturers or any alternate manufacturer of finished drug product experiences any significant difficulties in its respective manufacturing processes for our active pharmaceutical ingredient, or API, or our finished products or should cease doing business with us, we could experience significant interruptions in the supply of our drug candidates or may not be able to create a supply of our drug candidates at all. Were we to encounter manufacturing issues, our ability to produce a sufficient supply of our drug candidates might be negatively affected. Our inability to coordinate the efforts of our third party manufacturing partners, or the lack of capacity available at our third party manufacturing partners, could impair our ability to supply our drug candidates at required levels. Because of the significant regulatory requirements that we would need to satisfy in order to qualify a new bulk or finished product manufacturer, if we face these or other difficulties with our current manufacturing partners, we could experience significant interruptions in the supply of our drug candidates if we decided to transfer the manufacture of our drug candidates to one or more alternative manufacturers in an effort to deal with the difficulties.

We cannot guarantee that our manufacturing and supply partners will be able to manufacture our drug candidates at commercial scale on a cost-effective basis. If the commercial-scale manufacturing costs of our drug candidates are higher than expected, these costs may significantly impact our operating results. In order to reduce costs, we may need to develop and implement process improvements. However, in order to do so, we will need, from time to time, to notify or make submissions with regulatory authorities, and the improvements may be subject to approval by such regulatory authorities. We cannot be sure that we will receive these necessary approvals or that these approvals will be granted in a timely fashion. We also cannot guarantee that we will be able to enhance and optimize output in our commercial manufacturing process. If we cannot enhance and optimize output, we may not be able to reduce our costs over time.

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 four 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 Amarex, a full service contract research organization, to manage our clinical trials. As a result, we will be 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 our BLA filing for our leronlimab drug candidate or other products or commercialize any products that are approved, 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 may involve several 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 drug candidates, increase our cost of goods sold and result in lost sales.

We will need substantial additional funding to complete our Phase 1b/2 clinical trial for triple-negative breast cancer, to continue our Phase 2 clinical trial for GvHD, to fund development of leronlimab for other indications, such as cancer and immunologic 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 further development and clinical trials of leronlimab for other indications, such as cancer, and immunological disorders continue to appear promising and we elect to fund its development and commercialization, 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 our product candidate;
- acquire or license additional internal systems and other infrastructure;
- hire and support additional management and scientific personnel; and
- explore additional indications for leronlimab, such as in the area of cancer and immunology.

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 through 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 the trading price of our common stock is lower at the time of any financing. 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 shareholder. Any debt financing could involve substantial restrictions on activities and creditors could seek a pledge of some or all of our assets. We have not identified potential sources for the additional financing that we will require, and 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, and our results, 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 our funding requirements increase or are otherwise greater than we expect.

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, including our Phase 1b/2 clinical trial for triple-negative breast cancer, our Phase 2 clinical trial for GvHD, a potential pivotal Phase 3 monotherapy trial for HIV and 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 Inc.;
- 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 operations, financial condition, ability to continue operations 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 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;

- the time and costs involved to complete the remaining two sections of our BLA submission;
- the time and costs involved in obtaining regulatory approvals;
- whether our outstanding convertible notes are converted into equity or we receive additional cash upon the exercise of our outstanding common stock warrants;
- whether we receive additional cash upon the exercise of our outstanding warrants and options for common stock;
- 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 fail to raise additional funds on a timely basis we will need to scale back our business plans, which would adversely affect our business, financial condition, and stock price, and we may even be forced to discontinue our operations and liquidate our assets.

We are currently focused on the development of a single product candidate.

Our product development efforts are currently focused on a single product, leronlimab, for which we are researching multiple indications. If leronlimab fails to achieve clinical endpoints or exhibits unanticipated toxicity or if a superior product is developed by a competitor, our prospects for obtaining regulatory approval and commercialization may be negatively impacted. In the long-term, we hope to establish a pipeline of product candidates, and we have identified additional product candidates that we may be able to acquire or license in the future. However, at this time we do not have any formal agreements granting us any rights to such additional product candidates.

Clinical trials are expensive, time-consuming and subject to delay.

Clinical trials are subject to rigorous regulatory requirements and are expensive and time-consuming to design, implement and manage. The length of time and number of trial sites and patients required for clinical trials vary substantially based on the type, complexity, novelty, intended use and any safety concerns relating to a drug candidate. Clinical trials for other indications for leronlimab may take significantly longer to complete than leronlimab's HIV trial program, if clinical trials for other indications are pursued at all.

The commencement and completion of clinical trials could be delayed or prevented by many factors, including, but not limited to:

- periodic amendments to clinical trial protocols to address certain variables which arise during the course of a trial must be negotiated with and approved by the FDA;
- slower than expected rates of patient recruitment and enrollment which has occurred in connection with certain of our trials, including as a result of competition with other clinical trials for patients, limited numbers of patients that meet the enrollment criteria, or the introduction of alternative therapies or drugs by others;
- our ability to obtain regulatory or other approvals to commence and conduct clinical trials in the manner we or our partners consider appropriate for timely development;
- our ability to identify and reach agreement on acceptable terms with prospective clinical trial sites and entities involved in the conduct of our clinical trials;
- unforeseen issues with our relationship with our contract clinical management services provider;
- delays in paying third-party vendors of biopharmaceutical services;
- lack of effectiveness of our drug candidates during clinical trials; or
- unforeseen safety issues.

Product development costs for our products will increase if we have delays in testing or approval or if we need to perform more or larger clinical studies than planned. Additionally, changes in regulatory requirements and policies may occur and we may need to amend study protocols to reflect these changes. Amendments may require us to resubmit our study protocols to the FDA and institutional review boards, or IRBs, for reexamination, which may impact the costs, timing or successful completion of that study. If we experience delays in completion of, or if we, the FDA or other regulatory authorities, any IRBs, or other reviewing entities, or

any of our clinical study sites suspend or terminate any of our clinical studies of our drug candidates, our commercial prospects may be materially harmed and our ability to generate product revenues will be delayed. Any delays in completing our clinical trials will increase our costs, slow down our development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical studies may also ultimately lead to the denial of regulatory approval of our drug candidates. In addition, if one or more clinical studies are delayed, our competitors may be able to bring products to market before we do, and the commercial viability of our drug candidates could be significantly reduced.

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 or non-U.S. regulatory authorities

We must successfully initiate and complete a clinical trial for leronlimab as a monotherapy for HIV before we can apply for marketing approval. Although test results have been positive thus far, 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.

The results from the prior clinical trials of leronlimab may not necessarily be predictive of the results of future clinical trials orpre-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. 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.

Further, leronlimab may not be approved even after if it achieved its primary endpoint in its pivotal Phase 3 clinical trial. In addition, any of these regulatory authorities may change its requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a pivotal 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 and non-U.S. 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 preclinical trials, clinical studies 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.

Clinical trials may fail to demonstrate the desired safety and efficacy of our product candidate, which could prevent or significantly delay completion of clinical development and regulatory approval.

Prior to receiving approval to commercialize leronlimab or any other product candidates, we must adequately demonstrate to the FDA and any foreign regulatory authorities in jurisdictions in which we seek approval that leronlimab or any other product candidate is sufficiently safe and effective with substantial evidence from well-controlled clinical trials, which we believe we have achieved in our Phase 3 combination therapy trial. In clinical trials, we will need to demonstrate efficacy for the treatment of specific indications and monitor safety throughout the clinical development process and following approval. If clinical work by us or others leads to undesirable adverse effects in patients, it could delay or prevent us from furthering the regulatory approval process or cause us to cease clinical trials with respect to any drug candidate. If our current or future preclinical studies or clinical trials are unsuccessful, our business will be significantly harmed and our stock price would be negatively affected.

Our product candidate is subject to the risks of failure inherent in drug-related product development. Preclinical studies may not yield results that adequately support our regulatory applications. Even if these applications are filed with respect to our product candidate, the results of preclinical studies do not necessarily predict the results of clinical trials. In addition, even if we believe the data collected from clinical trials of our product candidate are promising, these data may not be sufficient to support approval by the FDA or foreign regulatory authorities. If regulatory authorities do not approve our product, or if we fail to maintain regulatory compliance, we would be unable to commercialize our product, and our business, results of operations and financial condition would be harmed.

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

Identifying and qualifying patients to participate in clinical trials of our 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 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.

Leronliamb may cause undesirable side effects or have other properties that delay or prevent its regulatory approval or limit their commercial potential.

Undesirable side effects caused by our product candidate or even competing products in development that utilize a common mechanism of action could cause regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities and potential product liability claims. While leronlimab was generally well tolerated and no drug-related serious adverse events or dose-proportional adverse events were reported, our understanding of the relationship between adverse events reported in future clinical trials of other product candidates may change as we gather more information, and unexpected adverse events may be observed. Routine review and analysis of post-marketing safety surveillance and clinical trials will provide additional information, for example, potential evidence of rare, population-specific or long-term adverse reactions, and may adversely affect the commercialization of the product, and even lead to the suspension or withdrawal of product marketing authorization.

If we or others identify undesirable side effects caused by leronlimab either before or after receipt of marketing approval, a number of potentially significant negative consequences could result, including:

- our clinical trials may be put on hold;
- we may be unable to obtain regulatory approval for our product candidate;
- regulatory authorities may withdraw approvals of our products;
- regulatory authorities may require additional warnings on the label;
- a medication guide outlining the risks of such side effects for distribution to patients may be required;

- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining marketing approvals for and market acceptance of our product candidate and could have a material adverse effect on our business and financial results.

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 one or more of our product candidates. 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 that we will be able to enter into strategic relationships with a pharmaceutical company or others in the near future or at all, or maintain our current relationships. In addition, we cannot assure you 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.

Although PRO 140 has been designated for fast track approval by the FDA, our ability to obtain accelerated approval may be lost.

The FDA designated PRO 140 for fast track consideration in 2006. The letter ascribing this designation stated that, if the clinical development program pursued for PRO 140 did not continue to meet the criteria for fast track designation, the IND application would not be reviewed under the fast track program. There is no assurance that the FDA will ultimately consider PRO 140 for approval on an accelerated basis. Failure to maintain eligibility for fast track review will likely result in requirements for longer or additional clinical trials and a slower approval process, resulting in additional costs and, therefore, additional capital, which will likely result in further delay in the potential realization of revenues from commercialization of PRO 140.

Although we have applied with the FDA for breakthrough therapy designation for leronlimab, for certain HIV-related treatments, such a designation may not lead to a faster development or regulatory review or approval process, and it may not increase the likelihood that leronlimab will receive marketing approval in the United States.

We applied with the FDA for breakthrough therapy designation for leronlimab, for certain HIV-related treatments. The FDA, in its comments to us, requested additional trial data to support our request for such designation. We currently plan to submit additional data to the FDA as it becomes available to us from our pivotal Phase 2b/3 combination trial. A breakthrough therapy is defined as a product that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and for which preliminary clinical evidence indicates substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs and biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the applicant can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Products designated as breakthrough therapies by the FDA may, in some cases, also be eligible for accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe leronlimab PRO 140 meets the criteria for designation as a breakthrough therapy, the FDA may disagree. In any event, the receipt of a breakthrough therapy designation for leronlimab may not result in a faster development process, review or approval compared to products considered for approval under conventional FDA procedures and, in any event, does not assure ultimate approval by the FDA. In addition, even if leronlimab does qualify as a breakthrough therapy, the FDA may later decide that leronlimab no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. The foregoing considerations could result in additional costs and/or delay in the potential realization of revenues from commercialization of leronlimab.

If we are not able to obtain any 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.

Our clinical trials may be unsuccessful, which would materially harm our business. Even if our ongoing clinical trials are successful, we will be required to conduct additional clinical trials to establish the safety and efficacy of our drug candidates, before an NDA or BLA can be filed with the FDA for marketing approval of any of our drug candidates.

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 can 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 our 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 any of our drug candidates as prescription pharmaceutical products in the United States until we receive approval of an NDA or 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 an NDA or 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 an NDA or BLA to the FDA and even fewer are eventually approved for commercialization. We have never submitted an NDA or BLA to the FDA or any comparable applications to other regulatory authorities. If our development efforts for our drug candidates, including regulatory approval, are not successful for our planned indications, or if adequate demand for our drug candidates is not generated, our business will be harmed.

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

We have only limited experience in filing the applications necessary to gain regulatory approvals and expect 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 candidates 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.

The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon, among other things, the type, complexity and novelty of the product candidates involved, the jurisdiction in which regulatory approval is sought and the substantial discretion of regulatory authorities. Changes in the regulatory approval policy during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for a submitted product application may cause delays in the approval or rejection of an application. Regulatory approval obtained in one jurisdiction does not necessarily mean that a product candidate will receive regulatory approval in all jurisdictions in which we may seek approval, but the failure to obtain approval in one jurisdiction may negatively impact our ability to seek approval in a different jurisdiction. Failure to obtain regulatory marketing approval for our drug candidate in any indication will prevent us from commercializing such product candidate, and our ability to generate revenue will be materially impaired.

Even if we obtain marketing approval for leronlimab, we must successfully commercialize it.

Approval of leronlimab 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.

At present, we have no sales or marketing personnel. In order to commercialize products that are approved for commercial sales, we must either collaborate with third parties that have such commercial infrastructure or develop our own sales and marketing infrastructure. If we are not successful in entering into appropriate collaboration arrangements, or recruiting sales and marketing personnel or in building a sales and marketing infrastructure, we will have difficulty successfully commercializing leronlimab, which would adversely affect our business, operating results and financial condition.

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 PRO 140 may be approved;
- new procedures or methods of treatment that may reduce the incidences of any of the indications in which our drug candidates 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 any of our 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 candidates 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 candidates 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. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render our drug candidates not commercially viable. For example, regulatory authorities may approve our drug candidates for fewer or more limited indications than we request, may not approve the prices we intend to charge for our drug candidates, may grant approval contingent

on the performance of costly post-marketing clinical trials, or may approve our drug candidates with labels that do not include the labeling claims necessary or desirable for the successful commercialization of a particular indication. Further, the FDA or comparable foreign regulatory authorities may place conditions on approvals, such as risk management plans and a Risk Evaluation and Mitigation Strategy, or REMS, to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without an approved REMS, if required. 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. The FDA may also require a REMS for an approved product when new safety information emerges. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of our drug candidates. Moreover, product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following the initial marketing of the product. Any of the foregoing scenarios could materially harm the commercial success of our drug candidates.

We currently have no sales and marketing organization. If we are unable to secure a sales and marketing partner or establish satisfactory sales and marketing capabilities, we may not successfully commercialize it.

Approval of leronlimab 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.

At present, we have no sales or marketing personnel. In order to commercialize products that are approved for commercial sales, we must either collaborate with third parties that have such commercial infrastructure or develop our own sales and marketing infrastructure. If we are not successful in entering into appropriate collaboration arrangements, or recruiting sales and marketing personnel or in building a sales and marketing infrastructure, we will have difficulty successfully commercializing leronlimab, which would adversely affect our business, operating results and financial condition.

We may have limited or no control over the sales, marketing and distribution activities of third parties in connection with current and future collaboration agreements. Our future revenues may depend heavily on the success of the efforts of these third parties. If we elect to establish a sales and marketing infrastructure we may not realize a positive return on this investment. In addition, we will have to compete with established and well-funded pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. Factors that may inhibit our efforts to commercialize our drug candidates without strategic partners or licensees include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our drug candidates;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

Even if we obtain marketing approval for leronlimab, we will be subject to ongoing regulatory obligations and oversight.

Even if we obtain marketing approval for leronlimab, we will be subject to ongoing obligations and continued regulatory review, which will result in significant risks and significant additional expenses. Additionally, leronlimab could be subject to labeling and other restrictions and withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements, or if we experience unanticipated problems with leronlimab.

Even if we obtain FDA approval of leronlimab for an indication, the FDA may still impose significant restrictions on its indicated uses or marketing or the conditions of approval, or impose ongoing requirements for potentially costly and time-consuming post-approval studies, including Phase 4 clinical trials, and post-market surveillance to monitor safety and efficacy. Leronlimab will also be subject to ongoing regulatory requirements governing the manufacturing, labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping and reporting of adverse events and other post-market information. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current cGMPs, which are requirements relating to quality control, quality assurance and corresponding maintenance of records and documents.

With respect to sales and marketing activities by us or any future partner, advertising and promotional materials must comply with FDA rules in addition to other applicable federal, state and local laws in the United States and similar legal requirements in other countries. In the United States, the distribution of product samples to physicians must comply with the requirements of the U.S. Prescription Drug Marketing Act. Application holders must obtain FDA approval for product and manufacturing changes, depending on the nature of the change. We may also be subject, directly or indirectly through our customers and partners, to various

fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute, U.S. False Claims Act, and similar state laws, which impact, among other things, our proposed sales, marketing, and scientific/educational grant programs. If we participate in the U.S. Medicaid Drug Rebate Program, the Federal Supply Schedule of the U.S. Department of Veterans Affairs, or other government drug programs, we will be subject to complex laws and regulations regarding reporting and payment obligations. All of these activities are also potentially subject to U.S. federal and state consumer protection and unfair competition laws. Similar requirements exist in many of these areas in other countries.

In addition, if any of our drug candidates are approved for an indication, our product labeling, advertising and promotion would be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for any of our drug candidates, physicians may nevertheless legally prescribe such products to their patients in a manner that is inconsistent with the approved label. However, if we are found to have promoted such off-label uses, we may become subject to significant liability and government fines. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed.

If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency or problems with the facility where the product is manufactured, or if we or our manufacturers fail to comply with applicable regulatory requirements, we may be subject to the following administrative or judicial sanctions:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- issuance of warning letters or untitled letters;
- injunctions or the imposition of civil or criminal penalties or monetary fines;
- suspension of any ongoing clinical trials;
- refusal to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- suspension of, or imposition of restrictions on, operations, including costly new manufacturing requirements; or
- product seizure or detention or refusal to permit the import or export of product.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our drug candidates and generate revenue. Adverse regulatory action, whether pre- or post-approval, can also potentially lead to product liability claims and increase our product liability exposure.

Although the FDA has granted orphan drug designation for leronlimab for the prevention of GvHD, we may not be able to obtain or maintain orphan drug exclusivity for leronlimab.

We have received orphan drug designation by the FDA for leronlimab in connection with our Phase 2 trial for GvHD. We may not be able to obtain or maintain orphan drug exclusivity for leronlimab. Generally, a product with orphan drug designation only becomes entitled to orphan drug exclusivity if it receives the first marketing approval for the indication for which it has such designation, in which case the FDA will be precluded from approving another marketing application for the same drug for that indication for the applicable exclusivity period. The applicable exclusivity period is seven years in the United States. Orphan drug exclusivity may be lost if the FDA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Even with orphan drug exclusivity for leronlimab, such exclusivity may not effectively protect the product from competition, because FDA has taken the position that, under certain circumstances, another drug with the same active moiety can be approved for the same condition. Specifically, the FDA's regulations provide that it can approve another drug with the same active moiety for the same condition, if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

Our future growth depends, in part, on our ability to enter into and succeed in markets outside of the United States, where we may choose to rely on third party collaborations and will be subject to additional regulatory and commercial burdens, risks and other uncertainties.

Our future profitability will depend, in part, on our ability to gain approval of and commercialize our drug candidates in non-U.S. markets. In some or all of these non-U.S. markets, we intend to enter into licensing and contractual collaborations with third parties to handle some or all of the tasks and responsibilities necessary to succeed. Our activities in non-U.S. markets are subject to additional risks and uncertainties, including:

- our ability to enter into favorable licensing and contractual arrangements with our partners;
- our ability to select partners who are capable of achieving success at the tasks they agree to perform;
- obtaining timely and sufficient favorable approval terms for our drug candidates;
- obtaining favorable pricing and reimbursement;
- our inability to directly control commercial activities because we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

International sales of our drug candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, and trade restrictions and changes in tariffs, any of which may adversely affect our results of operations.

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

We are engaged in the HIV treatment sector of the biopharmaceutical industry, which is intensely competitive. 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, our product candidate 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; or
- introduce therapies or market drugs that render our product candidate obsolete.

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

- developing drug and other product candidates;
- undertaking preclinical 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.

We may not be able to successfully manufacture our product candidate in sufficient quantities for late-stage clinical development, and scale-up manufacturing processes for commercial production, which would delay or prevent us from developing our product candidate and commercializing approved product, if any.

In order to conduct larger-scale or late-stage clinical trials, we need to maintain sufficient product inventory. A failure to manufacture a product candidate in a timely manner or unexpected failure of product in inventory due to unacceptable test results may lead to significant delays in clinical development. For commercialization of any resulting product, if that candidate is approved for sale, we will need to manufacture it in larger quantities while preserving its quality. Our CMOs may not be able to successfully increase the manufacturing capacity for our product candidate in a timely or cost-effective manner, or at all. In addition, quality issues may arise during development, scale-up and validation of commercial manufacturing processes. If we are unable to successfully develop robust, commercial-scale processes to manufacture our product candidate in sufficient quality and quantity, the regulatory approval or commercial launch of our product candidate may be delayed, which could significantly harm our business.

We may be subject to potential product liability and other claims that could materially affect our business and financial condition.

The development and sale of medical products exposes us to the risk of significant damages from product liability and other claims, and the use of our product candidate in clinical trials may result in adverse effects. We cannot predict all the possible harms or adverse effects that may result. We maintain a modest amount of product liability insurance to provide some protections from claims. Nonetheless, we may not have sufficient resources to pay for any liabilities resulting from a personal injury or other claim, even if it is partially covered by insurance. In addition to the possibility of direct claims, we may be required to indemnify third parties against damages and other liabilities arising out of our development, commercialization and other business activities, which would increase our liability exposure. If third parties that have agreed to indemnify us fail to do so, we may be held responsible for those damages and other liabilities as well.

If we market our drug candidates in a manner that violates healthcare fraud and abuse laws, or if we violate government price reporting laws, we may be subject to civil or criminal penalties.

The FDA enforces laws and regulations which require that the promotion of pharmaceutical products be consistent with the approved prescribing information. While physicians may prescribe an approved product for a so-called “off label” use, it is unlawful for a pharmaceutical company to promote its products in a manner that is inconsistent with its approved label and any company which engages in such conduct may be subject to significant liability. Similarly, industry codes in the European Union and other foreign jurisdictions prohibit companies from engaging in off-label promotion and regulatory agencies in various countries enforce violations of the code with civil penalties. While we intend to ensure that our promotional materials are consistent with our label, regulatory agencies may disagree with our assessment and may issue untitled letters, warning letters or may institute other civil or criminal enforcement proceedings. In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare fraud and abuse laws have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. These laws include the U.S. Anti-Kickback Statute, U.S. False Claims Act and similar state laws. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of these laws.

The U.S. Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted broadly to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not, in all cases, meet all of the criteria for safe harbor protection from anti-

kickback liability. Moreover, recent health care reform legislation has strengthened these laws. For example, the Health Care Reform Law, among other things, amends the intent requirement of the U.S. Anti-Kickback Statute and criminal health care fraud statutes; a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the Health Care Reform Law provides that the government may assert that a claim including items or services resulting from a violation of the U.S. Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the U.S. False Claims Act. Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid.

Over the past few years, pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as: allegedly providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion that caused claims to be submitted to Medicare or Medicaid for non-covered, off-label uses; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. Most states also have statutes or regulations similar to the U.S. Anti-Kickback Statute and the U.S. False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include substantial civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, substantial criminal fines and imprisonment.

Legislative, regulatory, or medical cost reimbursement changes may adversely affect our business.

New laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, that relate to the health care system in the U.S. and in other jurisdictions may change the nature of and regulatory requirements relating to drug discovery, clinical testing and regulatory approvals, limit or eliminate payments for medical procedures and treatments, or subject the pricing of pharmaceuticals to government control. Outside the U.S., and particularly in the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In addition, third-party payers in the U.S. are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drug products. Consequently, significant uncertainty exists as to the reimbursement status of newly approved health care products. Significant changes in the health care system in the U.S. or elsewhere, including changes resulting from adverse trends in third-party reimbursement programs, could have a material adverse effect on our projected future operating results and our ability to raise capital, commercialize products, and remain in business.

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 candidates 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 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 May 31, 2019, 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 may not be able to attract or retain a majority of independent directors.

Our board of directors may not be comprised of a majority of independent directors in the future. In the absence of a majority of independent directors, our executive officers could establish policies and enter into transactions without independent review and approval thereof. If we are unable to attract and retain qualified, independent directors, the management of the business could be compromised.

We currently do not have a majority of independent directors serving on our Board of Directors, which may afford less protection to our stockholders than if our Board of Directors had a majority of independent directors, and our audit committee currently does not have a "financial expert" as defined by applicable SEC requirements. If we are unable to attract and retain qualified, independent directors, the oversight of our business could be compromised.

As of the date of this annual report, a majority of our directors did not satisfy the standards for independence as specified by the SEC and the listing standards of The Nasdaq Stock Market (the "NASDAQ Rules") pursuant to which we evaluate director independence. If our Board of Directors is not made up of a majority of independent directors, there may be a lower level of oversight on executive management, and our Board of Directors 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 our Board of Directors may afford less protection to our stockholders than if our Board of Directors were composed of a majority of independent directors.

A lack of independent directors may also make it difficult to create board committees meeting the requirements of our board committee charters and the NASDAQ Rules pursuant to which we evaluate director independence. Historically, we have strived to have an audit committee comprised of at least three independent directors and other board committees comprised solely of independent directors. Currently, our audit committee has only one member, who is independent under the NASDAQ Rules and applicable SEC requirements, and our other board committees include certain non-independent directors. Due to the lack of independent directors, it may be difficult to establish effective operating board committees comprised of independent members to oversee committee functions. This structure gives our executive officers additional control over certain corporate governance issues, including compensation matters and audit issues for internal control and reporting purposes, with more limited oversight of our executive officers' decisions and activities.

In addition, as previously reported in our Form 8-K filed August 14, 2019, the chairman of our audit committee resigned from the Board of Directors effective August 12, 2019. As a result, as of the date of this annual report, our audit committee no longer had a "financial expert" as defined by applicable SEC requirements. We are currently attempting to identify additional qualified individuals who are independent, and who have sufficient experience in finance and accounting to satisfy the definition of an audit committee "financial expert." Until we have done so, we may be unable to establish or maintain effective internal control over financial reporting, oversee the relationship with our independent auditing firm, adequately assess the impact on our financial reporting of any newly issued accounting rules or standards, adequately assess our processes relating to our risk and control environment and evaluate our internal and independent audit processes. As a result, we may discover material weaknesses in our internal control over financial reporting and/or disclosure controls and procedures, which we may not successfully remediate on a timely basis or at all. Any failure to remediate any future material weaknesses, or to implement required new or improved controls, could cause us to fail to meet our reporting obligations or result in material misstatements in our financial statements.

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.

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

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. Thus, 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 candidates 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.

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 our leronlimab product, 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 Inc. 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 each their respective agreements, Progenics has certain repurchase rights relating to the assets sold to us, and AbbVie Inc. 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 are filed, respectively, as Exhibits 2.1, 10.13 and 10.19 to this Form 10-K.

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 marketing, commercial production, and sale of leronlimab, there can be no assurance that this will be the case. 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 afreedom-to-operate search that identified other patents that could relate to our proposed leronlimab candidate. Sufficient research and analysis is currently being conducted to enable us to reach the conclusion that 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 that our actions 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.

We are subject to the oversight of the SEC and other regulatory agencies. Investigations by those agencies could divert management's focus and could 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. As a result, we may face legal or administrative proceedings by these agencies. We are unable to predict the effect of any 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.

Our information technology systems could fail to perform adequately or we may fail to adequately protect such information technology systems against 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 therefore could be materially adversely affected. In addition, security breaches or system failures of this infrastructure can create system disruptions, shutdowns, or unauthorized disclosure of confidential information. If we are unable to prevent such breaches or failures, our operations could be disrupted, or we may suffer financial damage or loss because of lost or misappropriated information.

If the FDA or comparable foreign regulatory authorities approve generic or biosimilar versions of any product candidate that receive marketing approval, or if any product approval we obtain does not provide us with the exclusivity periods we hope to achieve, sales of our product could be adversely affected.

As part of the ongoing efforts of governmental authorities to lower health care costs by facilitating generic competition to pharmaceutical products, the Biologics Price Competition and Innovation Act ("BPCIA") enacted as part of the Health Care Reform Law, created a new abbreviated regulatory approval pathway in the United States for biological products that are found to be "biosimilar" to or "interchangeable" with a biological "reference product" previously licensed under a BLA. This abbreviated approval pathway is intended to permit a biosimilar to come to market more quickly and less expensively by relying to some extent on the data generated by the reference product's sponsor and the FDA's previous review and approval of the reference product. Under the BPCIA, a biosimilar sponsor's ability to seek or obtain approval through the abbreviated pathway is limited by periods of exclusivity granted by the FDA to the holder of the reference product's BLA, and no biosimilar application may be accepted by the FDA for review until four years after the date the reference product was first licensed by the FDA, and no biosimilar application, once accepted, may receive final approval until 12 years after the reference product was first licensed by the FDA.

Once approved, biosimilars likely would compete with, and in some circumstances may be deemed under applicable laws to be "interchangeable with," the previously approved reference product. The extent to which a biosimilar, once approved, will be substituted for any one of our product candidates, if approved, 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. Although there is uncertainty regarding the impact of this new program, it seems likely that if any of our product candidates are approved by the FDA, there is risk that the approval of a biosimilar competitor to one of our products could have an adverse impact on our business. In particular, a biosimilar could be significantly less costly to bring to market and priced significantly lower than our product, if approved by the FDA.

We may also be subject to competition from biosimilar products in Europe. To date a number of biosimilar products have been authorized by the EMA. As in the United States the regulatory approval pathway for biosimilar products in Europe is abbreviated. A biosimilar sponsor must however still provide all of the preclinical and clinical data required to demonstrate the similarity of their product with the reference product. The level of data required is assessed on a case by case basis but it will be less than that required for an original biological product. The pathway is more complex than the abridged procedure that may be followed to obtain authorization of a generic version of a non-biological product but it would still allow the biosimilar product to be brought to market more quickly and less expensively than our original product. That said, in Europe applications for marketing authorizations in relation to biosimilar products are subject to the same data and market exclusivity as apply to generic non-biologic products so no biosimilar product could be approved or placed on the market during the periods such exclusivity applies to our product. Marketing authorization of a biosimilar product in Europe does not guarantee that the biosimilar product may be substituted for the reference product. Interchangeability of a biosimilar product with the reference product is not assessed by the EMA but this determination is left to each of the member states. We cannot know at this stage the extent to which any biosimilar product would be interchangeable with our reference product, and this may vary between member states.

Our business success partially depends on our ability to successfully commercialize novel diagnostic tests and services, which is time consuming and complex, and our development efforts may fail.

Part of our business strategy is to develop and commercialize the PCa Test. We believe the long-term success of our business partially depends on our ability to fully validate, develop and commercialize the PCa Test. Research, development and commercialization of diagnostic tests is time-consuming, uncertain and complex.

Our diagnostic test may not succeed in reliably diagnosing or predicting cancer with the sensitivity and specificity necessary to be clinically useful, and thus may not succeed commercially. Prior to commercializing our diagnostic test, we must undertake time-consuming and costly development activities, including clinical studies, and obtain regulatory clearance or approval, which may be denied. This development process involves a high degree of risk, substantial expenditures and will occur over several years. Our development efforts may fail for many reasons, including:

- failure of the test at the research or development stage;
- difficulty in accessing archival tissue samples, especially tissue samples with known clinical results; or
- lack of sufficient clinical validation data to support the effectiveness of the test.

Tests that appear promising in early development may fail to be validated in subsequent studies, and even if we achieve positive results, we may ultimately fail to obtain the necessary regulatory clearances or approvals. There is substantial risk that our research and development projects will not result in commercial tests, and that success in early clinical trials will not be replicated in later studies. At any point, we may abandon development of a test or be required to expend considerable resources repeating clinical trials, which would adversely impact the timing for generating potential revenues from the test. In addition, as we develop our test, we will have to make significant investments in research, development and marketing resources. If a clinical validation study of a particular test then fails to demonstrate the outlined goals of the study, we might choose to abandon the development of that test. Further, our ability to develop and launch any diagnostic tests will likely depend on our receipt of additional funding. Additionally, if the supply of reagents or equipment on which our test in development or commercial test relies becomes unavailable and we have to source replacement reagents or equipment for our test, additional validation activities will be required and we may need to obtain regulatory clearances or approvals for the modified test.

The diagnostic business is heavily regulated, and if we are unable to obtain regulatory clearance or approvals in the United States, if we experience delays in receiving clearance or approvals, or if we do not gain acceptance from customers, our diagnostics growth strategy may not be successful.

In the United States, diagnostic tests and services are regulated under CLIA, the Federal Food, Drug, and Cosmetic Act, and various state laws. Diagnostic tests offered solely for use within a proprietary laboratory may be marketed as laboratory developed tests ("LDTs"). LDTs are regulated by the Center for Medicare and Medicaid Services ("CMS") under CLIA, but, under the FDA's enforcement framework, are not currently regulated by FDA. Although the FDA has statutory authority to assure that medical devices, including LDTs, are safe and effective for their intended uses, the FDA has generally exercised its enforcement discretion and not enforced applicable regulations with respect to LDTs. Specifically, under current FDA enforcement policies and more recent draft guidance, LDTs generally do not require FDA premarket clearance or approval before commercialization.

Under our current strategy, the PCa Test would be subject to the FDA's applicable medical device regulations. For example, this test could become subject to the FDA's requirements for premarket review. Unless an exemption applies, generally, before a new medical device or a new use for a medical device may be sold or distributed in the United States, the medical device must receive premarket marketing authorization from the FDA, which is generally either FDA clearance of a 510(k) premarket notification or premarket approval of a Premarket Approval application. As a result, before we can market or distribute our test in the United States for use by other clinical testing laboratories, we must first obtain premarket marketing authorization (generally referred to as premarket clearance or premarket approval throughout this document) from the FDA. We have not yet applied for clearance or approval from the FDA, and would need to complete additional validations before we are ready to apply. We believe it would likely take two years or more to conduct the studies and trials necessary to obtain approval from the FDA to commercially launch the PCa Test. Once we do apply, we may not receive FDA clearance or approval for the commercial use of our test on a timely basis, or at all. If we are unable to obtain clearance or approval or if clinical diagnostic laboratories do not accept our test, our ability to grow our business by deploying our test could be compromised.

The commercial success of our prospective diagnostic business could be compromised if third-party payors, including insurance companies, managed care organizations and Medicare, do not provide coverage and reimbursement, refuse to enter into contracts with us, or delay payments for our diagnostic tests.

Pathologists and oncologists may not order our diagnostic test unless third-party payors, such as insurance companies, managed care organizations and government payors, such as Medicare and Medicaid, pay a substantial portion of the test price. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our diagnostic test. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. Coverage and reimbursement by a third-party payor may depend on a number of factors, including a payor's determination that test using our technologies are:

- not experimental or investigational;
- medically necessary;
- appropriate for the specific patient;
- cost-effective;
- supported by peer-reviewed publications; and
- included in clinical practice guidelines

Uncertainty surrounds third-party payor coverage and reimbursement of any test incorporating new technology, including the PCa Test. Even if we obtain marketing clearance or approval to market diagnostic tests, our future revenues will depend upon the size of any markets in which our product candidate has received clearance or approval, and our ability to achieve sufficient market acceptance, reimbursement from third-party payors and adequate market share for our product candidate in those markets.

Because each payor generally determines for its own enrollees or insured patients whether to cover or otherwise establish a policy to reimburse a diagnostic test, seeking payor approvals is a time-consuming and costly process. We cannot be certain that coverage for our tests (FDA-cleared/approved or LDT) will be provided in the future by third-party payors. If we cannot obtain coverage and reimbursement from private and governmental payors such as Medicare and Medicaid for our new tests or test enhancements that we may develop in the future, our ability to generate revenues from our diagnostic tests and clinical services could be limited, which may have a material adverse effect on our financial condition, results of operations and cash flow. Further, we may likely experience in the future, delays and temporary interruptions in the receipt of payments from third-party payors due to missing documentation and other issues, which could cause delay in collecting our future revenue.

If we are unable to successfully validate our laboratory tests and services, we will not be able to increase revenues

Prospective customers such as physicians may not order our proprietary test, and third-party payors may not reimburse for our test, unless we are able to provide compelling evidence that the test is useful and produces actionable information with respect to diagnosis and prognosis. We believe that we will need to finance and successfully complete additional and more powerful studies, and then effectively disseminate the results of those studies, to drive widespread adoption of our test.

If the market for our test and services does not experience significant growth or if our test and services do not achieve broad acceptance, our operations will suffer.

We cannot accurately predict the future growth rate or the size of the market for our prospective test and services. The expansion of this market depends on a number of factors, such as:

- the results of clinical trials;
- the cost, performance and reliability of our test and services, and the tests and services offered by competitors;
- customers' perceptions regarding the benefits of our test and services;
- customers' satisfaction with our test and services; and
- marketing efforts and publicity regarding our test and services.

If we are unable to execute our marketing strategy for our test and our test is unable to gain acceptance in the market, we may be unable to generate sufficient revenue to sustain our business.

Although we believe that our prospective diagnostic test represents promising commercial opportunities, our tests may never gain significant acceptance in the marketplace and therefore may never generate substantial revenue or profits for us. We need to develop a market for our test through physician education and awareness programs. Gaining acceptance in medical communities requires that we perform additional studies after validating the efficacy of our test and services for the diagnosis, prognosis and treatment of cancer, and that we obtain acceptance of the results of those studies using our tests for publication in leading peer-reviewed medical journals. The results of any studies are always uncertain and even if we believe such studies demonstrate the value of our tests, the process of publication in leading medical journals is subject to a peer review process and peer reviewers may not consider the results of our studies sufficiently novel or worthy of publication. Failure to have our studies published in peer-reviewed journals would limit the adoption of our tests. Our ability to successfully market the tests that we may develop will depend on numerous factors, including:

- whether health care providers believe our diagnostic test provides clinical utility;

- whether the medical community accepts that our diagnostic test is sufficiently sensitive and specific to be meaningfuln-patient care and treatment decisions; and
- whether health insurers, government health programs and other third-party payors will cover and pay for our diagnostic test and, if so, whether they will adequately reimburse us.

Failure to achieve widespread market acceptance of our diagnostic test would materially harm our business, financial condition and results of operations.

If we cannot develop tests to keep pace with rapid advances in technology, medicine and science, our operating results and competitive position could be harmed.

In recent years, there have been numerous advances in technologies relating to the diagnosis and treatment of cancer. There are several new cancer drugs under development that may increase patient survival time. There have also been advances in methods used to analyze very large amounts of genomic information. We must continuously develop new tests to keep pace with evolving standards of care. Our tests could become obsolete unless we continually innovate and expand them to demonstrate benefit in patients treated with new therapies. If we cannot adequately demonstrate the applicability of our tests to new treatments, sales of our tests and services could decline, which would have a material adverse effect on our business, financial condition and results of operations.

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 adequately fund our operations.

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, 2019. 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.

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

Since our inception, we have not achieved cashflows from revenues sufficient to cover basic costs. As a result, we have relied heavily on debt and equity financing. Equity financing, in particular, has created a dilutive effect on our common stock, which has hampered our ability to attract reasonable financing terms. For the foreseeable future, we will continue to rely upon debt and equity financing to maintain our operations and those of our subsidiaries.

The 2017 comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law new tax legislation, or the Tax Act, which significantly reforms the Internal Revenue Code of 1986, as amended. The Tax Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%; limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses); limitation of the deduction of net operating losses generated in tax years beginning after December 31, 2017 to 80% of taxable income, indefinite carryforward of net operating losses generated in tax years after 2018 and elimination of net operating loss carrybacks; changes in the treatment of offshore earnings regardless of whether they are repatriated; current inclusion in U.S. federal taxable income of certain earnings of controlled foreign corporations, mandatory capitalization of research and development expenses beginning in 2022; immediate deductions for certain new investments instead of deductions for depreciation expense over time; further deduction limits on executive compensation; and modifying, repealing and creating many other business deductions and credits, including the reduction in the orphan drug credit from 50% to 25% of qualifying expenditures. We continue to examine the impact this tax reform legislation may have on our business. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act is uncertain and our business and financial condition could be adversely affected. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. This periodic report does not discuss any such tax legislation or the manner in which it might affect us or our stockholders in the future. We urge our stockholders to consult with their legal and tax advisors with respect to such legislation.

Risks Relating to Our Common Stock

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 May 31, 2019, we have 14,501,872 shares subject to outstanding options under our stock option plans, 10,374,144 shares reserved for future issuance under our equity compensation plan and 164,089,977 shares issuable upon 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, this could have an adverse impact on the market price of our common stock, even if there is no relationship between such sales and the performance of our business.

The 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, 2017 through May 31, 2019, the market price of our common stock has fluctuated from a high of $0.79 per share in the quarter ended February 28, 2018, to a low of $0.37 per share in quarter ending May 31, 2019. 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.

If we implement a reverse stock split, there can be no assurances 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 you and other stockholders from influencing significant corporate decisions.

Our significant stockholders 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 transactions. These stockholders may also vote against a change of control, even if such a change of control would benefit our other stockholders. See “Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters” below.

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.

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.

Purchasers in future offerings may experience immediate and substantial dilution.

The current trading price of the common stock is higher than the current net tangible book value per share of our common stock. Therefore, if you purchase shares of common stock in future offerings, if any, you may incur immediate and substantial dilution in the pro forma net tangible book value per share of common stock from the price per share that you pay for the common stock. In addition, you will experience dilution when we issue additional shares of common stock that we are permitted or required to issue under outstanding options and warrants and under our equity incentive plan or other compensation plans.

Our certificate of incorporation allows for our Board of Directors 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 of Directors has the authority to fix and determine the relative rights and preferences of preferred stock. Currently, our Board of Directors has the authority to designate and issue up to 5,000,000 shares of our preferred stock without further stockholder approval. As a result, our Board of Directors could authorize the issuance of a 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 of Directors 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.

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 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.

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 of Directors 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 of Directors. 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 of Directors acting pursuant to a resolution approved by the affirmative majority of the entire Board of Directors.
- provide that 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.
- 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 our Board of Directors.

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.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our principal office location is 1111 Main Street, Suite 660, Vancouver, Washington 98660. We lease 1,812 square feet in a commercial office building pursuant to a lease that expires on April 30, 2021 at a current cost of $3,506 per month, plus modest annual increases. We also lease 1,911 square feet of office space in Fort Lauderdale, Florida pursuant to a lease that expires on March 31, 2022 at a cost of approximately $8,300 per month, plus modest annual increase. Such space is currently being marketed for a subtenant.

Item 3. Legal Proceedings.

None.

From time to time, we are involved in claims and suits that arise in the ordinary course of our business. Management currently believes that the resolution of any such claims against us, if any, will not have a material adverse effect on our business, financial condition or results of operations.

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. 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.

The following are high and low bid prices quoted on the OTCQB during the periods indicated. The quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions:

	High	Low
Fiscal Year Ended May 31, 2019:		
First quarter ended August 31, 2018	$0.71	$0.40
Second quarter ended November 30, 2018	$0.70	$0.50
Third quarter ended February 28, 2019	$0.62	$0.46
Fourth quarter ended May 31, 2019	$0.55	$0.37
Fiscal Year Ended May 31, 2018:		
First quarter ended August 31, 2017	$0.79	$0.56
Second quarter ended November 30, 2017	$0.70	$0.56
Third quarter ended February 28, 2018	$0.84	$0.52
Fourth quarter ended May 31, 2018	$0.79	$0.45

Holders

The number of record holders of our common stock on June 30, 2019 was approximately 860.

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 restrictions on our ability to pay dividends, 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.

Holders of 3,246 shares of Series C Convertible Preferred Stock are entitled to receive, at the option of the holder, cumulative dividends at the rate of ten percent (10%) per share per annum of the stated value of the Series C Preferred Stock, to be paid per share of Series C Preferred Stock. 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 Common Stock. Dividends on the Series C Preferred Stock are mandatory and cumulative and there are no sinking fund provisions applicable to the Series C Preferred Stock. The Series C Preferred Stock does not have redemption rights. The stated value per share for the Series C Preferred Stock is $1,000 (the "Stated Value"). Dividends payable to holders of Series C are payable on December 31 of each year and the holder can elect to be paid in cash or in common stock. If all holders elected to receive the 2019 dividend in the form of common stock, approximately 510,469 shares of common stock would be issued in the form of dividend. If such 2019 dividends were to be paid in the form of cash, such cash dividends would total approximately $255,000 at December 31, 2019.

Holders of 92,100 shares of Series B Convertible Preferred Stock 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 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. As of June 30, 2019, if we declared a dividend and elected pay such dividend in the form of common stock, approximately 391,000 shares of common stock would be issued in the form of dividend.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

During the year ended May 31, 2018 we purchased 159,011 shares of $0.001 par value treasury stock.

Unregistered Sales of Equity Securities

From June 3, 2019 to July 26, 2019, we received four redemption notices from the holder of our convertible note issued on June 26, 2018 requesting the redemptions of $655,000 of the outstanding balance thereof. In satisfaction of the redemption notices, we issued 1,984,769 shares of Common Stock to the note holder in accordance with the terms of the convertible note. Following the redemptions, the outstanding balance of the convertible note, including accrued but unpaid interest, was approximately $4.2 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. Selected Financial Data

Not applicable.

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.

Business Highlights

During the past fiscal year ending May 31, 2019, we commenced several initiatives to advance our lead product candidate, leronlimab (PRO 140). The following is a brief summary of key accomplishments during the most recent fiscal year:

- Raised approximately $57 million in capital through equity, convertible debt offerings and a warrant exchange offer;
- Filed with the FDA the first of three sections of our first BLA, with the remaining two sections anticipated for completion;
- Entered into a long-term commercial manufacturing agreement with Samsung BioLogics Co., Ltd. to ensure sufficient availability of cost efficient inventory of leronlimab to meet expected demand post approval;
- Filed a pivotal trial protocol with the FDA for leronlimab as a monotherapy for HIV patients;
- Defined and initiated our new strategic focus by rapidly and concurrently exploring opportunities for several cancer and immunologic indications for leronlimab;
- Completed the asset acquisition of ProstaGene LLC via an all-stock transaction;
- Initiated our first clinical trial in cancer for leronlimab, a Phase 1b/2 clinical trial for triple-negative breast cancer, which received Fast Track designation from the FDA in May 2019;
- Initiated pre-clinical studies with leronlimab for colon cancer and breast cancer, both of which have reported promising results;
- Initiated a pre-clinical study with leronlimab to assess its ability to prevent the progression ofNon-Alcoholic Fatty Liver Disease (NAFLD) into NASH;
- Continued exploratory discussions with third parties regarding licensing opportunities;
- Presented results of our clinical trials and pre-clinical studies at numerous medical and scientific conferences; and
- Collaborated with a scientific laboratory to develop a CCR5 receptor occupancy test for leronlimab, a CCR5 antagonist, which is anticipated to provide improved patient screening for two indications: (i) patient candidates for leronlimab as a HIV monotherapy in order to achieve optimal dosing and (ii) cancer patients, due to the over expression of CCR5 in certain forms of cancer.

Results of Operations

Clinical Trials Update

Phase 2b Extension Study for HIV, as Monotherapy

Currently, there are four patients in this ongoing extension study and each has surpassed four andone-half years of suppressed viral load with PRO 140 as a single agent therapy. This extension study will be discontinued upon any FDA approval of leronlimab.

Phase 2b/3 Pivotal Trial for HIV, as Combination Therapy

This trial was successfully completed and is the basis for our current BLA, for which the first of three sections was submitted to the FDA in March 2019. This trial for leronlimab as a combination therapy to existing HAART drug regimens for highly treatment experienced HIV patients achieved its primary endpoint with a p-value of 0.0032. Nearly all patients who have completed this trial have transitioned to aFDA-cleared rollover study, as requested by the treating physicians to enable the patients to have continued access to leronlimab.

Rollover Study for HIV as Combination Therapy

This study is designed for patients who successfully completed the pivotal Phase 2b/3 Combination Therapy trial and for whom the treating physicians request a continuation of leronlimab therapy in order to maintain suppressed viral load. This extension study will be discontinued upon any FDA approval of leronlimab.

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

Enrollment for this trial is now closed after reaching 500 patients. This trial assesses the subcutaneous use of leronlimab as a 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. The secondary endpoint is the length of time to virologic failure. We completed the evaluation two higher-dose arms, one with 525 mg dose (a 50% increase from the original dosage of 350 mg), as well as a 700 mg dose. We recently reported that interim data suggested that both the 525 mg and the 700 mg dosages are achieving a responder rate of approximately 90% after the initial 10 weeks. This trial has also been used to provide safety data for the BLA filing for leronlimab as a combination therapy. In view of the high responder rate at the increased dosage levels, coupled with the newly developed CCR5 occupancy test, we recently filed a pivotal trial protocol with the FDA for leronlimab as a monotherapy. Upon finalization with the FDA of the pivotal trial protocol for monotherapy, the Phase2b/3 investigative trial will likely be discontinued.

Cancer and Immunological Applications for Leronlimab

We are continuing to advance our exploration of opportunities for clinical applications for leronlimab involving the CCR5 receptor, other than HIV-related treatments, such as cancer, inflammatory conditions and autoimmune diseases.

The target of leronlimab is the important G protein coupled receptor CCR5. CCR5 is more than the pathway to HIV replication; it is also a crucial component of inflammatory responses and is a key mediator in many cancer metastasis. We believe this opens the potential for multiple pipeline opportunities for leronlimab. CCR5 is a protein located on the surface of white blood cells and cancer epithelial cells that serves as a receptor for 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 ofT-cells to these sites promoting further inflammation. We believe 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. CCR5 is also expressed on the surface of epithelial cells in certain cancers. Some disease processes that we believe could benefit from CCR5 blockade include many types of common cancers, GvHD (a reaction occurring in some patients after bone marrow transplantation), autoimmunity and chronic inflammation, such as rheumatoid arthritis and psoriasis. Recent published data has shown that the cancer cells within the tumor consist of two types of cells-one with CCR5 and others without them. The published data clearly indicated that cancer cells that can metastasize express CCR5. Metastases are the cause of death in the vast majority of cancer patients. A prior publication indicates that CCR5 antagonists can turn off certain calcium signaling and reduce the migration of CCR5 positive cancer cells. Inhibition of CCR5 signaling blocks the guided migration and reduces the metastasis. Leronlimab has demonstrated (in an in-vitro study) that it also turns off calcium signaling and blocks breast cancer cellular invasion. Furthermore, published studies showed current chemotherapy induces CCR5, and CCR5 antagonists enhance the effectiveness of current chemotherapies, potentially allowing a reduction in chemotherapy, which may provide an improved quality of life for patients.

Research has demonstrated three key properties of the CCR5's MOA in cancer. The first is that the CCR5 receptor on cancer cells was responsible for the migration and invasion of cells into the blood stream, which leads to metastasis of breast, prostate, and colon cancer. The second is that blocking the CCR5 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 of metastasis.

Due to its MOA, we believe leronlimab may have significant advantages over other CCR5 antagonists. Prior studies have demonstrated that leronlimab does not cause direct activation of T-cells. We have already reported encouraging human safety data for our clinical trials with leronlimab in HIV-infected patients.

We also previously initiated our first clinical trial with leronlimab in an immunological indication – a Phase 2 clinical trial with leronlimab for GvHD in patients with AML or MDS who are undergoing bone marrow stem cell transplantation. As noted below, enrollment under the amended protocol for the GvHD trial has been delayed subject to increased capital resources. In addition, we also intend to explore potential strategic partnerships with certain pharmaceutical companies, including for the development of follow-on technologies involving the use of leronlimab alongside their existing products.

We will require a significant amount of additional capital to complete the foregoing clinical trials for HIV and complete our BLA submission, as well as to advance our trials for triple-negative breast cancer, certain cancer indications and GvHD. See "Liquidity and Capital Resources" below.

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

We recently received clearance from the FDA for our IND submission to initiate a Phase 1b/2 clinical trial for metastatic triple-negative breast cancer patients. In May 2019, the FDA granted leronlimab Fast Track designation for use in combination with carboplatin. We have identified five clinical trial sites and expect to dose the first patients during the third quarter of calendar 2019. The change in circulating tumor cells ("CTCs") number will be evaluated every 21 days during treatment and will be used as an initial prognostic marker for efficacy. Up to 48 patients are expected to be enrolled in this study.

Pre-clinical Studies for Multiple Cancer Indications

We are initiating multiple pre-clinical studies with leronlimab for melanoma, pancreatic, breast, prostate colon, lung, liver and stomach cancers. An ongoing pre-clinical study conducted by us recently reported that leronlimab reduces by more than 98% human breast cancer metastasis in a murine xenograft model. Based upon these strong results, we filed for Orphan Drug Designation for its Phase 1b/2 triple negative breast cancer trial. In addition, pre-clinical results in a colorectal cancer study are likewise encouraging.

Phase 2 Trial for Graft-versus-Host Disease

This Phase 2 multi-center100-day study with 60 patients is designed to evaluate the feasibility of the use of leronlimab as anadd-on therapy to standard GvHD prophylaxis treatment for prevention of acute GvHD in adult patients with acute myeloid leukemia ("AML") or myelodysplastic syndrome ("MDS") undergoing allogeneic hematopoietic stem cell transplantation ("HST"). Enrollment of the first patient was announced in May of 2017. On October 5, 2017, we announced that the FDA had granted orphan drug designation to leronlimab (PRO 140) for the prevention of GvHD. In March 2018, we announced that the Independent Data Monitoring Committee ("IDMC") for leronlimab (PRO 140) Phase 2 trial in GvHD had completed a planned interim analysis of trial data on the first 10 patients enrolled. Following this review of data from the first 10 patients in the Phase 2 trial, we filed amendments to the protocol with the FDA. The amendments included switching the pretreatment conditioning regimen from aggressive myeloablative ("MA") conditioning to a reduced intensity conditioning ("RIC"), and switching from a blinded one-for-one randomized placebo-controlled design to an open-label design under which all enrollees receive leronlimab. The amendments also provide for a 100% increase in the dose of leronlimab, to 700 mg, to more closely mimic pre-clinical dosing. The next review of data by the IDMC will occur following enrollment of 10 patients under the amended protocol after each patient has been dosed for 30 days. Due to the necessary prioritization of limited capital, enrollment under the amended protocol has been temporarily delayed.

Licensing Opportunities

We are currently evaluating strategic opportunities with respect to the assets acquired in our November 2018 acquisition of ProstaGene, including potential licensing or other opportunities to monetize intellectual property assets relating to prostate cancer diagnostics. As an integral part of the acquisition of ProstaGene, we acquired the PCa Test, which provides substantial additive discriminative value for predicting outcomes of patients diagnosed with prostate cancer compared to the intermediate Gleason score, the current standard for prostate cancer diagnosis. The clinical objective is to more precisely guide therapeutic options for men, thereby avoiding unnecessary surgery (prostatectomy) and radiation and/or chemotherapy with its attendant side effects.

In addition, we continue to conduct exploratory discussions with third parties who have expressed an interest in a licensing arrangement for leronlimab for HIV indications; such proposed arrangements are country or region specific.

Results of operations for the year ended May 31, 2019, 2018 and 2017, are as follows:

For the years ended May 31, 2019, May 31, 2018 and 2017, we had no activities that produced revenues from operations. The following schedule sets forth the percentage of total expenses as a percent of net loss for the years ended May 31, 2019, 2018 and 2017.

	Percentage of Total Net Loss Years Ended May 31,					
	2019		2018		2017	
Operating expenses:						
General and administrative	$ 12,116,743	(0.22)%	$ 7,340,605	(0.15)%	$ 6,758,606	(0.26)%
Research and development	42,490,144	(0.76)	38,222,580	(0.76)	20,205,743	(0.78)
Amortization and depreciation	1,245,167	(0.02)	356,128	(0.01)	366,385	(0.01)
Total operating expenses	55,852,054	(0.99)	45,919,313	(0.92)	27,330,734	(1.06)
Operating loss	(55,852,054)	(0.99)	(45,919,313)	(0.92)	(27,330,734)	(1.06)
Other income (expense):						
Interest income	4,306	0.00	3,620	0.00	15,167	0.00
Loss on extinguishment of convertible notes	(1,519,603)	(0.03)	—	—	—	—
Change in fair value of derivative liability	1,666,469	0.03	1,690,935	0.03	2,164,533	0.08
Interest expense:						
Amortization of discount on convertible notes	(1,707,068)	(0.03)	(1,666,017)	(0.03)	—	—
Amortization of debt issuance costs	(459,085)	(0.01)	(435,609)	(0.01)	—	—
Interest related to derivative liability	—	—	—	—	(540,330)	(0.02)
Inducement interest related to warrant extension	—	—	(826,252)	(0.02)	(72,437)	(0.00)
Inducement interest related to warrant tender offer	(195,927)	(0.00)	(393,685)	(0.01)	—	—
Inducement interest related to convertible notes	—	—	(2,352,045)	(0.05)	—	—
Interest on convertible notes payable	(950,617)	(0.02)	(251,315)	(0.01)	—	—
Total interest expense	(3,312,697)	(0.06)	(5,924,923)	(0.12)	(612,767)	(0.02)
Loss before income taxes	(59,013,579)	(1.05)	(50,149,681)	(1.00)	(25,763,801)	(1.00)
Income tax benefit	2,826,919	0.05	—	—	—	—
Net loss	$ (56,186,660)	(1.00)%	$ (50,149,681)	(1.00)%	$ (25,763,801)	(1.00)%
Basic and diluted loss per share	$ (0.21)		$ (0.29)		$ (0.19)	
Basic and diluted weighted average common shares outstanding	272,040,933		174,885,422		138,004,461	

Results of operations for the years ended May 31, 2019 and 2018

For the years ended May 31, 2019 and 2018, we had a net loss of approximately $56.2 million and $50.1 million, respectively. The increase in net loss of approximately $6.1 million for fiscal 2019 over 2018 was primarily attributable to increased R&D expenses of approximately $4.3 million and an increase in G&A expenses of approximately $4.8 million, offset by a lower interest expense of $2.6 million. The loss per share for the fiscal year ended May 31, 2019 was $(0.21) compared to $(0.29) for the prior fiscal year.

Total operating expenses for the years ended May 31, 2019 and 2018 were approximately as follows:

	2019	2018
General and administrative:		
Salaries and other compensation	$ 3,781,000	$ 2,454,000
Stock-based compensation	3,388,000	1,291,000
Other	4,948,000	3,596,000
Total general and administrative	12,117,000	7,341,000
Research and development	42,490,000	38,223,000
Amortization and depreciation	1,245,000	356,000
Total operating expenses	$55,852,000	$45,920,000

For the fiscal year ended May 31, 2019 and May 31, 2018, operating expenses totaled approximately $55.9 million and $45.9 million, respectively, consisting primarily of research and development ("R&D") expenses of $42.5 million, general and administrative expenses of approximately $12.1 million and amortization and depreciation of approximately $1.2 million. The increase in operating expenses over the comparable 2018 period was attributable to an increase in R&D expenses of approximately $4.3 million owing to higher clinical trial and manufacturing-related expenses and to an increase in general and administrative expenses of approximately $4.8 million, or 65.1% over the prior fiscal year.

General and administrative expenses, totaled approximately $12.1 million and $7.3 million, respectively, for fiscal 2019 and 2018. General and administrative expenses were comprised of salaries and benefits, non-cash stock-based compensation expense, professional fees, insurance and various other expenses. The increase in general and administrative expenses of approximately $4.8 million, or 65.1%, for the fiscal year ended May 31, 2019 over the comparable 2018 period was primarily due to increased non-cash stock-based compensation, employee compensation and related expenses, along with higher professional services

We record research and development expenses where directly identifiable, which approximated the following for the years ended May 31, 2019 and 2018:

	2019	2018
Research and development:		
Clinical	$25,264,000	$22,543,000
Non-Clinical	155,000	$ 887,000
CMC	16,353,000	$14,240,000
Licenses and patent fees	718,000	$ 553,000
Total research and development	$42,490,000	$38,223,000

R&D expenses totaled approximately $42.5 million for the fiscal year ended May 31, 2019 and increased approximately $4.3 million, or 11.2%, over the same 2018 period. This increase was attributable to higher clinical trial expenses associated with the Phase 2b/3 investigative monotherapy trial and various oncology studies, offset in part by lower expenses for the completed Phase 3 combination therapy trial. Higher CMC-related expenses in connection with the preparation of our BLA filing also contributed to the increase in R&D expenses over the prior fiscal year. The future trend of R&D expenses will be dependent on the timing of FDA approval of our BLA filing, the timing of FDA clearance of our pivotal trial protocol for leronlimab as a monotherapy for HIV patients, the clinical progression of the triple-negative breast cancer and GvHD trials, along with the outcome of the pre-clinical studies for several cancer indications. R&D expenses will also increase due to CMC activities in preparation for approval and commercialization of leronlimab. Until satisfaction of the generally accepted accounting principles ("GAAP") standard for capitalization of such costs pursuant to ASC 350, all CMC manufacturing costs will continue to be expensed as R&D.

Amortization and depreciation expense of approximately $1.2 million rose by approximately $0.9 million due in part to the increased amortization attributable to the intangible assets acquired in the November 2018 transaction with ProstaGene LLC.

For the fiscal year ended May 31, 2019, we recognized an unrealized non-cash benefit from the decrease in derivative liability of approximately $1.7 million, as compared to a similar non-cash benefit in the comparable 2018 period. The total net change in derivative liability is attributable to three underlying financial instruments: (i) certain warrants that contain a contingent cash settlement provision, which originated in September 2016, accounted for approximately $0.9 million, (ii) a certain long-term convertible note payable, originating in June 2018, which was subsequently amended to provide for variable rate redemptions by the holder and (iii) a certain long-term convertible note payable, which originated in January 2019. The combined change in derivative liability ascribed to the two long-term convertible notes contributed approximately $0.8 million to the unrealized non-cash benefit for the fiscal year ended May 31, 2019. For each reporting period, we determine the fair value of the derivative liabilities and record a corresponding non-cash benefit or non-cash charge, as a consequence of a decrease or increase, respectively, in the calculated derivative liabilities.

Interest expense for the fiscal year ended May 31, 2019 of approximately $3.3 million decreased approximately $2.6 million from the 2018 fiscal year due primarily to lower non-cash inducement interest on a private warrant tender offer that was completed in May 2019, and no comparable inducement interest expense related to warrant extensions and convertible notes, which were in incurred in the 2018 fiscal year, offset by an increase in interest accrued on convertible notes payable of approximately $0.7 million.

The future trends of all expenses will be driven, in large part, by the future outcomes of clinical trials and the corresponding effect on research and development expenses, as well as general and administrative expenses, in addition to the manufacturing of new commercial leronlimab upon any FDA approval. 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.

Results of operations for the years ended May 31, 2018 and 2017

For the years ended May 31, 2018 and 2017, we had a net loss of approximately $50.1 million and $25.8 million, respectively. The increase in net loss of approximately $24.3 million for fiscal 2018 over 2017 was primarily attributable to increased R&D expenses of approximately $18.0 million, an increase in interest expense of approximately $5.3 million and a modest increase in general and administrative expense of approximately $0.6 million, combined with a reduction in the non-cash benefit in fair value of derivative liability of approximately $0.5 million. The loss per share for the fiscal year ended May 31, 2018 was $(0.29) compared to $(0.19) for the prior 2017 fiscal year.

The operating expenses for the years ended May 31, 2018 and 2017 and approximated as follows:

	2018	2017
General and administrative:		
Salaries and other compensation	$ 2,454,000	$ 2,332,000
Stock-based compensation	1,291,000	1,205,000
Other	3,596,000	3,222,000
Total general and administrative	7,341,000	6,759,000
Research and development	38,223,000	20,206,000
Amortization and depreciation	356,000	366,000
Total operating expenses	$45,920,000	$27,331,000

For the fiscal year ended May 31, 2018 and May 31, 2017, operating expenses totaled approximately $45.9 million and $27.3 million, respectively, consisting primarily of R&D expenses of $38.2 million, general and administrative expenses of approximately $7.3 million and amortization and depreciation of approximately $0.4 million. The increase in operating expenses over the comparable 2017 period was attributable to an increase in R&D expenses of approximately $18.0 million owing to higher clinical trial and manufacturing-related expenses and a modest increase in general and administrative expenses of approximately $0.6 million primarily related to an increase in consulting services and employee-related expenses.

General and administrative expenses, totaled approximately $7.3 million and $6.8 million, respectively, for fiscal 2018 and 2017. General and administrative expenses were comprised of salaries and benefits, non-cash stock-based compensation expense, professional fees, insurance and various other expenses. The increase in general and administrative expenses of approximately $0.6 million, or 8.6%, for the fiscal year ended May 31, 2018 over the comparable 2017 period was primarily due to increased consulting services and employee-related expenses.

R&D expenses, which totaled approximately $38.2 million for the fiscal year ended May 31, 2018, increased approximately $18.0 million, or 89.2%, over the same 2017 period. This increase was attributable to higher clinical trial expenses, combined with an expansion of our CMC activities in connection with the preparation of a BLA. We expect R&D expenses to maintain at this level, as the two ongoing Phase 2b/3 trials with leronlimab for HIV therapy continue, along with their related rollover studies, combined with the Phase 2 GvHD trial, and the expenses to continue activities related to manufacturing cGMP leronlimab material for the BLA and for future use.

We record research and development expenses where directly identifiable, approximately as follows for the years ended May 31, 2018 and 2017:

	Year Ended May 31,	
	2018	2017
Research and development:		
Clinical	$22,543,000	$ 9,846,000
Non-Clinical	$ 887,000	$ 691,000
CMC	$14,240,000	$ 8,998,000
Licenses and patent fees	$ 553,000	$ 671,000
Total research and development	$38,223,000	$20,206,000

For the fiscal year ended May 31, 2018, we recognized an unrealizednon-cash benefit from the decrease in derivative liability of approximately $1.7 million, as compared to an approximate non-cash benefit of $2.2 million in the comparable 2017 period. The warrants that contain a contingent cash settlement provision, which gives rise to a derivative liability, originated in September 2016. For each reporting period, we determine the fair value of the derivative liability and record a corresponding non-cash benefit or non-cash charge, as a consequence of a decrease or increase, respectively, in the calculated derivative liability.

Interest expense for the fiscal year ended May 31, 2018 of approximately $5.9 million increased approximately $5.3 million over the 2017 fiscal year due primarily to an increase in non-cash interest of approximately $3.5 million related to inducement interest on (i) convertible notes; (ii) the expiration date extension of certain warrants and (iii) the warrant tender offer that was completed in March 2018, coupled with cash interest expense of approximately $0.3 million on a convertible note and an increase in amortization of debt discount and issuance costs of approximately $2.1 million, offset by a reduction in interest related to derivative liability of approximately $0.5 million.

The future trends of all expenses will be driven, in large part, by the future outcomes of clinical trials and the correlative effect on research and development expenses, as well as general and administrative expenses, in addition to the manufacturing of new commercial leronlimab, along with the increasing activities to prepare and file a BLA. 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.

Fluctuations in Quarterly Operating Results

We have historically experienced significant fluctuations in our quarterly operating results and we expect such fluctuations to continue in the future. Our 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 protocol. As a non-revenue generating company, we are regularly conducting offerings to raise capital, which can create various forms of amortization of issuance costs or non-cash interest expense. In addition, a portion of the aforementioned derivative liabilities is tied to a probability estimate of a fundamental transaction and to our stock price, which can vary substantially from quarter to quarter, thereby creating a non-cash charge or benefit.

Liquidity and Capital Resources

Our cash position of approximately $3.5 million at May 31, 2019 increased approximately $2.2 million as compared to a balance of approximately $1.2 million at May 31, 2018. The increase was attributable to net cash provided by financing activities of approximately $52.7 million exceeding net cash used in operating activities of approximately $50.5 million by approximately $2.2 million. Despite our negative working capital position, vendor relations remain accommodative and we do not currently anticipate delays in our BLA filing schedule due to liquidity constraints.

Cash Flows

Net cash used in operating activities totaled approximately $50.5 million during the fiscal year ended May 31, 2019, which reflects an increase of approximately $20.6 million of net cash used in operating activities over the approximate $29.9 million in fiscal 2018. The increase in net cash used in operating activities was due to an increase in net loss of approximately $6 million, and a net change in the components of net working capital of approximately $13.4 million.

We made nominal investments in equipment and website development costs totaling approximately $45,000 during the fiscal year ended May 31, 2019.

Net cash provided by financing activities of approximately $52.7 million for the year ended May 31, 2019 increased approximately $23.3 million over $29.4 million of net cash provided by financing activities during fiscal year ended May 31, 2018. The increase in net cash provided from financing activities was primarily attributable to an increase in net proceeds from the sale of common stock and warrants of approximately $13.1 million, coupled with an increase of approximately $10.6 million in proceeds from convertible notes and net proceeds of approximately $3.1 million from a preferred convertible stock offering in the 2019 fiscal year.

Capital Requirements

We have not generated revenue to date, and do not expect to generate product revenue until FDA approval of leronlimab. We expect that we will continue to incur operating losses as expenses continue to increase as we proceed with completion of our BLA, prepare for commercialization of leronlimab and continue our pre-clinical and clinical trial programs. The future trends of all expenses will be driven, in large part, by the timing of the anticipated approval of our BLA, the magnitude of our commercialization readiness, future clinical trial strategy and timing of the commencement of our future revenue stream. We will require a significant amount of additional capital in the future in anticipation of a fully commercialized leronlimab product.

Contract Manufacturing

During the fourth quarter of fiscal 2019, we entered into a Master Services Agreement and Product Specific Agreement (collectively, the "Samsung Agreement") with Samsung BioLogics Co., Ltd. ("Samsung"), pursuant to which Samsung will perform technology transfer, process validation, manufacturing and supply services for the commercial supply of leronlimab. In April 2019 we delivered to Samsung a purchase order for $33 million worth of process validation and technology transfer services related to the manufacture of leronlimab, with payments by us scheduled to be made throughout calendar 2020. Under the Samsung Agreement, the purchase order is binding and we are obligated to pay the full amount.

Under the terms of the Samsung Agreement, we are obligated to make specified minimum purchases of leronlimab from Samsung pursuant to forecasted requirements which we will provide to Samsung. The first forecast will be delivered to Samsung by March 31, 2020. Thereafter, we must provide Samsung with a rolling quarterly forecast setting forth the total quantity of commercial grade leronlimab that we expect to require in the following years. We estimate that initial ramp-up costs to manufacture commercial grade leronlimab at scale could total approximately $60 million, with approximately $30 million payable over the course of calendar 2020, and approximately $30 million payable in the first quarter of 2021. Thereafter, we will pay Samsung per 15,000L batch according to the pricing terms specified in the Samsung Agreement.

The Samsung Agreement has an initial term ending in December 2027 and will be automatically extended for additional two year periods unless either party gives notice of termination at least six months prior to the then current term. Either party may terminate the Samsung Agreement in the event of the other party's insolvency or uncured material breach, and we may terminate the agreement in the event of a voluntary or involuntary complete market withdrawal of leronlimab from commercial markets, with one and half year's prior notice. Neither party may assign the agreement without the consent of the other, except in the event of a sale of all or substantially all of the assets of a party to which the agreement relates.

In addition to the Samsung Agreement, we have also previously entered into an arrangement with another third party contract manufacturer to provide process transfer, validation and manufacturing services for leronlimab. In the event that we terminate the agreement with this manufacturer, we may incur certain financial penalties which would become payable to the manufacturer. Conditioned upon the timing of termination, the financial penalties may total approximately $8.3 million. These amount and timing of the financial commitments under an agreement with our secondary contract manufacturer will depend on the timing of the anticipated approval of our BLA and the initial product demand forecast, which is critical to align the timing of capital resources in order to ensure availability of sufficient quantities of commercial product.

Management believes that two contract manufacturers may best serve our strategic objectives for the anticipated 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.

Contract Research

We have entered into project work orders for each of our clinical trials with our CRO and related laboratory vendors. Under the terms of these agreements, we have prepaid certain execution fees for direct services costs. In connection with our clinical trials, we have entered into separate project work orders for each trial with our CRO. In the event that we terminate any trial, we may incur certain financial penalties which would become payable to the CRO. Conditioned upon the form of termination of any one trial, the financial penalties may range up to $0.3 million. In the remote circumstance that we terminate all clinical trials, the collective financial penalties may range from an approximate low of $0.5 million to an approximate high of $1.2 million.

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 of the date of this filing, while we have completed and filed the first of three portions of our BLA, it remains uncertain as to when the remaining two portions will be filed. Further, if 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, thus the future milestone payments payable to Progenics and its sub-licensors are deemed contingent consideration and, therefore, are not currently accruable.

Going Concern

As reported in the accompanying financial statements, during the year ended May 31, 2019, May 31, 2018 and May 31, 2017, we incurred net losses of approximately $56.2, $50.1 million and $25.8 million respectively. We have no activities that produced revenue in the periods presented and have sustained operating losses since inception.

We currently require and will continue to require a significant amount of additional capital to fund operations, pay our accounts payables, and our ability to continue as a going concern is dependent upon our ability to raise such additional capital, commercialize our product and achieve profitability. If we are not able to raise such additional capital on a timely basis or on favorable terms, we may need to scale back our operations or slow down or cease completion of the remaining two sections of our BLA filing, including related CMC activities, which could materially delay the filing of the last two sections of the BLA submission. Our failure to raise additional capital could also affect our relationships with key vendors, disrupting our ability to timely execute our business plan. In extreme cases, we could be forced to file for bankruptcy protection, discontinue our operations or liquidate our assets.

Since inception, we have financed our activities principally from the sale of public and private equity securities and proceeds from convertible notes payable and related party notes payable. We intend to finance our future operating activities and our working capital needs largely from the sale of equity and debt securities, combined with additional funding from other traditional financing sources. As of the date of this filing, we have approximately 104 million shares of common stock authorized and available for issuance under our certificate of incorporation, as amended, and approximately $156 million available for future registered offerings of securities under our universal shelf registration statement on Form S-3, which was declared effective on March 7, 2018 (assuming the full exercise of outstanding warrants, at the currently applicable exercise prices, that were previously issued in registered transactions thereunder).

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 we raise additional funds through the issuance of preferred stock, convertible debt securities or other debt financing, these activities or other debt could contain covenants that would restrict our operations. On January 30, 2019, we entered into a long-term convertible note, which is secured by all of our assets, except for our intellectual property and also includes certain restrictive provisions, such as a limitation on 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 us to relinquish valuable rights. We may require additional capital beyond currently anticipated needs. Additional capital, if available, may not be available on reasonable or non-dilutive terms. Please refer to the matters discussed under the heading "Risk Factors" above.

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. We have incurred losses for all periods presented and have a substantial accumulated deficit. As of May 31, 2019, these factors, among several others, raise substantial doubt about our ability to continue as a going concern.

The consolidated financial statements do not include any adjustments relating to the recoverability and classification of liabilities that might be necessary should we be unable to continue as a going concern. Our continuation as a going concern is dependent upon our ability to obtain a significant amount of additional operating capital, complete development of our product candidate, obtain FDA approval, outsource manufacturing of our product, and ultimately to attain profitability. We intend to seek additional funding through equity or debt offerings, licensing agreements or 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 Policies and Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

We believe that the following critical policies affect our more significant judgments and estimates used in preparation of our consolidated financial statements.

We follow the provisions of FASB ASC815-Derivatives and Hedging (“ASC 815”), FASB ASC480-Distinguishing liabilities from equity (“ASC 480”), ASC 470- Debt and debt with conversion and other options (“ASC 470”). We have 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. We have followed the general extinguishment model to record certain conversion and the extinguishment of derivative liabilities. 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 convertible options, including early conversions. The assumptions in the model are subject to estimates and judgement.

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 volatility, expected term and risk-free interest rates in determining the fair value of the stock-based awards.

We periodically issue stock options and warrants to consultants for various services. Costs for these transactions are measured at the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more readily measurable. This determination requires judgment in terms of the consideration being measured.

We have historically issued convertible promissory notes with detachable warrants to purchase common stock. The conversion options are fixed, but may be beneficial to the note holders at the respective commitment dates. The valuation of the beneficial conversion feature of the notes and of the warrants gives rise to the recognition of a debt discount, which requires the use of certain assumptions inherent in the Black-Scholes option pricing model, including various judgments and estimates.

As discussed in Notes 8 and 9 to the consolidated financial statements, 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.

Item 8. Financial Statements and Supplementary Data.

CYTODYN INC.

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, 2019 and 2018 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, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the years in the three-year period ended May 31, 2019, 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, 2019, 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 August 14, 2019, expressed an unqualified opinion.

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 $56,187,000 for the year ended May 31, 2019 and has an accumulated deficit of approximately $229,363,000 through May 31, 2019, 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 consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Warren Averett, LLC

We have served as the Company's auditor since 2007.
Birmingham, Alabama
August 14, 2019

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of 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, 2019, 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, 2019, 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 consolidated balance sheets and the related consolidated statements of operations, changes in stockholders' (deficit) equity, and cash flows of the Company, and our report dated August 14, 2019, 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 financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

/s/ Warren Averett, LLC

Birmingham, Alabama
August 14, 2019

CytoDyn Inc.
Consolidated Balance Sheets

	May 31, 2019	May 31, 2018
Assets		
Current assets:		
Cash	$ 2,612,910	$ 1,231,445
Restricted cash	853,599	—
Miscellaneous receivables	90,824	—
Prepaid expenses	107,211	227,173
Prepaid service fees	1,704,876	1,862,009
Total current assets	5,369,420	3,320,627
Furniture and equipment, net	29,251	11,228
Intangibles, net	15,475,454	1,567,143
Total assets	$ 20,874,125	$ 4,898,998
Liabilities and Stockholders' (Deficit) Equity		
Current liabilities:		
Accounts payable	$ 16,239,434	$ 15,841,859
Accrued liabilities and compensation	1,588,552	757,778
Accrued license fees	208,600	133,600
Accrued interest on convertible notes	212,777	—
Accrued dividends on Series C convertible preferred stock	37,351	—
Convertible notes payable, net	3,586,035	—
Current portion of long-term convertible notes payable	4,200,000	—
Warrant tender offer proceeds held in trust	853,599	—
Total current liabilities	26,926,348	16,733,237
Long-term liabilities:		
Convertible notes payable, net	454,568	—
Derivative liability	2,407,269	1,323,732
Total long-term liabilities	2,861,837	1,323,732
Total liabilities	29,788,185	18,056,969
Commitments and Contingencies	—	—
Stockholders' (Deficit) Equity		
Preferred Stock, $0.001 par value; 5,000,000 shares authorized		
Series C convertible preferred stock, $0.001 par value; 5,000 shares authorized; 3,246 issued and outstanding at May 31, 2019	3	—
Series B convertible preferred stock, $0.001 par value; 400,000 shares authorized, 92,100 shares issued and outstanding at May 31, 2019 and May 31, 2018, respectively	92	92
Common stock, $0.001 par value; 700,000,000 and 375,000,000 shares authorized, 329,554,763 and 216,881,790 issued and 329,395,752 and 216,722,779 outstanding at May 31, 2019 and May 31, 2018, respectively	329,555	216,881
Additional paid-in capital	220,119,856	159,764,611
Accumulated (deficit)	(229,363,407)	(173,139,396)
Less: treasury stock, at par (159,011 shares at $0.001)	(159)	(159)
Total stockholders' (deficit)	(8,914,060)	(13,157,971)
Total liabilities and stockholders' (deficit) equity	$ 20,874,125	$ 4,898,998

See accompanying notes to consolidated financial statements.

CytoDyn Inc.
Consolidated Statements of Operations

	Years ended May 31,		
	2019	2018	2017
Operating expenses:			
General and administrative	$ 12,116,743	$ 7,340,605	$ 6,758,606
Research and development	42,490,144	38,222,580	20,205,743
Amortization and depreciation	1,245,167	356,128	366,385
Total operating expenses	55,852,054	45,919,313	27,330,734
Operating loss	(55,852,054)	(45,919,313)	(27,330,734)
Other income (expense):			
Interest income	4,306	3,620	15,167
Change in fair value of derivative liability	1,666,469	1,690,935	2,164,533
Loss on extinguishment of convertible notes	(1,519,603)	—	—
Interest expense:			
Amortization of discount on convertible notes	(1,707,068)	(1,666,017)	—
Amortization of debt issuance costs	(459,085)	(435,609)	—
Interest related to derivative liability	—	—	(540,330)
Inducement interest related to warrant tender offer	(195,927)	(393,685)	—
Inducement interest related to warrant extension	—	(826,252)	(72,437)
Inducement interest related to convertible notes	—	(2,352,045)	—
Interest on convertible notes payable	(950,617)	(251,315)	—
Total interest expense	(3,312,697)	(5,924,923)	(612,767)
Loss before income taxes	(59,013,579)	(50,149,681)	(25,763,801)
Income tax benefit	2,826,919	—	—
Net loss	$(56,186,660)	$ (50,149,681)	$ (25,763,801)
Basic and diluted loss per share	$ (0.21)	$ (0.29)	$ (0.19)
Basic and diluted weighted average common shares outstanding	272,040,933	174,885,422	138,004,461

See accompanying notes to consolidated financial statements.

CytoDyn Inc.
Consolidated Statements of Changes in Stockholders' (Deficit) Equity

	Preferred Stock		Common Stock		Treasury Stock	
	Shares	Amount	Shares	Amount	Shares	Amount
Balance May 31, 2016	95,100	$ 95	123,335,634	$123,336	—	$ —
Interest expense related to warrant extension	—	—	—	36	—	—
Stock-based compensation	—	—	—	—	—	—
Legal fees in connection with registered offerings	—	—	—	—	—	—
Proceeds from private equity offering ($1.00/share)	—	—	729,500	730	—	—
Proceeds from registered direct offering ($0.75/share)			24,538,994	24,539	—	—
Offering costs related to equity offering	—	—	—	—	—	—
Debt discount related to convertible notes payable	—	—	—	—	—	—
Conversion of Series B Convertible Preferred ($0.50/share)	(3,000)	(3)	40,602	3	—	—
Proceeds from warrant exercise ($0.50/share)	—	—	730,765	730	—	—
Proceeds from warrant exercise ($0.75/share)	—	—	43,332	44	—	—
Cashless exercise of warrants	—	—	49,417	50	—	—
Net (loss) for the year ended May 31, 2017						
Balance May 31, 2017	92,100	$ 92	149,468,244	$149,468	—	$ —
Stock-based compensation	—	—	—	—	—	—
Stock issued for board compensation	—	—	—	—	—	—
Stock issued for bonuses and tendered for income tax	—	—	310,526	311	159,011	(159)
Proceeds from private equity offering ($0.50/share)	—	—	35,286,904	35,286	—	—
Offering costs related to private equity offering	—	—	—	—	—	—
Proceeds from registered direct offering ($0.50/share)	—	—	25,493,853	25,494	—	—
Offering costs related to registered direct offering	—	—	—	—	—	—
Legal fees in connection with equity offerings	—	—	—	—	—	—
Proceeds from warrant exercise ($0.50/share)	—	—	6,322,263	6,322	—	—
Offering costs related to warrant tender offer	—	—	—	—	—	—
Debt discount related to convertible notes payable	—	—	—	—	—	—
Interest expense related to warrant extension	—	—	—	—	—	—
Interest expense realted to warrant tender offer	—	—	—	—	—	—
Interest expense related to conversion of notes payable	—	—	—	—	—	—
Net (loss) for the year ended May 31, 2018						
Balance May 31, 2018	92,100	$ 92	216,881,790	$216,881	159,011	$ (159)
Acquisition of ProstaGene LLC	—	—	18,658,000	18,658	—	—
Issuance of stock payment shares	—	—	8,342,000	8,342	—	—
Issuance of stock for note payable redemption	—	—	3,756,406	3,757	—	—
Proceeds from registered direct offering ($0.50/share)	—	—	23,629,480	23,629	—	—
Offering costs related to registered direct offering	—	—	—	—	—	—
Proceeds from private equity offering ($0.50/share)	—	—	46,975,170	46,976	—	—
Offering costs related to private equity offering	—	—	—	—	—	—
Offering costs related to debt offering	—	—	—	—	—	—
Debt discount and issuance costs related to offering	—	—	—	—	—	—
Beneficial conversion feature on note payable and relative fair value associated with warrants	—	—	—	—	—	—
Proceeds from private warrant exchange	—	—	11,311,917	11,312	—	—
Offering costs related to private warrant exchange	—	—	—	—	—	—
Inducement interest expense on private warrant exchange	—	—	—	—	—	—
Proceeds from Series C Convertible Preferred offering	3,246	3	—	—	—	—
Dividends on Series C Convertible Preferred shares	—	—	—	—	—	—
Legal fees in connection with equity offerings	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—
Net (loss) for the year ended May 31, 2019						
Balance May 31, 2019	95,346	95	329,554,763	329,555	159,011	(159)

CytoDyn Inc.
Consolidated Statements of Changes in Stockholders' (Deficit) Equity

	Additional Paid-In Capital	Accumulated Deficit	Total
Balance May 31, 2016	$107,307,933	$ (97,225,914)	$ 10,205,450
Interest expense related to warrant extension	72,398	—	72,434
Stock-based compensation	1,204,791	—	1,204,791
Legal fees in connection with registered offerings	(280,883)	—	(280,883)
Proceeds from private equity offering ($1.00/share)	728,770	—	729,500
Proceeds from registered direct offering ($0.75/share)	14,019,713	—	14,044,252
Offering costs related to equity offering	(1,804,249)	—	(1,804,249)
Debt discount related to convertible notes payable	91,389	—	91,389
Conversion of Series B Convertible Preferred ($0.50/share)	—	—	—
Proceeds from warrant exercise ($0.50/share)	364,653	—	365,383
Proceeds from warrant exercise ($0.75/share)	32,456	—	32,500
Cashless exercise of warrants	(50)	—	—
Net (loss) for the year ended May 31, 2017	—	(25,763,801)	(25,763,801)
Balance May 31, 2017	$121,736,921	$(122,989,715)	$ (1,103,234)
Stock-based compensation	1,290,777	—	1,290,777
Stock issued for board compensation	260,190	—	260,190
Stock issued for bonuses and tendered for income tax	104,394	—	104,546
Proceeds from private equity offering ($0.50/share)	17,608,165	—	17,643,451
Offering costs related to private equity offering	(1,717,597)	—	(1,717,597)
Proceeds from registered direct offering ($0.50/share)	13,585,925	—	13,611,419
Offering costs related to registered direct offering	(857,149)	—	(857,149)
Legal fees in connection with equity offerings	(533,436)	—	(533,436)
Proceeds from warrant exercise ($0.50/share)	3,154,809	—	3,161,131
Offering costs related to warrant tender offer	(85,381)	—	(85,381)
Debt discount related to convertible notes payable	1,645,011	—	1,645,011
Interest expense related to warrant extension	826,252	—	826,252
Interest expense realted to warrant tender offer	393,685	—	393,685
Interest expense related to conversion of notes payable	2,352,045	—	2,352,045
Net (loss) for the year ended May 31, 2018	—	(50,149,681)	(50,149,681)
Balance May 31, 2018	$159,764,611	$(173,139,396)	$(13,157,971)
Acquisition of ProstaGene LLC	11,539,342	—	11,558,000
Issuance of stock payment shares	(8,342)	—	—
Issuance of stock for note payable redemption	1,451,243	—	1,455,000
Proceeds from registered direct offering ($0.50/share)	11,791,110	—	11,814,739
Offering costs related to registered direct offering	(1,129,516)	—	(1,129,516)
Proceeds from private equity offering ($0.50/share)	23,440,608	—	23,487,584
Offering costs related to private equity offering	(2,697,149)	—	(2,697,149)
Offering costs related to debt offering	260,636	—	260,636
Debt discount and issuance costs related to offering	3,059,159	—	3,059,159
Beneficial conversion feature on note payable and relative fair value associated with warrants	3,534,992	—	3,534,992
Proceeds from private warrant exchange	2,955,200	—	2,966,512
Offering costs related to private warrant exchange	(266,986)	—	(266,986)
Inducement interest expense on private warrant exchange	195,927	—	195,927
Proceeds from Series C Convertible Preferred offering	3,083,697	—	3,083,700
Dividends on Series C Convertible Preferred shares	—	(37,351)	(37,351)
Legal fees in connection with equity offerings	(242,771)	—	(242,771)
Stock-based compensation	3,388,095	—	3,388,095
Net (loss) for the year ended May 31, 2019	—	(56,186,660)	(56,186,660)
Balance May 31, 2019	220,119,856	(229,363,407)	(8,914,060)

See accompanying notes to consolidated financial statements

CytoDyn Inc.
Consolidated Statements of Cash Flows

	Years ended May 31,		
	2019	2018	2017
Cash flows from operating activities:			
Net loss	$(56,186,660)	$(50,149,681)	$(25,763,801)
Adjustments to reconcile net loss to net cash used in operating activities:			
Amortization and depreciation	1,245,167	356,128	366,385
Amortization of debt issuance costs	459,085	435,609	—
Amortization of discount on convertible notes	1,707,068	1,666,017	—
Loss on extinguishment of convertible notes	1,519,603	—	—
Deferred income tax benefit	(2,826,919)	—	—
Inducement interest expense	195,927	—	72,437
Interest expense associated with warrant extension	—	826,252	—
Interest expense association with warrant tender offer	—	393,685	—
Interest expense associated with conversion of notes	—	2,352,045	—
Interest expense associated with derivative liability	—	—	540,330
Interest expense associated with accretion of convertible notes payable	512,594	—	—
Change in fair value of derivative liability	(1,666,469)	(1,690,935)	(2,164,533)
Stock-based compensation	3,388,095	1,290,777	1,204,791
Changes in current assets and liabilities:			
Decrease (increase) in miscellaneous receivables	(90,824)	—	—
Decrease (increase) in prepaid expenses	(464,201)	2,256,173	(2,492,789)
Increase (decrease) in accounts payable and accrued expenses	1,741,370	12,365,959	1,504,712
Net cash used in operating activities	(50,466,164)	(29,897,971)	(26,732,468)
Cash flows from investing activities:			
Furniture and equipment purchases	(25,731)	—	(11,114)
Intangibles	(19,553)	—	—
Net cash used in investing activities	(45,284)	—	(11,114)
Cash flows from financing activities:			
Proceeds from sale of common stock and warrants	38,268,839	25,224,212	19,133,755
Proceeds from sale of preferred stock	3,083,700	—	—
Proceeds from warrant exercises	—	3,161,131	397,883
Proceeds from convertible notes payable	15,460,000	4,888,500	1,150,000
Payment of offering costs	(4,336,426)	(3,558,789)	(1,804,249)
Payment of debt issuance costs	(583,200)	—	—
Payment of payroll taxes related to tender of common stock for income tax withholding	—	(102,064)	—
Repayment of principal and interest on convertible note	—	(259,157)	—
Proceeds from warrant tender offer in process—held in trust	853,599	—	—
Net cash provided by financing activities	52,746,512	29,353,833	18,877,389
Net change in cash	2,235,064	(544,138)	(7,866,193)
Cash, beginning of period	1,231,445	1,775,583	9,641,776
Cash, end of period	$ 3,466,509	$ 1,231,445	$ 1,775,583

CytoDyn Inc.
Consolidated Statements of Cash Flows

	Years ended May 31,		
	2019	2018	2017
Supplemental disclosure of cash flow information:			
Cash paid during the period for interest	—	$ 9,157	—
Non-cash investing and financing transactions:			
Accrued interest converted into note payable	$ 225,245	—	—
Accrued dividends on Series C Convertible Preferred stock	$ 37,351	—	—
Common stock issued for acquisition of ProstaGene LLC	$11,558,000	—	—
Derivative liability associated with convertible notes payable	$ 2,750,006	—	—
Beneficial conversion feature and fair value of warrant issued with note payable	$ 3,534,992	—	—
Debt discount associated with convertible notes payable	$ 3,059,159	$1,574,628	$ 91,389
Financing costs associated with investor warrants	—	—	$ 819,200
Common stock issued in connection with an employment agreement	$ 8,342	—	—
Common stock issued for accrued bonus compensation	—	$ 214,263	—
Common stock issued for board compensation	—	$ 260,190	—
Common stock issued for conversion redemption	$ 1,455,000	—	—
Common stock issued upon conversion of convertible debt	—	$5,788,500	—
Common stock issued for accrued interest payable	—	$ 242,158	—
Financing costs associated with placement agent warrants	$ 260,636	$ 70,383	—
Derivative liability associated with warrants	—	—	$5,179,200

See accompanying notes to consolidated financial statements.

Note 1 – Organization

CytoDyn Inc. (the "Company") was originally incorporated under the laws of Colorado on May 2, 2002 under the name RexRay Corporation (its previous name) and, effective August 27, 2015, reincorporated under the laws of Delaware. The Company is a clinical-stage biotechnology company developing innovative treatments for multiple therapeutic indications based on leronlimab, a novel humanized monoclonal antibody targeting the CCR5 receptor. CCR5 appears to play a key role in the ability of Human Immunodeficiency Virus ("HIV") to enter and infect healthy T-cells. The CCR5 receptor also appears to be implicated in human metastasis and in immune-mediated illnesses such as graft-vs-host disease ("GvHD") and Non-Alcoholic Steatohepatitis ("NASH"). The Company's lead product candidate, leronlimab, belongs to a class of HIV therapies known as entry inhibitors. These therapies block HIV from entering into and infecting certain cells.

The Company has developed a class of therapeutic monoclonal antibodies to address unmet medical needs in the areas of HIV and GvHD. In addition, we are expanding the clinical focus with leronlimab to include the evaluation in certain cancer and immunological indications where CCR antagonism has shown initial promise.

Note 2 – Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of CytoDyn Inc. and its wholly owned subsidiaries, CytoDyn Operations Inc., Advanced Genetic Technologies, Inc. ("AGTI") and CytoDyn Veterinary Medicine LLC ("CVM"), of which both AGTI and CVM are dormant entities. 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 2019 presentation. These reclassifications did not have any effect on total current assets, total assets, total current liabilities, total liabilities, total stockholders' (deficit) equity, net loss or earnings per shares.

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 $56,186,660, $50,149,681 and $25,763,801 for the years ended May 31, 2019, May 31, 2018, and May 31, 2017, respectively, and has an accumulated deficit of $229,363,407 as of May 31, 2019. These factors, among several 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, obtain U.S. Food and Drug Administration (the "FDA") approval, outsource manufacturing of the product candidate, and ultimately achieve initial revenues and attain profitability. The Company is currently engaging in significant research and development activities related to its product candidate, 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 assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash

Cash is maintained at federally insured financial institutions and, at times, balances may exceed federally insured limits. The Company has never experienced, nor does it expect to experience any losses related to these balances. Balances in excess of federally insured limits at May 31, 2019 and May 31, 2018 approximated $3.3 million and $1.1 million, respectively, which included restricted cash of approximately $0.9 million and $-0-, respectively.

Identified Intangible Assets

The Company follows the provisions of FASB ASC Topic 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. There were no impairment charges for the years ended May 31, 2019, May 31, 2018, and May 31, 2017. 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 Notes 7 and 9.

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. Where contingent milestone payments are due to third parties under research and development collaboration arrangements or other contractual agreements, the milestone payment obligations are expensed when the milestone conditions are probable and the amount of payment is reasonably estimable.

Pre-launch Inventory

The Company may scale-up and make commercial quantities of its product candidate prior to the date it anticipates that such product will receive final FDA approval. The scale-up and commercial production of pre-launch inventories involves the risk that such products may not be approved for commercial use by the FDA on a timely basis, or ever. This risk notwithstanding, the Company may scale-up and build pre-launch inventories of product that have not yet received final governmental approval when the Company believes that such action is appropriate in relation to the commercial value of the product launch opportunity. The determination to capitalize is made once the Company (or its third party development partners) has filed a BLA, that has been acknowledged by the FDA as containing sufficient information to allow the FDA to conduct its review in an efficient and timely manner and management is reasonably certain that all regulatory and legal hurdles will be cleared. This determination is based on the particular facts and circumstances relating to the expected FDA approval of the drug product being considered. As of May 31, 2019 and May 31, 2018, the Company did not have pre-launch inventory that qualified for capitalization pursuant to U.S. GAAP ASC 330 Inventory.

Fair Value of Financial Instruments

At May 31, 2019 and May 31, 2018, 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. The Company carries 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 income.

Fair Value Hierarchy

The three levels of inputs that may be used to measure fair value are 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 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 the Company was unable to corroborate with observable market data.

Liabilities measured at fair value on a recurring basis by level within the fair value hierarchy as of May 31, 2019 and May 31, 2018 is as follows:

	Fair Value Measurement at May 31, 2019 (1)		Fair Value Measurement at May 31, 2018 (1)	
	Using Level 3	Total	Using Level 3	Total
Liabilities:				
Derivative liability - warrants	$2,005,137	$2,005,137	$ —	$ —
Derivative liability - convertible note redemption provision	402,132	402,132	1,323,732	1,323,732
Total liability	$2,407,269	$2,407,269	$1,323,732	$1,323,732

(1) 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, 2019 and May 31, 2018.

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. The Company uses 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 are 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 May 31, 2019:

Investor warrants issued with registered direct equity offering	$ 4,360,000
Placement agent warrants issued with registered direct equity offering	819,200
Fair value adjustments	(3,855,468)
Balance at May 31, 2018	1,323,732
Inception date value of redemption provisions	2,750,006
Fair value adjustments - convertible notes	(744,869)
Fair value adjustments - warrants	(921,600)
Balance at May 31, 2019	$ 2,407,269

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 expense is to be recognized over the period during which an employee is required to provide services in exchange for the award (requisite service period) or when designated milestones have been achieved.

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. The risk-free interest rate assumption is based upon 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 on monthly intervals. The computation of the expected option term is based on the "simplified method," as the Company issuances are considered "plain vanilla" options. For stock-based awards with defined vesting, the Company recognizes compensation expense over the requisite service period or when designated milestones have been achieved. 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.

Common Stock

On June 7, 2018, at a special meeting of the Company's stockholders, a proposal was approved to increase the total number of authorized shares of common stock of the Company from 375,000,000 to 450,000,000. On November 8, 2018, at the 2018 Annual Meeting of Stockholders, a proposal was approved to increase the total number of authorized shares of common stock of the Company from 450,000,000 to 600,000,000. Subsequently, on May 22, 2019, at a special meeting of stockholders, a proposal was approved to increase the total number of authorized shares of common stock of the Company from 600,000,000 to 700,000,000.

Preferred Stock

The Company's Board of Directors is authorized to issue up to 5,000,000 shares of preferred stock without stockholder approval. As of May 31, 2019, the Company has authorized the issuance of 400,000 shares of Series B convertible preferred stock and 5,000 shares of Series C convertible preferred stock, of which 92,100 shares and 3,246 shares, respectively, were outstanding. The remaining preferred shares authorized have no specified rights.

Treasury Stock

Treasury stock purchases are accounted for under the par value method, whereby the cost of the acquired stock is recorded at par value. As of the year ended May 31, 2019, the Company has purchased a total of 159,011 shares of $0.001 par value treasury stock.

Debt Discount

During the years ended May 31, 2019, May 31, 2018 and May 31, 2017, the Company incurred approximately $4.2 million, $1.5 million, and $92,000, respectively, of debt discount related to the issuance of short-term convertible promissory notes issued with detachable warrants, as described in Note 4. The discount was amortized over the life of the convertible promissory notes and the Company recognized approximately $1.7 million, $1.6 million, and $-0-, of related amortization expense for the years ended May 31, 2019, May 31, 2018 and May 31, 2017, respectively.

Debt Issuance Costs

During the years ended May 31, 2019 and May 31, 2018, the Company incurred direct costs associated with the issuance of short-term convertible promissory notes, as described in Note 4, and recorded approximately $1.0 million and $0.4 million, respectively, of debt issuance costs. The Company recognized approximately $0.5 million, $0.4 million, and -0- of related amortization expense for the years ended May 31, 2019, May 31, 2018 and May 31, 2017, respectively.

Offering Costs

During the years ended May 31, 2019, May 31, 2018 and May 31, 2017, the Company incurred approximately $4.3 million, $3.5 million, and $1.8 million respectively, in direct incremental costs associated with the sale of equity securities. The offering costs were recorded as a component of equity upon receipt of the proceeds, as fully described in Notes 10 and 11.

Stock for Services

The Company periodically issues warrants to consultants for various services. The Black-Scholes option pricing model, as described more fully above, is utilized 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.

Loss per Common Share

Basic loss per share is computed by dividing the net loss 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 share 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. For this reason, common stock options and warrants to purchase 178,591,849, 132,385,269; and 77,859,626 shares of common stock were not included in the computation of basic and diluted weighted average common shares outstanding for the years ended May 31, 2019, May 31, 2018 and May 31, 2017, respectively. As of May 31, 2019 shares of Series C and Series B convertible preferred stock in the aggregate of 95,346 shares can potentially convert into 7,413,000 shares of common stock.

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 bases. Future tax benefits for net operating loss carry forwards 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 of the deferred tax assets will not be realized.

The Company follows the provisions of FASB ASC740-10 Uncertainty in Income Taxes ("ASC740-10"). 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 as a result of 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, we utilized a federal statutory rate of 21% for our fiscal 2019 tax year. The net tax expense for the year ended May 31, 2019, is a benefit of $2.8 million. The Company has a full valuation allowance as of May 31, 2019, as management does not consider it more than likely than not that the benefits from the deferred taxes will be realized.

Note 3 – Recent Accounting Pronouncements

Recent accounting pronouncements, other than below, issued by the Financial Accounting Standards Board ("FASB") (including its EITF), the American Institute of Certified Public Accountants and the U.S. Securities and Exchange Commission (the "SEC") did not or are not believed by management to have a material effect on the Company's present or future financial statements.

In May 2017, the FASB issued ASU 2017-09 "Compensation-Stock Compensation (Topic 718), Scope of Modification Accounting." The amendments in this update provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. The amendments in this update are effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted, including adoption in any interim period, for public business entities for reporting periods for which financial statements have not yet been issued. The adoption of ASU 2017-09 did not have a material impact on the Company's consolidated financial statements.

In August 2018, FASB issued Accounting Standards Update ("ASU")No. 2018-13 "Fair Value Measurement (Topic 820) Disclosure Framework Changes to the Disclosure Requirements for Fair Value Measurement". The amendments in this Update provides guidance that remove, modify and add to the disclosure requirements related to fair value measurements. The guidance removes the requirements to disclose the amount and reasons for transfers between Level 1 and Level 2 assets, the policy for timing and transfers between levels and the valuation process for Level 3 fair value measurements. The guidance modifies disclosure requirements for investments in certain entities that calculate net asset value and clarifies the purpose of the measurement uncertainty disclosure. The guidance adds requirements to disclose changes in unrealized gains or losses included in other comprehensive income for recurring Level 3 fair value measurements and to disclose the range and weighted average used to develop significant unobservable inputs for Level 3 fair value measurements. The guidance is effective for fiscal years beginning after December 15, 2019 and interim periods within those fiscal years. The Company does not expect the adoption to have a material impact on its consolidated financial statements.

In June 2018, FASB issued ASUNo. 2018-07 "Compensation – Stock Compensation (Topic 718), Improvements to Nonemployee Share Based Payment Accounting". The amendments in this Update expand the scope of stock compensation to include share-based payment transactions for acquiring goods and services from nonemployees. The guidance in this Update does not apply to transactions involving equity instruments granted to a lender or investor that provides financing to the issuer. The guidance is effective for fiscal years beginning after December 31, 2018 including interim periods within the fiscal year. The Company is currently assessing the impact this Update may have on its consolidated financial statements.

In March 2018, FASB issued ASUNo. 2018-05 "Income Taxes (Topic 740), Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118". The amendments in this Update add various Securities and Exchange Commission ("SEC") paragraphs pursuant to the issuance of SEC Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act ("Act") ("SAB 118"). The SEC issued SAB 118 to address concerns about reporting entities' ability to timely comply with the accounting requirements to recognize all of the effects of the Act in the period of enactment. SAB 118 allows disclosure that timely determination of some or all of the income tax effects from the Act are incomplete by the due date of the financial statements and if possible, to provide a reasonable estimate. The Company has provided a reasonable estimate in the notes to the consolidated financial statements.

In July 2017, the FASB issued ASUNo. 2017-11 "Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815)." The amendments in Part I of this Update change the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity's own stock. The amendments also clarify existing disclosure

requirements for equity-classified instruments. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. For freestanding equity classified financial instruments, the amendments require entities that present earnings per share ("EPS") in accordance with Topic 260 to recognize the effect of the down round feature when it is triggered. That effect is treated as a dividend and as a reduction of income available to common shareholders in basic EPS. Convertible instruments with embedded conversion options that have down round features are now subject to the specialized guidance for contingent beneficial conversion features (in Subtopic 470-20, Debt—Debt with Conversion and Other Options), including related EPS guidance (in Topic 260). The amendments in Part II of this Update recharacterize the indefinite deferral of certain provisions of Topic 480 that now are presented as pending content in the Codification, to a scope exception. Those amendments do not have an accounting effect. For public business entities, the amendments in Part I of this Update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted for all entities, including adoption in an interim period. If an entity early adopts the amendments in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. Management is currently assessing the impact the adoption of ASU 2017-11 will have on the Company's consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02 "Leases (Topic 842)" and subsequent amendments to the initial guidance: ASU No. 2017-13, ASU No. 2018-10, ASU No. 2018-11, ASU No. 2018-20 and ASU No. 2019-01 (collectively, Topic 842). Topic 842 amends a number of aspects of lease accounting, including requiring lessees to recognize leases with a term greater than one year as a right-of-use asset and corresponding liability, measured at the present value of the lease payments. In July 2018, the FASB issued supplemental adoption guidance and clarification to Topic 842 within ASU 2018-10 "Codification Improvements to Topic 842, Leases" and ASU 2018-11 "Leases (Topic 842): Targeted Improvements." The guidance will become effective for us beginning in the first quarter of 2020. The modified retrospective transition approach is required. The Company does not expect the adoption to have a material impact on its consolidated financial statements.

Note 4 – Convertible Instruments

Series C Convertible Preferred Stock

On March 20, 2019, the Company authorized 5,000 shares and issued 3,246 shares of Series C, $0.001 par value Convertible Preferred Stock ("Series C Preferred Stock") at $1,000.00 per share for cash proceeds totaling $3,083,700 net of placement agent fees of $162,300, of which 3,246 shares remain outstanding at May 31, 2019. The Certificate of Designation provides, among other things, that holders of Series C Preferred Stock shall be entitled to receive, at the option of the holder, cumulative dividends at the rate of ten percent (10%) per share per annum of the stated value of the Series C Preferred Stock, to be paid per share of Series C Preferred Stock. Any dividends paid by the Company will first 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 mandatory and cumulative and there are no sinking fund provisions applicable to the Series C Preferred Stock. The Series C Preferred Stock does not have redemption rights. The stated value per share for the Series C Preferred Stock is $1,000 (the "Stated Value"). In the event of any liquidation, dissolution or winding up of the Company, the Series C Preferred Stock will be paid, prior and in preference to any payment or distribution on any shares of common stock, currently outstanding series of preferred stock, or subsequent series of preferred stock, an amount per share equal to the Stated Value and the amount of any accrued and unpaid dividends. The holders of the Series C Preferred Stock will then receive distributions along with the holders of common stock on a pari passu basis according to the number of shares of common stock the Series C Preferred holders would be entitled if they converted their shares of Series C Preferred Stock at the time of such distribution. If, at any time while the Series C Preferred Stock is outstanding, the Company effects any reorganization, merger or sale of the Company or substantially all of its assets (each 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 the Company's common stock determined by dividing the Stated Value by the conversion price of $0.50 per share (subject to adjustment as set forth in the Certificate of Designation). No fractional shares will be issued upon the conversion of the Series C Preferred Stock. Except as otherwise provided in the Certificate of Designation or as otherwise required by law, the Series C Preferred Stock has no voting rights. As of May 31, 2019, the accrued dividends were approximately $65,000 or 130,000 shares of common stock.

Series B Convertible Preferred Stock

During fiscal 2010, the Company issued 400,000 shares of Series B, $0.001 par value Convertible Preferred Stock ("Series B Preferred Stock") at $5.00 per share for cash proceeds totaling $2,009,000, of which 92,100 shares remain outstanding at May 31, 2019. Each share of the Series B Preferred Stock is convertible into ten shares of the Company's $0.001 par value common stock, including any accrued dividends, with an effective fixed conversion price of $0.50 per share. The holders of the Series B Preferred Stock can only convert their shares to common shares provided the Company has sufficient authorized common shares at the time of conversion. Accordingly, the conversion option was contingent upon the Company increasing its authorized common shares, which

occurred in April 2010, when the Company's stockholders approved an increase in the authorized shares of common stock to 100,000,000. At the commitment date, which occurred upon such stockholder approval, the conversion option related to the Series B Preferred Stock was beneficial. The intrinsic value of the conversion option at the commitment date resulted in a constructive dividend to the Series B Preferred Stock holders of approximately $6,000,000. The constructive dividend increased and decreased additional paid-in capital by identical amounts. The Series B Preferred Stock has liquidation preferences over the common shares at $5.00 per share plus any accrued dividends. Dividends are payable to the Series B Preferred Stock holders when 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. The Series B Preferred Stock holders have no voting rights. As of May 31, 2019 and May 31, 2018, the undeclared, accrued dividends were approximately $216,000 or 432,000 shares of common stock and approximately $199,000 or 387,000 shares of common stock, respectively.

2018 Short-term Convertible Notes

During the fiscal year ended May 31, 2018, the Company issued approximately $4.89 million in aggregate principal of short-term Convertible Notes, (the "2018 Short-term Convertible Notes") with a maturity date of January 31, 2018, and related warrants to investors for cash. The principal amount of the 2018 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 shares at any time prior to maturity at a conversion price of $0.75 per share. The 2018 Short-term Convertible Notes bore simple interest at the annual rate of 7%. Principal and accrued interest, to the extent not previously paid or converted, is due and payable on the maturity date. At the commitment date, the Company determined that the conversion feature related to these 2018 Short-term Convertible Notes to be 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 2018 Short-term Convertible Notes for the fair value of the related warrants. In connection with the sale of the 2018 Short-term Convertible Notes, detachable common stock warrants to purchase a total of 4,025,656 common shares, with an exercise price of $1.00 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
Expected dividend yield	0%
Stock price volatility	69.80%
Expected term	5 year
Risk-free interest rate	1.77 - 1.93%
Grant-date fair value	$0.30 - $0.39

The fair value of the warrants, coupled with the beneficial conversion features, were recorded as a debt discount to the 2018 Short-term Convertible Notes and a corresponding increase to additional paid-in capital was amortized over the term of the 2018 Short-term Convertible Notes. The Company incurred debt discount of approximately $1.6 million related to the beneficial conversion feature and detachable warrants issued with the notes during the year ended May 31, 2018. Accordingly, the Company recognized approximately $-0- and $1.6 million of non-cash debt discount during the year ended May 31, 2019 and May 31, 2018, respectively. In connection with the 2018 Short-term Convertible Notes, the Company incurred direct issuance costs of approximately $0.4 million during the year ended May 31, 2018. The issuance costs were amortized over the term of the 2018 Short-term Convertible Notes and accordingly the Company recognized approximately $-0- and $0.4 million of debt issuance costs during the years ended May 31, 2019 and May 31, 2018, respectively. On January 31, 2018, in connection with a registered direct equity offering, as fully described in Note 11, the 2018 Short-term Convertible Notes in an aggregate principal amount of $5,788,500, plus accrued unpaid interest of approximately $243,000 were sold for 12,062,728 shares of common stock. The 2018 Short-term Convertible Note investors also received warrants to purchase 7,718,010 shares of common stock. The securities were sold at a combined purchase price of $0.50 per share of common stock and related warrants, for aggregate gross proceeds to the Company of approximately $6.0 million. The Company repaid one 2018 Short-term Convertible Note, including accrued interest in the aggregate of approximately $259,000. During the years ended May 31, 2019 and May 31, 2018, the Company recognized approximately $-0- and $75,000, of interest expense related to the note.

Activity related to the 2018 Short-term Convertible Notes was as follows:

	2018
Face amount of Short-Term Convertible Notes	$ 6,038,500
Unamortized discount	—
Registered direct offering	(5,788,500)
Note repayment	(250,000)
Carrying value of Short-term Convertible Notes	$ —

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, is 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 bear simple interest at the annual rate of 10%. Principal and accrued interest, to the extent not previously paid or converted, is 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 to be 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 Notes, detachable common stock warrants to purchase a total of 5,460,000 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, were 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" comprised of warrants covering 972,000 shares of common stock and a cash fee of $583,200. The placement agent warrants are exercisable at a price of $0.50 per share and will expire five years from the date of issuance and include a cashless exercise provision. During the year ended May 31, 2019, and in connection with the 2019 Short-term Convertible Notes, the Company incurred debt discount and issuance costs of approximately $3.0 million, related to the beneficial conversion feature and detachable warrants issued with the 2019 Short-term Convertible Notes and approximately $0.8 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. Activity related to the 2019 Short-term Convertible Notes was as follows:

	May 31, 2019	May 31, 2018
Face value of Short-term convertible Notes	$ 5,460,000	$ —
Unamortized discount	(1,469,625)	—
Unamortized issuance costs	(404,340)	—
Carrying value of Short-term Convertible Notes	$ 3,586,035	$ —

The Company recognized approximately $213,000 and $-0- of interest expense during the years ended May 31, 2019 and May 31, 2018, respectively.

Long-term Convertible Notes - 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 gave consideration of $5.0 million to the Company. The June 2018 Note bears interest of 10% and is convertible into common stock, at $0.55 per share. The June 2018 Note is convertible in total, or in part, of the outstanding balance, at any time after six months from the issue date upon five trading days' notice, subject to certain adjustments and ownership limitations specified in the June 2018 Note. The Investor may redeem any portion of the June 2018 Note, at any time after six months from the issue date upon five trading days' notice, subject to a maximum monthly redemption amount of $350,000. The securities purchase agreement requires 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 are now 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 $350,000 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 own stock. As of November 15, 2018, the redemption provision requires bifurcation as a derivative liability at fair value under the guidance in ASC Topic No. 815, "Derivatives and Hedging."

The amendment of the June 2018 Note was also evaluated under ASC Topic470-50-40, "Debt Modifications and Extinguishments." Based on the guidance, the instruments were determined to be substantially different, and debt extinguishment accounting was applied. We 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 includes a write-off of unamortized debt issuance costs and the debt discount associated with the original the June 2018 Note.

During the twelve months ended May 31, 2019 and May 31, 2018, the Company recognized approximately $386,000 and$-0-, of interest expense related to the June 2018 Note. During the twelve months ended May 31, 2019, the Company received redemption notices from the holder of the Company's June 2018 Note, requesting an aggregate redemption of $1,455,000 of the outstanding balance thereof. In satisfaction of the redemption notices, the Company issued shares of common stock totaling 3,756,406 to the June 2018 Note holder in accordance with the terms of the June 2018 Note. Following the redemptions, the outstanding balance of the convertible June 2018 Note, including accrued but unpaid interest, was approximately $4.5 million.

Long-term Convertible Notes - 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 (the "January 2019 Note") with a two-year term to the holder of the June 2018 Note in the initial principal amount of $5.7 million. In connection with the issuance of the January 2019 Note, the Company granted a lien against all of 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 gave 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 bears interest of 10% and is convertible into common stock, at $0.50 per share. The January 2019 Note is convertible in total, or in part, of the outstanding balance, at any time after six months from the issue date upon five trading days' notice, subject to certain adjustments and ownership limitations specified in the Note. The Company analyzed the conversion option for derivative accounting treatment under ASC 815 and determined that the embedded conversion option did not qualify for derivative accounting.

The Investor may redeem any portion of the January 2019 Note, at any time after six months from the issue date upon five trading days' notice, subject to a maximum monthly redemption amount of $350,000. The monthly redemption amount may be paid in cash or 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 meets the definition of a derivative instrument and does not meet the criteria to be considered indexed to the Company's own stock. Therefore, the redemption provision requires bifurcation as a derivative liability at fair value under the guidance in ASC Topic No. 815 ("ASC 815"). The securities purchase agreement requires the Company to reserve 20,000,000 shares for future conversions or redemptions.

In conjunction with the January 2019 Note, the investor received a warrant to purchase 5,000,000 shares of common stock with an exercise price of $0.30 which is exercisable until the 5-year anniversary of the date of issuance. 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:

	January 30, 2019
Fair value of redemption provision	$ 1,465,008
Relative fair value of equity classified warrants	858,353
Beneficial conversion feature	2,676,639
	$ 5,000,000

Under the guidance of ASC 815, 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 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 years ended May 31, 2019 and May 31, 2018, the Company recognized approximately $126,000 and $-0-, respectively, of interest expense related to the January 2019 Note.

Activity related to the June 2018 Note and the January 2019 Note is as follows:

	Short Term	Long Term	Total
June 2018 Note	$2,100,000	$ 3,600,000	$ 5,700,000
Monthly redemption provision	2,100,000	(2,100,000)	—
Note amendment, net	—	111,410	111,410
Redemptions	—	(1,455,000)	(1,455,000)
Interest accretion - June 2018 and January 2019 Notes	—	298,158	298,158
Carrying value of Notes at May 31, 2019	$4,200,000	$ 454,568	$ 4,654,568

Note 5—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 in the event that there is a fundamental transaction (contractually defined as a merger, sale of substantially all assets, tender offer or share exchange, whereby such other 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 warrantholder 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 and ASC 815 and are recorded at fair value.

The following tables summarize the fair value of the warrant derivative liability and related common shares as of inception date September 15, 2016, May 31, 2018 and May 31, 2019:

	Shares Indexed	Derivative Liability
Inception to date September 15, 2016	7,333,334	$ 5,179,200
Balance May 31, 2018	7,733,334	1,323,732
Balance May 31, 2019	7,733,334	$ 402,132

Changes in the fair value of the derivative liability are reported as “Change in fair value of derivative liability” in the Consolidated Statements of Operations. During the years ended May 31, 2019, May 31, 2018, and May 31, 2017, the Company recognized a net, non-cash gain of approximately $0.9 million, $1.7 million and $2.2 million, respectively, due to the changes in the fair value of the liability associated with such classified warrants. ASC 820 provides requirements for disclosure of liabilities that are measured at fair value on a recurring basis in periods subsequent to the initial recognition. Fair values for the warrants were determined using a Binomial Lattice Model.

The Company estimated the fair value of the warrant derivative liability as of inception, May 31, 2018 and May 31, 2019, using the following assumptions:

	September 15, 2016	May 31, 2018	May 31, 2019
Fair value of underlying stock	$ 0.78	$ 0.49	$ 0.39
Risk free rate	1.20%	2.63%	1.94%
Expected term (years)	5	3.3	2.29
Stock price volatility	106%	64%	61%
Expected dividend yield	—	—	—
Probability of Fundamental Transaction	50%	50%	50%
Probability of holder requesting cash payment	50%	50%	50%

Due to the fundamental transaction provisions, 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 and managements assumptions related to the fundamental transaction provision.

As described in Note 4 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 date of November 15, 2018, January 30, 2019 and May 31, 2019:

	November 15, 2018	January 30, 2019	May 31, 2019	
			June Note	January 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%

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

		Derivative Liability	
	Net Proceeds	Inception Date	May 31, 2019
Inception date June 2018 Note, November 15, 2018	$5,000,000	$ 1,284,988	$ 847,103
Inception date January 2019 Note, January 30, 2019	5,000,000	1,465,008	1,158,034
			$2,005,137

The Company recognized approximately $745,000 of non-cash gain, due to the changes in the fair value of the liability associated with such classified redemption provision between the inception date and May 31, 2019.

Note 6 – Stock Options and Warrants

The Company has one active stock-based equity plan at May 31, 2019, the CytoDyn Inc. 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"). The 2012 Plan was approved by stockholders at the Company's 2012 annual meeting to replace the 2004 Plan. The 2012 Plan was amended by stockholder approval in February 2015 to increase the number of shares available for issuance from 3,000,000 to 5,000,000 shares of common stock and in March 2016 to increase the number of shares available for issuance from 5,000,000 to 7,000,000 shares of common stock. At the annual meeting of stockholders held on August 24, 2017, the stockholders approved an amendment to the 2012 Plan to increase the number of shares available for issuance from 7,000,000 to 15,000,000 shares of common stock. At a special meeting of stockholders held on May 22, 2019, the stockholders approved an amendment to the 2012 Plan to increase the number of shares available for issuance from 15,000,000 to 25,000,000 shares of common stock. As of May 31, 2019, the Company had 10,374,144 shares available for future stock-based grants under the 2012 Plan, as amended.

Stock Options

During the year ended May 31, 2019, the Company granted annual stock option awards to directors to purchase a total of 1,219,726 shares of common stock with an exercise prices ranging between $0.49 and $0.57 per share. These option awards vest quarterly over one year and have a ten-year term. The grant date fair value related to these options ranged from $0.29 per share to $0.31 per share.

During the year ended May 31, 2019, the Company granted, to executive management and employees, stock options covering an aggregate of 3,715,000 shares of common stock, with exercise prices ranging between $0.48 and $0.57 per share. The option awards vest annually over three years, except for one award covering 950,000 shares, which vests ratably by month over 24 months. All awards have a ten-year term and grant date fair values ranging from $0.26 per share to $0.41 per share.

On January 4, 2019, in connection with the resignation of a director, the Company's Board of Directors approved the acceleration of all outstanding unvested stock options held by the director, to vest immediately upon the effectiveness of his resignation and to retain the stock options' exercise period through their respective expiration date. Stock options covering 1,145,834 shares of common stock were subject to acceleration. The other terms of the accelerated stock options remained otherwise unchanged. In addition, the expiration terms of certain other previously awarded stock options covering an aggregate of 150,000 shares common stock were extended from five years to 10 years. The other terms of the extended stock options remained otherwise unchanged.

Warrants

On June 15, 2018, in connection with a registered direct equity offering, as fully described in Note 11, the Company issued warrants covering 1,970,000 shares of common stock to investors. The investor warrants have a five-year term and an exercise price of $0.75 per share. In connection with the registered direct offering, the Company also issued warrants covering 133,600 shares of common stock to the placement agent. The placement agent warrants have a five-year term and an exercise price of $0.55 per share.

During the year ended May 31, 2019, in connection with a private equity offering, as fully described in Note 10, the Company issued warrants covering a total of 23,487,585 shares of common stock to investors. The investor warrants have a five-year term and an exercise price of $0.75 per share. In connection with this offering, the Company also issued warrants covering 4,446,917 shares of common stock to the placement agent. The placement agent warrants have a five-year term, an exercise price of $0.50 per share and a cashless exercise provision.

During the year ended May 31, 2019 the Company issued compensable warrants covering an aggregate of 300,000 shares of common stock to consultants. The warrants have a five-year term, an exercise price of $0.56 per share and a grant date fair value of $0.30 per share. In addition the Company issued a warrant covering 500,000 shares of common stock to a director. The warrant has a ten-year term, an exercise price of $0.51 per share and a grant date fair value of $0.28 per share.

During the year ended May 31, 2019 in connection with the offering of 2019 Short-term Convertible Notes, as fully described in Note 4, the Company issued warrants covering a total of 5,460,000 shares of common stock to investors. The investor warrants have a five-year term and an exercise price of $0.30 per share. In connection with this offering, the Company also issued warrants covering 972,000 shares of common stock to the placement agent. The placement agent warrants have a five-year term, an exercise price of $0.50 per share and a cashless exercise provision.

On January 31, February 7 and February 13, 2019, in connection with a registered direct equity offering, the Company issued warrants covering a total of 5,364,240 shares of common stock to investors. The investor warrants have a five-year term and an exercise price of $0.50 per share. In connection with this offering, the Company also issued warrants covering 965,563 shares of common stock to the placement agent. The placement agent warrants have a five-year term, an exercise price of $0.50 per share and a cashless exercise provision.

During the year ended May 31, 2019, in connection with a Secured Convertible Promissory Note, the Company issued warrants covering a total of 5,000,000 shares of common stock to an investor. The investor warrants have a five-year term and an exercise price of $0.30 per share.

During the year ended May 31, 2019, in connection with the issuance of Series C Convertible Preferred Stock, the Company issued warrants covering a total of 3,895,000 shares of common stock to investors. The investor warrants have a five-year term and an exercise price of $0.50 per share. In connection with this offering, the Company issued warrants to two lead investors covering an aggregate of 1,000,000 shares of common stock. The lead investor warrants have a five-year term, and an exercise price of $0.50 per share.

On April 5, 2019 and April 15, 2019, in connection with a registered direct equity offering, as fully described in Note 11, the Company issued warrants covering 5,465,500 shares of common stock to investors. The investor warrants have a five-year term and an exercise price of $0.50 per share. In connection with the registered direct offering, the Company also issued warrants covering 938,790 shares of common stock to the placement agent. The placement agent warrants have a five-year term and an exercise price of $0.50 per share.

Compensation expense related to stock options and warrants for the fiscal years ended May 31, 2019, May 31, 2018 and May 31, 2017 was approximately $3.4 million, $1.3 million and $1.2 million, respectively. The grant date fair value of options and warrants vested during the fiscal years ended May 31, 2019, May 31, 2018 and May 31, 2017 was approximately $2.1 million, $1.4 million and $0.9 million, respectively. As of May 31, 2019, there was approximately $4.3 million of unrecognized compensation expense related to share-based payments for unvested options, with is expected to be recognized over a weighted-average period of approximately 2.41 years.

The following table represents stock option and warrant activity for the year ended May 31, 2019:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Options and warrants outstanding - May 31, 2018	132,385,269	$ 0.80	3.78	$ 3,673
Granted	64,834,121	$ 0.57	—	—
Exercised	(7,541,279)	$ 0.40	—	—
Forfeited/expired/cancelled	(11,086,262)	$ 0.81	—	—
Options and warrants outstanding - May 31, 2019	178,591,849	0.71	3.75	896,400
Outstanding exercisable - May 31, 2019	175,116,515	$ 0.71	3.66	$ 896,400

Note 7 – Acquisition of patents and intangibles

As discussed in Note 9 below, the Company consummated an asset purchase on October 16, 2012, and paid $3,500,000 for certain assets, including intellectual property, certain related licenses and sublicenses, FDA filings and various forms of the 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, 2019, the Company

has recorded and is amortizing $3,500,000 of intangible assets in the form of patents. The Company estimates the acquired patents have 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 PRO 140 and formulations comprising PRO 140 out through at least 2031 and 2038, respectively, in various countries.

On November 16, 2018, the Company completed the acquisition of substantially all of the assets of ProstaGene, LLC ("ProstaGene"), a biotechnology start-up company, which included patents related to clinical research, a proprietary CCR5 technology for early cancer diagnosis, and a noncompetition agreement with ProstaGene's founder and Chief Executive Officer, Richard G. Pestell, M.D., Ph.D. The Company accounted for the ProstaGene acquisition as an asset acquisition under ASC 805-10-55 "Business Combinations" because the assets retained from ProstaGene do not include an assembled workforce, and the gross value of the assets acquired meets 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 expands the Company's clinical development of leronlimab (PRO 140) into cancer indications and potential commercialization of certain cancer diagnostic tests. The aggregate purchase price paid for the ProstaGene acquisition was $11,558,000 based on the issuance of 20,278,000 shares of the Company's common stock at $0.57 per share, including 1,620,000 shares earned, but not yet issued, by the investment bank for advisory services. In connection with the purchase, the Company entered into a Stock Restriction Agreement (the "Stock Restriction Agreement"), restricting the transfer of 8,342,000 shares of common stock payable to Dr. Pestell for a three-year period from the closing date of the ProstaGene transaction (the "Restricted Shares"). In the event Dr. Pestell's employment with the Company is terminated, as defined in Dr. Pestell's employment agreement with the Company, the Company will have an option to repurchase such Restricted Shares from Dr. Pestell at a purchase price of $0.001 per share. The Restricted Shares will vest and be released from the Stock Restriction Agreement in three equal annual installments commencing one year after the closing date of the acquisition of ProstaGene.

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

	Prostagene LLC
CytoDyn Inc. Equity	$ 11,558,000
Acquisition Expenses	741,297
Release of Deferred Tax Asset	2,826,919
Total Cost of Acquisition	$ 15,126,216
Intangible Assets	$ 15,126,216
Other	—
Allocation of Acquisition Costs	$ 15,126,216

Assets acquired from ProstaGene include (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 approximates the consideration paid. The Company did not assume any liabilities. The fair value of the technology acquired is identified using the Income Approach. The fair value of the patents acquired is identified using the Cost to Reproduce Method. The fair value of noncompetition agreement acquired is identified using the Residual Value Method. Goodwill is not recorded as the transaction represents 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 is recorded as a cost of the acquisition

As of May 31, 2019, the Company has recorded and is amortizing $4,600,000 of intangible assets in the form of patents attributable to the PRO 140 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 PRO 140 and formulations comprising PRO 140 out through at least 2031 and 2038, respectively, in various countries.

The following presents intangible assets activity, inclusive of patents:

	May 31, 2019	May 31, 2018
Gross carrying amounts	$ 3,500,000	$ 3,500,000
Intangible asset acquisition:		
Prostagene, LLC	15,126,216	—
Website development costs	19,553	
Accumulated amortization	(3,170,315)	(1,968,846)
Total amortizable intangible assets, net	15,475,454	1,531,154
Patents currently not amortized	—	35,989
Carrying value of intangibles, net	$15,475,454	$ 1,567,143

Amortization expense related to all intangible assets was approximately $1,237,000 for the fiscal year ended May 31, 2019 and approximately $350,000 for each of the fiscal years ended May 31, 2018 and May 31, 2017. The estimated aggregate future amortization expense related to the Company's intangible assets with finite lives is estimated to be approximately $2 million per year for the next two years, approximately $1.7 million the following year, and approximately $1.4 million for the next year and $1.2 million for the following year.

Note 8 – License Agreements

The Company has a license agreement with a third-party licensor covering the licensor's "systemknow-how" technology with respect to the Company's use of proprietary cell lines to manufacture new PRO 140 material. The Company accrues an annual license fee of £300,000 (approximately US$365,000 utilizing current exchange rates), which is payable annually in December. The December 2018 payment date was extended to April 15, 2019 and the December 2017 date payment was extended to March 15, 2018. Future annual license fees and royalty rate will vary depending on whether the Company manufactures PRO 140, 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 2% of net sales when the Company commences their first commercial sale, which will continue as long as the license agreement is maintained.

Note 9 – Commitments and Contingencies

Under the Progenics Purchase Agreement, the Company acquired rights to the HIV viral-entry inhibitor drug candidate PRO 140, a humanized anti-CCR5 monoclonal antibody, as well as certain other related assets, including the existing inventory of bulk PRO 140 drug product, intellectual property, certain related licenses and sublicenses, and FDA regulatory filings. In connection with purchase, the Company has one remaining milestone payment of $5.0 million, which will become due 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 PRO 140. In addition, the Company will incur royalty payments of up to 5% on net sales during the period beginning on the date of the first commercial sale of 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.

During the year ended May 31, 2016 the Company paid a milestone obligation of $1.5 million owed to Progenics as a result of the first dosing in a U.S. Phase 3 trial. To the extent that the 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 the Company thereunder. As of the date of this filing, it is management's conclusion that the probability of achieving the subsequent future scientific research milestone is not reasonably determinable, thus the future milestone payments payable to Progenics and its sub-licensors are deemed contingent consideration and, therefore, are not currently accruable.

Payments to the third-party licensor and 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.) ("PDL") and Progenics, which was assigned to the Company in the Progenics Purchase Agreement, pursuant to which the Company has 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 PRO 140 antibody developed by PDL under the agreement the Company has paid various milestone obligations, with two remaining milestone payments of $0.5 million each, one payment of $0.5 million upon filing a BLA with the FDA or non-U.S. equivalent regulatory body and a second payment of $0.5 million, which will become due upon FDA approval or approval by another non-U.S. equivalent regulatory body. In addition, the Company will incur 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 or until annual royalties paid exceed that amount. To the extent the remaining milestone payment and royalties are not timely made, under the terms of the PDL License, AbbVie Inc. has certain termination rights relating to the Company's license of PRO 140 thereunder. As of the date of this filing, it is management's conclusion that the probability of achieving the subsequent future scientific research milestones is not reasonably determinable, thus the future milestone payments payable to PDL, Progenics and its sub-licensors are deemed contingent consideration and, therefore, are not currently accruable.

During the fourth quarter of fiscal 2019, the Company entered into a Master Services Agreement and Product Specific Agreement (collectively, the "Samsung Agreement") with Samsung BioLogics Co., Ltd. ("Samsung"), pursuant to which Samsung will perform technology transfer, process validation, manufacturing and supply services for the commercial supply of leronlimab. In April 2019 the Company delivered to Samsung a purchase order for $33 million worth of process validation and technology transfer services related to the manufacture of leronlimab, with payments by the Company scheduled to be made throughout calendar 2020. Under the Samsung Agreement, the purchase order is binding and the Company is obligated to pay the full amount of the purchase order. Under the terms of the Samsung Agreement, the Company is obligated to make specified minimum purchases of leronlimab from Samsung pursuant to forecasted requirements which the Company will provide to Samsung. The first forecast will be delivered to Samsung by March 31, 2020. Thereafter, the Company must provide Samsung with a rolling quarterly forecast setting forth the total quantity of commercial grade leronlimab that the Company expects to require in the following years. The Company estimates that initial ramp-up costs to manufacture commercial grade leronlimab at scale could total approximately $60 million, with approximately $30 million payable over the course of calendar 2020, and approximately $30 million payable in the first quarter of 2021. Thereafter, the Company will pay Samsung per 15,000L batch according to the pricing terms specified in the Samsung Agreement. The Samsung Agreement has an initial term ending in December 2027 and will be automatically extended for additional two year periods unless either party gives notice of termination at least six months prior to the then current term. Either party may terminate the Samsung Agreement in the event of the other party's insolvency or uncured material breach, and the Company may terminate the agreement in the event of a voluntary or involuntary complete market withdrawal of leronlimab from commercial markets, with one and half year's prior notice. Neither party may assign the agreement without the consent of the other, except in the event of a sale of all or substantially all of the assets of a party to which the agreement relates.

In addition to our manufacturing agreement with Samsung, the Company also previously entered into an arrangement with another third party contract manufacturer to provide process transfer, validation and manufacturing services for leronlimab. In the event that the Company terminates the agreement with this manufacturer, the Company may incur certain financial penalties which would become payable to the manufacturer. Conditioned upon the timing of termination, the financial penalties may total approximately $8.3 million. These amount and timing of the financial commitments under an agreement with our secondary contract manufacturer will depend on the timing of the anticipated approval of our BLA and the initial product demand forecast, which is critical to align the timing of capital resources in order to ensure availability of sufficient quantities of commercial product.

The Company has entered into project work orders, as amended, for each of its 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 which would become payable to the CRO. Conditioned upon the form of termination of any one trial, the financial penalties may range up to $0.3 million. In the remote circumstance that the Company would terminate all clinical trials, the collective financial penalties may range from an approximate low of $0.5 million to an approximate high of $1.2 million.

From time to time, the Company is involved in routine litigation that arises in the ordinary course of business. There are no pending significant legal proceedings to which the Company is a party for which management believes the ultimate outcome would have a material adverse effect on the Company's financial position.

Note 10—Private Securities Offerings

On November 30, 2017, the Company completed an offer and sale (the "Make-Whole Offering") of an aggregate of 503,015 shares of Common Stock (the "Make-Whole Shares") and warrants to purchase up to 251,504 shares of common stock (the "Make-Whole Warrants" and, collectively with the Make-Whole Shares, the "Make-Whole Securities"). The Make-Whole Securities issued were unregistered.

The Make-Whole Securities were offered pursuant to a form of Waiver and Subscription Agreement (the "Waiver and Subscription Agreement"). The Make-Whole Securities represent the difference in the numbers of shares of Common Stock and warrants that would have been sold to investors in the September 2017 Offering had the reduced purchase price of $0.65 per share of Common Stock and related Warrants in the October 2017 Offering, registered direct offering (as compared to $0.75 in the September 2017 Offering) and the reduced warrant exercise price of $0.75 in the October 2017 Offering (as compared to $1.00 in the September 2017 Offering) applied to the September 2017 Offering as well. The Make-Whole Securities were offered as

consideration for the release of potential claims by participating investors. In connection with these arrangements, the exercise prices of any warrants previously sold in the September 2017 Offering to participating investors has also been reduced to $0.75 from $1.00. In addition, warrants previously issued to the placement agent (or its designees) in respect of participating investors have also been proportionately adjusted to reflect a reduced exercise price of $0.715 (as compared to $0.825 in the September 2017 Offering) and 26,702 additional shares.

In connection with the November 24, 2017 Offer to amend and exercise certain eligible warrants at a reduced exercise price of $0.50 per share of common stock, on March 23, 2018, the Company issued 2,470,585 shares of common stock to warrant holders who participated in the Offer, in exchange for their eligible warrants, in a private securities offering.

During the year ended May 31, 2018, the Company conducted a private equity offering, in which accredited investors purchased unregistered common stock at $0.50 per share with warrant coverage ratio of 100%, based on the number of shares of common stock purchased. Pursuant to the offering, the Company sold a total of 35,286,904 shares of common stock for aggregate gross proceeds of $17.6 million and issued warrants covering an aggregate of 35,286,904 shares of common stock with a five-year term and an exercise price of $0.75 per share. In connection with the offering, the placement agent received a warrant covering 2,813,491 shares of common stock, with a five-year term, an exercise price of $0.55 per share, and include a cashless exercise provision.

During the year ended May 31, 2019, the Company conducted private equity offerings (the “Equity Offerings”), in which accredited investors purchased unregistered common stock at $0.50 per share with warrant coverage of 50% based on the number of shares of common stock purchased. Pursuant to the Equity Offerings, the Company sold a total of 46,975,170 shares of common stock, $0.001 par value, for aggregate gross proceeds of approximately $23.5 million and issued five-year warrants covering 23,487,585 shares of common stock. In conjunction with the 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 4,446,917 shares of common stock to the placement agent as additional compensation.

On May 8, 2019, the Company entered into a private warrant exchange in which accredited investors purchased unregistered common stock at the lower of the stated exercise price on their warrant or $0.40 per share of common stock. The Company sold 7,541,279 shares of common stock, as well as 3,770,638 additional shares as an inducement to exercise their warrants, for a total of 11,311,917 shares of common stock, $0.001 par value. 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.

Note 11—Registered Direct Equity Offerings

On June 15, 2018, the Company entered into subscription agreements with certain investors for the sale of 1,970,000 shares of common stock at a purchase price of $0.50 per shares in a registered direct offering (the “June 2018 Offering”), pursuant to a registration statement on Form S-3. The investors in the June 2018 Offering also received warrants to purchase 1,970,000 shares of common stock with an exercise price of $0.75 per share and a five-year term. The Company received net proceeds from the June 2018 Offering of approximately $0.9 million. In addition, the placement agent received warrants covering 133,600 shares of common stock (or 8% of total shares sold to investors) with a per share exercise price of $0.55, a five-year term and include a cashless exercise provision.

Between January 31, 2019 and February 13, 2019 the Company entered into subscription agreements with certain investors for the sale of 10,728,480 shares of common stock at a purchase price of $0.50 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 5,364,240 shares of common stock with an exercise price of $0.50 per share and a five-year term. The Company received net proceeds from the offering of approximately $4.8 million. In addition, the placement agent received warrants covering 965,563 shares of common stock (or 9% of total shares sold to investors) with a per share exercise price of $0.50 and a five-year term and included a cashless exercise provision.

On April 5, 2019 and April 15, 2019, the Company entered into subscription agreements with certain investors for the sale of 10,931,000 shares of common stock at a purchase price of $0.50 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 5,465,500 shares of common stock with an exercise price of $0.50 per share and a five-year term. The Company received net proceeds from the offering of approximately $5.0 million. In addition, the placement agent received warrants covering 938,790 shares of common stock (or 9% of the total shares sold to investors) with a per share exercise price of $0.50 and a five-year term and included a cashless exercise provision.

Note 12 – Employee Benefit Plan

The Company has an employee savings plan (the "Plan") pursuant to Section 401(k) of the Internal Revenue Code (the "Code"), covering all of its employees. The Company makes a qualified non-elective contribution of 3%, which consequently vests immediately. In addition, participants in the Plan may contribute a percentage of their compensation, but not in excess of the maximum allowed under the Code. During the year ended May 31, 2019, May 31, 2018 and May 31, 2017, the Company incurred an expense of approximately $111,000, $61,000 and $40,300, respectively, for qualified non-elective contributions.

Note 13 – 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, 2019, May 31, 2018 and May 31, 2017.

Reconciliation of the federal statutory income tax rate of 21% for the year ended May 31, 2019,the federal statutory blended rate of 28.6% for the year ended May 31, 2018 and the federal statutory rate of 34% for the year ended May 31, 2017, to the effective income tax rate is as follows for all periods presented:

	2019	2018	2017
Income tax provision at statutory rate:	21.0%	28.6%	34.0%
State income taxes net	—	—	—
Rate Change	—	(34.8)	—
Loss on debt extinguishment	(0.5)	—	—
Derivative gain/loss	0.6	1.0	2.8
Valuation allowance release from Asset Acquisition	4.8	—	—
Non-deductible debt issuance costs	—	(0.2)	—
Non-deductible interest on conversion	(0.3)	(0.1)	—
Inducement charge	(0.1)	(2.0)	(1.0)
Other	—	(1.1)	—
Miscellaneous	—	(0.1)	(0.1)
Current year credits generated	—	4.4	—
Credit carry forward generated (released)	(3.8)	4.1	—
Valuation allowance	(16.9)	0.3	(35.7)
	4.8%	0%	0%

Net deferred tax assets and liabilities are comprised of the following as of May 31, 2019 and 2018:

	2019	2018
Deferred tax asset (liability) non-current:		
Net Operating Loss	39,996,561	29,230,279
Credits	2,062,692	4,260,470
ASC 718 Expense on NQO's	3,628,085	2,916,585
Charitable Contribution - Carry forward	—	—
Accrued Expenses	251,293	117,880
Fixed Assets	(340)	174
Amortization	329,360	139,875
Capitalized Debt Issuance Costs	—	—
Debt Discount	(308,621)	—
Basis difference in acquired assets	(2,826,919)	—
Valuation allowance	(43,132,111)	(36,665,263)
	—	—
Noncurrent asset	43,132,111	36,665,263
Valuation Allowance	(43,132,111)	(36,665,263)
	—	—

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.

At May 31, 2019, May 31, 2018 and May 31, 2017 the Company had available net operating loss carry forwards of approximately $190.5 million, $139.2 million and $95.6 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, 2015 through 2018.

Note 14 – Related Party Transactions

On July 26, 2017, Jordan G. Naydenov, a director with the Company, participated in the private placement of 2017 Notes, as fully described in Note 4 above. Mr. Naydenov purchased a promissory note, bearing interest of 7%, for $100,000 in aggregate principal and received a warrant covering 66,666 shares of common stock at an exercise price of $1.00. The terms and conditions of Mr. Naydenov's investment were identical to those offered to all other investors in the offering and his investment was approved by the Audit Committee of the Board of Directors.

On July 28, 2017, AVCP, participated in the private placement of 2017 Notes, as fully described in Note 4 above. Carl C. Dockery, the principal of AVCP, is a director of the Company. AVCP purchased a promissory note, bearing interest of 7%, for $50,000 in aggregate principal and received a warrant covering 33,333 shares of common stock at an exercise price of $1.00. The terms and conditions of the AVCP investment were identical to those offered to all other investors in the offering and his investment was approved by the Audit Committee of the Board of Directors.

On November 8, 2017, in connection with a private equity offering, a limited liability company in which Anthony D. Caracciolo, Executive Chairman of the Company, holds a partial ownership interest, purchased $100,000 of common stock and warrants on terms identical to those applicable to the other investors in the private equity offering.

On January 31, 2018 each of Mr. Caracciolo, Mr. Naydenov and AVCP participated with other investors in the offering of common stock and warrants in satisfaction of the payment obligations relating to the 2017 Notes, as fully described in Note 11 above.

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 of Directors. 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 of Directors 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 500,000 shares 100,000 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, as described in Note 7. In connection with the closing of the acquisition, the Company hired Dr. Pestell as its Chief Medical Officer. As previously disclosed by the Company, Dr. Pestell is the holder of approximately 77.2% of the outstanding equity interests in ProstaGene and consequently holds an indirect interest in approximately (i) 8,611,427 of 13,258,000 shares of the Company's common stock and (ii) 4,171,013 of 5,400,000 shares of common stock, currently held in escrow for the benefit of ProstaGene and its members, which are subject to forfeiture to satisfy certain indemnity obligations of ProstaGene and will be released ratably every six months over the eighteen-month period following the closing date. In addition, as specified in a Stock Restriction Agreement with the Company entered into on the closing date, 8,342,000 additional shares of common stock previously distributed to Dr. Pestell in the ProstaGene acquisition are currently subject to transfer restrictions and forfeiture obligations, subject to certain continuing employment obligations of Dr. Pestell, which will vest ratably each year over the three-years period following the closing date.

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 may participate in the development and license of certain intellectual property created by Dr. Pestell, in connection with Dr. Pestell's ongoing research obligations to outside academic institutions. The Company also has 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 named Chairman of the Board of Directors. On December 19, 2018, the Compensation Committee of the Board of Directors approved an amendment to certain compensation arrangements for Anthony D. Caracciolo, pursuant to which his employment with the Company would be 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 10 years of the expiration terms of certain previously awarded stock options covering an aggregate of 150,000 shares of the Company's common stock, provided that such stock options were out-of-the-money upon the date of such extension. These arrangements were conditioned upon Mr. Caracciolo's agreement to resign from the Board of Directors upon identification by the Company of an appropriately qualified candidate to fill the vacancy. Mr. Caracciolo had agreed to the foregoing terms and his 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, as fully described in Note 4. Michael A. Klump, the manager of Argonne, is a director of the Company. Argonne purchased a convertible promissory note, bearing interest of 10% for $500,000 in aggregate principal and received a warrant covering 500,000 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 his investment was approved by the Audit Committee of the Board of Directors.

On May 8, 2019, Dr. David F. Welch entered into Exercise Agreements for warrants beneficially owned by him, covering an aggregate of 1,651,281 shares of common stock and 825,640 additional shares. Additionally, Michael A. Klump entered into Exercise Agreements for warrants beneficially owned by him, covering an aggregate of 3,625,000 shares of common stock and 1,812,499 additional shares. Dr. Welch and Mr. Klump are members of the Company's board of directors and participated on terms identical to those applicable to other investors.

The Audit Committee of the Board of Directors reviews and approves all related party transactions. The above terms and amounts are not necessarily indicative of the terms and amounts that would have been incurred had comparable transactions been entered into with independent parties.

Note 15 – Subsequent Events

On May 14, 2019, the Company commenced the June 2019 Tender Offer, offering the holders of such warrants the opportunity to amend and exercise their warrants at the lower of the warrant exercise price or $0.40 per share in exchange for which the Company would issue participating holders an additional 50% of the number of shares issuable upon exercise of their original warrants. The terms and conditions of the June 2019 Tender Offer were included in the Company's Schedule TO-I filed with the SEC on May 14, 2019. The June 2019 Tender Offer closed on June 12, 2019 with net proceeds of approximately $8.3 million after the payment of placement agent fees of approximately $0.8 million.

From June 3, 2019 to July 26, 2019, the Company received four redemption notices from the holder of the Company's convertible note, requesting redemptions in the aggregate amount of $655,000 of the outstanding balance thereof. In satisfaction of the redemption notices, the Company issued 1,984,769 shares of Common Stock to the note holder in accordance with the terms of the convertible note. Following the redemptions, the outstanding balance of the convertible note, including accrued but unpaid interest, was approximately $4.2 million.

In connection with the Company's warrant tender offer (the "June 2019 Tender Offer") which closed on June 12, 2019, Dr. Scott A. Kelly validly tendered warrants beneficially owned by him, covering an aggregate of 50,000 shares of common stock, and received 25,000 additional shares of common stock. Additionally, two entities affiliated with Carl C. Dockery, a director of the Company, validly tendered warrants beneficially owned by him, covering an aggregate of 1,425,000 shares of common stock, and received 712,500 additional shares. Dr. Kelly and Mr. Dockery are members of the Company's board of directors and participated on terms identical to those applicable to other participating warrant holders.

On June 11, 2019, the Compensation Committee of the board of directors approved a stock option award to an employee covering 75,000 shares of common stock with an exercise price of $0.43 per share. The option vests ratably over three years with a 10-year term.

On June 16, 2019, the Compensation Committee of the board of directors approved a stock option award to two employees covering 25,000 shares of common stock to each employee with an exercise price of $0.44 per share. Each option vests ratably over three years with a 10-year term.

On June 18, 2019, the board of directors approved a stock option award to an employee covering 100,000 shares of common stock with an exercise price of $0.52 per share. The option vests ratably over three years with a 10-year term.

On June 18, 2019, the board of directors approved the recommendation from the Compensation Committee to maintain the current non-employee director compensation plan for the 2020 fiscal year without modification. Accordingly, the board of directors approved an annual stock option award covering 100,000 shares of common stock for each of the six non-employee directors with an exercise price of $0.52 per share. Each option vests in four equal quarterly installments over one year with a 10-year term. In addition, the board of directors approved a stock option award to an employee covering 50,000 shares of common stock with an exercise price of $0.90 per share. The option was fully vested upon grant date with a 10-year term.

On June 24, 2019, the Company commenced the July 2019 Tender Offer, offering the holders of such warrants the opportunity to amend and exercise their original warrants upon identical terms as the June 2019 Tender Offer. The terms and conditions of the July 2019 Tender Offer were included in the Company's Schedule TO-I filed with the SEC on June 24, 2019, as amended. The July 2019 Tender Offer closed on July 31, 2019 with net proceeds of approximately $2.5 million after the payment of placement agent fees of approximately $237,000.

On July 15, 2019, the Company entered into a Consulting Agreement with Scott A. Kelly, M.D., who is currently Chairman of the Board of Directors. The agreement names Dr. Kelly to the non-executive position of Chief Science Officer, with compensation of $20,000 in cash per month payable in arrears and the grant of a stock option to be determined by the Board of Directors, which are in addition to any fees that Dr. Kelly currently earns as a director. The Company expects to evaluate the term of the agreement on a month-to month basis.

On July 15, 2019, the Company entered into a Consulting Agreement with David F. Welch, Ph.D. who is currently a member of the Board of Directors. The agreement names Dr. Welch to the non-executive position of Strategy Advisor, with compensation of $20,000 in cash per month payable in arrears and the grant of a stock option to be determined by the Board of Directors, which are in addition to any fees that Dr. Welch currently earns as a director. The Company expects to evaluate the term of the agreement on a month-to month basis.

On July 25, 2019, the board of directors of the Company terminated the employment of Dr. Richard G. Pestell, the Company's Chief Medical Officer, for cause pursuant to the terms of his employment agreement with the Company and effective immediately. Pursuant to the terms of his employment agreement, upon such termination, Dr. Pestell resigned from his position as a director of the Company. Dr. Pestell was not a member of any board committees. As of the date of this filing, the Company does not believe the carrying value of certain intangible assets acquired in the asset acquisition with ProstaGene, LLC are impaired, including an assessment of the fair value of the non-compete agreement with Dr. Pestell, which effectiveness survives one year following the termination of his employment for any reason.

In connection with the Company's warrant tender offer, which closed on July 31, 2019, Dr. David F. Welch tendered Original Warrants beneficially owned by him, covering an aggregate of 1,000,000 shares of Common Stock, and received 500,000 Additional Shares. Dr. Welch is a member of the Company's board of directors and participated on terms identical to those applicable to other holders of Original Warrants.

On August 12, 2019, Gregory A. Gould submitted his resignation from the board of directors effective immediately.

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

None.

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures

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

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we have evaluated the effectiveness of our disclosure controls and procedures as of May 31, 2019. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were effective as of May 31, 2019.

Internal Control Over Financial Reporting.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed by, or under the supervision of, our Chief Executive Officer and our Chief Financial Officer and effected by our board of directors, management and other personnel, 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. Internal control over financial reporting includes policies and procedures that (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect our transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures of the Company's assets are being made only in accordance with authorizations of our management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our 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 our Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of May 31, 2019. This evaluation was based on the framework established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "2013 COSO Framework"). Based upon that evaluation, our management concluded that our internal control over financial reporting was effective as of May 31, 2019.

Attestation Report of Independent Registered Public Accounting Firm

The effectiveness of our internal control over financial reporting has been audited by Warren Averett, LLC, an independent registered public accounting firm, as stated in their report, which appears herein.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting during the quarter ended May 31, 2019.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by Item 10 relating to our directors, executive officers and corporate governance is incorporated herein by reference to our definitive proxy statement for the 2019 Annual Meeting of Stockholders, to be filed with the SEC within 120 days of the end of the Company's fiscal year May 31, 2019 (the "2019 Proxy Statement").

We have adopted a Code of Ethics for our Senior Executive Officers (the Chief Executive Officer, Chief Financial Officer, Treasurer, and Secretary), as well as an Insider Trading Policy for the Company. Copies are available on our website at www.cytodyn.com.

Item 11. Executive Compensation.

The information required by Item 11 relating to executive compensation is incorporated herein by reference to our 2019 Proxy Statement.

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 is incorporated herein by reference to our 2019 Proxy Statement.

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 is incorporated herein by reference to our 2019 Proxy Statement.

Item 14. Principal Accountant Fees and Services.

The information required by Item 14 relating to principal accountant fees and services is incorporated herein by reference to our 2019 Proxy Statement.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

The following are filed as part of this Annual Report on Form10-K:

Consolidated Financial Statements

The Consolidated Financial Statements for the years ended May 31, 2019 and 2018 are included under Item 8 of this report.

Exhibits

Exhibits are listed in the Exhibit Index which appears immediately following the signature page of this report.

Item 16. Form 10-K Summary.

None.

Exhibit Number	Description
	Plan of Acquisition
2.1	Asset Purchase Agreement, dated as of July 25, 2012, between CytoDyn Inc. and Progenics Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed July 30, 2012).
2.2	Acquisition Agreement by and among CytoDyn Inc., Point NewCo, Inc., Point Merger Sub, Inc., ProstaGene, LLC, and Dr. Richard Pestell, dated August 27, 2018 (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K, as amended, filed August 28, 2018).
	Articles of Incorporation and Bylaws
3.1	Amended and Restated Certificate of Incorporation of CytoDyn Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K12G3 filed November 19, 2018).
3.2	Certificate of Designation, Series C Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed March 20, 2019).
3.3	Amended and Restated Bylaws of CytoDyn Inc. (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K12G3 filed November 19, 2018).
	Instruments Defining Rights of Security Holders
4.1	Form of Convertible Promissory Note (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed June 22, 2017).
4.2	Form of Convertible Promissory Note Warrant (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed June 22, 2017).
4.3	Form of Convertible Promissory Note (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed June 27, 2018).
4.4	Amended and Restated Convertible Promissory Note (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K12G3 filed November 19, 2018).
4.5	Form of Convertible Promissory Note (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed January 3, 2019).
4.6	Convertible Promissory Note by and between CytoDyn Inc. and Iliad Research and Trading, L.P. (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed January 30, 2019).
4.7	Convertible Promissory Note Warrant Agreement by and between CytoDyn Inc. and Iliad Research and Trading, L.P. (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed January 31, 2019).
4.8	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K12G3 filed September 1, 2015).
4.9	Form of Warrant Agreement (Private Offerings) (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed September 4, 2018).

4.10	Form of Warrant Agreement (Registered Offerings) (incorporated by reference to Exhibit 4.1 to the Form8-K filed on April 5, 2019).
4.11	Form of Warrant to Purchase Common Stock (December 2018 Convertible Note Offering) (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed January 3, 2019).
4.12	Form of Inducement Warrant (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed June 25, 2015).
4.13	Form of Placement Agent Warrant (Private Offerings, as Amended) (incorporated by reference to Exhibit 4.11 to the Registrant's Annual Report, as amended, on Form 10-K filed July 27, 2018).
4.14	Form of Placement Agent Warrant (Registered Offerings, as Amended) (incorporated by reference to Exhibit 4.12 to the Registrant's Annual Report, as amended, on Form 10-K filed July 27, 2018).
4.15	Form of Consultant Warrant (incorporated by reference to Exhibit 4.4 to the Registrant's Registration Statement onForm S-1 filed February 3, 2016).
4.16	Form of Consultant Warrant (incorporated by reference to Exhibit 4.4 to the Registrant's Current Report onForm 8-K filed June 22, 2017).
4.17	Form of Series C Warrant Agreement (Series C Convertible Preferred Stock Offering) (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed March 20, 2019).
4.18	Description of the Registrant's Capital Stock

Material Contracts

10.1	Patent License Agreement between Allen D. Allen and CytoDyn of New Mexico Inc. (incorporated by reference to Exhibit 10.2 to the Registrant's Annual Report on Form 10-KSB filed September 14, 2004).
10.2	Amendment to Patent License Agreement (incorporated by reference to Exhibit 10.6.1 to the Registrant'sForm SB-2/A filed March 21, 2005).
10.3	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 (incorporated by reference to Exhibit 10.21 to the Registrant's Annual Report on Form 10-K filed August 29, 2013).
10.4	License Agreement between CytoDyn Inc. and Lonza Sales AG dated July 29, 2015 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed August 4, 2015, as amended on August 19, 2015).
10.5	Development and Manufacturing Services Agreement, dated as of November 9, 2016, by and between CytoDyn Inc. and CMC ICOS Biologics, Inc. (incorporated by reference to Exhibit 10.4 to the Registrant's Periodic Report on Form 10-Q filed April 13, 2017).
10.6	Work Statement No. 01, dated as of November 9, 2016, by and between CytoDyn Inc. and CMC ICOS Biologics, Inc. (incorporated by reference to Exhibit 10.5 to the Registrant's Periodic Report on Form 10-Q filed April 13, 2017).
10.7	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.2 to the Registrant's Periodic Report on Form10-Q filed on October 9, 2018).
10.8	Escrow Agreement, dated as of November 16, 2018, by and among ProstaGene, LLC, CytoDyn Inc., and Computershare Trust Company, N.A. (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K12G3 filed November 19, 2018).
10.9	Stock Restriction Agreement, dated as of November 16, 2018, by and among CytoDyn Inc., ProstaGene, LLC and Dr. Richard G. Pestell (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K12G3 filed November 19, 2018).
10.10	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 (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K12G3 filed November 19, 2018).
10.11***	Master Services Agreement between CytoDyn Inc. and Samsung BioLogics Co., Ltd, dated April 1, 2019.
10.12***	Product Specific Agreement between CytoDyn Inc. and Samsung BioLogics Co., Ltd, dated April 1, 2019.

Offering Documents

10.13	Form of Registration Rights Agreement (incorporated by reference to Exhibit 10.40 to the Registrant's Registration Statement on FormS-1 filed February 3, 2016).
10.14	Form of Securities Purchase Agreement (December 2016 Offering) (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed December 12, 2016.
10.15	Form of Securities Purchase Agreement (September 2017 Offering) (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed September 8, 2017).
10.16	Form of Waiver and Subscription Agreement (Make-Whole Offering) (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed December 6, 2017).
10.17	Securities Purchase Agreement, dated June 26, 2018, by and between CytoDyn Inc. and Iliad Research and Trading. L.P. (incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K filed on June 27, 2018).
10.18	Securities Purchase Agreement, dated January 30, 2019, by and between CytoDyn Inc. and Iliad Research and Trading. L.P. (incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K filed on January 30, 2019).
10.19	Form of Subscription Agreement (Series C Convertible Preferred Stock Offering) (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed March 20, 2019).
10.20	Form of Exercise Agreement (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form8-K filed May 9, 2019).

Compensatory Arrangements

10.21*	CytoDyn Inc. 401(k) Profit Sharing Plan (incorporated by reference to Exhibit 10.11 to the Registrant's Amendment No. 1 to Annual Report on Form 10-K filed August 5, 2011).
10.22*	CytoDyn Inc. 2004 Stock Incentive Plan (the "2004 Plan") (incorporated by reference to Exhibit 10.10 to the Registrant's Amendment No. 1 to Annual Report on Form 10-K filed August 5, 2011).
10.23*	Form of Stock Option Award for Employees under the 2004 Plan (incorporated by reference to Exhibit 10.5 to the Registrant's Annual Report on Form 10-K filed August 29, 2013).
10.24*	Form of Stock Option Award Agreement for Employees under the 2012 Plan (incorporated by reference to Exhibit 10.8 to the Registrant's Annual Report on Form 10-K filed August 29, 2013).
10.25*	Form of Stock Option Award Agreement for Non-Employee Directors under the 2012 Plan (incorporated by reference to Exhibit 10.9 to the Registrant's Annual Report on Form 10-K filed August 29, 2013).
10.26*	Form of Stock Option Award Agreement for Employees granted under an arrangement not approved by the Registrant's shareholders (incorporated by reference to Exhibit 10.10 to the Registrant's Annual Report on Form 10-K filed August 29, 2013).
10.27*	Form of Stock Option Award for Non-Employee Directors under the 2004 Plan (incorporated by reference to Exhibit 10.6 to the Registrant's Annual Report on Form 10-K filed August 29, 2013).
10.28*	Form of Stock Option Award Agreement for Non-Employee Directors granted under an arrangement not approved by the Registrant's shareholders (incorporated by reference to Exhibit 10.11 to the Registrant's Annual Report on Form 10-K filed August 29, 2013).
10.29*	Consulting Agreement between CytoDyn Inc. and Denis R. Burger dated February 21, 2014. (incorporated by reference to Exhibit 10.25 to the Registrant's Annual Report on Form 10-K filed July 10, 2014).
10.30*	Amended and Restated Employment Agreement by and between CytoDyn Inc. and Nader Pourhassan dated January 6, 2015 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed January 7, 2015).

10.31*	Employment Agreement by and between CytoDyn Inc. and Michael D. Mulholland dated January 6, 2015 (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed January 7, 2015).
10.32*	Amendment to Consulting Agreement between CytoDyn Inc. and Denis R. Burger dated November 3, 2014 (incorporated by reference to Exhibit 10.25 to the Registrant's Annual Report on Form 10-K filed July 10, 2015).
10.33*	Amendment to Consulting Agreement between CytoDyn Inc. and Denis R. Burger dated January 19, 2016 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed January 22, 2016).
10.34*	Amended and Restated CytoDyn Inc. 2012 Equity Incentive Plan (the "2012 Plan") (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-8 filed March 23, 2018).
10.35*	Consulting Agreement between CytoDyn Inc. and Richard G. Pestell, M.D., Ph.D. dated as of August 27, 2018 (incorporated by reference to Exhibit 10.3 to the Registrant's Periodic Report on Form 10-Q filed October 9, 2018).
10.36*	Employment Agreement, dated as of November 16, 2018, by and among CytoDyn, Inc., CytoDyn Operations Inc. and Dr. Richard G. Pestell (incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K12G3 filed November 19, 2018).
10.37*	Employment Agreement by and between CytoDyn Inc. and Dr. Nitya G. Ray, dated December 22, 2018 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed December 26, 2018).
	Other
21	Subsidiaries of the Registrant.
23	Consent of Warren Averett, LLC.
24	Power of Attorney of executive officers and directors.
	Certifications
31.1	Certification of Chief Executive Officer under Rule 13a-14(a).
31.2	Certification of Chief Financial Officer under Rule 13a-14(a).
32**	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350.
	XBRL
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

* Management contract or compensatory plan or arrangement.
** Furnished herewith.
*** 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.

Note: All exhibits incorporated by reference to filings other than registration statements are incorporated by reference to filings that have SEC File No. 000-49908.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: August 14, 2019

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 August 14, 2019.

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/ Michael D. Mulholland
Michael D. Mulholland
Chief Financial Officer, Treasurer and Corporate Secretary

Remaining Directors:

*
Scott A. Kelly, M.D.

*
Carl C. Dockery

*
Michael A. Klump

*
Jordan G. Naydenov

*
David F. Welch, Ph.D.

* By /s/ Michael D. Mulholland
Michael D. Mulholland
Attorney-In-Fact

DESCRIPTION OF CAPITAL STOCK

General

We are authorized to issue up to 705,000,000 shares of capital stock, including 700,000,000 shares of common stock, par value $0.001 per share, and 5,000,000 shares of preferred stock, par value $0.001 per share. As of June 30, 2019, we had 364,748,563 shares of common stock, 92,100 shares of Series B Preferred Stock (as defined below) and 3,246 shares of Series C 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. You should refer to our certificate of incorporation, as amended and bylaws, both of which are on file with the SEC as exhibits to previous SEC filings, for additional information. The summary below is qualified by provisions of applicable law.

Common Stock

Each outstanding share of common stock entitles the holder to one vote, either in person or by proxy, on all matters submitted to a vote of stockholders, including the election of directors. There is no cumulative voting in the election of directors. All actions required or permitted to be taken by stockholders at an annual or special meeting of the stockholders must be effected at a duly called meeting, with a quorum present of a majority in voting power of the shares entitled to vote thereon. Special meetings of the stockholders may only be called by our Board of Directors acting pursuant to a resolution approved by the affirmative majority of the entire Board of Directors. 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.

Preferred Stock

Our Board of Directors is authorized to issue up to 5,000,000 shares of preferred stock, par value $0.001 per share, in one or more series, 4,595,000 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 CytoDyn; 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 CytoDyn.

Series B Convertible Preferred Stock

Our Board of Directors previously established a series of preferred stock designated as Series B Convertible Preferred Stock ("Series B Preferred Stock"), comprising 400,000 shares of Preferred Stock, of which 92,100 shares remain outstanding as of May 31, 2019. Subject to superior rights of any other outstanding preferred stock from time to time, each outstanding share of Series B Preferred Stock is 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 stock, accrued and unpaid dividends will be paid in cash or with shares of common stock. In the event we elect to pay dividends with shares of common stock, the shares issued will be valued at $0.50 per share. Series B Preferred Stock does not have any voting rights. In the event of liquidation, each share of Series B Preferred Stock is entitled to receive, in preference to the common stock, a liquidation payment equal to $5.00 per share plus any accrued and unpaid dividends. If there are insufficient funds to permit full payment, the assets legally available for distribution will be distributed pro rata among the holders of the Series B Preferred Stock.

Each share of Series B Preferred Stock may be converted into ten fully paid shares of common stock at the option of a holder as long as we have sufficient authorized and unissued shares of common stock available. The conversion rate may be adjusted in the event of a reverse stock split, merger or reorganization.

Series C Convertible Preferred Stock

Our Board of Directors previously established a series of preferred stock designated as Series C Convertible Preferred Stock ("Series C Preferred Stock"), comprising 5,000 shares of Preferred Stock, of which 3,246 shares remain outstanding as of May 31, 2019. The Series C Preferred Stock Certificate of Designation provides, among other things, that holders of Series C Preferred Stock shall be entitled to receive, at the option of the holder, cumulative dividends at the rate of ten percent (10%) per share per annum of the stated value of the Series C Preferred Stock, to be paid per share of Series C Preferred Stock. 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 Common Stock. Dividends on the Series C Preferred Stock are mandatory and cumulative and there are no sinking fund provisions applicable to the Series C Preferred Stock. The Series C Preferred Stock does not have redemption rights. The stated value per share for the Series C Preferred Stock is $1,000 (the "Stated Value").

In the event of any liquidation, dissolution or winding up of the Company, the Series C Preferred Stock will be paid, prior and in preference to any payment or distribution on any shares of Common Stock, currently outstanding series of preferred stock, or subsequent series of preferred stock, an amount per share equal to the Stated Value and the amount of any accrued and unpaid dividends. The holders of the Series C Preferred Stock will then receive distributions along with the holders of Common Stock on a pari passu basis according to the number of shares of Common Stock the Series C Preferred holders would be entitled if they converted their shares of Series C Preferred Stock at the time of such distribution.

If, at any time while the Series C Preferred Stock is outstanding, we effect any reorganization, merger or sale of the Company or substantially all of its assets (each 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 Stated Value by the Conversion Price (subject to adjustment as set forth in the Certificate of Designation). No fractional shares will be issued upon the conversion of the Series C Preferred Stock.

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, 2019, we had issued and outstanding warrants to purchase up to 164,089,977 shares of common stock, exercisable at prices ranging from $0.30 per share to $1.35 per share.

Stock Options

As of May 31, 2019, we had issued and outstanding options to purchase up to 14,501,872 shares of common stock, exercisable at prices ranging from $0.47 per share to $2.90 per share.

Exhibit 10.11

Certain identified information has been excluded because it is both not material and would likely cause competitive harm if publicly disclosed.

MASTER SERVICES AGREEMENT

between

SAMSUNG BIOLOGICS CO., LTD.

and

CYTODYN INC.

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MASTER SERVICES AGREEMENT

This Master Services Agreement (this "**MSA**") is made and entered into as of the date of last signature below (the "**Effective Date**") by and between CytoDyn Inc., a Delaware corporation having its principal place of business at 1111 Main Street, Suite 660, Vancouver, WA 98660 (**"Client"**), and Samsung BioLogics Co., Ltd., a company with offices at 300, Songdo bio-daero, Yeonsu-gu, Incheon, 21987, Republic of Korea (**"SBL"**). Client and SBL are sometimes referred to herein individually as a **"Party"** and collectively as the **"Parties".**

WHEREAS, Client and SBL wish to enter into a business relationship whereby SBL will provide Client with certain biologics manufacturing and/or development services;

NOW, THEREFORE, in consideration of the mutual promises, covenants and agreements hereinafter set forth and for other valuable consideration, the Parties agree as follows:

SECTION 1 DEFINITIONS

Each of the following capitalized terms as used in this MSA, whether in the singular or plural, shall have the respective meanings set forth below.

1.1 "Acceptance Procedure" means the review of the Batch Related Documents and any additional test(s) of a Batch of Product which are performed to verify that the Product delivered meets the Specifications and complies with Regulatory Authority requirements, which are conducted by Client after SBL's release of a Batch of Product, to determine whether to accept the same, in accordance with the applicable PSA and QAG.

1.2 "Affected Party" is defined in Section 17.3.

1.3 "Affiliate" means any corporation, company, partnership or other entity which directly or indirectly, controls, is controlled by or is under common control with either Party hereto. A corporation or other entity shall be regarded as controlling another corporation or other entity if it owns or directly or indirectly controls more than fifty percent (50%) of the voting stock or other ownership interest of the corporation or other entity, or if it possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of the corporation or other entity or the power to elect or appoint more than fifty percent (50%) of the members of the governing body of the corporation or other entity.

1.4 "Applicable Laws" means any and all applicable laws of any jurisdiction which are applicable to the Services in this MSA or any PSAs that may be in effect from time to time, and shall include all statutes, enactments, acts of legislature, laws, ordinances, rules, regulations, notifications, guidelines, directions, directives and orders of any Regulatory Authority, statutory authority, stock exchange, securities regulatory agency, tribunal, board, or court or any central or state government or local authority or other governmental entity in such jurisdictions.

1.5 "Background IP" means any Intellectual Property related to a Product and/or its use, or the Manufacture of such Product, in each case, which is owned and/or controlled by a Party prior to the Effective Date or outside or not relating to the performance of the MSA.

1.6 "Batch" means the quantity of Product Manufactured by SBL which results from a single run of the applicable Manufacturing Process.

1.7 "Batch Record" is defined in the applicable QAG.

1.8 "Batch Related Documents" means Manufacturing Documentation in support of the SBL's release of a Product.

1.9 "Binding Year" shall be defined in the applicable PSA.

1.10 "Cell Line" means in respect of a given Product, the cell bank vials supplied or otherwise made available to SBL by Client to perform the Services.

1.11 "Certificate of Analysis" is defined in the applicable QAG.

1.12 "Certificate of Compliance" is defined in the applicable QAG.

1.13 "Change" is defined in Section 6.1.

1.14 "Client" is defined in the preamble.

1.15 "Client Materials" means Client reagents and other materials supplied by Client or its third party supplier to be used in the Service hereunder, as each is further defined in the PSA and/or applicable QAG. In the case of a Drug Product PSA, Client Materials shall also include Drug Substance and/or other active pharmaceutical ingredients, which may or may not be Manufactured by SBL.

1.16 "Client Technology" means know-how, technology, research and other information of Client including and relating to the Manufacturing Process, analytical methods, quality control analysis, specifications, transportation and storage requirements provided by Client to SBL in connection with this MSA and applicable PSA.

1.17 "Clinical Product" means a Drug Substance or Drug Product which is Manufactured by SBL pursuant to a PSA and which is to be used by Client in a research study or studies that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.

1.18 "Commercial Product" means a Drug Substance or Drug Product which is Manufactured by SBL which is intended for commercial sale and use by humans and for importation or exportation into countries or regions designated in each PSA.

1.19 "Commercially Reasonable Efforts" means with respect to an activity to be carried out by a Party pursuant to this MSA, the carrying out of such activity in a diligent manner, and using efforts and resources comparable to the efforts and resources commonly used in the contract manufacturing of biologics (in the case of SBL) or in the biopharmaceutical industry (in the case of Client) by companies with resources and expertise similar to those of such Party. "Commercially Reasonable Efforts" requires prompt assignment of responsibility for such task or activity to specific qualified employee(s) and allocation of resources designed to advance progress with respect to such task or activity but does not require the taking of actions (a) which would require or is likely to require a material adverse change in such Party's existence or solvency, or significant assets, (b) disproportionate to the benefits received under this MSA, or (c) would require either Party to violate Applicable Laws or materially breach any existing contractual commitments with third parties which were entered into prior to the Effective Date.

1.20 "Common Raw Materials" is defined in Section 5.3.1.

1.21 "Confidential Information" means any data, know-how and other information, whether technical or non-technical disclosed by one Party (hereinafter the "Disclosing Party") or otherwise became known to the other Party (hereinafter the "Receiving Party") hereunder relating to the subject matter of the MSA, regardless of form or manner of disclosure, i.e., whether disclosed in writing, in electric file or format or in other tangible manner, or orally, visually or in other intangible manner.

1.22 "Control" (including, with correlative meanings, "Controlled") means possession, directly or indirectly, of power to direct or cause the direction of management or policies (whether through ownership of securities or other ownership interest, by contract or otherwise) of that person or entity and/or the ownership of more than 50% of the voting shares of that person or entity.

1.23 "Core Team" is defined in Section 3.3.

1.24 "Current Good Manufacturing Practices" or "cGMP" means current good manufacturing practices and regulations applicable to the Manufacture of Product that are promulgated by any Regulatory Authority, including as promulgated under and in accordance with (i) the U.S. Federal Food, Drug and Cosmetic Act, Title 21 of the U.S. Code of Federal Regulations, Parts 210, 211, 600, 601 and 610, (ii) relevant EU legislation, including European Directive 2003/94/EC or national implementations of that Directive, (iii) relevant guidelines, including the EU Guidelines for Good Manufacturing Practices for Medicinal Products (Eudralex Vol. 4 and Annexes thereto), (iv) International Conference on Harmonisation Good Manufacturing Practice Guide for Active Pharmaceuticals Ingredients and (v) and any analogous set of regulations, guidelines or standards as defined, from time to time, by any relevant Regulatory Authority having jurisdiction over the development, manufacture or commercialization of the Product, as applicable, in each case as in effect as of the date such manufacturing for the Product are or were conducted.

1.25 "Damages" means any direct damages, costs, expenses, fines, penalties (including reasonable attorneys' fees and costs), losses and liabilities.

1.26 "Dispute" is defined in Section 16.1.

1.27 "Drug Product" means a finished or intermediate dosage form that contains a Drug Substance, generally, but not necessarily, in association with one or more other ingredients.

1.28 "Drug Substance" means an active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body, but does not include intermediates used in the synthesis of such ingredient.

1.29 "Effective Date" is defined in the preamble.

1.30 "EMA" means the European Medicines Agency, or any successor agency.

1.31 "Engineering Batch" means a commercial-scale Batch that is intended to demonstrate the transfer of the Manufacturing Process to the Facility. After Manufacture, Client shall have the right to make whatever further use of non-cGMP Engineering Batches as it shall determine, provided that Client pays for such Batches according to this MSA, and such use is not for human use and does not violate any Applicable Laws. SBL makes no warranty that Engineering Batches will meet cGMP or the Specifications.

1.32 "Facility" means one or more of the manufacturing facilities of SBL where the Services shall be performed, located at 300, Songdo bio-daero, Yeonsu-gu, Incheon, 21987, Republic of Korea.

1.33 "FDA" means the United States Food and Drug Administration or any successor agency thereto.

1.34 "Firm Period" shall be defined in the applicable PSA.

1.35 "Force Majeure Event" is defined in Section 17.3.

1.36 "Implementation Plan and Budget" is defined in Section 6.2(b).

1.37 "Indemnified Party" is defined in Section 13.3.

1.38 "Indemnifying Party" is defined in Section 13.3.

1.39 "Intellectual Property" is means (a) patents, patent rights, provisional patent applications, patent applications, designs, registered designs, registered design applications, industrial designs, industrial design applications and industrial design registrations, including any and all divisions, continuations, continuations-in-part, extensions, restorations, substitutions, renewals, registrations, revalidations, reexaminations, reissues or additions, including supplementary certificates of protection, of or to any of the foregoing items; (b) copyrights, copyright registrations, copyright applications, original works of authorship fixed in any tangible medium of expression, including literary works (including all forms and types of computer software, including all source code, object code, firmware, development tools, files, records and data, and all documentation related to any of the foregoing), pictorial and graphic works; (c) trade secrets, technology, developments, discoveries and improvements, know-

how, proprietary rights, formulae, confidential and proprietary information, technical information, techniques, inventions, designs, drawings, procedures, processes, models, formulations, manuals and systems, whether or not patentable or copyrightable, including all biological, chemical, biochemical, toxicological, pharmacological and metabolic material and information and data relating thereto and formulation, clinical, analytical and stability information and data which have actual or potential commercial value and are not available in the public domain; (d) trademarks, trademark registrations, trademark applications, service marks, service mark registrations, service mark applications, business marks, brand names, trade names, trade dress, names, logos and slogans, Internet domain names, and all goodwill associated therewith; and (e) all other intellectual property or proprietary rights, in each case whether or not subject to statutory registration or protection.

1.40 "Joint Steering Committee" or "JSC" is defined in Section 3.2.1.

1.41 "Manufacturing" or to "Manufacture" means the manufacturing of the Product, and any services relating to such manufacturing, including, but not limited to, testing, quality control, documentations, archiving, and packaging, and up to release of the Product, to be performed by SBL at the Facility under the MSA and any applicable PSA.

1.42 "Manufacturing Documentation" means with respect to a given Product, the data acquired and generated, documents and records describing or otherwise related to the Manufacturing Process including, without limitation: documents and records consisting of or containing process descriptions, requirements and specifications; Client Materials and Specifications; analytical methods, process trend and variability data; validations protocols and reports; process development reports; Batch Records; Batch Related Documents, and SOPs, including, without limitation, SOP's for the Raw Materials handling, the Manufacturing operations, equipment operation, in-process, final Product and stability quality control testing, quality assurance, validation, storage and shipping.

1.43 "Manufacturing Process" means, with respect to a given Product, the mutually agreed production process and analytical methods for the Manufacturing of the Product pursuant to the applicable PSA, as summarily described in the applicable QAG and as described in the Manufacturing Documentation, as such process may be changed from time to time in accordance with the MSA.

1.44 "Non-Affected Party" is defined in Section 17.3.

1.45 "Non-Conforming Product" means an entire Batch of Product that fails to conform to the Specifications, cGMP (if applicable), and any/or other mutually agreed upon written express requirements for SBL to follow under the applicable PSA and the applicable QAG.

1.46 "Party" and "Parties" is defined in the preamble.

1.47 "Pilot Batch" means a Batch of Product designated as a pilot Batch which shall not comply with cGMP and is not required to meet the Specifications.

1.48 "Pre-Approval Inspection" or "PAI" means an on-site inspection of the Facility by the Regulatory Authority prior to granting the Regulatory Approval for a Commercial Product as required by various Regulatory Authorities to ensure that the Manufacturing Process and the Facility meet the appropriate requirements and comply with cGMP.

1.49 "Process Validation Batch" means a Batch of Commercial Product produced from a process validation run conducted by SBL hereunder to (i) demonstrate and document the consistency and reproducibility of the Manufacturing Process at the Facility, and (ii) support the Regulatory Approval of both the Product Manufactured and the Manufacturing Process at the Facility each as defined in the Project Plan.

1.50 "Product" means Clinical Product or Commercial Product to be Manufactured by SBL pursuant to this MSA and any applicable PSA.

1.51 "Product Purchase Commitment" is defined in Section 5.7.

1.52 "Product specific agreement" or "PSA" is defined in Section 2.1.

1.53 "Project Management Team Leader" is defined in Section 3.3.2.

1.54 "Project Plan" means a formal, approved document used to guide both project execution and project control. The primary uses of the Project Plan are to document planning assumptions and decisions, facilitate communication among project stakeholders, and document approved scope, cost, and schedule baselines. The Project Plan will contain the description and overall objectives of the Services for Manufacturing a Product and may include, among other things: (a) JSC and Core Team membership rosters, (b) change request procedures, (c) details, intentions, and deliverables for Technology Transfer, (d) project schedule, (e) detailed procurement plan, as needed, and (f) project budgets and invoicing plans.

1.55 "PSA Effective Date" means the effective date of any PSA governed by this MSA.

1.56 "Purchase Order" is defined in Section 5.6.

1.57 "Quality Agreement" or "QAG" means that certain quality agreement that governs the responsibilities related to quality systems and quality requirements for the Product(s) Manufactured hereunder, including quality control, testing and release of such Product(s) at the Facility entered into by the Parties.

1.58 "Quarter" means each period of three (3) consecutive calendar months beginning on January 1, April 1, July 1, or October 1.

1.59 "Raw Materials" means those materials that are used in the Services, including, but not limited to, chemicals, reagents, filters, excipients, disposable consumables, and secondary packaging materials. Raw Materials exclude the Client Materials.

1.60 "Reference Standards" means standard materials prepared by Client and/or SBL in accordance with the applicable QAG.

1.61 "Regulatory Approval" means all approvals, licenses, registrations or authorizations thereof of any national, regional, state or local regulatory agency, department, bureau or other governmental entity in any jurisdiction where the Product is marketed or intended to be marketed, necessary for the manufacture and sale of the Product, which manufacturing includes the Manufacturing of the Products at the Facility.

1.62 "Regulatory Authority" means any national (e.g., the FDA), supra-national (e.g., the EMA), regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity, in any jurisdiction responsible for granting the Regulatory Approval.

1.63 "SBL Assignable Error" means: [***].

1.64 "Service" or "Services" is defined in Section 2.1.

1.65 "Service Fee" is defined in Section 9.1.

1.66 "Specialized Raw Materials" is defined in Section 5.3.1.

1.67 "Specification(s)" means the criteria for the Products, Client Materials, or Raw Materials, as the case maybe, which details are provided in documentation as reviewed and approved in writing by the Parties.

1.68 "Standard Operating Procedure(s)" or "SOP(s)" means the standard operating procedures established by and mutually agreed upon by both Parties regarding the Manufacturing Process.

1.69 "Technology Transfer" means the activities by the Parties necessary to Manufacture the Product for Client at the Facility as further described in the applicable Project Plan which may include: (i) transfer of the Client Technology and Client Material from Client to SBL; (ii) implementation of the Manufacturing Process at the Facility, including establishing a small scale Manufacturing Process model at SBL; (iii) Manufacturing Process fit activities, including required small- and large-scale process development and validation work as allocated between the Parties to SBL and process engineering required to modify / equip, qualify and validate the Facility for the Manufacturing of the Commercial Product; (iv) stability testing, if applicable, for the Product required for licensure; (v) comparability testing to the appropriate reference product, and (vi) regulatory support for Regulatory Approvals.

1.70 "Term" is defined in Section 15.1.

1.71 "Warehouse" means SBL's warehouse for storage of the Product located at 300, Songdo bio-daero,Yeonsu-gu, Incheon, 21987, Republic of Korea.

SECTION 2 RELATED AGREEMENTS AND EXHIBITS

2.1 **Product specific agreements.** Pursuant to one or more product specific agreements entered into and mutually agreed from time to time by duly authorized representatives of the Parties (**"Product specific agreements" or "PSAs"**), SBL will perform manufacturing services for Client as specified in such PSAs and applicable Project Plan and in accordance with the terms and conditions of this MSA (**"Services"**). Each PSA shall refer to this MSA and contain as applicable (i) a high level scope of work of the Services to be performed under such PSA which describes key activities, (ii) the Product for which Samsung will perform such Services for Client, (iii) a description of the Cell Line; (iv) fees to be paid to SBL by Client for the Services with a general timing plan for invoicing and a more detailed plan to be in the Project Plan, (v) if the Services pertain to the manufacture of the Product, the number of batches of Product to be manufactured by SBL and delivered to Client and the Specifications, (vi) any other deliverables, (vii) the Samsung facility where the Services are to be performed, and (viii) the Regulatory Approvals to be obtained by the Parties. Services shall be governed by the terms and conditions of this MSA, the applicable PSA, and any applicable Quality Agreement. In the event of a conflict between a Quality Agreement and either any provision of this MSA or any PSA, the MSA or PSA shall control except with respect to Product quality terms, in which case, the Quality Agreement will control. In the event of a conflict between any provision of this MSA and the PSA, this MSA shall control, except as explictly specified in the PSA.

2.2 **Project Plan.** Concurrently with the execution of a PSA or within a reasonable time after the PSA effective date, the Parties shall agree upon a Project Plan which will specify in detail scope and schedule of the Services, including Technology Transfer and Manufacture. The Project Plan shall also set forth the JSC members (if applicable), Core Team members, and Project Management Team Leader for the Services as well as the frequency and duration of meetings. The Project Plan may be updated as needed by the mutual agreement of the Client and SBL and is governed by and incorporated into the applicable PSA by reference. If there is a conflict between the Project Plan and the applicable PSA, the PSA shall control. If any of the assumptions on which the Parties have relied upon in defining the scope of the activities required to effect the Technology Transfer and/or other Services including but not limited to Manufacture, and the associated timeframes, fees, expenditures and costs proves to be invalid, or if for any reason it becomes apparent that additional activities are required as part of or in connection with the Technology Transfer and/or other Services including but not limited to Manufacture, the Parties shall (acting reasonably and in good faith) discuss and seek to agree appropriate revisions to the Technology Transfer activities, and associated timelines and pricing.

2.3 **Quality Agreement (QAG).** The Parties shall agree upon and finalize a Quality Agreement within a reasonable period time after each PSA Effective Date which shall cover such PSA and such Quality Agreement shall be incorporated into this MSA. The Quality Agreement may be amended from time to time, subject to the JSC's approval followed by the Parties' written agreement pursuant to Section 17.9 (if applicable).

SECTION 3 MANAGEMENT OF SERVICE

3.1 **General.** Each Party will be responsible for its internal decision making process and for reasonably informing the other Party of decisions affecting the Service in a regular and timely manner. Without limiting the foregoing, the Parties shall establish the joint committees or teams set forth herein to advise the Parties on certain matters including, without limitation, the Facility modification, the Technology Transfer, and optimization of the Manufacturing operation relating to the Product.

3.2 Joint Steering Committee.

3.2.1 Formation and Composition. The applicable Project Plan will set forth a Joint Steering Committee for that Product (the "**Joint Steering Committee**" or "**JSC**") if the Parties mutually agree that such JSC is necessary. The JSC will be a cross-functional committee composed of an equal number of representatives appointed by each of Client and SBL with each of Client and SBL having at least three (3) representatives, and with one (1) representative from each of Client and SBL having oversight for quality activities, and with one (1) representative from each of Client and SBL having oversight for manufacturing and supply chain activities, including the transfer and implementation of the Manufacturing Process at the Facility. Either Party may replace any or all of its representatives at any time. Such Party shall notify, in writing, of such replacement to the other Party.

3.2.2 Responsibilities. The JSC shall (i) establish and oversee the governance structure for the Service including the formation of the subcommittee herein; (ii) monitor any Facility modification and the Technology Transfer and Manufacturing strategy of the Product at the Facility, including strategies for the Regulatory Approval of the Facility to Manufacture the Product; (iii) provide strategic guidance to the Core Team as required by the Project Plan; (iv) conduct high level project stage reviews with the Core Team as required by the Project Plan at appropriate milestones or completion of key deliverables or a sequence of event to review and approve key deliverables, evaluate the Core Team's progress and performance, all in order to ensure that the Manufacturing Process is being implemented appropriately; (v) advise on and/or resolve business, manufacturing, supply chain, quality, regulatory or other issues unresolved at the Core Team level; (vi) review and recommend for approval by the Parties any changes to the MSA or the applicable PSA; (vii) review and approve changes to the Specifications, analytical methods, the Manufacturing Process, the Facility or equipment as escalated to the JSC by the Core Team or by a Party pursuant to Section 3.6 below; (viii) review completion of the Service; (ix) settle disputes or disagreements unresolved by a subcommittee; and (x) perform such other functions as appropriate to further the purposes of the MSA as determined by the Parties.

3.3 Core Team.

3.3.1 Formation and Composition. The applicable Project Plan will set forth a Core Team for that Product (the "**Core Team**"). The Core Team shall be composed of an equal number of representatives from each of SBL and Client, with at least four (4) representatives appointed by each of Client and SBL. Such representatives will include the Project Management Team Leaders of Client and SBL as well as their representatives from manufacturing, technical operations, supply chain, quality assurance, quality control, regulatory affairs or other individuals with expertise and responsibilities for those functions required to execute the Facility modification, the Technology Transfer and Manufacturing. Either Party may replace any or all of its representatives at any time. Such Party shall notify, in writing, of such replacement to the other Party.

3.3.2 **Appointment of Project Management Team Leader.** Each Party shall appoint a Project Management Team Leader (each, a "**Project Management Team Leader**") to act as the primary contact for such Party in connection with matters related to the Service. Each Project Management Team Leader, unless otherwise mutually agreed, shall serve as the leaders of the Core Team. A Party may replace its Project Management Team Leader at any time and from time to time for any reason. Such Party shall notify, in writing, of such replacement to the other Party.

3.3.3 **Responsibilities.** The Core Team shall (i) develop and maintain the Project Plan and monitor, review and manage the Service according to the MSA and applicable PSA; (ii) conduct project stage reviews with the JSC as required by the Project Plan at appropriate milestones or completion of key deliverables or a sequence of event to review key deliverables, review its progress and performance against plans; (iii) develop a change management process to identify, review and recommend any significant changes in the project scope, time, fee or risk to the JSC; (iv) investigate and resolve business, manufacturing, supply chain, quality, regulatory or other issues arising during the Service; (v) review and escalate to the JSC, as needed, changes to the Project Plan or applicable QAG; (vi) review and recommend to the JSC changes to the Specifications, analytical methods, the Manufacturing Process, the Facility or equipment; (vii) coordinate the activities of the Parties relating to the Manufacturing hereunder, including but not limited to: managing the technical operations and quality aspects of routine manufacturing, conducting Product testing technical operations and quality aspects of routine manufacturing, conducting Product testing and release, and managing supply chain activities including shipping and delivery logistics; (viii) report periodically on operation and quality progress and performance; and (ix) perform such other tasks and undertake such other responsibilities as may be specifically delegate to the Core Team by mutual agreement of the Parties.

3.4 **Meetings**

3.4.1 **JSC.** The JSC shall meet by audio or video teleconference as agreed by the JSC or as necessary to make determinations as required of it. Any member of the JSC may designate a substitute to attend and perform the functions of that member at any meeting of the JSC and each Party may, in its reasonable discretion, invite non-member representatives of such Party to attend such meetings with advance notice to the other Party.

3.4.2 **Core Team.** The Core Team shall meet by audio or video teleconference as agreed by the Core Team. Any member of the Core Team may designate a substitute to attend and perform the functions of that member at any meeting of the Core Team and each Party may, in its reasonable discretion, invite non-member representatives of such Party to attend such meetings with advance notice to the other Party.

3.4.3 **Travel Expenses.** Each Party shall be responsible for all of its own expenses of traveling to and participating in any joint committee or team meeting, including the JSC and Core Team.

3.5 **Decisions.** All decisions of JSC, the Core Team and any other joint committee or team formed under the MSA or any applicable PSA, except as expressly set forth herein, shall be made by the unanimous agreement of all of its members or their designated representatives, and shall be reflected in written

meeting reports which summarily address topics discussed, delegation of work, schedules and decision of such committee or team. Written reports of the JSC and Core Team shall be subject to approval by the authorized representatives of the Parties; provided, however, that no joint committee or team herein may amend or waive any provision of the MSA or applicable PSA, including without limitation, the financial terms set forth in Section 9. It being understood that the MSA or any PSA may be amended, and provision of the MSA or any PSA may be waived pursuant to Section 17.9 only.

3.6 Disputes.

3.6.1 General. In the event that the Core Team and any other joint committee or team formed under the MSA or any applicable PSA, is unable, despite the good faith efforts of all members, to resolve a disputed issue that is within the purview of such joint committee or team within fourteen (14) days of meeting request by either party, the disputed issue shall be referred immediately by such joint committee or team to the JSC. If the disputes still cannot be resolved within an additional thirty (30) days of meeting request by the JSC, the matter may be handled in accordance with Section 16.

3.6.2 Project Management Team Leaders. Subject to Section 3.6.1, the Project Management Team Leaders (or their respective designee) will in good faith attempt to mutually resolve in a timely fashion any disagreement with respect to the Service hereunder, which could reasonably affect the quality of the Manufacturing of the Product, including without limitation, the related management processes and operations, control of production planning and scheduling, prioritization decisions, allocation of resources, timing of in-process and release testing, oversight of auxiliary facilities (e.g., in-process tests that need to be conducted at laboratories other than those at the Facility), Facility modification, the Technology Transfer, registration and troubleshooting decisions, and any other matters relating to implementation of the Manufacturing Process and the Manufacturing of the Product hereunder.

SECTION 4 SERVICES

4.1 Services. During the Term, in accordance with and subject to the terms and conditions set forth in this MSA, applicable PSA, and the applicable QAG, SBL shall provide the Services to Client relating to the Product(s). SBL and Client shall at all times make Commercially Reasonable Efforts to complete the Services in accordance with the timelines set forth in the applicable PSA. Except as otherwise expressly set forth in the MSA, applicable PSA, or the applicable QAG or as otherwise mutually agreed in writing by the Parties.

4.2 Compliance with Applicable Law. Subject to the provisions of Section 6 below, SBL shall maintain the Facility in accordance with cGMP and in such condition as will allow SBL to Manufacture the Products in accordance with the terms of the MSA and the applicable QAG. SBL shall perform the Services under the MSA in conformance of cGMP, if applicable, the Specifications, any requirements of the Regulatory Authorities that shall be mutually agreed upon by the Parties, and all Applicable Laws.

4.3 **Project Personnel.** SBL shall adequately staff the Facility with personnel necessary (including consultants and contractors), and with sufficient technical expertise to perform its obligations under the MSA. Notwithstanding anything to the contrary and in addition to the JSC and Core Team meetings described in Section 3 above, Client and SBL may arrange for core project personnel to have regular meetings, which shall be by audio or video teleconference. The Project Plan shall specify the frequency and duration of such meetings; provided that the associated costs for meetings requested solely by Client in excess of the agreed amount shall be passed through to Client by SBL.

4.4 **Subcontract.** SBL may not subcontract any portion of the Services without prior approval from the Client. In the event SBL subcontracts any portion of the Services, SBL shall be primarily obligated to Client for any subcontracted services as if it were providing the Services itself. All costs associated with activities outsourced to 3rd party contractors will be passed through to Client with an additional [***] handling fee (e.g. [***]).

4.5 **Development and Manufacturing Site.** Unless otherwise agreed by Client, all Services shall be performed by SBL at the Facility.

4.6 **Manufacturing Documentation**. SBL shall maintain Manufacturing Documentation to be true and accurate, and shall keep in strict confidence and shall not use for purposes other than providing or performing the Service or other obligations hereunder. SBL shall maintain all such Manufacturing Documentation for at least that period specified in the applicable QAG. Upon written request of Client and at mutually agreeable times, Client shall have the right to review Manufacturing Documentation, including the Batch Records, at the Facility as further defined in the applicable QAG. Client may also request scanned or printed copies of such Manufacturing Documentation, but shall be responsible for reasonable costs associated therewith. SBL shall record and maintain such records, data, documentation and other information in the language as so required in the applicable QAG or as so required by a Regulatory Authority and in compliance with Applicable Law. To the extent necessary, SBL may redact or withhold Manufacturing Documentation provided pursuant this MSA or any applicable PSA to protect the confidential information of its other clients or third parties. The form and style of Batch documents, including, but not limited to, Batch production records, lot packaging records, equipment set up control, operating parameters, and data printouts, raw material data, and laboratory notebooks are the exclusive property of SBL. Notwithstanding anything to the contrary, SBL SOPs not specific to the Client's Products may be provided to Client for on-site review if deemed necessary by both SBL and Client. Such SOPs cannot be removed from the SBL premises, copied, photographed or otherwise replicated.

SECTION 5 SERVICE DESCRIPTIONS

5.1 **Technology Transfer.**The Parties shall make their personnel available at the Facility to enable the transfer and implementation in accordance with the Project Plan. Client shall transfer to and [***] to SBL in accordance with the plan, timelines and quantities set forth in the Project Plan. In the event that Client agrees to utilize SBL's [***] portal for Technology Transfer, Client agrees that (a) in the event of any relevant change that affects a Client user's authorization to use such portal, Client shall immediately notify SBL so that SBL may disable their usernames and remove / change passwords in order to secure the SBL Portal and (b) Client shall ensure that all of Client's users have up-to-date antivirus software installed on the computer devices used to access such portal.

5.2 **Facility Modification and Equipment.** Except as otherwise specifically provided herein to the contrary, and upon mutual agreement of the Parties, Client and SBL will agree on what equipment in the Facility is necessary to perform the Services, and if it is necessary or Client deems it necessary to procure additional equipment beyond that which is in the Facility as of the applicable PSA Effective Date, the Core Team shall determine equitable allocation of costs including, as applicable, procurement, validation, installation, maintenance, commissioning, and decommissioning/validation (which determination shall be escalated to the JSC if in dispute). Thereafter, if any additional equipment is necessary, such costs shall be dealt with by the Change provisions of this MSA. Except as provided in this MSA or any applicable PSA, the Facility, Warehouse and all the equipment shall be mantained, tested, validated, calibrated and qualified for their intended use by SBL at SBL's expenses.

5.3 **Raw Materials.**

5.3.1 **Management**. SBL shall procure and maintain a reasonable quantity of the Raw Materials, required for the Services in accordance with the MSA and any applicable PSA. On a per-Product basis, the Core Team shall finalize the categorization of the Raw Materials into Raw Materials which shall be used for that specific Product only ("**Specialized Raw Materials**"), Raw Materials which can be used across multiple products and/or customers ("**Common Raw Materials**"), and Raw Materials which will not be charged on a cost-plus basis to the Client, and shall attach such list to the applicable PSA. Such list of common and specialized Raw Materials may be amended from time to time, subject to the Parties' approval. During Technology Transfer, the Core Team shall agree on estimates for Raw Materials anticipated to be consumed in the Manufacture of each Batch. Although SBL will make Commercially Reasonable Efforts to use no more than those amounts, SBL will not be responsible for Raw Materials used in excess of the agreed-upon estimate; provided, however, that SBL shall be responsible for [***]. Client shall agree to SBL's strategies regarding Raw Material safety stock and sourcing from qualified vendors. In the event SBL is not able to utilize any capacity reserved to Manufacture Product according to an agreed-upon forecast or manufacturing plan due to Client's failure to agree to such strategies, then Client shall be responsible for the costs of such reserved capacity regardless of whether it is utilized or not.

5.3.2 **Raw Material Specifications** Client and SBL shall agree on the Specifications of the Raw Materials, including without limitation analytical methods, supplier information including supplier site information, and other information concerning the stability, storage, and safety thereof that are required for the Manufacturing hereunder, as further described in the applicable QAG.

5.3.3 **Testing and Evaluation**. SBL or vendors qualified by SBL shall perform all testing and evaluation of the Raw Materials as required by the Specifications for the Raw Materials and the cGMPs, as further described in the applicable QAG, if applicable.

5.3.4 **Storage.** SBL shall secure sufficient and suitable cGMP storage for the Raw Materials; provided that such storage requirements shall be customary within SBL's industry. SBL shall exercise reasonable care to preserve and protect the Raw Materials [***], Client shall be responsible for the risk of loss of the Raw Materials. At the end of each calendar year of the relevant PSA, Client shall be responsible for the loss of Raw Material to the extent purchased in reliance on a Purchase Order, Firm Period, or Binding Year which expires or becomes obsolete because Client fails to honor such Purchase Order, Firm Period or Binding Year and SBL cannot reasonably otherwise utilize such Raw Material.

5.3.5 **Service Fee Related to Raw Material.** Common Raw Materials and Specialized Raw Materials will be charged on a cost-plus basis to Client in accordance with Sections 9.1(ii) and 9.2.2, subject to any changes in the scope of work.

5.4 Client Materials.

5.4.1 **Management.** Client shall provide, either by itself or through its third party supplier, to SBL free of charge, Client Materials in amounts reasonably necessary to carry out the Services as agreed by the Parties. The applicable PSA shall set forth the exact timing of such provision of Client Materials to SBL. SBL shall make Commercially Reasonable Efforts to import the Client Materials to the Republic of Korea in a timely manner, provided that Client provides reasonable assistance. Delivery conditions for the Client Materials shall be [***]. During Technology Transfer, the Core Team shall agree on estimates for Client Material anticipated to be consumed in the Manufacture of each Batch. Although SBL will make Commercially Reasonable Efforts to use no more than those amounts, SBL will not be responsible for Client Materials used in excess of the agreed-upon estimate; provided, however, that (a) SBL shall be responsible for [***] and (b) notwithstanding anything to the contrary, SBL will not in any circumstance be responsible for [***]. Client shall agree to SBL's strategies regarding Client Material safety stock and sourcing from qualified vendors. In the event SBL is not able to utilize any capacity reserved to Manufacture Product according to an agreed-upon forecast or manufacturing plan due to Client's failure to agree to such strategies, then Client shall be responsible for the costs of such reserved capacity regardless of whether it is utilized or not.

5.4.2 **Client Materials Specifications.** Client shall provide SBL with the Specifications of the Client Materials, including without limitation analytical methods, supplier information, and other information concerning the stability, storage, and safety thereof that are required for the Manufacturing hereunder, as further described in the applicable QAG.

5.4.3 **Testing and Evaluation.** SBL shall perform testing of the Client Materials in accordance with the applicable QAG and/or Client's instruction prior to the performance of the Manufacturing hereunder, in order to determine whether such Client Materials meet the Specification described in the applicable QAG (if applicable). SBL shall inform Client of (a) any damage to the Client Materials received that is visually obvious (e.g., damaged or punctured containers and temperature monitoring results outside of predetermined Specifications) within [***] after SBL's receipt of the Client Materials and (b) any non-conformance of the Client Materials to Specification either: (i) within [***] of SBL's discovery of such non-conformance; or (ii) within [***] days after SBL's receipt of the Client Materials or (iii) if release testing of

Client Materials is not performed until it is needed for Manufacture, within [***] days after such release testing is performed; or (iv) as other wise agreed between the Parties. If, prior to performing any Service on the Client Materials, SBL determines that such Client Materials are defective or damaged, SBL shall not perform the Service on such Client Materials and shall follow Client's written instructions regarding disposal or return of such Client materials to Client, such disposal or return to be at Client's discretion and cost.

5.4.4 **Storage.** SBL shall secure sufficient and suitable cGMP storage for the Client Materials; provided that such storage requirements shall be customary within SBL's industry. SBL shall exercise reasonable care to preserve and protect the Client Materials from [***], Client shall be responsible for the risk of loss of the Client Materials.

5.4.5 **Service Fee Related to Client Material.** Handling fees relating to the Client Material will be charged to Client in accordance with Sections 9.1(iii) and 9.2.3.

5.5 **Forecasts.** For each Commercial Product, the Parties shall determine a mutually agreeable mechanism for forecasting of each Product, which shall be detailed in writing and attached to each relevant PSA. For Clinical Product, the Parties shall agree upon the number and schedule of Batches to be Manufactured by SBL in the applicable PSA. In the event SBL is not able to utilize any capacity reserved to Manufacture Product according to an agreed-upon forecast or manufacturing plan due to a reason attributable to Client, then Client shall be responsible for the costs of such reserved capacity regardless of whether it is utilized or not to the extent that SBL is not able to reassign such reserved capacity.

5.6 **Purchase Orders.** For each Clinical Product or Commercial Product, Client shall notify SBL in a binding form and procedure to be agreed upon in the applicable PSA requesting a specific amount of Product to be Manufactured (a "**Purchase Order**").

5.7 **Product Purchase Commitment.** As further set forth in a PSA, during the Term the Parties may agree that Client will purchase a minimum quantity of batches of a certain Product in a given year (a "**Product Purchase Commitment**").

5.8 **Batch Failure during Manufacture**

5.8.1 If, during Manufacture of a Batch and prior to SBL's batch release, the Core Team determines that all of a Batch is Non-Conforming Product (a "**Batch Failure**"), SBL shall use Commercially Reasonable Efforts to promptly re-Manufacture and deliver to Client a replacement Batch on a date to be mutually agreed by the Parties, which Service Fees and associated costs/fees (as set forth in Section 9.1 below) shall be invoiced and paid for by the Client. Client shall ensure that SBL has adequate Client Materials to Manufacture such Batches. The remedies contained in Section 5.8 of this MSA shall be the sole and exclusive remedies of Client regarding a Batch Failure and a Batch Failure shall not constitute a material breach of this MSA or a PSA unless SBL fails to provide the remedies contained in this Section 5.8.

5.8.2 The Parties shall conduct a root cause analysis of the Batch Failure, which shall be done through SBL's deviation process and which result will be reviewed and confirmed by the JSC. If either the Core Team does not agree on the Batch Failure root cause, or the JSC does not agree on the results of the Core Team's Batch Failure root cause analysis, the Parties shall refer to an independent mutually agreed-on laboratory or firm with international repute, acting as a neutral arbiter, to conduct a root cause analysis of the Batch Failure. The costs of the independent laboratory will be shared by the Parties equally; provided, however, that the Party that is determined to be incorrect as to the Batch Failure will be responsible for those reasonable costs and must reimburse the correct Party for its share of the reasonable costs incurred. The decision of the independent laboratory must be in writing and will be binding on the Parties.

5.8.3 The PSA applicable to such Product Batch Failure shall set forth responsibility among the Parties of the following costs in the event of a Batch Failure: [***]. Notwithstanding anything to the contrary, SBL shall not be responsible in the event of Batch Failure for: [***].

5.8.4 In the event that any of the foregoing procedures results in a Batch being delivered in a different year than the year in which the original Batch was ordered for delivery by Client, the Service Fee for such re-Manufactured Batch shall be the Service Fee in effect in the Year in which such re-Manufactured Batch is actually delivered by SBL.

5.9 Storage, Packaging and Delivery.

5.9.1 Service Deliverables other than Products. Storage, packaging and delivery of the Service deliverables other than Products Manufactured, and the Products Manufactured hereunder shall be made in accordance with the terms of this MSA, applicable PSA, Project Plan, applicable QAG and the Applicable Laws.

5.9.2 Products.

(a) Release by SBL and Acceptance by Client.

(i) SBL shall perform all testing in accordance with the Specifications of the Product and release Product satisfying the Specifications in accordance with the terms of the applicable QAG. Upon such release SBL shall deliver to Client copy of Manufacturing Documentation in support of the SBL's release of the Product for each Batch ("**Batch Related Documents**"), including a Certificate of Analysis and Certificate of Compliance, in accordance with the applicable QAG;

(ii) **Acceptance of Product.** Client will complete the Acceptance Procedure and determine the acceptability of such Product in accordance with the applicable QAG and notify SBL of the result within [***] of Client's receipt of the Batch Related Documents. Upon Client's acceptance, SBL will have no liability for such Product, except as set forth in Section 5.9.2(a)(iv) regarding Latent Defects. If Client does not reject such Product within the [***] period, the Product will be deemed to have been accepted by Client.

(iii) **Non-Conforming.** If, during the Acceptance Procedure, any Product is determined by Client as Non-Conforming Product, and SBL confirms such non-conformity, such non-conformity shall be treated as a Batch Failure, and the remedy set forth in Section 5.8 above shall apply to the Non-Conforming Product *mutatis mutandis*. The remedies contained in this Section 5.9.2 shall be the sole and exclusive remedy of client in the event of Non-Conforming Product.

(iv) **Latent Defect.** After completion of review of the Batch Related Documents, if Client finds any hidden defects of the Product which could not have been reasonably discovered through the review of the Batch Related Documents (**"Latent Defect"**), Client shall promptly give notice of such claim in writing to SBL. In such case, if the Latent Defect is solely due to SBL Assignable Error, the above Section 5.9.2(a)(iii) and Section 13.1 shall apply. If no written claim for Latent Defect of the Product is received by SBL within [***], the Product shall be deemed as irrevocably accepted. Notwithstanding anything to the contrary; such claim for Latent Defect must be made within [***] from Client's initial acceptance of the Product.

(b) **Delivery.** Shipping conditions for the Product Manufactured hereunder shall be [***], unless otherwise agreed to in the applicable PSA. The title to Product hereunder shall be transferred from SBL to Client when the Product is made available at the point of delivery consistent with [***] or the Incoterm set forth in the PSA. The Parties further agree as follows:

(i) After SBL's release of the Product and prior to eachpick-up by Client or Client's designated carrier, SBL shall propose to Client a delivery schedule of the Product, in order for the Parties to agree on it in advance for each pick-up. SBL shall schedule Delivery with the carrier selected and paid for by Client;

(ii) SBL shall not deliver the Product until it has been instructed to by Client in accordance with the applicable QAG. Client shall confirm specific delivery instructions with SBL prior to SBL release. Upon SBL's release of Product, SBL shall store the Manufactured Product as described in Section 5.9.2(c) and Client shall compensate SBL for storage costs for the Manufactured Product as set forth in the applicable PSA;

(iii) SBL shall provide Client with invoice, packing lists, supporting export documents as specified by Client by separate delivery and shipment documentation instructions, together with each shipment of the Product (or such other deliverables); and

(iv) In cooperation with Client and subject to the delivery schedule agreed by the Parties, SBL shall adhere to the first-expire-first-out (FEFO) principle in shipping all released Product.

(c) Storage, Packaging and Shipping Container.

(i) Pursuant to the terms of this MSA and any applicable PSA, and subject to the availability of space and storage conditions, SBL shall store the Products Manufactured hereunder.

(ii) SBL shall store, package, label and prepare shipment according to the Specifications for the Product Manufactured hereunder, the applicable QAG and the SOPs, and using storage and/or shipping containers determined in the applicable PSA.

(iii) If Client does not direct SBL to prepare Manufactured Product to be picked up by Client or Client's designated carrier with a pick-up [***] days of Client's receipt of the Batch Related Documents, SBL shall store the Product at the Warehouse, subject to the availability of space and storage conditions, and Client shall pay storage fees to SBL as set forth in Section 9.1 for the period of storage at the Warehouse until the actual delivery date. SBL shall be responsible for [***].

SECTION 6 CHANGES TO THE SPECIFICATIONS, ANALYTICAL METHODS, MANUFACTURING PROCESS, FACILITY OR EQUIPMENT

6.1 Approval for Change. SBL shall not make any change to the Manufacturing Process, the Services, or the Specifications (a "**Change**"), without the prior written consent of Client in accordance with the applicable QAG.

6.2 Changes Required by cGMP, Regulatory Authorities or Requested by Client. Except as otherwise expressly set forth to the contrary in the applicable QAG, in the event that cGMP, a Regulatory Authority, Applicable Law, or any other regulatory or legal authority requires, or Client requests, a Change, SBL shall accommodate such requirements or requests, subject to the following:

(a) Client shall promptly notify SBL in writing of the required and/or requested Change(s), and provide information necessary for SBL to evaluate the effect of such Change(s), and SBL shall promptly advise Client as to any (i) additional equipment required, modifications to the Facility or equipment, and/or additional equipment and the Facility qualification and validation requirements; (ii) Manufacturing Process development, transfer, scale-up, testing, qualification, or validation requirements; (iii) regulatory requirements pursuant to such Changes; (iv) changes to the Manufacturing scheduling and/or Product delivery schedule; and (v) other impacts on the Facility or SBL's ability to manufacture products (including the Products) in the Facility, if any, which may result from such Change(s). The notification and formal approval procedure of such Changes shall be in accordance with the applicable QAG (i.e., change control procedures) (if applicable). The Parties shall meet in a timely manner to identify and discuss such Changes as appropriate;

(b) Prior to implementation of any such Change(s), SBL shall provide Client with an estimated plan and budget of the reasonable and necessary costs that would be incurred by SBL as a result of the implementation of any such Change(s), including, but not limited to for (i) process and analytical development; (ii) equipment and/or the Facility modifications, qualification, validation, maintenance, and decommissioning/disposal; (iii) process and analytical validation; (iv) document revisions or changes, the Facility, equipment, and system modifications or changes; (v) additional stability testing; and (vi) preparing submissions to Regulatory Authorities (collectively, the "**Implementation Plan and Budget**"). Following review and approval by Client of such Implementation Plan and Budget, subject to the Core Team's approval and agreement followed by the Parties' written agreement pursuant to Section 17.9 (if applicable), SBL shall commence implementation of such Change(s);

(c) During any such implementation, SBL shall provide Client with regular updates on the progress of implementation. Subject to any timeframe imposed by Applicable Law, SBL shall implement the Change according to the Implementation Plan and Budget's target completion date. SBL shall provide written notice to Client if SBL becomes aware of any cause which may create delay with the implementation of Changes. Following any such notice, both Parties shall discuss an amendment of Implementation Plan and Budget; and

(d) Upon the approval of the Implementation Plan and Budget for Change(s), both Parties shall negotiate in good faith to determine the allocation of the costs incurred by SBL for the implementation of any such Change(s) between the Parties, in accordance with the following principles:

(i) the costs for the general Facility Changes required by cGMP, any Regulatory Authority, or any Applicable Laws related to the maintaining the Manufacturing Facility by SBL as set forth in Section 7.2, shall be borne by SBL, provided that where the Change relates exclusively or partially to the Manufacture of Product in which case the costs shall be borne by Client fully or proportionally, respectively;

(ii) the costs for the Changes other than (i) above, and requested by Client and required uniquely to the Manufacture of the Product and beneficial solely to Client shall be borne by Client; and

(iii) the costs for the Changes other than (i) and (ii) above shall be discussed in good faith by the Parties to achieve equitable allocation of costs.

SECTION 7 REGULATORY APPROVALS AND INSPECTIONS.

7.1 **Regulatory Approvals.** SBL shall provide reasonable assistance and cooperation in order for Client to obtain and maintain the Regulatory Approvals. The costs and fees associated with such assistance and cooperation, to the extent not detailed in the MSA or PSA shall be borne by Client, or as otherwise mutually agreed between the Parties. As specified in the applicable PSA, the Parties shall agree on which Regulatory Approvals are to be obtained.

7.2 **Regulatory Approvals for the Facility.** SBL shall obtain and maintain all approvals, licenses, registrations or authorizations of any federal, state or local regulatory agency, department, bureau or other governmental entity (other than the Regulatory Approvals, which will be obtained or maintained by Client) that are required to Manufacture and ship the Product at the Facility and perform the Services.

7.3 **Regulatory Inspections.** SBL shall facilitate on-site inspections of the Facility conducted by Regulatory Authorities. SBL shall notify Client according to the applicable QAG provisions of any contacts or inquiries by the Regulatory Authorities, including inspections, Pre-Approval Inspections, sample requests, and written correspondence and its result, related to the Product, as further defined in the applicable QAG. Any expenses or costs incurred by SBL for such inspections including Pre-Approval Inspections at the Facility shall be borne by Client.

SECTION 8 QUALITY COMPLIANCE

8.1 **Quality Agreement**. Both Parties shall adhere to the provisions of the applicable QAG and the Parties agree that all elements of quality assurance, quality control and the like shall be governed by the terms and conditions of the applicable QAG. In the event of a conflict between the MSA and the applicable QAG, the MSA shall prevail over those of the applicable QAG with the exception of Product quality-related matters, cGMP and related regulatory requirements in which case, the terms of the applicable QAG shall prevail.

8.2 **Audit.** Upon Client's request, but no more than [***], except in the event of afor-cause audit, SBL shall accept a formal audit of the Facility and, if necessary, the Warehouse, by Client to allow Client to inspect the Manufacture of the Product during provision of the Services solely to ascertain compliance by SBL with the terms of this MSA or any applicable PSA; provided, however that in the event Client uses a designee, SBL must provide prior written consent. SBL shall be reimbursed for its reasonable costs for audits beyond the audit described in the first sentence of this Section 8.2.1. SBL will make Commercially Reasonable Efforts to require vendors or subcontractor to accept an audit or visit to the their facilities by Client upon similar notice as described in Section 8.3.2 below. Client will provide SBL with written notice at least [***] prior to any visits, and the Parties shall decide on a mutually agreeable date, duration, visitor list, and agenda prior to the audit. While at the Facility, all such Client personnel shall have reasonable access to all areas as are relevant to SBL's performance of the Service hereunder, provided that SBL may reasonably restrict Client personnel's access to the Facility as it deems necessary and visitors pursuant to this Section shall comply with all applicable SBL policies and procedures including but not limited to safety, confidentiality, and cGMP.

SECTION 9 CONSIDERATION AND PAYMENT TERMS

9.1 **Consideration**. In consideration for SBL's performing the Service and other obligations undertaken by SBL pursuant to a PSA, Client shall pay SBL amounts as set forth in the applicable PSA (the "**Service Fee**"); (ii) a handling surcharge of a certain percentage or certain amount to be set forth in the applicable PSA of the costs of Raw Materials paid by SBL (including but not limited to taxes and customs duties/fees); (iii) a handling surcharge of a certain percentage or certain amount to be set forth in the applicable PSA related to the Client Materials (which shall be based on the actual costs of such materials as supported by reasonable documentary evidence as opposed to the market value thereof and which may include taxes and customs duties/fees); and (iv) storage fees as set forth in the relevant PSA.

9.2 **Invoices.**

9.2.1 **Service Fee of the Project Stages and Batches.** Batches of Product shall be invoiced upon SBL's release of a Batch of Product. Otherwise, Service Fees shall be invoiced according to the invoicing plan set forth in the applicable Project Plan or applicable PSA. SBL's invoices pursuant to this MSA shall be electronic, unless otherwise agreed by the Parties.

9.2.2 **Raw Materials.** With respect to the Raw Materials, SBL shall submit invoices to Client for the applicable Raw Materials cost (including any agreed upon safety stock) as set forth according to Section 9.1 as follows. SBL shall submit an invoice to Client (i) for the cost of Specialized Raw Materials [***]; and (ii) for the cost of Common Raw Materials [***]. Notwithstanding the foregoing, the Parties shall collaborate in the selection of the vendors of the Raw Materials. All such vendors shall be approved by Client before supplying SBL with Raw Materials for Product.

9.2.3 **Client Materials.** With respect to the Client Materials, which shall be supplied by Client to SBL at no cost during SBL's performance the Service, SBL shall submit an invoice to Client in an amount as set forth in Section 9.1 upon SBL's completion of such project stage of the Service SBL's release of a Batch of Product, as applicable.

9.3 **Payment**.

9.3.1 **Mode of Payment; Foreign Exchange**. All payments to SBL due under the MSA or any applicable PSA shall be made in USD $ within [***] from the receipt of SBL's invoice in USD $ by means of telegraphic transfer to the account with the bank designated by SBL in the foregoing invoice. For the purpose of computing payment amounts incurred by SBL in a currency other than USD $, such currency shall be converted into USD $ using the basic exchange rate published by the Korean Exchange Bank (or its successor institution) at the opening of business on such invoice date.

9.3.2 **Taxes**. All prices and charges are exclusive of any applicable taxes, levies, imposts, duties and fees of whatever nature imposed by any law or regulations in any country in respect of the Services, importation or exportation of Raw Materials, Client Materials, Batches, and Product, which shall be paid by Client. For the avoidance of doubt, the foregoing shall not include any taxes imposed on the income or profit of SBL and any withholding tax lawfully levied on any payment to be made by Client to SBL, each of which shall be solely borne by SBL. Client shall pay or reimburse SBL for all customs duties and taxes in connection with the purchase, sale, importation or exportation of any Raw Materials, Client Materials, Batches, or Product or the provision of Services, except to the extent such duties and taxes are recoverable by or refundable to SBL. SBL agrees to assist Client in claiming exemption under double taxation or similar agreement or treaty from time to time in force to obtain a refund of any customs duties, value added taxes, and other taxes payable by SBL.

9.3.3 **Price Adjustments**. The Service Fees as set forth in the applicable PSA, shall be adjusted annually on January 1 of each year during the Term, effective immediately, by the percentage change in the consumer price index as published by the Bank of Korea for the immediately preceding twelve (12) months. The relevant date for price adjustment under this Section shall be the issue date of SBL's invoice.

9.3.4 **Default Interest.** Any reasonably undisputed amount that is not paid by a Party to the other when due under the MSA or any PSA shall bear default interest at the rate of [***]. In the event there is a reasonably undisputed amount which is invoiced by SBL but not paid by Client for more than [***] after the due date, such event shall be considered a material breach of the relevant PSA.

SECTION 10 CONFIDENTIALITY

10.1 **Confidential Information.** If a Party intends to disclose such information in writing, in electric file or format or in other tangible manner, such Party will make reasonable efforts to indicate it is confidential; and if to disclose orally, visually or in other intangible manner, such Party will make reasonable efforts to reduce it in writing or in electric file or format, identified as confidential and delivered to another Party within thirty (30) days after such oral or visual disclosure: provided, however, that, in each case of the foregoing, a failure to do so shall not constitute a breach of this term nor shall deny, negate or destroy the confidential nature thereof, and no such failure shall serve as conclusive evidence that the disclosed information shall not be considered Confidential Information by and between the Parties. Furthermore, the existence and terms of the MSA shall be deemed to be the Confidential Information of both Parties.

Notwithstanding the foregoing, Confidential Information shall not include the information, which as evidenced by written records:

(a) was at the time of disclosure by the Disclosing Party hereunder publicly known or available;

(b) after disclosure by the Disclosing Party hereunder, became publicly known or available by publication or otherwise, other than by an authorized act or omission by the Receiving Party;

(c) was in the possession of the Receiving Party without confidentiality restriction at the time of the disclosure by the Disclosing Party hereunder;

(d) was lawfully received from any third party having the lawful right to make such disclosure, without obligation of confidentiality; or

(e) was independently developed by the Receiving Party's directors, officers or employees without reference to the Confidential Information, as demonstrated by records contemporaneous with such development.

10.2 **Confidentiality.** The Receiving Party recognizes the proprietary and confidential nature of the Disclosing Party's Confidential Information and agrees that no right, title, ownership, license, or interest of any character in the Disclosing Party's Confidential Information other than as specifically granted herein, is conveyed or transferred to the Receiving Party. Both Parties further agree to maintain the Disclosing Party's Confidential Information in confidence and not to disclose or divulge the Disclosing Party's Confidential Information, in whole or in part, to any third party, and not use the Disclosing Party's Confidential Information for any purpose other than pursuing the MSA. Each Party shall guard such Confidential Information using the same degree of care as it normally uses to guard its own confidential or proprietary information of like importance, but in any event no less than reasonable care. The Receiving Party shall limit disclosure of the Disclosing Party's Confidential Information to its and those of its Affiliates' directors, officers, employees, consultants and agents ("**Representatives**") who have a need to know the Disclosing Party's Confidential Information for performance of the Service and implementation of the MSA, provided that, the Receiving Party shall undertake procedures to ensure that each of its Representatives to whom the Disclosing Party's Confidential Information is disclosed understands (i) the confidential nature of the Disclosing Party's Confidential Information and (ii) that he or she is under an obligation similar to those contained herein to hold the Disclosing Party's Confidential Information disclosed strictly confidential.

10.3 **Authorized Disclosures.** Disclosure is permitted in the event that (a) the Disclosing Party's Confidential Information is reasonably required to obtain or maintain any Regulatory Approvals for the Products in any or all jurisdictions or (b) the Disclosing Party needs to disclose such Confidential Information to comply with Applicable Law; provided that such Receiving Party shall exercise its Commercially Reasonable Efforts to limit disclosure of the Disclosing Party's Confidential Information to that which is necessary for compliance and to otherwise maintain the confidentiality of the Confidential Information.

10.4 **Survival of confidential obligations.** The confidential obligations of the Receiving Party shall survive for a period of five (5) years from the expiration or termination of this MSA.

10.5 **Return of the Confidential Information.** All written, printed or other tangible Confidential Information of the Disclosing Party disclosed under the MSA, and all copies thereof shall be returned to the Disclosing Party (or destroyed at the Disclosing Party's request) by the Receiving Party within thirty (30) days from the written request by the Disclosing Party. All Confidential Information disclosed electronically shall be completely deleted and destroyed by the Receiving Party within thirty (30) days from the written request by the Disclosing Party. Notwithstanding the foregoing, (i) digital backup files automatically generated by the Receiving Party's customary electronic data processing system may be retained and properly stored as confidential files for the sole purpose of backup and will be deleted in accordance with the Receiving Party's retention policy, and (ii) a single copy of the Confidential Information may be retained in the secured files of the Receiving Party for the sole purpose of determining the scope of obligations incurred by it under the MSA provided that the Receiving Party shall keep such Confidential Information in confidence and will use the Confidential Information solely to comply with the terms of the MSA as well as the applicable law, rule and regulation.

SECTION 11 OWNERSHIP OF MATERIALS AND INTELLECTUAL PROPERTY

11.1 Reference Standard, Client Technology, Client Materials, Cell Line, and Product. SBL hereby understands and agrees that all rights to, titles of and interests in the Reference Standards, Client Technology, Client Materials, and Cell Line belong to Client, unless otherwise provided herein.

11.2 Background Intellectual Property. It is acknowledged that each Party possesses Background IP. Any Intellectual Property relating to the Reference Standards, Client Technology, Client Materials and Cell Line owned and/or controlled by Client as of the date of provision of such Reference Standards, Client Technology, Client Materials and Cell Line by Client to SBL pursuant to Section 5.1, shall be deemed to be included in the Background IP of Client. Client hereby grants SBL [***] license to use such Intellectual Property relating to such Reference Standards, Client Technology, Client Materials, Cell Line, during the Term for the sole purposes of Manufacturing of the Product or Services in accordance with the MSA.

11.3 Inventions. Any Intellectual Property arising out of or resulting from the Service under the MSA, including but not limited to those contained in the Manufacturing Documentation, shall be hereinafter collectively called an "**Invention**".

11.3.1 Client Invention. Any Invention that [***] shall be a "Client Invention". SBL shall notify Client of such Client Invention(s) to Client immediately after SBL, the Project Management Team Leader, respective project personnel, SBL employees or officers or other applicable third parties working for SBL hereunder makes, conceives or reduces to practice such Client Invention, and shall take all necessary measures so that Client would have [***] of any and all Client Invention. Client may use any Client Invention for any purpose, including filing patent application and SBL shall provide reasonable cooperation to Client at the expense of Client (as to all reasonable out-of-pocket expenses incurred by SBL that are supported by adequate documentation).

11.3.2 SBL Invention. Any Invention that [***], shall be the property of SBL ('**SBL Invention**"), and shall not be deemed to be Client Invention or Joint Invention for the purposes of the MSA.

11.3.3 Client-SBL Joint Invention. Any Invention that [***] and which is not a Client Invention shall be jointly owned by Client and SBL (a "**Joint Invention**"), and shall not be a Client Invention or SBL Invention for the purposes of the MSA. Subject to the terms and conditions of the MSA, any such Joint Invention may be exploited by SBL or Client without compensation and liability of other obligation (including accounting obligations) to the other Party, and each Party has a [***]. This license shall continue for the life of the applicable right.

SECTION 12 WARRANTIES.

12.1 The Parties General Warranties. Each Party warrants and represents that: (i) it has the corporate power and authority to enter into this MSA and has taken all necessary action on its part required to authorize the execution, delivery and performance of this Agreement; (ii) it is aware of no legal, contractual or other restriction, limitation or condition that might adversely affect its ability to enter into this MSA and perform its obligations hereunder; (iii) it is duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is incorporated; (iv) this MSA (a) has been duly executed and delivered by a duly authorized representative of it, and (b) is the legal,

valid and binding obligation of it, enforceable against it in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or other similar laws now or hereafter in effect relating to or affecting creditors' rights generally; and (v) the execution, delivery and performance of this Agreement by it does not and will not (a) violate any Applicable Laws applicable to it, or (b) violate or conflict with any provision of its Articles of Incorporation or By-laws or other organizational documents.

12.2 **Client's Warranties**. Client represents and warrants to SBL that as of the Effective Date of the MSA and during the Term: (a) the formulation and composition of the Product shall comply with all Applicable Laws and that during the Term, Client will perform all obligations and take other necessary actions to be in compliance with such requirements, Applicable Laws, rules and regulations, including applicable cGMPs; (b) Client will comply with all Applicable Laws, and that it will keep SBL informed of any information known to Client which would affect SBL's provision of the Service hereunder; (c) all Reference Standard, Client Technology, Client Materials, and Cell Line provided to SBL by or on behalf of Client will be suitable for the Manufacture of the Product; and (d) SBL's use of the Client Materials, Manufacturing Process and Client Technology for the purpose of the Service and to the extent as set forth in the MSA will not infringe any third party's Intellectual Property rights.

12.3 **SBL's Warranties**. SBL represents and warrants that:

12.3.1 As of the Effective Date and during the Term, (i) SBL is the lawful owner, lessee, operator, or licensee of the Facility, equipment, machinery, as has all licenses, consents or permissions required, to enable SBL to perform its obligations under this MSA, and (ii) none of the SBL Inventions or SBL Background IP infringes any third party Intellectual Property Right

12.3.2 All Product Batches, at the time of delivery to Client's designated carrier, shall (a) conform to the Specifications (except for Pilot Batches and Engineering Batches unless otherwise agreed); (b) be Manufactured, packaged, handled and stored in compliance with the requirements of cGMPs (except for Pilot Batches and Engineering Batches unless otherwise agreed) and all Applicable Laws; (c) comply with the Standard Operating Procedures; (d) be Manufactured in compliance with the Quality Agreement; and (e) be transferred free and clear of any liens, claims or encumbrances of any kind.

12.4 **No Other Warranties.** THE REPRESENTATIONS AND WARRANTIES CONTAINED IN THIS SECTION ARE EXPRESSLY IN LIEU OF AND EXCLUDE, AND THE PARTIES HEREBY EXPRESSLY DISCLAIM AND NEGATE, TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAWS, ALL OTHER REPRESENTATIONS AND WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED (ARISING BY OPERATION OF LAW OR OTHERWISE), INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, EVEN IF THAT PURPOSE IS KNOWN.

SECTION 13 INDEMNIFICATION

13.1 **Indemnification by SBL.** SBL shall indemnify and hold harmless Client, its Affiliates, and their officers, directors, employees or agents from and against any Damages arising or resulting from any third party (which shall exclude Client Affiliates) claims to the extent such Damages are relating to, arising out of, in connection with, or resulting from claims, demands, or actions based upon negligence or willful misconduct, or breach of cGMP of SBL or its officers, directors, employees or agents with respect to Services under this MSA, except to the extent that such Damages are caused by the causes as set forth in Section 13.2 for which Client is obliged to indemnify.

13.2 **Indemnification by Client.** Client shall indemnify and hold harmless SBL, its Affiliates, and their officers, directors, employees or agents from and against any Damages arising or resulting from any third party (which shall exclude SBL Affiliates) claims to the extent such Damages are relating to, arising out of, in connection with, or resulting from claims, demands or actions based upon (i) negligence or willful misconduct of Client or its officers, directors, employees or agents, or (ii) any claim that any SBL activity undertaken for the purposes of or in relation to the Services pursuant to the MSA or any PSA (including but not limited to use of the Client Materials, Manufacturing Process and Client Technology, as well as any tests, studies, experiments, or other activities undertaken at the request of, or with the consent of, Client) infringes any third party's Intellectual Property rights; in each case (i) and (ii) except to the extent that such Damages are caused by the causes as set forth in Section 13.1 for which SBL is obliged to indemnify.

13.3 **Indemnification Procedure.** The foregoing indemnification by SBL or Client shall be conditioned, if and to the extent Damages are based on or related to a third party claim, upon a Party who intends to claim indemnification under Sections 13.1 and 13.2 (the "**Indemnified Party**") (i) providing written notice to the other Party ("**Indemnifying Party**") within twenty (20) calendar days after the Indemnified Party have been given written notice of such third party claim, provided that absence or delay of such prior written notice will not relieve the Indemnifying Party of its obligation to indemnify except to the extent such absence or delay materially prejudices the Indemnifying Party's ability to defend the third party claim; (ii) permitting the Indemnifying Party, upon timely notice by the Indemnified Party, the opportunity to assume full responsibility (at the Indemnifying Party's cost and expense) for the investigation and defense of any such claim with counsel reasonably satisfactory to the Indemnified Party, provided, however, that the Indemnifying Party shall keep the Indemnified Party informed as to the progress of the defense of any claim and that the Indemnified Party shall cooperate in such defense and shall make available all records, materials and witness reasonably requested by the Indemnifying Party in connection therewith; and (iii) not settling or compromising any such claim without the Indemnifying Party's prior written consent, with such consent not to be unreasonably denied, withheld or conditioned.

SECTION 14 DISCLAIMER OF CONSEQUENTIAL DAMAGES; LIMITATION OF LIABILITY

14.1 **Disclaimer of Consequential Damages.** EXCEPT IN THE EVENT OF A PARTY'S [***], NEITHER PARTY WILL BE LIABLE UNDER THIS AGREEMENT FOR ANY SPECIAL, PUNITIVE, CONSEQUENTIAL, INCIDENTAL OR OTHER INDIRECT DAMAGES OF ANY TYPE OR NATURE, WHETHER BASED IN CONTRACT, TORT, STRICT LIABILITY, NEGLIGENCE OR OTHERWISE, INCLUDING LOSS OF PROFITS OR REVENUES.

14.2 **Limitation of Liability.** Specific caps on Damages shall be set forth in the applicable PSA.

SECTION 15 TERM AND TERMINATION OF AGREEMENT

15.1 Term. This MSA will become effective as of the Effective Date and will be in effect for as long as a PSA is in effect (the "**Term**"). Each PSA will have its own initial term as stated therein and shall automatically renew for successive terms of two (2) years each unless either Party gives written notice to the other Party of its intention to terminate the Product Agreement at least six (6) months prior to the end of the then current PSA term.

15.2 Termination. This MSA or a PSA may be earlier terminated as set forth in this Section 15.2.

15.2.1 Material Breach. A Party may terminate any PSA for a material breach by the other Party; provided, however, that the non-breaching Party shall give the breaching Party written notice of such breach and if the breaching Party [***] after receipt of such written notice, then the non-breaching Party may terminate this Agreement on [***] written notice after expiration of such [***] period. This MSA shall terminate if all effective PSAs are terminated.

15.2.2 Insolvency. This MSA may be terminated by either Party upon written notice at any time during the MSA if the other Party: (a) files in any court pursuant to any statute a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of such Party, or of its assets; (b) proposes a written agreement of composition for extension of its debts; (c) is served with an involuntary petition against it, filed in any insolvency proceeding which is admitted in the court; or (d) makes an assignment for the benefit of its creditors. The Party affected shall immediately notify the other Party in writing of the occurrence of any of the foregoing events.

15.2.3 Termination for Market Withdrawal. If during the period starting from the date of completion of Manufacture of the last Process Validation Batch until the end of the Term, Client decides or is required to withdraw from all markets in the world for any scientific, medical or efficacy reasons, Client may terminate the applicable PSA for the Product upon one and a half (1.5) year prior written notice to SBL, subject to Section 15.3 below.

15.2.4 Force Majeure. Either Party may terminate a PSA if a Party is unable to perform its obligations pursuant to a PSA in the event of a Force Majeure Event in accordance with Section 17.3.

15.3 Effect of Expiration or Termination.

15.3.1 Payment of Amounts Due. Expiration or termination of the MSA or PSA for any reason shall not exempt any Party from paying to any other Party any amounts owing to such Party at the time of such expiration or termination.

15.3.2 **Decommissioning**. Upon expiration or termination of a PSA for any reason, SBL shall cease and refrain from the Services described in any applicable PSA (including the Manufacturing and supplying the Product) for Client unless otherwise provided in the following Sections 15.3.2(a) to 15.3.2(d), and both Parties shall pursue decommissioning activities as set forth hereunder.

(a) Fully Manufactured Product.

(i) If Client terminates a PSA pursuant to Section 15.2.1 or 15.2.2, upon Client's election, SBL shall, at Client's election, (i) deliver already fully Manufactured Product to Client in accordance with the terms and conditions of the MSA and applicable PSA or (ii) destroy such Product. If Client elected (i) above, Client shall pay the Service Fees and any related costs or fees for the Service relating to such Product in accordance with the terms and conditions of the MSA and applicable PSA, and if Client elected (ii) above, SBL shall bear the costs and expenses for such destruction.

(ii) If SBL terminates a PSA pursuant to Section 15.2.1 15.2.2 or, Client terminates a PSA pursuant to Section 15.2.3, upon payment of any amounts owed to SBL under the applicable PSA, SBL shall deliver the fully Manufactured Product to Client in accordance with the terms and conditions of the MSA and applicable PSA (including the current Firm Period period or Binding Year in the PSA). Client shall pay the Service Fee and any related costs or fees for the Service relating to such Product in accordance with the terms and conditions of the MSA and applicable PSA.

(iii) If either Party terminates a PSA pursuant to Section 15.2.4, both Parties shall negotiate in good faith manner for the handling of the fully Manufactured Product and the allocation of costs and expenses between the Parties.

(iv) If a PSA is naturally expired or terminated pursuant to Section 15.1, the provisions of (ii) above shall apply.

(b) Client Materials being used for the Service (Product in Process).

(i) If Client terminates a PSA pursuant to Section 15.2.1 or 15.2.2, upon Client's election, SBL shall (i) continue to use the Client Materials being used for the Manufacturing hereunder (the Product in process) and deliver the fully Manufactured Product to Client in accordance with the terms and conditions of the MSA and applicable PSA, or (ii) deliver to Client or destroy such Product in process. If Client elected (i) above, Client shall pay the Service Fee and any related costs or fees for the Service relating to the fully Manufactured Product in accordance with the terms and conditions of the MSA and applicable PSA, and if Client elected (ii) above, SBL shall bear the costs and expenses for such activities.

(ii) If SBL terminates a PSA pursuant to Section 15.2.1, 15.2.2, or Client terminates a PSA pursuant to Section 15.2.3, upon payment of any amounts owed to SBL under the applicable PSA, SBL shall continue to use the Client Materials being used for the Manufacturing hereunder (the Product in process) and deliver the fully Manufactured Product to Client in accordance with the terms and conditions of the MSA and applicable PSA. Client shall pay the Service Fee and any related costs or fees for the Service relating to the fully Manufactured Product in accordance with the terms and conditions of the MSA.

(iii) If either Party terminates a PSA pursuant to Section 15.2.4, both Parties shall negotiate in good faith manner for the handling of the Client Materials being used for the Manufacturing hereunder (Product in process) and the allocation of costs and expenses between the Parties.

(iv) If a PSA is naturally expired or terminated pursuant to Section 15.1, the provisions of (ii) above shall apply.

(c) Client Materials, Cell Line, and Reference Standards. Upon expiration or termination of a PSA, upon Client's election, SBL shall deliver to Client and/or destroy all remaining Client Materials (subject to Sections 15.3.2(a) and 15.3.2(b)), all remaining Cell Line vials, Reference Standards and other materials required for Manufacturing.

The costs and expenses for such activities shall be borne by the Parties as follows:

(i) If Client terminates aPSA pursuant to Section 15.2.1 or 15.2.2, SBL shall deliver or dispose at no additional cost to Client and SBL shall bear such costs and expenses for such activities;

(ii) If SBL terminates a PSA pursuant to Section 15.2.1, 15.2.2, or Client terminates the PSA pursuant to Section 15.2.3, Client shall bear such costs and expenses for such activities;

(iii) If either Party terminates a PSA pursuant to Section 15.2.4, both Parties shall negotiate in good faith manner the allocation of all such costs and expenses for such activities; and

(iv) If a PSA is naturally expired or terminated pursuant to Section 15.1, the provisions of (ii) above shall reply.

(d) Raw Materials.

(i) If Client terminates a PSA pursuant to Section 15.2.1 or 15.2.2 and if Client so elects, SBL shall deliver the remaining Raw Materials to Client for Client's payment of SBL's cost to procure such Raw Materials, or dispose of them at Client's election. SBL shall bear the costs and expenses for the delivery of the Raw Materials.

(ii) If SBL terminates a PSA pursuant to Section 15.2.1 or 15.2.2, or Client terminates a PSA pursuant to Section 15.2.3, SBL shall deliver the remaining Specialized Raw Materials to Client. Client shall pay SBL's cost to procure such Specialized Raw Materials and bear the costs and expenses for the delivery of such Specialized Raw Materials by SBL. In the case of Common Raw Materials, the Parties shall discuss in good faith whether to have SBL keep, send to Client, or dispose of the remaining Common Raw Materials.

(iii) If either Party terminates a PSA pursuant to Section 15.2.4, both Parties shall negotiate in good faith manner for the handling of the Raw Materials and the allocation of costs and expenses between the Parties.

(iv) If a PSA is naturally expired or terminated pursuant to Section 15.1, the provisions of (ii) above shall apply.

(e) Outstanding Obligations Regarding Purchase of Product.

(i) If Client terminates a PSA pursuant to Section 15.2.1 or 15.2.2, Client shall [***].

(ii) If SBL terminates a PSA pursuant to Section 15.2.1 or 15.2.2, or Client terminates a PSA pursuant to Section 15.2.3, [***].

(iii) For all other cases of termination of a PSA, subsection (ii) shall apply, and the Parties will discuss in good faith the extent to which Client will be released from such obligations.

(f) **Survival**. Any termination or expiration of this MSA shall not affect any outstanding obligations due hereunder prior to such termination or expiration, nor shall it prejudice any other remedies that the parties may have under this MSA. For greater certainty, except as otherwise expressly provided, termination or expiration of this MSA, irrespective of the cause, shall not affect any rights or obligations which, from the context thereof, are intended to survive termination or expiration of this MSA, including but not limited to Sections 8, 9, 10, 11, 12, 13, 14, 15, 16 and 17.3.

SECTION 16 ARBITRATION

16.1 **Informal Discussions.** Except as otherwise provided herein, in the event of any controversy or claim arising out of or relating to this MSA, or the rights or obligations of the Parties hereunder, the Parties shall first try to settle their differences amicably between themselves through the Core Team and then JSC level. Thereafter, either Party may initiate informal dispute resolution on the Executive level by sending written notice of the dispute to the other Party, and within thirty (30) days after such notice appropriate Executives of the Parties shall meet for attempted resolution by good faith negotiations. If such representatives are unable to resolve promptly such disputed matter within the said thirty (30) days, either Party may refer the matter by written notice to the Chief Executive Officer of the other Party, or his/her designee, and the Chief Executive Officer of such Party, for discussion and resolution. If such individuals or their designees are unable to resolve such dispute within thirty (30) days of such written notice, either Party may initiate arbitration proceedings in accordance with the provisions of this Article 16.

16.2 **Arbitration.** If the Parties do not fully settle a dispute pursuant to Section 16.1, and a Party wishes to pursue the matter, each such dispute, controversy or claim shall be finally resolved by binding arbitration in accordance with the Commercial Arbitration Rules of the International Chamber of Commerce ("ICC"), and judgment on the arbitration award may be entered in any court having jurisdiction thereof to enforce the arbitration award. The arbitration shall be conducted by a panel of three persons experienced in the pharmaceutical business, and within thirty (30) days after initiation of arbitration, each Party shall select one person to act as arbitrator and the two Party-selected arbitrators shall select a third arbitrator within thirty (30) days of their appointment. If the arbitrators selected by the Parties are unable or fail to agree upon the third arbitrator, the third arbitrator shall be appointed by the ICC. The place of arbitration shall be New York, New York, United States and all proceedings and communications shall be in English. Either Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending the arbitration award. The arbitrators shall have authority to award punitive any other type of damages not measured by a Party's direct compensatory damages, and in all cases, any decision or determination by the arbitrators shall comply with Article 14, as applicable. The Parties agree that, in the event of a good faith dispute over the nature or quality of performance under this Agreement, neither Party may terminate this Agreement until final resolution of the dispute through arbitration or other judicial determination. The Parties further agree that any payments made pursuant to this Agreement pending resolution of the dispute shall be refunded if an arbitrator or court determines that such payments are not due.

16.3 **Costs and Fees.** Each Party shall bear its own attorneys' fees, costs, and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the arbitrators. Absent the filing of an application to correct or vacate the arbitration award as permitted by Applicable Law, each Party shall fully perform and satisfy the arbitration award within fifteen (15) days after the service of the award on such Party.

SECTION 17 MISCELLANEOUS

17.1 **Notices.** Any notice required or permitted under the MSA shall be in writing with duly authorized signature and made to the following addresses or facsimile numbers:

If to Client:

CytoDyn Inc.
1111 Main Street
Suite 660
Vancouver, WA 98660
Attention:
Facsimile: (360) 980-8549

If to SBL:

Samsung BioLogics Co., Ltd.
300, Songdo bio-daero, Yeonsu-gu
Incheon 21987, South Korea
Attention: Head of Corporate Business Planning
Facsimile: +82-32-455-3242

With copy to: SBL Legal & Compliance Team

Either Party may change its designated address and facsimile number by notice to the other Party in the manner provided in this Section 17.1.

Any notice shall be deemed to have been delivered on the date of delivery of delivered personally, or on the next day of sending if sent by facsimile, or on the fifth day of posting if sent by registered or certified mail with return receipt requested and postage prepaid.

17.2 **Governing Law.** This MSA shall be construed and interpreted in accordance with the laws of State of New York, United States and all rights and remedies shall be governed by such laws without regard to principles of conflicts of law. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to the transactions contemplated by the MSA.

17.3 **Effect of Force Majeure Event**. Except as set forth in this Section 17.3, neither Party (the "**Affected Party**") shall be liable to the other Party (the "**Non-Affected Party**") for failure or delay to perform its obligation under the MSA or any applicable PSA when such failure or delay is due to riots, storms, fires, explosions, floods, earthquakes, war, embargoes, blockades, insurrections, an act of God or any other cause which is beyond the reasonable control of the Affected Party including those affected upstream suppliers ("**Force Majeure Event**").

Each Party agrees to give the other Party prompt written notice of the occurrence of any Force Majeure Event, the nature thereof, and the extent to which the affected Party will be unable fully to perform its obligations under the MSA. If a condition constituting Force Majeure Event as defined herein exists for more than [***], the Parties shall negotiate a mutually satisfactory solution to the problem, if practicable, including termination of this MSA upon [***] written notice from the failure of reaching a mutually satisfactory solution to the Force Majeure Event, or the use of a third party to fulfill the obligations hereunder of the party invoking Force Majeure Event, at the expense of the party invoking Force Majeure Event.

17.4 **Assignment**. Neither Party shall assign, in whole or in part, the MSA without the prior written consent of the other Party, such approval not to be unreasonably withheld, except in the event of a sale of all, or substantially all of the assets of a Party to which this MSA relates, in which case no consent shall be required, in which case, the Party shall provide a written notice to the other Party within one (1) month of the sale. For clarity, in the event that any Party assigns the MSA as permitted under this Section 17.4, it shall be required to contemporaneously assign any and all PSAs which are then in effect together with this MSA.

17.5 **No Grant of License.** Nothing in the MSA shall affect, or grant any right to, patents, know-how or other intellectual property owned by either Party prior to the commencement of the MSA unless otherwise expressly provided in the MSA.

17.6 **No Right to Use Names.** Except as expressly provided herein, no right, expressed or implied, is granted by the MSA to use in any manner the name of either of the Parties or any other trade name, symbol, logo or trademark of the other Party in connection with the performance of the MSA, without the prior written consent of the other Party.

17.7 **Independent Contractors**. The Parties hereto are independent contractors and nothing contained in the MSA shall be deemed or construed to create a partnership, joint venture, employment, franchise, agency or fiduciary relationship between the Parties.

17.8 **Integration**. This MSA constitutes the entire agreement between the Parties relating to the subject matter of the MSA and supersedes all previous oral and written communications between the Parties with respect to the subject matter of the MSA.

17.9 **Amendment; Waiver**. Except as otherwise expressly provided herein, no alteration of or modification to the MSA shall be effective unless made in writing and executed by an authorized representative of both Parties. No course of dealing or failing of either Party to strictly enforce any term, right or condition of the MSA in any instance shall be construed as a general waiver or relinquishment of such term, right or condition. The observance of any provision of the MSA may be waived (either generally or any given instance and either retroactively or prospectively) only with the written consent of the Party granting such waiver.

17.10 **Severability**. The Parties do not intend to violate any applicable law. However, if any sentence, paragraph, clause or combination of the MSA is in violation of any law or is found to be otherwise unenforceable, such sentence, paragraph, clause or combination of the same shall be deleted and the remainder of the MSA shall remain binding, provided that such deletion does not alter the basic purpose and structure of the MSA.

17.11 **Construction**. The Parties mutually acknowledge that they have participated in the negotiation and preparation of the MSA. Ambiguities, if any, in the MSA shall not be construed against any Party, irrespective of which Party may be deemed to have drafted the MSA or authorized the ambiguous provision.

17.12 Interpretation. The captions and headings to the MSA are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of the MSA. Unless context otherwise clearly requires, whenever used in the MSA: (a) the words "include" or "including" shall be construed as incorporating, also, "but not limited to" or "without limitation"; (b) the words "hereof," "herein," "hereby" and derivative or similar words refer to the MSA; (c) the word "law" or "laws" means any applicable, legally binding statute, ordinance, resolution, regulation, code, guideline, rule, order, decree, judgment, injunction, mandate or other legally binding requirement of a governmental authority (including a court, tribunal, agency, legislative body or other instrumentality of any (i) government or country or territory, (ii) any state, province, county, city or other political subdivision thereof, or (iii) any supranational body); and (d) all references to the word "will" are interchangeable with the word "shall" and shall be understood to be imperative or mandatory in nature. All references to days, months, quarters or years are references to calendar days, calendar months, calendar quarters, or calendar years. Whenever any matter hereunder requires consent or approval, such consent or approval shall not be unreasonably withheld or delayed.

17.13 Counterparts. This MSA may be executed in two or more counterparts, 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 executed the MSA as of the date first above written.

CYTODYN INC.

Signature: /s/ Nader Pourhassan
Name: Dr. Nader Pourhassan
Title: President and CEO

Date: 30 March 2019

SAMSUNG BIOLOGICS CO., LTD.

Signature: /s/ Dr. Tae Han Kim
Name: Dr. Tae Han Kim
Title: Representative Director and President

Date: April 1, 2019

Certain identified information has been excluded because it is both not material and would likely cause competitive harm if publicly disclosed.

SAMSUNG BIOLOGICS CO., LTD.

PRODUCT SPECIFIC AGREEMENT

COMMERCIAL DRUG SUBSTANCE

This Product Specific Agreement (this "**PSA**") is made effective as of the date of last signature below (the "**PSA Effective Date**") by and between CytoDyn Inc., a Delaware corporation having its principal place of business at 1111 Main Street, Suite 660, Vancouver, WA 98660 ("**Client**") and Samsung BioLogics Co., Ltd., a company with offices at 300, Songdo bio-daero, Yeonsu-gu, Incheon, 21987, Republic of Korea ("**SBL**"). Client and SBL are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**".

WHEREAS, Client and SBL entered into a Master Services Agreement effective on the Effective Date (the "**MSA**") and whereas pursuant to Section 2.1 of the MSA, the Parties wish to enter into this PSA whereby SBL will provide certain Services as detailed herein;

NOW, THEREFORE, the Parties agree as follows:

1. **Relationship to the MSA**. All capitalized terms not defined in this PSA will have the meanings given to them in the MSA. This PSA is hereby incorporated by reference into the MSA.

2. **Definitions**

   a. "Annual Forecast" is defined in Section 5(f)(i)(1).

   b. "Campaign" shall mean a series of Batches of the Product that are produced in sequence using the same manufacturing equipment (including but not limited to the same bioreactor) followed by validated cleaning of such equipment and purification suite, and for the purposes of counting the number of Product batches in a Campaigns in a given period, the start date of such Campaign shall be the determining factor. A Campaign will be deemed to end upon the completion of such cleaning.

   c. "Firm Period" has the meaning set forth in Section 5(e)(i)(1).

   d. "New Batch" has the meaning set forth in Section 5(e)(iii)(1).

   e. "Product Purchase Commitment Shortfall" has the meaning set forth in Section 5(e)(iv).

   f. "Quarterly Forecast" is defined in Section 5(f)(ii).

   g. "Year" means each one (1) year period that begins on January 1 and ends on December 31.

3. **General Information**.

   a. Product: PRO-140 drug substance

   b. Product Specification: The Product Specification will be contained in mutually agreed upon cGMP documentation.

c. Cell Line: CHO Cell Line expressing PRO-140

d. Manufacturing Facility: SBL 15kL scale facilities in [***], located at 300, Songdobio-daero, Yeonsu-gu, Incheon 21987, Republic of Korea.

4. **Raw Materials**.

a. **Client Materials**. Client Materials to be supplied by Client to SBL free of charge by itself or a third party designee.

i. List: See Exhibit A: Client Materials.

ii. Handling Fee: [***].

iii. Timing of provision of Client Materials to SBL: [***]

b. **Raw Materials**. The Parties shall finalize the categorization of Raw Materials to be used in performing the Services of this PSA into Specialized Raw Materials and Common Raw Materials pursuant to Section 5.3 of the MSA, and shall attach this list to this PSA as Exhibit B.

i. Handling Fee for Common Raw Materials to be procured by SBL at Client's expense: [***].

ii. Handling Fee for Specialized Raw Materials to be procured by SBL at Client's expense: [***].

5. **Technology Transfer, Manufacturing, and Supply Services**. SBL shall perform the Services as set forth in this Section 5.

a. **Services.**

i. SBL shall provide the Services as set forth in Exhibits C, D, and E in accordance with this PSA and the Project Plan.

ii. Fees and invoicing.

1. Services shall be invoiced upon completion of activities by SBL, or otherwise as agreed by the Parties in this PSA or a Project Plan. Notwithstanding Section 9.3.1 of the MSA, the Parties agree that payment for all Specialized Raw Materials ordered prior to June 1, 2020, inclusive of Specialized Raw Materials used for small scale runs, plus applicable handling fee, shall be due [***] days from the receipt of SBL's invoice.

2. Batches of Product shall be invoiced upon release by SBL pursuant to MSA Section 5.9.2(a)(i).

b. **Service Fees**. In consideration for SBL's performance of the Services pursuant to this Section 5(b), Client shall pay the Service Fees as set forth in Exhibit C. Additional Service Fees and costs may be detailed in an amendment to this PSA or in a Change Implementation Plan and Budget pursuant to Section 6.2(b) of the MSA.

c. **Excess Production**. If, in the course of manufacturing pursuant to a Client Purchase Order, SBL manufactures more than the amount ordered in the Client Purchase Order due to the mutually agreed manufacturing plan, such additional batches shall be purchased by Client as if manufactured pursuant to a Client Purchase Order.

d. **Forecasts / Purchase Orders**

i. **Annual Forecast** – **Drug Substance**

1. Each Year of the PSA term, Client shall provide to SBL a rolling five (5) Year Forecast (the "Annual Forecast") at least by the December 1 of the previous Year. The first three (3) Years shall be binding or partially binding as set forth in this Section, and the fourth (4th) and fifth (5th) Years shall be non-binding, good-faith estimates of Product to be delivered by SBL in such Years. The first Annual Forecast shall be provided by March 31, 2020. Any binding forecasts will be dependent on FDA approval of the Post Approval Submission for manufacturing at SBL. If the approval immediately above is delayed or does not occur, Client will not be liable for committed volume for 2021 and 2022. Upon receipt, SBL shall provide a written confirmation or comments on the Annual Forecast within thirty (30) days of receipt, upon which the first two (2) Years of each Annual Forecast (the "Firm Period") shall be [***] firm and binding as to the total number of Batches of Product that are to be delivered in each Year of the Firm Period. The third (3rd) Year of each Annual Forecast shall be partially binding on Client as follows: when the third (3rd) Year of any Annual Forecast becomes the second (2nd) Year of the next Annual Forecast, such second (2nd) Year must forecast between [***] and [***] of the third (3rd) Year of the previous Annual Forecast, rounded up to the nearest batch. By way of example, if Client submits an Annual Forecast on December 1, 2017 which forecasts ten (10) Batches of Product for 2020, when Client submits the next Annual Forecast on December 1, 2018, it must forecast between [***] and [***] Batches of Product for 2020.

2. Each Annual Forecast issued by Client shall be consistent with the Product Purchase Commitment and the previously issued Annual Forecast in terms of Batches of Product forecasted for each Year falling in the Firm Period.

3. Notwithstanding anything to the contrary, SBL shall use Commercially Reasonable Efforts to Manufacture Batches in excess of the number of Batches set forth in any Firm Period subject to SBL's existing commitments.

ii. **Quarterly Forecast**.

1. Each Quarter of the PSA term, Client shall provide to SBL a rolling eight (8) Quarter Forecast (the "Quarterly Forecast") at least by thirty (30) days before the end of the then-current Quarter. The first Quarterly Forecast shall be provided by March 31, 2020.

2. The Quarterly Forecast shall set forth Batches of Product that are requested by Client to be delivered in each Quarter of the Quarterly Forecast. Quarterly Forecasts shall be consistent with the then-current Annual Forecast when requesting Batches to be delivered in a Quarter falling in the Firm Period of any Annual Forecast. If there is a conflict between any Quarterly Forecast and any Annual Forecast, the Annual Forecast shall supersede unless agreed to by SBL.

iii. Purchase Orders

1. Each time Client submits a Quarterly Forecast to SBL pursuant to Section 5(e)(ii), SBL and Client shall discuss in good-faith the Manufacturing schedule for any Batches of Product that are requested to be delivered in such new Quarter entering the Quarterly Forecast (each a "New Batch"). The Parties shall discuss in good-faith for up to [***] and shall agree upon a manufacturing schedule for the New Batches covered by the Quarterly Forecast, upon which Client shall issue a binding Purchase Order for each New Batch which is consistent with the Parties' agreement and the Quarterly Forecast. The Purchase Order shall detail the Batch requested, and estimated delivery date(s) for such Batch, which delivery date shall be finalized upon SBL's release of the Batch pursuant to Section 5.9.2(b)(i) of the MSA.

2. When deciding a manufacturing schedule for the New Batches, the Parties agree that (a) all Manufacturing shall be on a [***] Campaign per Year basis, [***], (b) if there are more than one (1) Campaigns per Year scheduled as a result of a Quarterly Forecast then Client will be subject to a changeover fee of [***] per additional Campaign, provided that SBL Manufactures the full number of Batches specified by Client per Campaign in the applicable Quarterly Forecast and Purchase Order(s). The changeover fee [***]. If the Parties agree to add the New Batches to a Campaign that was already scheduled pursuant to a previous Quarterly Forecast, Client shall re-issue the previously issued Purchase Orders to align with such new agreement.

e. **Product Purchase Commitment**.

i. Notwithstanding anything to the contrary, during [***], both inclusive, Client shall pay SBL, on a minimum take or pay basis, for the greater of (a) [***] Batches of Product and (b) the number of Batches Forecasted by Client for the [***] period, and .

ii. Notwithstanding anything to the contrary, during [***], both inclusive, Client shall pay SBL, on a minimum take or pay basis, for the greater of (a) [***] Batches of Product and (b) the number of Batches Forecasted by Client for each Year (commitments in Sections 5(e)(i) and (ii) each, the "Product Purchase Commitment").

iii. Upon execution of this PSA, Client shall issue Purchase Orders for the following pre-commercial Batches, which shall be fully binding and on a minimum take or pay basis and the pricing for which shall be as set forth in Exhibit C: [***], [***], and [***]. The [***]. In addition, upon completion of the Engineering Batch, the JSC will [***]. The JSC may determine [***].

iv. Each Year, Client shall pay to SBL the price set forth in this PSA for each of the number of Batches of Product falling short of the Product Purchase Commitment (the "Product Purchase Commitment Shortfall") for Client's reserved but unused capacity. For any Year for which a Product Purchase Commitment Shortfall payment is owed to SBL, such payment shall be made either: (a) on January 1 of such Year if Client notifies SBL prior to such Year that there will be a Product Purchase Commitment Shortfall, or (b) on December 31 of the Year when there is a Product Purchase Commitment Shortfall for such Year.

f. **Batch Failure**. Pursuant to Section 5.8.3 of the MSA, the Parties shall be responsible for costs related to Batch Failure as follows:

i. To the extent the Batch Failure is caused solely as a result of SBL Assignable Error, SBL shall be responsible for [***]. Such cost responsibility shall be issued as a credit against future invoices by SBL.

ii. In all Batch Failure cases other than solely as a result of SBL Assignable Error, Client shall be responsible for costs (1)-(4) in Section 5(f)(i) above.

iii. Notwithstanding anything to the contrary, SBL shall not be responsible in the event of Batch Failure for Cell Line that is Client Material pursuant to this PSA, and SBL shall meet its cost reimbursement obligations pursuant to this Section 5(f) solely through providing Client with a credit of equivalent value to be used against future invoices by SBL.

6. **Regulatory Approvals**. The Regulatory Approvals covered by this PSA are the FDA. SBL shall use Commercially Reasonable Efforts to support Client's submissions or applications to any new Regulatory Authority, provided Client has provided SBL with reasonable notice, the Parties agree on an implementation plan, and Client pays SBL additional fees and costs, if applicable. Details of the scope of SBL's Service in regards to Regulatory Approvals shall be detailed in the Project Plan.

7. **Equipment Investment.** Pursuant to Section 5.2 of the MSA, Client and SBL will agree on the new equipment in the Facility that is necessary to perform the Services (the "Specialized Equipment"), as shown in Exhibit E of this PSA. Client shall be responsible for the purchase price and any supplier provided services related to the Specialized Equipment. SBL shall be responsible for [***] the Specialized Equipment. [***] SBL.

8. **Storage**. Pursuant to Section 5.9 of the MSA, if Client does not direct SBL to prepare Manufactured Product to be picked up by Client or Client's designated carrier with a pick-up date within [***] days of Client's receipt of the Batch Related Documents, SBL shall store the Product at the Warehouse and Client shall pay storage fees to SBL for the period of storage at the Warehouse until the actual delivery date, provided, however, that such storage period shall not exceed [***] days.

9. **Limitation of Liability**. In addition to the limitation of liability in Section 14.1 of the MSA for special, punitive, indirect or consequential damages, the Parties' liability under the PSA shall be as set forth in this Section 9. Except for (i) [***] of the MSA or [***] of the MSA; (ii) [***] of the MSA; and (iii) Damages arising out of the attributable Party's [***], a Party's maximum aggregate liability to compensate the other Party for all Damages under this PSA will be set on a per calendar year basis and for the calendar year in which the cause of such liability lies or exists (whether in contract, tort, strict liability, statute, or otherwise) and shall be limited to [***] paid or payable by Client to SBL in such calendar year (excluding costs of Raw Materials, SBL handling fees, and other expense or cost reimbursements). For Damages relating to (i), (ii) and (iii) in the immediately preceding sentence, a Party's maximum aggregate liability to compensate the other Party for Damages under this PSA will be unlimited.

10. **Term**. This PSA will commence as of the PSA Effective Date and will continue in full force and effect until December 31, 2027 or unless earlier terminated in accordance with the provisions of this PSA and/or Section 15.2 of the MSA.

The Parties have entered into this PSA as of the PSA Effective Date by their respective duly authorized representatives.

SAMSUNG BIOLOGICS CO., LTD.

By: /s/ Dr. Tae Han Kim
Name: Tae Han Kim
Title: Representative Director & President
Date: April 1, 2019

CYTODYN INC.

By: /s/ Nader Pourhassan
Name: Dr. Nader Pourhassan
Title: President and CEO
Date: 30 March 2019

Exhibit A: Client Materials

1. [***]

Other Client Materials may be identified at a future date if agreed upon by the Parties.

Exhibit B: Categorization of Raw Materials

Specialized Raw Material is defined [***]. This definition may be further refined with mutual agreement from the Parties. All other Raw Materials will be defined as Common Raw Materials.

Exhibit C: Services

Service		Price (USD)	Comments
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

Note: DS Pricing based on Pricing Assumptions below

PRICING AND PAYMENT ASSUMPTIONS

Pricing includes labor and use of facilities. Standard pricing and payment terms are listed below.

- The pricing chart above is based on information provided in the RFP regarding the product and manufacturing process. Further communication between Samsung BioLogics and CytoDyn regarding the specifics of the project may result in changes to the scope of work and associated price.
- Commercial batch pricing is based on [***].
- Pricing is based [***]. Additional charges will apply [***].
- DS Batch price is based on [***].

- Increasing or decreasing the length of commercial term will effect batch price.
- The proposed prices are valid for year 2019 and will be **adjusted annually based on the Korean Consumer Price Index**.
- DS Batch prices do **not include** the cost of all raw materials and consumables ([***])
- Common Raw Materials will incur a [***] **handling surcharge**.
- Specialized Raw Materials (typically [***] requires alignment between both parties) will incur a [***] **handling charge**.
- The prices are based on regulatory requirements that complies with FDA regulation. Prices may change depending on the additional requirements necessary to comply with other regulatory authorities.
- Invoices will be issued at completion of agreed upon milestones and deliverables.
- Invoices are expected to be paid by CytoDyn within [***] **days** of receipt.
- Balance due for each batch shall be invoiced upon [***].
- All costs associated with activities outsourced to 3rd party contractors will be passed through to CytoDyn with a [***] handling surcharge.
- All prices exclude freight charges, insurance, duties, taxes, travel expenses, etc.

Exhibit D: Estimated Timeline and Scope of Work

NOTE: Timeline is based on current availability at the time proposal is issued and subject to change based on conditions at time of contract.

[***]

DS SCOPE OF WORK (15,000L)

[***]

[***]

[***]

Scope of Work APPENDIX A: PRODUCT/PROJECT INFORMATION

1 Key Product Information

Product Name	PRO 140 (Leronlimab)
Product Description	Human monoclonal antibody produced in CHO cell line
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

2 [***]

[***]

	[***]		[***]					[***]			
			[***]		[***]		[***]	[***]		[***]	
[***]					[***]		[***]	[***]		[***]	
[***]					[***]		[***]	[***]		[***]	
[***]					[***]		[***]	[***]			
[***]				[***]	[***]		[***]	[***]		[***]	[***]
[***]					[***]		[***]				
[***]					[***]		[***]				
[***]			[***]		[***]		[***]	[***]		[***]	
[***]			[***]		[***]		[***]	[***]		[***]	
[***]					[***]		[***]	[***]		[***]	

	[***]	[***]					[***]		
		[***]	[***]	[***]	[***]	[***]		[***]	
[***]				X	X	X		X	
[***]			X	X	X	X		X	
[***]			X	X	X	X		X	
[***]			X	X	X	X		X	
[***]				X	X	X		X	
[***]				X		X			
[***]			X	X					
[***]			X	X					
[***]			X	X					
[***]			X	X	X				
[***]							X		X
[***]							X		X
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[***]			X						
[***]									

[***]

[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]

[***]

[***]

[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

- [***]
- [***]

Exhibit 21

SUBSIDIARIES

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

Exhibit 23

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on FormS-8 (333-206813 and 333-223884) and Registration Statements Form S-3 (Nos. 333-213866 and 333-228991 and 333-223195 and 333-223563) of our reports dated August 14, 2019, 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, 2019. Our report on the consolidated financial statements contains an explanatory paragraph regarding CytoDyn, Inc.'s ability to continue as a going concern.

/s/ Warren Averett, LLC

Birmingham, Alabama
August 14, 2019

Exhibit 24

POWER OF ATTORNEY

WHEREAS, the undersigned officers and directors of CytoDyn Inc. desire to authorize Nader Z. Pourhassan and Michael D. Mulholland to act as their attorneys-in-fact and agents, for the purpose of executing and filing the registrant's Annual Report on Form 10-K for the year ended May 31, 2019, including all amendments and supplements thereto,

NOW, THEREFORE,

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Nader Z. Pourhassan and Michael D. Mulholland, and each of them, his or her 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 year ended May 31, 2019, 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.

IN WITNESS WHEREOF, the undersigned have executed this power of attorney in the following capacities as of August 14, 2019.

Signatures	Title
/s/ Scott A. Kelly, M.D. Scott A. Kelly, M.D.	Director
/s/ Carl C. Dockery Carl. C. Dockery	Director
/s/ Michael A. Klump Michael A. Klump	Director
/s/ Jordan G. Naydenov Jordan G. Naydenov	Director
/s/ David F. Welch, Ph.D. David F. Welch, Ph.D.	Director
/s/ Nader Z. Pourhassan, Ph.D. Nader Z. Pourhassan, Ph.D.	Director, President and Chief Executive Officer (Principal Executive Officer)
/s/ Michael D. Mulholland Michael D. Mulholland	Chief Financial Officer, Treasurer and Corporate Secretary (Principal Financial Officer and Principal Accounting Officer)

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 annual report is being prepared;

b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report, based on such evaluation; and

d. disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the registrant's most-recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

5. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):

a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and

b. any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: August 14, 2019

/s/ Nader Z. Pourhassan
Nader Z. Pourhassan, Ph. D.
President and Chief Executive Officer

Exhibit 31.2

Certification of Chief Financial Officer

I, Michael D. Mulholland, certify that:

1. I have reviewed this Annual Report on Form 10-K of CytoDyn Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;

4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:

a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report, based on such evaluation; and

d. disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the registrant's most-recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

5. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):

a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and

b. any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: August 14, 2019

/s/ Michael D. Mulholland
Michael D. Mulholland
Chief Financial Officer

Exhibit 32

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350

In connection with the Annual Report of CytoDyn Inc. (the "Company") on Form10-K for the year ended May 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned certify, pursuant to 18 U.S.C. § 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
August 14, 2019

/s/ Michael D. Mulholland
Michael D. Mulholland
Chief Financial Officer
August 14, 2019

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.